Development of recommendations to improve patient experiences of brachytherapy for locally advanced cervical cancer

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Dedication

I dedicate this thesis to my beautiful mum, Pat.

Abstract

Brachytherapy is a type of internal radiation treatment where a radioactive source is placed close to a tumour. For locally advanced cervical cancer (LACC), too advanced to be cured by a hysterectomy, radiotherapy with chemotherapy is the standard treatment. Typically, brachytherapy follows five weeks of daily external beam radiotherapy alongside weekly chemotherapy. Brachytherapy requires patients to have applicators/needles positioned inside them in an operating theatre and to remain lying flat and still on a bed for the planning and treatment delivery. Currently, the way the brachytherapy is given is not standardised. It may be given as three or four day case procedures, or one or two inpatient stays for up to three days where the applicators stay in place for this duration. Brachytherapy is a highly invasive procedure and is known to cause pain, anxiety and distress. Currently there is no consensus on how to minimise this in the context of a rapidly developing technique with wide variations in delivery.

This research was undertaken to better understand patient experiences of brachytherapy for LACC, to identify areas needing improvement and ways to reduce distress caused by brachytherapy. A total of three studies were carried out. The first study was a survey to ascertain current UK brachytherapy service provision, including pain management and procedures to provide patient care and support. This found that many different treatment regimens were in use, confirming the lack of standardisation of procedures. The second study was a qualitative interview study, to explore patient experiences of brachytherapy across a number of UK centres where brachytherapy is delivered in different ways. This showed that some women had difficult and traumatic experiences with periods of severe pain and a perception of poor nursing care on the wards. Others described more positive experiences, with some having had no pain. Aspects of what had gone well were identified as well as suggestions for how the treatment could be improved.

In the final stage of the research, study data were used to develop potential patient care recommendations. These were discussed and ranked by service providers and service users meeting together in nominal group technique workshops. Some recommendations were

amended to improve clarity and a few new recommendations were created in the workshops. From the workshops a list of potential recommendations was produced to be taken forwards for future development, with the aim of improving standards and consistency of care in brachytherapy for LACC.

Table of contents

List of tables

List of figures

List of abbreviations

BGCS	British Gynaecological Cancer Society
CA	Content analysis
CASP	Critical Appraisal Skills Programme
CNS	Clinical nurse specialist
COVID-19	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
CSE	Combined spinal epidural
CT	Computed Tomography
CTV	Clinical target volume
EBCD	Experience-based co-design
EBRT	External beam radiotherapy
EMBRACE	IntErnational MRI-guided BRAchytherapy in CErvical cancer
ESGO	European Society of Gynaecological Oncology
ESTRO	European Society for Radiotherapy and Oncology
ESTRO-HERO	European Society for Radiotherapy and Oncology-Health Economics in Radiation Oncology
FIGO	The International Federation of Gynecology and Obstetrics
FREC	Faculty Research Ethics Committee
GA	General anaesthetic
GEC-ESTRO	Groupe Européen De Curiethérapie-European Society for Therapeutic Radiology and Oncology
GP	General Practitioner
GTV	Gross target volume
HAS	Health and Applied Sciences
HDR	High dose rate
HPV	Human Papilloma Virus
HRA	Health Research Authority
ICBT	Intracavitary brachytherapy
IMRT	Intensity modulated radiotherapy
IRAS	Integrated Research Application System
ISBT	Interstitial brachytherapy
KM	Knowledge mobilisation
LA	Local anaesthetic
LACC	Locally advanced cervical cancer
LDR	Low dose rate
MDT	Multidisciplinary team
MR	Magnetic Resonance
NCCN	National Comprehensive Cancer Network
NGT	Nominal group technique
NHS	National Health Service
NICE	National Institute for Health and Care Excellence(formerly National Institute for Clinical Excellence)
NIHR	National Institute for Health and Care Research (formerly National Institute for Health Research)
OARs	Organs at risk
PCA	Patient-controlled analgesia
PCEA	Patient-controlled analgesia epidural route
PCIA	Patient-controlled analgesia intravenous route

PDR	Pulsed dose rate
PIS	Participant Information Sheet
PPIE	Patient and public involvement and engagement
PRDA	The Pelvic Radiation Disease Association
PRD	Pelvic radiation disease
PREM	Patient-reported experience measure
PRO	Patient reported outcome
PTSD	Post-traumatic stress disorder
QI	Quality indicator
QoL	Quality of life
RCR	Royal College of Radiologists
RCT	Randomised controlled trial
REC	Research Ethics Committee
RTA	Reflexive Thematic Analysis
SA	Spinal anaesthetic
SLR	Systematic literature review
UWE	University of the West of England
VMAT	Volumetric arc technique
VR	Virtual reality
VTE	Venous thromboembolism

Chapter One: Introduction, background and rationale

This thesis explores patient experiences of brachytherapy for locally advanced cervical cancer (LACC) and UK service provision. Aspects of the treatment that need improvement were identified by patients and healthcare professionals and ways to reduce distress and improve patient experiences are explored throughout the thesis. This chapter presents an introduction to image-guided adaptive brachytherapy in the context of a diagnosis of LACC. It provides the medical and psychological context for brachytherapy for LACC and how this treatment fits within the cervix cancer treatment pathway. Key concepts relating to brachytherapy for LACC and the treatment pathway are explored and explained.

1.1 Introduction to cervical cancer

The cervix is the lower part of the womb (uterus) which joins to the top of the vagina and is sometimes called the neck of the womb. Human Papilloma Virus (HPV) is the primary cause of pre-invasive and invasive cervical cancer and can occur after infection with high-risk HPV types, such as HPV 16 or HPV 18. HPV is detected in 99% of cervical tumours, particularly the oncogenic subtypes of HPV 16 and 18 (Marth *et al.*, 2017). HPV infections are usually transmitted through sexual contact and may lead to the development of abnormal cell changes, such as squamous intraepithelial lesions, usually in the surface of the transformation zone of the cervix. An individual's immune system may eliminate these pre-cancerous lesions over a period of 6-12 months, however some lesions may develop into invasive cervical cancer, typically over a period of 10 years or more (Canadian Cancer Society, 2022; Zhang *et al.*, 2020). Cancerous cells may develop from the proliferation of squamous cells on the outer lining of the cervix, or from glandular type cells typically found in the inner lining of the cervical canal, giving rise to the most common types of cervical cancer: squamous cell or adenocarcinoma. Cervix cancer can arise in any person with a cervix, including women, non-binary or transgender (trans) men and people assigned female at birth (Macmillan Cancer Support, 2021).

The 2018 GLOBOCAN (Global Cancer Incidence, Mortality and Prevalence) data estimates the worldwide annual incidence of cervical cancer at 570,000 newly diagnosed cases and 311,000 deaths, and is globally the 4th most common cancer in women (Bray *et al.*, 2018). However, there is a disproportionately higher incidence in less developed countries,

accounting for 85% of global cervical cancer incidence, and higher mortality rates where there is less access to diagnostic and therapeutic health services. In 28 countries, cervical cancer was identified as the most commonly diagnosed cancer in women (Bray *et al.*, 2018). In 2018 the World Health Organisation called for action towards the global elimination of cervical cancer by the end of the century (Gultekin *et al.*, 2020), through a global strategy for screening and vaccination. As indicated previously, the main risk factor associated with development of cervical cancer is chronic HPV infection. Other associated risk factors include smoking, long-term use of oral contraception, high number of childbirths, early age of first intercourse, chlamydia, Human Immunodeficiency Viruses and familial history of cervical cancer (He and Li, 2021; Zhang *et al.*, 2020; Bray *et al.*, 2018). The HPV vaccination programme was introduced across Europe from 2006, and from 2008 in the UK, vaccinating adolescent girls aged 9-14, preferably before first sexual intercourse, and in some countries boys are also vaccinated (He and Li, 2021; Reed *et al.*, 2021). Approximately 3,200 new cases of cervical cancer are diagnosed each year in the UK (Cancer Research UK, 2022). The overall UK trend for cervical cancer incidence is decreasing, with further reductions predicted over the next 10 years (Cancer Research UK, 2022). Data from Sweden and UK on the efficacy of vaccination has shown substantial reductions in pre-cancer and cervical cancer after the introduction of HPV immunisation, and almost complete elimination in girls born after 1995 (Falcaro *et al.*, 2021; Lei *et al.*, 2020). However, despite national screening programmes, seven Western countries including the UK, have reported increases in cervical cancer in women under 50 (He and Li, 2021). This is thought to be related to increased numbers of sexual partners and reduced cervical screening uptake (He and Li, 2021; Bajos *et al.*, 2010).

1.2 Staging of cervical cancer

The location and possible spread of cervical cancer can be described using the International Federation of Gynecology and Obstetrics (FIGO) staging system. Prior to 2018, FIGO staging was defined by disease at clinical examination but has been updated to include imaging (Magnetic Resonance (MR) imaging and fluorodeoxyglucose-Positron Emission Tomography/ Computed Tomography) to report tumour size, parametrial and nodal disease (Salib *et al.*, 2020; Bhatla *et al.*, 2018). Use of a global staging system assists clinicians in determining appropriate treatment and likely survival outcomes from the disease at

presentation (Bhatla *et al.*, 2019). The updated FIGO staging was introduced in the UK from January 2020 (Singh, Rous and Ganesan, 2019). See Table 1 FIGO staging of carcinoma of the cervix uteri (2018) from Bhatla *et al.* (2019, p.131).

Table 1 FIGO staging of carcinoma of the cervix uteri (2018)

Stage	Description
I	The carcinoma is confined to the cervix (extension to the uterine corpus should be disregarded)
IA	Invasive carcinoma that can be diagnosed only by microscopy, maximum depth of invasion <5 mm[1]
IA1	Measured stromal invasion <3 mm in depth
IA2	Measured stromal invasion ≥3 mm and <5 mm in depth
IB	Invasive carcinoma with measured deepest invasion ≥5 mm (greater than Stage IA), lesion limited to the cervix uteri[2]
IB1	Invasive carcinoma ≥5 mm depth of stromal invasion, and <2 cm in greatest dimension
IB2	Invasive carcinoma ≥2 cm and <4 cm in greatest dimension
IB3	Invasive carcinoma ≥4 cm in greatest dimension
II	The carcinoma invades beyond the uterus, but has not extended onto the lower third of the vagina or to the pelvic wall
IIA	Involvement limited to upper two-thirds of the vagina without parametrial involvement
IIA1	Invasive carcinoma <4 cm in greatest dimension
IIA2	Invasive carcinoma ≥4 cm in greatest dimension
IIB	With parametrial involvement but not up to the pelvic wall
III	The carcinoma involves lower third of vagina and/or extends to the pelvic wall and/or causes hydronephrosis or non-functioning kidney and/or involves pelvic and/or para-aortic lymph nodes[3]
IIIA	The carcinoma involves the lower third of the vagina, with no extension to the pelvic wall
IIIB	Extension to the pelvic wall and/or hydronephrosis or non-functioning kidney (unless known to be due to another cause)
IIIC	Involvement of pelvic and/or para-aortic lymph nodes, irrespective of tumour size and extent (with r and p notations)[3]
IIIC1	Pelvic lymph node metastasis only
IIIC2	Para-aortic lymph node metastasis
IV	The carcinoma has extended beyond true pelvis or has involved (biopsy proven) mucosa of the bladder or rectum. (A bullous oedema, as such, does not permit a case to be allotted to Stage IV)
IVA	Spread to adjacent pelvic organs
IVB	Spread to distant organs

[1] Imaging and pathology can be used, when available, to supplement clinical findings with respect to tumour size and extent, in all stages.

[2] The involvement of vascular/lymphatic spaces does not change the staging. The lateral extent of the lesion is no longer considered.

[3] Adding notation of r (imaging) and p (pathology) to indicate the findings that are used to allocate the case to stage IIIC. For example, if imaging indicates pelvic lymph node metastasis, the stage allocation would be stage IIIC1r and, if confirmed by pathological findings, it would be Stage IIIc1p. The type of imaging modality or pathology technique used should always be documented. When in doubt, the lower staging should be assigned.

1.3 Locally advanced cervical cancer

Despite a comprehensive UK cervical screening and vaccination programme, about a third of women diagnosed with cervical cancer present with locally advanced disease, meaning they are unsuitable for surgery as a primary or definitive treatment. Although there is some controversy about which stages of cervical cancer are locally advanced, the stages from IB3 to IVA are generally considered to fit this definition. These are stages where cancer has spread into tissues beyond the cervix or cannot be completely removed by surgery (Reed *et al.*, 2021; Cibula *et al.*, 2018). Stages IB to IIA may be considered suitable for either surgery or radiotherapy and outcomes have been found to be similar in previous studies (Landoni *et al.*, 2017, Landoni *et al.*, 1997). There are about 1,000 women in the UK diagnosed with LACC per year, and chemotherapy and radiotherapy (including brachytherapy) is the standard treatment (Cancer Research UK, 2022; Reed *et al*., 2021; Chargari *et al.*, 2019).

1.4 Radiotherapy

Radiotherapy involves the use of ionising radiation to target and eliminate cancer cells. For LACC a typical course of radiotherapy requires external beam radiotherapy (EBRT) to be given in daily treatments (Monday to Friday) using a machine such as a linear accelerator, (see Figure 1) followed by brachytherapy (internal radiotherapy) (Reed *et al.*, 2021; Cibula *et al.*, 2018).

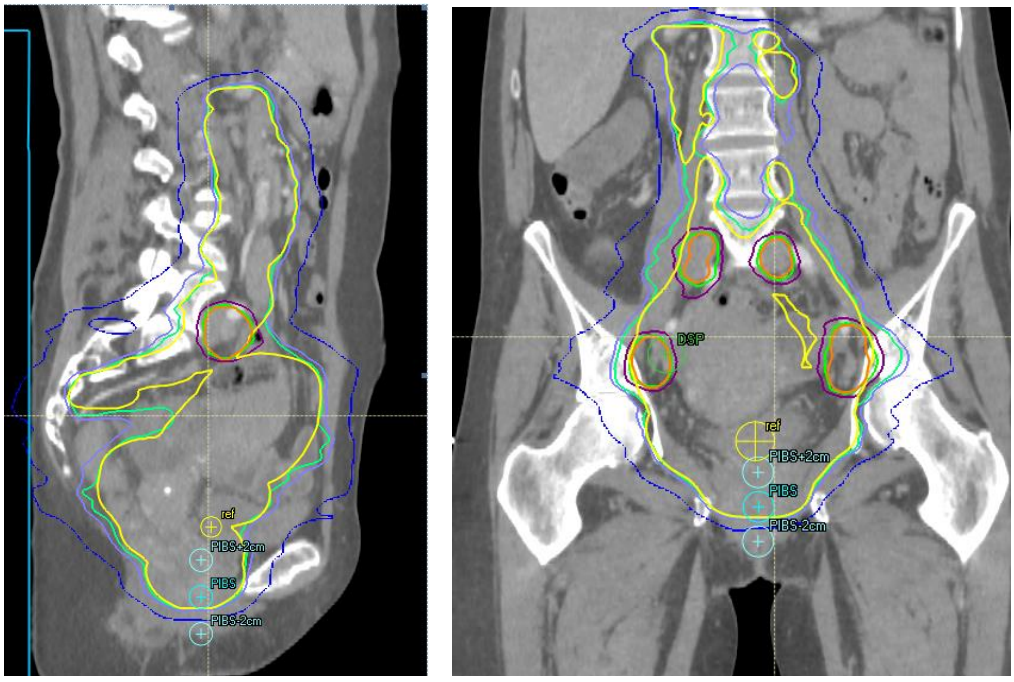
Figure 1 Image of a Truebeam™ Varian Linear accelerator

(Image from https://www.varian.com/products/radiotherapy/treatment-delivery/truebeam reproduced with permission from Varian Medical Systems)

Modern EBRT techniques aim to deliver a conformal radiation dose: a high radiation dose to the tumour and most likely areas of spread such as the pelvic lymph nodes with a lower dose to the surrounding tissues to minimise side effects or treatment toxicity. Techniques such as intensity modulated radiotherapy (IMRT), volumetric arc techniques (VMAT), and tomotherapy are commonly used to deliver highly conformal radiotherapy (Reed *et al*., 2021). Studies of intra and inter-fraction motion have given rise to concerns about internal motion of the cervix and uterus due to rectal and bladder filling and tumour regression (Taylor and Powell, 2008; van de Bunt *et al.*, 2008). This has led to development of bladder filling and rectal emptying protocols, adaptation of margins for tumour volumes and introduction of daily imaging to mitigate these potential inaccuracies in treatment. The irradiated volume (clinical target volume, CTV) should include all known disease (gross tumour volume, GTV), entire cervix, parametrium, upper half of the vagina (at least 2 cm below GTV) and entire uterus (Reed *et al.*, 2021; Pötter *et al.*, 2018; Haie-Meder *et al.*, 2005). The CTV should also include all involved nodes, common iliac lymph nodes, internal and external iliac lymph nodes, obturator nodes, pre-sacral lymph nodes and para-aortic nodes (see Figure 2).

Figure 2 Images of CTV outlining on CT planning images

(Images from hospital planning system, with patient consent to use of anonymised images)



A dose of 45-50 Gray[4] is typically prescribed to the CTV, with five treatments given per week for five weeks, with a total of 25 treatments and a dose of 1.8-2.0 Gray per day (Reed *et al.*, 2021; Cibula *et al.*, 2018). In addition, a radiation boost to the involved lymph nodes is recommended in patients with unequivocally involved pelvic lymph nodes on imaging. This may include pelvic lymph nodes and para-aortic lymph nodes if indicated, up to a dose of 55-60Gy total. This may be given as a simultaneous or integrated boost at the same time as the pelvic EBRT or a sequential boost after pelvic EBRT has been completed (Reed *et al.*, 2021).

1.5 Chemotherapy for LACC

Standard treatment includes weekly chemotherapy, usually with single agent radio-sensitising chemotherapy, such as cisplatin, for those who are medically fit and where chemotherapy is not contra-indicated (Reed *et al.*, 2021; Cibula *et al.*, 2018). Typical side effects from cisplatin chemotherapy include nausea and vomiting, effects on blood cell production leading to lower red blood cell levels (anaemia), low platelet levels (thrombocytopaenia) and low white cell and neutrophil levels (neutropaenia). Chemotherapy is usually given on the same day as a dose of EBRT, so may be known as concomitant or concurrent chemotherapy, or sometimes referred to as chemoradiotherapy (Macmillan Cancer Support, 2021). Chemotherapy is thought to act as a radiosensitiser and chemoradiation has been shown to give a 5% overall survival benefit when compared with radiotherapy alone (Chemoradiotherapy for Cervical Cancer Meta-Analysis Collaboration, 2008).

1.6 Brachytherapy for LACC

Brachytherapy is a type of internal radiation therapy where a radioactive source is placed close to or within the tumour (Horton *et al.*, 2014; Hoskin and Coyle, 2011). The term ‘brachy’ comes from the Greek work ‘brachys’ meaning close to or short distance (Skowronek, 2017; Horton *et al.*, 2014). To deliver the radiation dose to treat LACC, hollow applicators are placed in the uterus and vagina and the radioactive source is passed into the

[4] The Gray (symbol: Gy) is the unit of ionizing radiation dose in the International System of Units (SI), defined as the absorption of one joule of radiation energy per kilogram of matter

hollow applicators. This is known as 'intracavitary' or 'intracavity' brachytherapy (ICBT), putting a radioactive source into a body cavity (Chargari *et al.*, 2019). Brachytherapy for LACC usually commences after the five weeks of chemoradiation has been completed, or sometimes in the last week of the five week course. This allows for maximal tumour shrinkage which optimises the effectiveness of brachytherapy. Whether the radiation delivered through the brachytherapy applicators is able to reach all the residual tumour depends on the size and shape of the residual tumour after EBRT and how close to the tumour the applicators can be positioned.

The benefit of using brachytherapy (putting a radioactive source close to or into the tumour or tumour bed) is due to the law of physics known as the 'inverse-square law' (Albuquerque *et al.*, 2019; Skowronek, 2017; Banerjee and Kamrava, 2014; Pötter *et al.*, 2006). The inverse-square law means that radiation intensity is inversely proportional to the *square of the distance from the source*, so in practical terms there is a rapid reduction in dose with increasing distance from the radioactive source. Therefore, a high radiation dose can be delivered to the tumour while giving a much lower dose to the normal tissues around the tumour. This is known as a steep or sharp dose gradient and is the reason for the dosimetric advantages that brachytherapy techniques have over EBRT (Chargari *et al.*, 2019; Hoskin and Coyle, 2011).

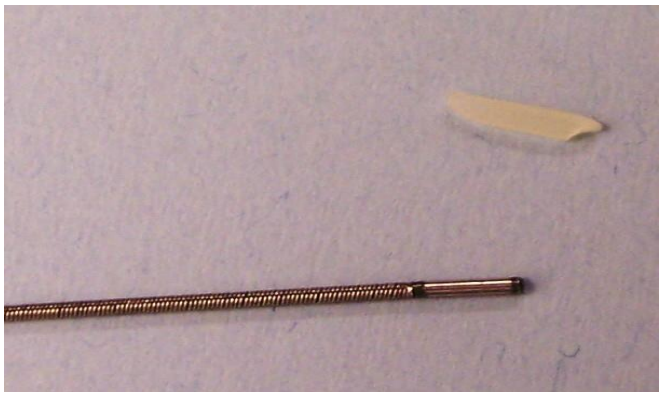
From the 1930s brachytherapy was delivered using low dose rate (LDR) radioactive sources (typically radium) with treatment times in the region of two to three days. In the 1970s and 1980s radium was replaced with safer radioisotopes, such as caesium or cobalt (Skowronek, 2017). Patients had hollow applicators placed inside them, usually in an operating theatre, and then transferred to a radiation room on a ward. Manual loading of radioactive sources was replaced by LDR afterloading treatment machines, where the radiation would be passed remotely by compressed air through a plastic tube, into the applicators inside the patient (Hoskin and Coyle, 2011). This afterloading technique meant that hospital staff were no longer exposed to any radiation dose, compared to the previous technique of manual loading of radium sources (Horton *et al.*, 2014). Patients were immobilised and in isolation during this LDR treatment to prevent irradiation of hospital staff (Chargari *et al.*, 2019). The radiation could be switched off for short periods to allow nursing care, medication delivery

and food and drink supplies. However, breaks in treatment were minimised to keep the overall time with applicators in place as short as possible. No visitors were allowed during this time as the radiation would have been interrupted, prolonging the duration of immobilisation with applicators in place (Warnock, 2005; Velji and Fitch, 2001). This was the most common type of brachytherapy for LACC until the early 2000s.

Due to radiation safety issues and lack of availability of replacements for the LDR afterloaders and their caesium sources, from 2000 onwards most UK departments replaced the old LDR afterloading machines with a high dose rate (HDR) afterloader so the treatment could be delivered in minutes (Pearce *et al.*, 2009) (See image of an afterloader in Figure 3a). The HDR afterloader typically uses a radioactive isotope of iridium (iridium-192), a very small high activity sealed source, the size of a grain of rice (Chargari *et al*., 2019; Hoskin and Coyle, 2011). See image of an iridium source in Figure 3b.

Figure 3 HDR brachytherapy afterloader and radioactive source

a) b)



a) Varian GammaMed afterloader (own image)

b) Iridium 192 radioactive source compared with a grain of rice (own image)

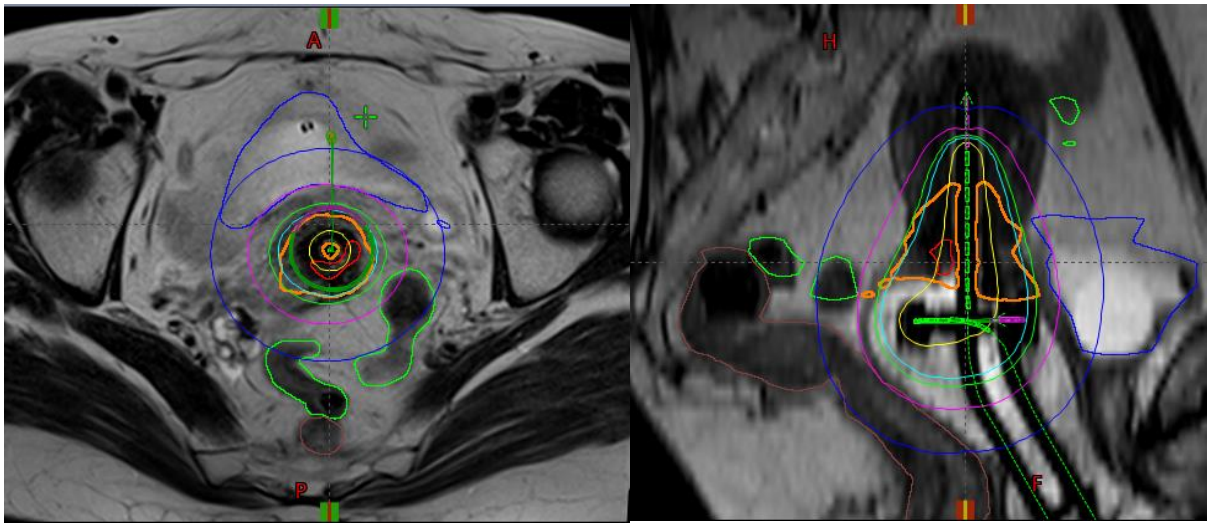
Apart from the change in dose rate from LDR to HDR, typically moving treatment delivery away from hospital wards to radiotherapy departments, there have been several other technical developments in gynaecological brachytherapy. Due to the development of brachytherapy applicators which are Computerised Tomography (CT) and Magnetic Resonance (MR) imaging compatible, it has now become possible to acquire CT and MR

scans with applicators inside the patient (Tan *et al*., 2018; Sturdza *et al*., 2016; Pötter *et al*., 2008a).

From these images the brachytherapy dose delivery can be planned more accurately than before. Previously imaging would have been carried out with orthogonal (perpendicular) x-ray images only, so planning would have been two-dimensional (2D), referring to point doses for prescribing and aiming not to exceed dose limits to specific points within the bladder and rectum (Pötter *et al.*, 2006). With the development of new treatment planning software, it became possible to use three-dimensional (3D) CT and MR images and prescribe doses to a volume rather than a point, and consequently minimise dose to structures sensitive to radiation, known as organs at risk (OARs) (Pötter *et al.*, 2008a, Pötter *et al.*, 2008b). Excessive radiation dose to OARs is known to cause both short term (acute) and long-term (chronic) side effects (Pötter *et al.*, 2021; Reed *et al.*, 2021).

Figure 4 MR brachytherapy planning images (axial and sagittal)

(Images from hospital planning system, with patient consent to use of anonymised images)



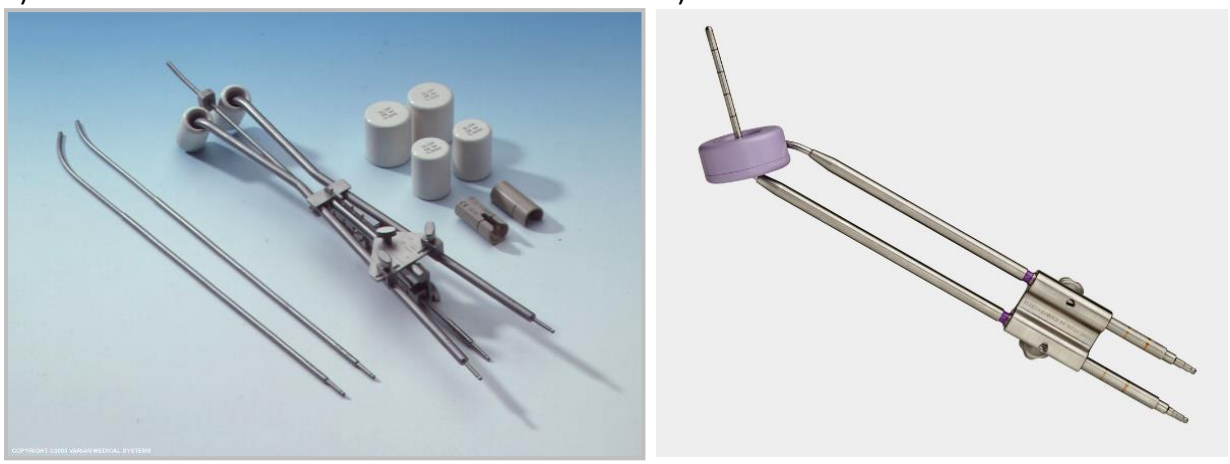
With MR imaging it is possible to see the true extent of the cervical tumour at the time of brachytherapy, enabling a more conformal and individualised dose to the tumour, compared with CT imaging (Mayadev *et al.*, 2017; Pötter *et al.*, 2011). This has led to the ability to escalate the dose to the treatment target area, and consequently to an increase in local tumour control. At the same time, it has been possible to limit or decrease the dose to

OARs, which has led to a reduction in radiation toxicity (Mazeron *et al.*, 2016; Kirchheiner *et al.*, 2014a). See Figure 4 showing axial and sagittal MR images with brachytherapy ring and tandem applicator in place. GTV is marked in red, high risk CTV marked in orange, bladder marked in blue, bowel marked in green and brown, isodose distribution[5] displayed in turquoise, green , purple and blue.

A further development in image-guided brachytherapy is the insertion of hollow needles into the cervix tumour itself, which has been shown to increase local tumour control and reduce side effects, achieving 85-100% local tumour control (Sturdza *et al.*, 2016; Lindegaard *et al.*, 2013; Pötter *et al.*, 2011; Tan *et al.*, 2009; Pötter *et al.*, 2007). This is known as interstitial brachytherapy (ISBT), into tissue, or more typically a hybrid technique is used which combines intracavitary and interstitial applicators (ICBT/ISBT). Examples of intracavitary applicators are shown in Figure 5, hybrid applicators in Figure 6 and interstitial applicators in Figure 7).

Figure 5 Examples of intracavitary applicators

a) b)



a) Varian fletcher applicator, intrauterine probe with ovoids

b) Varian CT compatible ring and tandem applicator

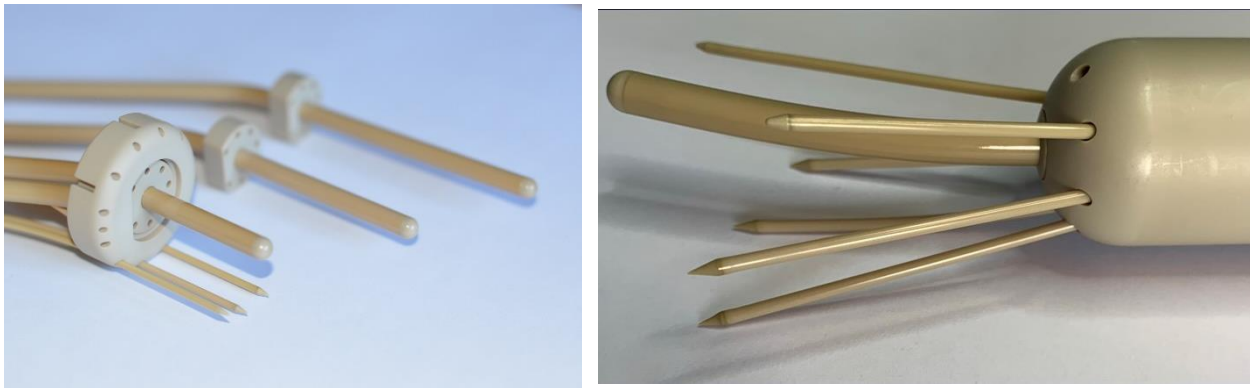
(Images reproduced with permission from Varian Medical Systems)

[5] An isodose distribution represents points of equal dose

Figure 6 Examples of hybrid applicators

(Combined intracavitary and interstitial applicators)

a) b)



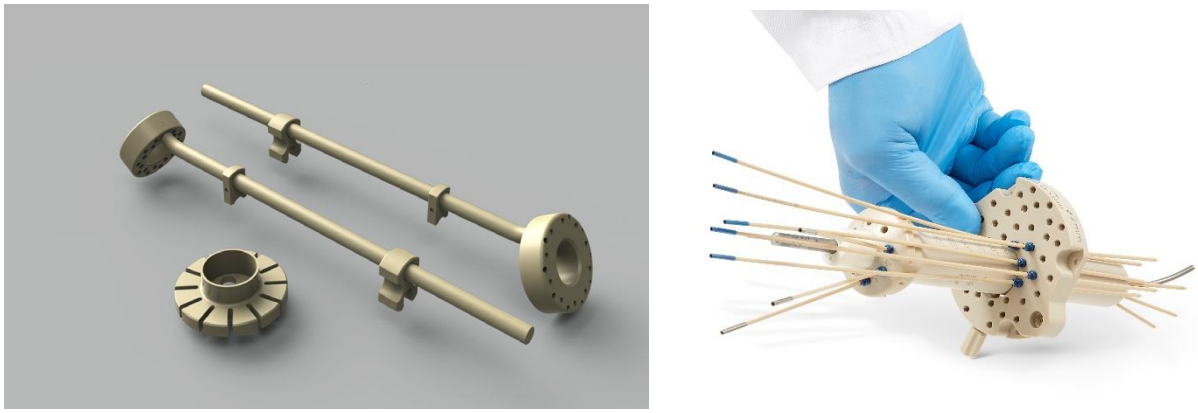
a) Varian 3D interstitial ring and tandem applicator with interstitial needles

b) Varian interstitial cylinder applicator, intrauterine probe and interstitial needles

(Images supplied by Varian representative Sophie Wetherall and reproduced with permission from Varian Medical Systems)

Figure 7 Examples of Interstitial applicators

a) b)



a) Varian Aarhus applicators

b) Varian Kelowna applicator

(Images supplied by Varian representative Sophie Wetherall and reproduced with permission from Varian Medical Systems)

As the planning has become more complex, with oncologists, radiographers and physicists required to draw the tumour (target volume), OARs and register the applicator positions onto the 3D images, so the time taken to plan the treatments has increased. This change

from the use of a library or standard plan to an individualised plan with extra applicators or needles has had a significant impact on planning time. This technique is known as image-guided adaptive brachytherapy as the volume irradiated is adapted to fit the shape of the tumour. It has been found that the overall planning time has increased from a matter of minutes to check applicator positioning using a radiograph or CT scan to several hours for an individualised plan. This has been reported to increase the overall procedure time to between two and six hours for each implant (Kim *et al.*, 2018; Harkenrider *et al.*, 2017; Damato *et al.*, 2015; Mayadev *et al.*, 2014).

Due to these imaging and planning developments, different brachytherapy regimes have been developed in each centre, so that sufficient staff and imaging resources can be accessed (Chatterjee *et al.*, 2019; Holschneider *et al.*, 2019; Banerjee and Kamrava, 2014). Some centres give HDR brachytherapy as a day case procedure. Typically, the patient would arrive in the morning for anaesthetic and theatre procedure for applicator/needle insertion, then CT and/or MR imaging, planning, treatment delivery, applicator removal and discharge home the same day. In other centres patients stay in hospital overnight with applicators/needles remaining in place and repeat the dose delivery over two to three days. Although the patient does not need to remain in isolation in a radiation treatment room, like the old LDR treatments, it does mean they have to remain immobile in bed for a long time. However, their treatment may be completed in one or two hospital visits and only requires one or two theatre and anaesthetic procedures. Some centres deliver two treatments for one theatre procedure with one overnight stay with applicators in place; repeated a week later (Kirchheiner *et al.*, 2014b). Some centres deliver three or four treatments from one theatre procedure with two overnights stays with applicators in place (Locke *et al.*, 2022). Some centres deliver the radiation in hourly pulses, using a source which is typically one tenth of the activity of an HDR source (Pulsed dose rate, PDR) (Chargari *et al.*, 2019; Skowronek, 2017).

PDR is preferred by some clinicians as it mimics the effect of a LDR source and the consequential radiobiological advantages (Skowronek, 2017) . This is usually given in an isolation room on a ward, but the patient does not need to remain in isolation between the pulses and therefore nursing care can be continued between pulses of radiation. The

introduction of interstitial needles to this technique may have increased the pain that women experience, and some centres have altered their anaesthesia and analgesia techniques to help women cope (Locke *et al.*, 2022; Murata *et al.*, 2021; Viswanathan *et al.*, 2012a; Janaki *et al.*, 2008).

1.7 Brachytherapy research studies

In 2000 a gynaecological brachytherapy working group was set up by the Groupe Européen De Curiethérapie-European Society for Therapeutic Radiology and Oncology (GEC-ESTRO) to lead and support the development of image-guided adaptive gynaecological brachytherapy. A number of guidelines were published in the mid-2000s to help centres to develop common standards and terminology in the technical aspects of brachytherapy (Pötter *et al.*, 2008a; Pötter *et al.*, 2007; Pötter *et al.*, 2006; Haie-Meder *et al.*, 2005). In 2008 the first international multicentre observational EMBRACE study (IntErnational MRI-guided BRAchytherapy in CErvical cancer) was set up to prospectively evaluate image-guided brachytherapy (Tanderup *et al.*, 2015). Since 2008 over 20 analyses have been undertaken or are in progress, addressing questions such as local, nodal and systemic recurrences; bladder, bowel, and vaginal morbidity; quality of life (QoL); prognostic and predictive parameters; physics parameters, and 3D quality assurance. A vaginal sub-study is currently being undertaken to evaluate vaginal side effects, vaginal dose and patient reported outcome measures. The major studies have been EMBRACE I, RetroEMBRACE and EMBRACE II which opened in 2016 and closed to recruitment in 2021. EMBRACE III is now in development. The EBRT and brachytherapy protocol for the EMBRACE II study have now become the international gold standard for EBRT and brachytherapy (Reed *et al.*, 2021; Cibula *et al.*, 2018; International Commission on Radiation Units and Measurements (ICRU) Report 89, 2013).

1.8 Treatment outcomes

Cervical cancer outcomes are typically reported as local or pelvic control rates (loco-regional control rates) and overall survival rates. Cancer Research UK have reported increasing survival rates over the last decade with outcomes in England of five-year survival rates between 2013 and 2017 as 99% for stage one and 50% for stage four cervical cancer (Office for National Statistics, 2019). For brachytherapy studies, local or regional control rates are

typically reported as this is likely to be related to EBRT and brachytherapy techniques, whereas overall survival may be governed more by metastatic disease. The link between overall survival and a localised treatment is more problematic to demonstrate as development of metastatic disease may also have been reduced due to the introduction of systemic therapies, such as concomitant cisplatin chemotherapy for LACC approximately 20 years ago (Castelnau-Marchand *et al.*, 2015).

A USA study of 7359 patients who received EBRT between 1988 and 2009 found that patients who were treated with combined EBRT and brachytherapy had a significantly better overall survival rate than those treated with EBRT alone (65% and 50%, respectively) (Han *et al.*, 2013). Consequently there are concerns about the trend in declining use of brachytherapy in the USA as some clinicians replace brachytherapy with an EBRT boost (Tanderup *et al.*, 2014; Han *et al.*, 2013). The multinational observational study RetroEMBRACE showed improved rates of local and pelvic control and an overall survival benefit of 10% when image guided brachytherapy was implemented (Sturdza *et al.*, 2016). This followed two decades of developments in image-guided brachytherapy techniques, leading to brachytherapy dose escalation without increasing side effects (Pötter *et al.*, 2018). Although it is known that comparisons with historical data can be fraught with uncertainties due to changes in systemic treatments, overall survival benefits of 10% are higher than those reported after the introduction of chemotherapy for LACC and are therefore likely to show some of the benefits of improved radiotherapy and brachytherapy techniques. Outcomes from the EMBRACE I study, including analysis of disease for 1341 patients from 24 centres across Europe, Asia and North America, was an improved overall five-year survival from 67% (Sturdza *et al*., 2016) to 74% (Pötter *et al.*, 2021). Data from both these analyses are in the concomitant chemotherapy era and therefore demonstrate a positive development in treatment of LACC (Pötter *et al.*, 2021).

Factors that are reported to influence local control include tumour size, histology, overall treatment duration and dose (Schiff *et al.*, 2022; Mazeron *et al.*, 2015). A comparison of results from seven cervix brachytherapy studies showed two to five year local control rates ranging between 78.5 and 100% (Vargo and Beriwal, 2014). More recent data from the 1351

patients in the EMBRACE I study reported overall 5-year local control was 92% (95% confidence interval 90–93) (Pötter *et al.*, 2021).

1.9 Brachytherapy medical complications

During and after brachytherapy for LACC, many medical complications and side effects have been reported with a multitude of known or potential causes (Chen *et al.*, 2021; Glaser *et al.*, 2021; Morris *et al.*, 2017; Morris and Haboubi, 2015; Jain, Mishra and Bhatnagar, 2007; Maduro *et al.*, 2003). Brachytherapy is typically carried out after five weeks of pelvic radiotherapy which has common side effects of radiation-induced diarrhoea, fatigue and nausea. Tan, Russell and Burgess (2004) reported that 80.6% of women experienced diarrhoea, 66.7% malaise and 62.5% nausea during chemoradiotherapy for cervical cancer. Even with modern EBRT techniques such as IMRT the impact of diarrhoea is reduced but still significant, with a third of women who received pelvic IMRT for gynaecological cancers reporting frequent or almost constant diarrhoea at the end of radiotherapy (Klopp *et al.*, 2018). The peak of acute radiation toxicity has been found to coincide with the initiation of brachytherapy, therefore brachytherapy patients may be at increased risk of dehydration and metabolic changes due to their pre-existing physical condition (Radojevic *et al.*, 2020). Most brachytherapy patients will have completed five cycles of cisplatin chemotherapy at the same time as the pelvic radiotherapy. The most common acute side effects of concomitant chemotherapy are nausea and vomiting and haematological toxicity with nausea and vomiting occurring in 12-14% and haematological toxicity in 37% of women during chemoradiotherapy (Maduro *et al.*, 2003). The myelosuppressive effects of Cisplatin chemotherapy can cause reduced white blood cell levels, including a lower neutrophil level, therefore increased infection risk; reduced blood haemoglobin levels, therefore more likelihood of fatigue and shortness of breath on exertion; and reduced platelet count, therefore increased bleeding risk (Macmillan Cancer Support, 2022). This is an important consideration during brachytherapy where there are reported procedural complications of uterine perforation, vaginal laceration and haemorrhage, although this a rare occurrence in approximately 2-3% of procedures (Gupta, Aich and Deb, 2014; Lanciano *et al.*, 1994). However, bleeding risk at applicator removal is thought to be higher when interstitial

needles are used, with 5-10% of women requiring a blood transfusion after brachytherapy (Kamrava, Alrashidi and Leung, 2021).

A diagnosis of cancer is known to increase the incidence of development of venous thromboembolism (VTE) such as blood clots in the lungs (pulmonary embolism) or legs (deep vein thrombosis). Incidence of VTE is increased up to seven fold compared with the general population (Zhao *et al.*, 2022; Glaser *et al.*, 2021; Mandalà, Falanga and Roila, 2011). For women with cervical cancer, VTE occurrence is approximately 12% (Matsuo *et al.*, 2016; Jacobson *et al.*, 2009) and both chemotherapy and LACC are associated with increased incidence above this level. VTE occurrence is associated with poorer survival outcomes in women with cervical cancer (Matsuo *et al.*, 2016). VTE risks associated with brachytherapy relate to the duration of immobility during the procedure and while waiting for planning and treatment delivery (Glaser *et al.*, 2021). Brachytherapy is considered to be a moderate risk procedure and therefore the need for VTE prophylaxis needs to be assessed on an individual basis due to the possibility of bleeding from the cervical tumour (Matsuo *et al.*, 2016).

Incidence of neutropaenia ≥ grade 3 was found to be 19.3% in women having chemoradiotherapy for LACC (Mell *et al.*, 2017) and therefore likely to increase infection risks during brachytherapy procedures. Analysis of brachytherapy insertion related acute side effects reported by Chen *et al.* (2021) showed infection rates (fever incidence) of 6.1%, which was similar to Nielsen *et al.* (2017) at 6.3% with interstitial or hybrid brachytherapy and higher than (Gupta, Aich and Deb, 2014) at 2.4% without use of interstitial needles. Other studies reported perineal infection or urinary tract infections as the most common acute toxicity at brachytherapy (Schiff *et al.*, 2022; Mendez *et al.*, 2017b).

Lying flat for many hours or days waiting for brachytherapy planning and then treatment delivery carries a risk of development of pressure sores. Pressure sore development has been shown to be increased after epidural anaesthesia or patient-controlled analgesia, even with young healthy women who are immobile for a short time after labour or caesarean section (Alfirevic, Argalious and Tetzlaff, 2004; Shah, 2000). Duncan, Mason and Thirlwell (2015) report concerns regarding the risk of development of pressure sores from long periods of bed rest and limited opportunities to turn patients or relieve pressure on key areas such as sacrum and heels during brachytherapy. Preventative strategies such as

regular skin assessments and use of special pressure reducing mattresses are recommended to minimise these risks (Duncan, Mason and Thirlwell, 2015; Erickson and Gillin, 1997; Rollison and Strang, 1995).

1.10 Pain

When brachytherapy applicators are introduced into the uterus, cervix and vagina, this has been reported by patients to cause pain (Humphrey, Bennett and Cramp, 2018; So and Chui, 2007; Warnock, 2005; Velji and Fitch, 2001; Rollison and Strang, 1995). Pain is a subjective experience that can mean different things to different people. The definition that is globally accepted by healthcare professionals is:

> *"An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage"* (Raja *et al.*, p1, 2020).

Pain during brachytherapy has been described by patients as being worse than the pain experienced during childbirth (Dzaka and Maree, 2016). The causes of pain and discomfort during gynaecological brachytherapy are considered to be multifactorial with theoretical mechanisms described by Pellizzon (2018) and Smith, Todd and Symonds (2002). Dilation of the cervix to allow passing of the intrauterine applicator through the cervical canal into the uterus and distension of the uterus can cause cramping and lower abdominal pain which may be associated with nausea and vomiting. This is thought to be caused by stimulation of sympathetic autonomic afferents entering the spinal cord between the tenth thoracic and first lumbar vertebral levels (T10-L1) (Smith, Todd and Symonds, 2002). Lower back pain may be attributed to distension of the cervix and upper vagina by the introduction and presence of applicators and vaginal packing. This is thought to be caused by stimulation of parasympathetic autonomic nerve afferents from the splanchnic sacral and pudendal nerves from the second to fourth sacral levels (S2 to S4) (Smith, Todd and Symonds, 2002). Other stimuli such as presence of a urinary catheter or labial sutures may increase pain and discomfort (Pellizzon, 2018; Smith, Todd and Symonds, 2002). This pain may be worsened by movement, such as ward bed to trolley or couch transfers required for imaging and by prolonged duration lying flat, as backache and stiffness may increase over time (De Barros and Labate, 2008; So and Chui, 2007; Andersen *et al.*, 1984).

Management of pain during brachytherapy is a key aspect of care and there are many different time points in the procedure where either anaesthesia or analgesia are required, such as applicator insertion, patient transfers for imaging and applicator removal. Guidelines recommend that anaesthesia and analgesia should be provided during brachytherapy for cervical cancer (Reed *et al.*, 2021; Mahantshetty *et al.*, 2019; Cibula *et al.*, 2018; Marth *et al.*, 2017; Viswanathan and Thomadsen, 2012; Viswanathan *et al.*, 2012a). Many different types of anaesthesia and analgesia are used during brachytherapy, such as general anaesthesia, spinal or epidural anaesthesia. Research literature about pain management during brachytherapy for LACC is often vague, with little explanation of the types of anaesthesia and analgesia used. Terms and techniques used in brachytherapy for LACC are defined and explained in the following sections.

1.11 Anaesthesia

Anaesthesia is a term which means 'loss of sensation' and anaesthetics are medicines which can be used to prevent or reduce pain and discomfort during medical procedures (Royal College of Anaesthetists, 2021).

1.11.1 General anaesthesia (GA)

GA can be described in simple terms as a state of controlled unconsciousness (Royal College of Anaesthetists, 2021). GA can be used for a wide range of procedures, including introduction of brachytherapy applicators for treatment of LACC. Anaesthetic drugs are injected into a vein or sometimes administered as an inhaled anaesthetic agent to induce anaesthesia and are often given along with opiates and sedatives to induce sleep and manage pain. The anaesthetic drugs are thought to work by preventing or interrupting the synaptic transmission of pain messages from the body to the brain or spinal cord (Alkire, Hudetz and Tononi, 2008). This prevents the brain from responding or processing the messages of pain and usually causes a lack of memory of the procedure, known as an amnesic effect (Glannon, 2014; Hudetz, 2012). As the depth of anaesthesia is considered to be a spectrum, it is also defined as the point at which verbal contact with the patient is lost (Hudetz, 2012). GA drugs typically used include propofol (intravenous administration) or sevoflurane (inhalation agent) (Alkire, Hudetz and Tononi, 2008).

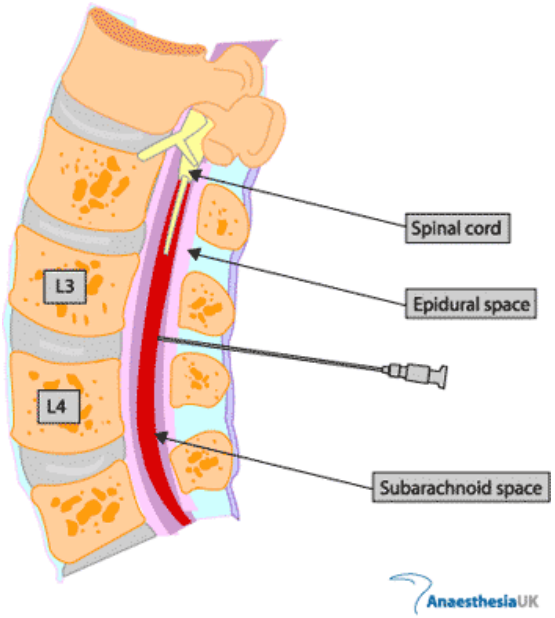
1.11.2 Regional anaesthesia

A local anaesthetic drug can be used to anaesthetise or 'numb' a part of the body when it is injected close to the nerve supply for that region (Royal College of Anaesthetists, 2021). It may be used to avoid the need for a GA or if the patient wants to or needs to remain awake during the procedure. It is sometimes used in combination with a sedative (sometimes referred to as an anxiolytic) so that the patient is comfortable or relaxed during the procedure, but not unconscious. The addition of a sedative may be useful for the brachytherapy procedure if the patient is anxious or does not want to have much awareness of the procedure. However, if they do not want to remember it afterwards then a GA may be required as sedation does not guarantee this (Royal College of Anaesthetists, 2021). Types of regional anaesthesia include spinal, epidural, combined spinal and epidural, paracervical block and local anaesthesia. These types of regional anaesthesia are described below.

Spinal anaesthesia

This is a type of regional anaesthesia where a local anaesthetic is injected into the cerebrospinal fluid surrounding the spinal cord, into the intrathecal (subarachnoid) space (Hunie *et al*., 2021), see diagram in Figure 8. It is a type of neuraxial anaesthesia and is also sometimes called a spinal block. It is typically used for procedures or surgery of the pelvis and lower abdomen and provides a short duration of numbness. The analgesic efficacy of the block may be enhanced by adding an opiate to the local anaesthetic agent, and may provide extended analgesia once the effect of the local anaesthetic agent has worn off. For example, this can be achieved using the local anaesthetic agent bupivacaine combined with an opiate such as fentanyl or diamorphine (Agarwala and Morrison, 2022). It has a relatively fast action of a matter of minutes, and duration of numbness or analgesia will be dependent on the local anaesthesia and type and dose of opiate used (Royal College of Anaesthetists, 2021).

Figure 8 Diagram of spinal anaesthesia into subarachnoid space



https://www.anaesthesiauk.com/images/pain_lumbar_puncture.gif

(Image reproduced with permission from Anaesthesia UK)

Epidural anaesthesia

This is a type of regional neuraxial anaesthesia where a fine tube is inserted into the epidural space and a local anaesthetic introduced. The tube is typically left in place so that further drugs can be introduced over a period of time and can therefore be used for prolonged analgesia after surgery (Faculty of Pain Medicine of the Royal College of Anaethetists, 2020). It typically has a slower onset of numbness and analgesia, in the region of 30 minutes and the density of the block may be less than that of a spinal anaesthetic, so it may be less ideal for longer surgical procedures

Combined spinal epidural anaesthesia (CSE)

The combined spinal–epidural technique (CSE) is increasingly popular in surgery and obstetric procedures (Ong and Sashidharan, 2007; Blanshard and Cook, 2004). This technique involves the injection of a local anaesthetic drug into the subarachnoid space (the spinal anaesthesia) and the placement of a catheter into the epidural space (the epidural anaesthesia) as part of the same procedure. The spinal part of the procedure uses a needle to introduce a local anaesthetic drug into the subarachnoid space, followed by the insertion

of a small catheter into the epidural space which then remains in place, allowing additional doses of anaesthetic and analgesia to be administered. (Simmons *et al.*, 2019; Ong and Sashidharan, 2007). The benefits of this technique is that you can achieve a dense and reliable block for surgery with the spinal and then 'top it up' with the epidural for prolonged surgery or ongoing analgesia (Ong and Sashidharan, 2007). This makes it well suited for use in brachytherapy for LACC, especially for interstitial applicators or long duration brachytherapy with multiple treatments over a number of days (Petitt *et al.*, 2020; Nielsen *et al.*, 2017; Janaki *et al.*, 2008; Kharod *et al.*, 2007; Benrath *et al.*, 2006).

Paracervical block and local anaesthesia (LA)

LA to the cervical area covers a range of interventions which aim to reduce painful experiences during dilation of the cervix and uterine interventions. These include introduction of LA agents by: intracervical injection; transcervical injection; paracervical injection and topical application of a gel or spray (Cooper, Khan and Clark, 2010). Overall, the benefits of all these types of LA are not well proven for minor gynaecological procedures as these procedures are reported to be reasonably well tolerated by most women (Tangsiriwatthana *et al.*, 2009; Yang and Vollenhoven, 2002). However, the systematic review and meta-analysis by Cooper, Khan and Clark (2010) compared the types of LAs and found superiority of paracervical LA over other LA methods (P=0.04). A paracervical block, also known as paracervical blockade or nerve block, involves injection of local anaesthetic into the tissues around the cervix, at the 'three and nine o'clock' positions (Tangsiriwatthana *et al.*, 2009). In the brachytherapy literature it is not always clear which type of LA has been used. For example, LA "with lidocaine spray" in Bhanabhai *et al.* (2013) may be interpreted as topical LA, or could mean paracervical *and* topical, and was later reported in a summary by Glaser *et al.* (2021) as use of paracervical block. However, some brachytherapy literature does specify LA using a paracervical block, often along with use of conscious sedation (Brunnhoelzl *et al.*, 2021; Leong *et al.*, 2017; Nielsen *et al.*, 2017) or the use of both topical and paracervical LA (Lim *et al.*, 2004).

1.11.3 Sedation

The continuum of sedation to general anesthesia is described in the American Society of Anesthiologists 2018 Practice Guidelines for Moderate Procedural Sedation (Apfelbaum *et al.*, 2018) and summarised in Table 2.

Table 2 Characteristics of levels of sedation and general anaesthesia

Level of sedation/anaesthesia	Description of characteristics of sedation level
Minimal sedation (anxiolysis)	The patient is very relaxed but still awake and able to respond to verbal questions and instructions.
Moderate or conscious sedation	The patient can give a purposeful response to verbal or tactile stimulation.
Deep sedation	The patient still gives some response but only after repeated or painful stimulation and the airway may need support.
General anaesthesia	The patient is unarousable, even with painful stimulus and airway support will be needed.

As an individual's response to sedative and anaesthetic drugs can be difficult to predict, there is inevitably some variability in the depth of sedation achieved as defined in the American Society of Anesthiologists continuum, although this can be titrated by the anaesthetist to achieve the desired effect (Apfelbaum *et al.*, 2018). Hence there is some variability in the descriptions reported in research literature of anaesthetic techniques on this continuum, typically from conscious sedation to GA in brachytherapy for LACC. Green *et al.* (2021) developed a consensus definition of sedation:

> "*The practice of procedural sedation is the administration of one or more pharmacological agents to facilitate a diagnostic or therapeutic procedure while targeting a state during which airway patency, spontaneous respiration, protective airway reflexes, and hemodynamic stability are preserved, while alleviating anxiety and pain."* (Green *et al.*, 2021, p.600).

Unspecified level of sedation, conscious sedation or deep sedation are referred to in some brachytherapy for LACC studies (Okonogi *et al.*, 2022; Damor *et al.*, 2021; Mahapatra *et al.*, 2021; Sommat *et al.*, 2021; Wilson *et al.*, 2021; Watanabe Nemoto *et al.*, 2015; Bhanabhai *et*

al., 2013; Oei-Lim *et al.*, 1996). Some studies call their technique GA but may be considered to be deep sedation (Locke *et al.*, 2022; Frankart *et al.*, 2018; Bansal *et al.*, 2015). Therefore there are likely to be differences in definitions and understanding of terms reported in these studies.

1.12 Analgesia

An analgesic is a type of medicine which is used to relieve pain (National Institute for Health and Care Excellence Clinical Knowledge Summaries, 2021). As pain is known to be a complex and multifactorial phenomenon, it is also thought that analgesia to relieve pain works via complex processes, but can be summarised as "decreasing excitation or increasing inhibition in the nervous system" (Vardanyan and Hruby, 2016). In brachytherapy for LACC there are many different routes for administration of analgesia, such as oral, intravenous, inhalation and intrathecal (Smith, Todd and Symonds, 2002). Use of opiates and non-steroidal anti-inflammatory drugs have been used for many years in conjunction with anaesthetic techniques. Techniques such as patient-controlled-analgesia (PCA) have been described more recently in the literature, especially if a long duration of analgesia is required in brachytherapy for LACC, such as multiple treatments per applicator insertion or overnight inpatient stays with applicators in place. This gives patients some control over the rate and quantity of self-administered analgesia with safety settings such as a 'lock-out' system to avoid overdosing (Smith, Todd and Symonds, 2002). Both epidural or intravenous routes are reported for PCA administration in brachytherapy for LACC (for example, Murata *et al.*, 2021; Argun, Gevenkiris and Unver, 2019; Brown, 2018; Nielsen *et al.*, 2017; Amsbaugh *et al.*, 2016; Chi *et al.*, 2015; Xu-Welliver and Lin, 2013).

1.13 Psychological context of brachytherapy

A diagnosis of cancer is a significant traumatic event in any person's life and can result in a range of emotional responses as they develop strategies to cope or adapt to their new situation (Brennan, 2001). Macmillan Cancer Support (2022) offer advice to patients and carers about normal emotions they may experience, such as shock, fear, sadness, anger, guilt or feeling alone. Feelings of anxiety or depression are also normal responses, which can be problematic if severe or long lasting (Macmillan Cancer Support, 2019).

1.13.1 Distress and post-traumatic stress disorder (PTSD)

Distress is commonly experienced by cancer patients and has been defined by the American National Comprehensive Cancer Network (NCCN) as:

> *"a multifactorial, unpleasant experience of a psychologic (ie, cognitive, behavioral, emotional), social, spiritual, and/or physical nature that may interfere with the ability to cope effectively with cancer, its physical symptoms, and its treatment."* (Riba *et al.*, p.1, 2019).

The NCCN report that the severity of distress can be described as a continuum, from common or normal feelings of distress to disabling symptoms such as anxiety, depression, feelings of social isolation, panic attacks and a spiritual or existential crisis (Riba *et al.*, 2019). Distress is a term deliberately chosen by the NCCN to encompass psychological distress, psychosocial distress and stress. High levels of distress among cancer patients are reported in many studies, ranging in frequency from 20-52% (Mehnert *et al.*, 2018; Taghizadeh *et al.*, 2018; Vitek, Rosenzweig and Stollings, 2007; Zabora *et al.*, 2001). It is known that high levels of distress are likely to impact on QoL and adherence to cancer treatment regimes (Riba *et al.*, 2019). There are many factors reported as influencing the level of distress experienced by cancer patients, however, poor prognosis is thought to be an important factor (Zabora *et al.*, 2001). Risk of death or an existential crisis are likely to create high levels of fear, anxiety and distress. There are many theories about how people may respond to the news of a cancer diagnosis, or other life-threatening conditions, such as adjustment, adaptation or use of coping mechanisms to help deal with multiple threats or new experiences (Brennan, 2001).

PTSD can be described as an anxiety disorder caused by a person experiencing traumatic, stressful or life-threatening events (Swartzman *et al.*, 2017). Typically this refers to experiences such as war, rape or sexual abuse, but can also have some resonance with people receiving a life-threatening diagnosis (Brennan, 2001). This may manifest as re-experiencing trauma through intrusive thoughts, nightmares and flashbacks, or protective responses such as hypervigilance or avoidance of situations that may retrigger trauma-related memories (Brewin and Joseph, 1996). PTSD symptoms, rather than the full PTSD disorder, may be experienced as a response to a cancer diagnosis, although unlike other types of trauma, this response may be to a future or potential threat or fear of dying rather

than a past event (Brennan, 2001). It is thought that PTSD in cancer survivors may be related to the multiple traumatic events that have occurred during diagnosis and treatment, which can be complex and repeated many times (Swartzman *et al.*, 2017). PTSD has been reported after brachytherapy for cervical cancer in 41% of patients 3 months after treatment (Kirchheiner *et al.*, 2014b).

Measures of health-related QoL have been used to demonstrate the physical and psychological impact of a cancer diagnosis, cancer treatment and side effects for women with cervical cancer (for example, Kirchheiner *et al.*, 2015 Kirchheiner *et al.*, 2014a,; Klee, Thranov and Machin, 2000). Brachytherapy for LACC has been reported to cause anxiety, stress and distress (for example, Benali *et al.*, 2022; Ehlers and Makanjee, 2018; Araujo *et al.*, 2017; Long, Friedrich-Nel and Joubert, 2016b; Dzaka and Maree, 2016; Kirchheiner *et al.*, 2014b). A range of strategies and interventions have been explored to reduce the frequency or severity of the psychological impact during and after treatments, such as providing better information and support, and use of complementary or integrative therapies (for example, Blackburn *et al.*, 2021; Long, Friedrich-Nel and Joubert, 2016b; Chi *et al.*, 2015).

1.13.2 Psychological impact of fertility loss

Radiotherapy to the pelvis is known to cause infertility due to radiation damage to the ovaries and uterus (Wo and Viswanathan, 2009). Some women are offered ovary transposition where ovaries can be surgically repositioned above the pelvic area needing irradiation. This can help to maintain the oestrogen production and prevent the effects of oestrogen deprivation, such as vaginal dryness, reduction in libido and osteoporosis in later life (McKenzie, Kennard and Ahmad, 2018). However, there are some risks that if the cancer has already spread to either of the ovaries then this surgical procedure could spread the cancer further, by lifting the ovaries above the radiation field and leaving them unirradiated so the cancer cells are left to continue growing (Moawad *et al.*, 2017). Ovary transposition is not recommended as a fertility preserving procedure, as the uterus would not be able to carry a pregnancy after pelvic radiotherapy. However, ovary transposition may be offered as an oestrogen preservation strategy (McKenzie, Kennard and Ahmad, 2018). Women may also be offered egg-harvesting prior to starting cancer treatments, but are counselled that

they would need to use a surrogate to carry their embryo which has low success (Somigliana *et al.*, 2020).

Loss of fertility in otherwise healthy women is known to cause high levels of depression and psychological distress, similar to experiencing a life-threatening condition (Carter *et al.*, 2005). Women report feeling angry, isolated, and having a sense of intense loss and grief. Feelings of grief may be experienced over a long period after treatment is completed, with significant impact on relationships and feelings of loss of sexuality or personal identity and meaning (Carter *et al.*, 2005). Brachytherapy for LACC, where applicators may remain in place for many hours or days while women are immobile and totally reliant upon healthcare professionals to meet their basic needs and deliver life saving treatment, needs to be viewed in the context of the loss of fertility and ensuing psychological trauma experienced by some patients.

1.14 Typical diagnosis and treatment pathway for patients with LACC

Acknowledging that there can be differences in the patient pathway due to local or regional service provision and variability in how patients present with their illness, the following section describes a typical patient diagnosis and treatment pathway at the doctoral fellow's centre.

Patients typically present with vaginal bleeding, between menstruation, during or after sexual intercourse or post-menopausal (Reed *et al.*, 2021). They are likely to see their General Practitioner (GP) initially and then be referred by the GP to a hospital gynaecology department. GP referrals account for the majority of new cervical cancer diagnoses, with approximately 17% referred through cervical screening and 10% through emergency admissions (Reed *et al.*, 2021). At the hospital appointment they are likely to see a gynaecology surgeon in a colposcopy clinic, and a full medical history will be taken and clinical examination carried out. To obtain a cancer diagnosis a tissue biopsy is taken from the patient's cervix, either during an outpatient clinic visit or a day case admission for examination under anaesthetic and biopsy in an operating theatre. The biopsy will be examined by a pathologist to determine if cancer cells are present, the grade of cancer (how abnormal or aggressive the cells appear to be) and the type of cells that the cancer cells are

arising from, such as squamous or adenocarcinoma. To assess the spread or stage of the cancer, imaging such as CT or MR is required. This would be carried out by diagnostic radiographers. At some point during the diagnosis stage, the patient is likely to meet a clinical nurse specialist (CNS) who can offer information and support to patients and carers during this process.

Once a cancer diagnosis has been confirmed by a pathologist, the details of the case would be discussed at a multidisciplinary (MDT) team meeting (Reed *et al.*, 2021). MDT members may include gynae-oncology surgeons, pathologists, CNSs, clinical and medical oncologists, therapeutic radiographers, clinical psychologists, palliative care specialists and an MDT co-ordinator. A proposed treatment plan will be agreed upon at the meeting and arrangements made to inform the patient of the diagnosis and proposed treatment plan. The diagnosis will typically be explained to the patient by the surgeon and then care handed over to a clinical oncologist. The clinical oncologist will explain the treatment options and potential side effects. If the patient agrees to the treatment plan they will sign a consent form and treatment will be booked. For EBRT planning purposes a CT scan will be carried out. This typically takes place in a radiotherapy department and is carried out by therapeutic radiographers. EBRT planning is carried out by medical physicists, clinical scientists or therapeutic radiographers. A five-week course of chemoradiotherapy for LACC typically starts with both chemotherapy and radiotherapy on the first day. Patients will receive weekly chemotherapy from chemotherapy trained nurses and daily radiotherapy from therapeutic radiographers. During the course of treatment, clinical assessments and reviews may be carried out by CNSs or therapeutic radiographers trained in treatment reviews. At weekly treatment reviews, information and support is offered to help patients manage the side effects of treatment and provide psychological support.

Brachytherapy information and a pre-operative assessment may be carried out in preparation for brachytherapy. An anaesthetist will explain the proposed anaesthetic process to the patient. During brachytherapy the patient will meet an operating theatre team, including anaesthetist, anaesthetic assistant, and theatre and recovery nurses. In some centres, therapeutic radiographers assist in brachytherapy procedures in the operating theatre, with roles such as circulating or scrub practitioner or they may be trained

to carry out transabdominal or transrectal ultrasound to guide the placement of the applicators. Applicator insertion is carried out by the clinical oncologist, or by a gynae-oncology surgeon in some centres. For inpatient brachytherapy, patients will be cared for by nurses on a ward. For day case brachytherapy, patients may be cared for by recovery nurses and therapeutic radiographers.

After treatment completion, follow-up appointments typically take place three monthly, to assess treatment response and check for any signs of recurrence or to offer advice on treatment side effects. Follow-up usually continues for five years after treatment. During the time from diagnosis, through treatment and follow-up, patients may be referred to a clinical psychologist for support.

1.15 The purpose of the thesis

1.15.1 Doctoral fellow perspective

Having worked as a therapeutic radiographer in the specialist area of brachytherapy since 2004, I have witnessed and been involved in the evolution and emergence of image-guided brachytherapy and hybrid intracavitary and interstitial techniques in brachytherapy for LACC. Discussions with UK based peers in the Brachytherapy Radiographers Forum, a special interest group of the Society and College of Radiographers, raised concerns about the introduction of these new techniques and the impact on patient experiences. How patients might cope with the prolonged overall procedure time was debated, acknowledging the greater complexity in planning the treatment and the need to add MR imaging, along with concerns about pain management for longer periods of time and with the addition of interstitial applicators. Concerns were expressed by radiographers that the move from LDR to HDR, despite reducing treatment times from days to minutes, was a worse experience for patients. Colleagues reported that multiple treatments for each applicator insertion was being discussed with clinical oncologists, nursing and medical physics colleagues and some centres had already implemented new fractionation schedules. I was disappointed to find that changes which were likely to have a significant impact on patient's experiences were being introduced without patient consultation. Although the clear intention of these changes was to improve local control, overall survival and reduce toxicity from the

programme of cancer treatment, the implications of these changes for treatment delivery need to be considered in consultation with patients.

1.15.2 Thesis rationale

The publication from Kirchheiner *et al*. (2014b), reporting that 41% of women had symptoms of PTSD at 3 months after brachytherapy, was considered to be a seminal work by the UK Brachytherapy Radiographers Forum members. The findings showed the potential psychological harm from the changes to fractionation and overall duration of brachytherapy. Further to this, there was no national or international guidance on patient care or pain management to mitigate for the impact on patient experience of the technical developments in brachytherapy for LACC. This demonstrated a clear need to examine the physical and psychological impact of brachytherapy to inform patient management and improve women's experiences.

1.15.3 Thesis aims

The overall aim of the programme of research was to develop an intervention to reduce distress caused by brachytherapy for LACC.

1.15.4 Thesis objectives

- To present an overall summary of research literature regarding women's experiences of brachytherapy for LACC.
- To complete a UK survey of practice to find out current brachytherapy provision for LACC, including treatment schedules, anaesthetic protocols and support strategies.
- To carry out semi-structured patient interviews to explore women's experiences of brachytherapy for LACC.
- To design an intervention to reduce distress caused by brachytherapy for LACC.

1.16 Patient research partners

The National Institute for Health Research (NIHR) strongly support the principles of patient and public involvement and engagement (PPIE), also known as 'community engagement and involvement', which have become enshrined in UK policy and practice (NIHR, 2019a). They consider 'public involvement' in research to occur when research is carried out 'with' or 'by' members of the public, rather than 'to', 'about' or 'for' them. The NIHR define 'public

engagement' as activities where research information and knowledge is shared with the public, such as the use of media, social media and research open days, to engage the public with research. PPIE in health research usually refers to involvement and engagement with key stakeholders such as patients, carers and staff working together to improve services (NIHR, 2019a). PPIE may include current, past and potential patients, carers and organisations representing patients (NIHR Centre for Engagement and Dissemination, 2021). Service users may be described as "experts on their own experiences" and their experiences can relate to the "past, present and future" (Visser *et al.*, 2005, p129 and 121).

At the beginning of this programme of research the importance of the involvement of patient research partners was explored. Potential roles were discussed with the PhD supervisory team. A national cervical cancer charity, Jo's Cervical Cancer Trust, was approached and they agreed to ask their members for volunteers to support this research programme. Two volunteers offered to help, both having personal experience of brachytherapy for cervical cancer. Guidance from INVOLVE, the national advisory group funded by the NIHR, was used to consider where public involvement could be utilised. In 2018, at the start of the research programme, INVOLVE provided support for public involvement in NHS, public health and social care research, including guidance for researchers (Hayes *et al.*, 2012). A public contributor role description template from the People in Health West of England was used as a starting point to develop an agreement with the research partners about the extent and duration of their involvement. Their primary role was to be a critical friend, offering advice to the research team. It was agreed that the research partners would become part of the research steering group, to provide a patient perspective on the research strategy and direction. The research partners agreed to examine research study documentation, such as participant information sheets and consent forms. A confidentiality agreement was included in the role description. Further detail of the contributions made by patient research partners are reported for each study within the programme of research. For role description, see Appendix 1.

1.17 Thesis structure

Chapter one has presented an overview of brachytherapy for LACC in the context of the medical and psychological impact within the whole cancer treatment pathway. Chapter two

will present an update of the pre-doctoral systematic literature review, to provide an overview of research literature in relation to women's experiences of brachytherapy for LACC. Chapters three, four and five present the primary research undertaken: 1) UK survey of brachytherapy practice for LACC; 2) Patient interview study; and 3) Development of patient care recommendations and nominal group technique workshops. Chapter six provides a summary of the thesis, including research findings, new knowledge, and implications for clinical practice and future research.

Chapter Two: Literature review

This chapter presents a review of evidence of the experiences of women receiving brachytherapy for cervical cancer. This includes a summary and critique of the findings of a pre-doctoral systematic literature review (SLR) that informed the successful NIHR Clinical doctoral research fellowship application and was subsequently published in Radiography (Humphrey, Bennett and Cramp, 2018; see pre-proof manuscript, Appendix 2). An update to the original SLR is also presented.

2.1 Introduction

2.1.1 Rationale for the pre-doctoral SLR

A SLR was originally chosen as the preferred method to search, analyse and synthesise current evidence to answer the question "What are women's experiences of brachytherapy for cervical cancer?" The review provided the background and rationale for the successful doctoral fellowship application. The systematic and methodical approach was selected to demonstrate that the literature had been searched rigorously, with a pre-specified criteria and protocol, without bias or "cherry-picking" of evidence. SLRs have sometimes been referred to as the "cleanest form of research" as they can offer a fair and unbiased synthesis of available literature (Goldacre, 2011). They may be considered to offer a more broad and accurate understanding of literature compared with a narrative review, incorporating multiple perspectives (Pati *et al.*, 2018), and can be used to identify gaps in knowledge or understanding of a subject (Centre for Reviews and Dissemination, 2009). The rigorous and methodical aspect of the SLR method typically derives from a pre-designed protocol. Authors may formulate the research question using the PICO tool: population; intervention; comparison and outcomes; or PICOS: population; intervention; comparison; outcomes and study design (Centre for Reviews and Dissemination, 2009; Jahan *et al.*, 2016). The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines are typically used to offer a structure to the development of a comprehensive protocol (Liberati *et al.*, 2009). However, there is also criticism that SLRs are not necessarily top of the hierarchy of reviews just because they are systematic, and there can be poor quality SLRs (Greenhalgh, Thorne and Malterud, 2018). In fact, Greenhalgh, Thorne and Malterud (2018) report that narrative reviews where experts have synthesised the evidence may provide a higher level

of undertsanding compared with a SLR where methodical processes have been followed without insightful critical reflection. Therefore it was important to capture the benefits of the SLR method to show that a rigorous approach to finding and evaluating current evidence had been undertaken, and use the extensive clinical knowledge and expertise of the doctoral fellow and SLR team to provide insightful and meaningful evaluation.

2.1.2 Summary of the pre-doctoral SLR

Brachytherapy is delivered using different schedules with some centres giving brachytherapy as short, day case procedures and others keeping patients in hospital overnight with applicators remaining in place and treatments repeated over two to three days. These regimes are thought to be equally effective in controlling the cancer, but it is not known whether there is a difference in relation to the patient experience. In some centres extra needle applicators are used to allow safe delivery of higher radiation doses and improved local control (Sturdza *et al.*, 2016; Lindegaard *et al.*, 2013; Pötter *et al.*, 2007, 2011; Tan *et al.*, 2009). However, this has increased complexity in imaging and radiation planning and is anecdotally reported to have increased planning time from minutes to many hours. In 2017, an SLR was carried out to determine women's experiences of brachytherapy for cervical cancer and inform aspects of treatment that needed improvement. The SLR was carried out following the PRISMA guidelines (Liberati *et al.*, 2009) and registered on PROSPERO (The International prospective register of systematic reviews) (Humphrey and Bennett, 2017).

Nineteen studies met the inclusion criteria for the SLR, with eight cohort studies, five randomised controlled trials (RCTs), five qualitative studies and one case control study. Twelve studies focussed on psychological aspects and seven on pharmacological aspects of patient experiences of brachytherapy. Two of the 12 studies focussing on psychological aspects investigated interventions to improve patient experiences of brachytherapy and 10 studies explored the lived experiences of women undergoing brachytherapy for gynaecological cancers. Across the 19 studies, themes of pain, anxiety, distress, informational needs, pharmacological and non-pharmacological interventions were reported. Overall, it was found that brachytherapy for gynaecological cancers caused varying levels of pain (from mild to severe), anxiety and distress. All seven studies of

pharmacological management reported on HDR brachytherapy techniques with five using short day case procedures and two reporting long duration brachytherapy techniques. Different approaches to peri- and post-operative pain management were presented, with no methods demonstrating superiority. Anxiety and distress were reported to be caused by brachytherapy in nine of the ten studies that investigated these concepts. Some reported that anxiety took a long time to reduce and was often reported as higher by patients in comparison to healthcare professionals' assessments. Two studies reported that women's informational needs were not being met. Non-pharmacological interventions were reported to have some benefit including reduction in anxiety and depression from relaxation with guided imagery and reduction in pain and anxiety with a music relaxation video. The development of brachytherapy from LDR to HDR was considered to be a positive change to reduce duration and improve patient experiences. However more complex imaging, planning and delivery of multiple treatment HDR fractions per insertion over several days may have increased overall duration of the procedure leading to greater anxiety and distress. Some studies showed that anxiety levels did not reduce with subsequent treatments and therefore a potential disadvantage of scheduling with shorter but multiple day case procedures is re-traumatisation. International brachytherapy guidelines do not consider the patient experience or QoL after brachytherapy.

The SLR indicated that better pain management, patient information and development of non-pharmacological interventions could improve patient's experiences of brachytherapy. It was suggested that the development of clinical support guidelines and regular service evaluation could improve future standards of care.

2.1.3 Critical evaluation of the published SLR

Reflecting on the quality and clarity of the pre-doctoral SLR (Humphrey, Bennett and Cramp, 2018), potential areas for improvement were identified. Any study which reported patient experiences of brachytherapy for cervical cancer was included, regardless of research method. This led to the inclusion of qualitative studies examining patient experiences as well as quantitative approaches evaluating interventions. With hindsight, the scope of the SLR was too broad and it would have been better to divide it into two separate reports, 1) patient experience studies and 2) intervention studies. Secondary data were not excluded

and therefore a literature review was included in the critical appraisal. This was problematic as the results were influenced by the data extraction and analysis from previous authors and could have led to double reporting of some studies. Restricting studies to primary research would allow more straightforward comparisons and avoid the introduction of prior evaluations, non-evidenced commentaries or opinion articles. The critical appraisal was reported separately to the synthesis and evaluation and two studies were excluded from the synthesis due to their poor methodological quality or lack of detail. Reflecting on this, it would have been better to integrate the quality evaluation with the synthesis to improve the clarity of the findings.

2.1.4 Doctoral fellow contribution to the SLR and publication of SLR

The published SLR was produced through a collaboration between the doctoral fellow; a therapeutic radiographer colleague, Claire Bennett (CB) and PhD director of studies, Fiona Cramp (FC) (Humphrey, Bennett and Cramp, 2018). At the time of undertaking the initial systematic review the doctoral fellow was supported by University Hospitals Bristol and Weston NHS Foundation Trust, Research Capability Funding [grant number 2016-17-23]. To develop knowledge and understanding of the SLR process, a University of the West of England (UWE) Bristol Masters level module was completed by the doctoral fellow (Systematic reviews in Health module). The SLR findings informed the NIHR Clinical doctoral research fellowship application, supervised by FC. The review was submitted for publication by the doctoral fellow in February 2018 and accepted for publication in June 2018 in Radiography, the official peer-reviewed journal of the Society and College of Radiographers and the European Federation of Radiographer Societies (Humphrey, Bennett and Cramp, 2018).

2.1.5 Rationale for SLR update

For the PhD research programme, an update to the pre-doctoral SLR was required. The aim of the SLR update was to find and analyse any new literature on women's experiences of brachytherapy for cervical cancer.

2.2 Methods

To inform the doctoral research the SLR was updated in 2022 using a similar procedure to that reported in the pre-doctoral publication (Humphrey, Bennett and Cramp, 2018). However, for the 2022 update, the doctoral fellow carried out the SLR without input from co-researchers. The databases and additional sources were searched using the same search terms as the pre-doctoral SLR (see Table 3).

Changes to the inclusion and exclusion criteria for the update were:

- All types of study design which reported primary research data were included.
- Literature reviews, short communications and technical notes were excluded.
- Search date limits were from April 2017 up to and including June 2022

Table 3 Key words and search terms

Key words and search extent	Search terms
Cancer, neoplasm or tumour in all text	cancer*, neoplasm*, tumo*
AND	
Cervix or gynaecological in all text	cervi*, gyn*
AND	
Brachytherapy or intracavitary in all text	brachytherapy*, intracavit*
AND	
Anaesthesia, sedation or analgesia in all text	anaesthesi*, anesthesi*, sedat*, analgesi*
OR	
Anxiety, stress, anxious, PTSD, psychology, coping, phenomenon, distress in all text	Anxiet*, stress*, anxious*, ptsd*, psychology*, coping*, phenomen*, distress*

Critical appraisal of the literature was carried out with the aid of specific CASP tools for each type of study design (Critical Appraisal Skills Programme, 2018), as for the pre-doctoral SLR. However, for the 2022 update, the quality assessment was integrated with the synthesis of the included studies instead of being reported separately.

2.3 Results

The SLR update search found 453 articles and removing duplicates reduced this to 387. Searching of grey literature produced no additional articles. Screening of titles excluded 326 articles, leaving 61. Screening of abstracts excluded 21 articles and full text articles were

obtained for the remaining 40. Snowballing and reverse snowballing found no new articles of relevance. A further 28 full text articles were rejected for the reasons shown in Table 4; leaving 12 articles for data extraction and appraisal. The identification and screening process is shown in Figure 9.

2.3.1 Characteristics of included studies

The data synthesis and analysis were reported in two main categories, reflecting the types of studies identified:

a) Qualitative patient experience studies (three studies) and

b) Intervention studies (nine studies).

The intervention studies were further divided into two sub-categories:

1) Non-pharmacological intervention studies (three studies) and
2) Medical management or toxicity studies (six studies).

The 'medical management or toxicity' studies included a mix of methodological approaches including prospective and retrospective observational studies. Some were studying a new intervention compared to previous practice whilst others had no comparator. The studies met the inclusion criteria for the SLR as they reported patient experiences in terms of patient reported outcomes, such as pain, distress, nausea and other treatment or medication related side-effects. One study was an analysis of acute toxicity and was included in the SLR as pain scores were reported and potential impact of toxicity on patient experiences was discussed. See characteristics of studies in Table 5 and data extraction in Table 6, Table 7 and Table 8.

Figure 9 PRISMA flow diagram of 2022 literature search and screening results

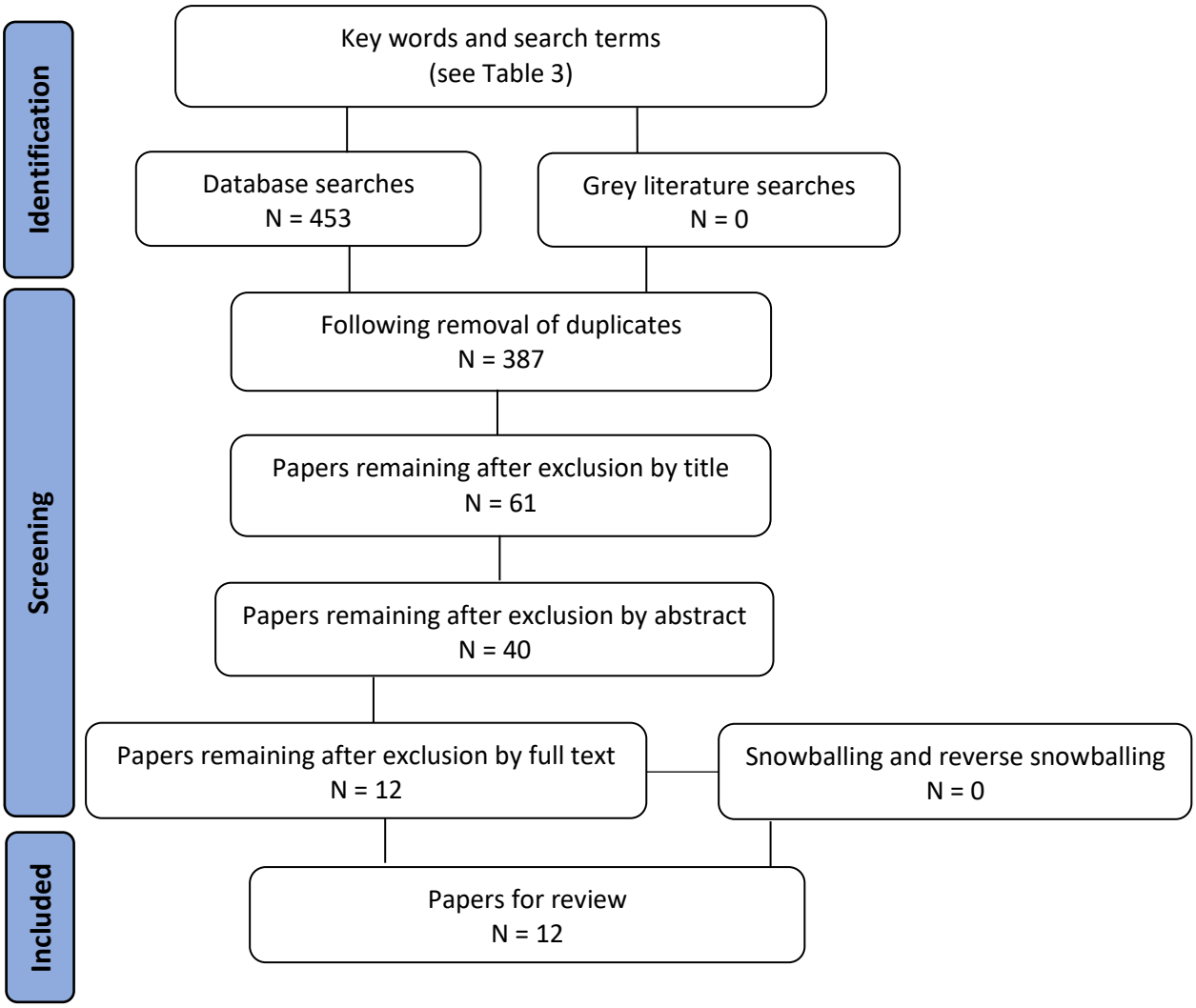


Table 4 Reason for exclusion from full text

Reason for exclusion	Number of articles
No full text available- conference abstract/poster only	18
No patient experience reported	8
Full text not in English	1
Included in pre-doctoral SLR (online article)	1

Table 5 Characteristics of included studies

Author	Pub. date	Country	Study method	HDR/LDR/PDR	ICBT/ISBT
Qualitative patient experience studies					
Araujo *et al.*	2018	Brazil	Semi-structured interviews	HDR	ICBT
Ehlers and Makanjee	2018	South Africa	Semi-structured interviews	HDR	ICBT
Da Rosa *et al.*	2021	Brazil	Semi-structured interviews	Probably HDR/PDR	Probably ICBT
Intervention studies: non-pharmacological					
Kissel *et al.*	2020	France	Cohort, prospective	HDR/PDR	ICBT
Varnier *et al.*	2021	France	Cohort, prospective	HDR/PDR	ICBT/ISBT
Blackburn *et al.*	2021	USA	RCT	HDR	ICBT
Intervention studies: medical management/toxicity					
Leong *et al.*	2017	Singapore	Cohort, retrospective	HDR	ICBT/ISBT
Nielsen *et al.*	2017	USA	Cohort, retrospective	HDR	ISBT
Mendez *et al.*	2017	Canada	Cohort, retrospective	HDR	ISBT
Murata *et al.*	2021	Japan	Cohort, retrospective	HDR	ISBT
Mahapatra *et al.*	2021	India	Cohort, retrospective	HDR	ICBT
Chen *et al.*	2021	China	Cohort, prospective	HDR	ICBT/ISBT

Abbreviations: HDR=high dose rate; PDR=pulsed dose rate; ICBT=intracavitary brachytherapy; ISBT=interstitial brachytherapy; RCT=randomised controlled trial

Table 6 Data extraction for qualitative patient experience studies

Author/ year	Study aim	Population/ recruitment	Age	Duration of study	Brachy procedure	Methods	Results	Quality	Recommendation/ Impact
Araujo *et al*., 2018	To identify the perception of pain for women in gynaecological brachytherapy	Recruitment from 2 hospitals in different cities. N=13 women.	Range 30-82 years, no mean or median	10 months in 2012	Not specified	Semi-structured interviews, closed questions for demographics then one open question about perception of pain resulting from brachytherapy.	Results combined with discussion. Only one theme mentioned: "Overcoming pain" with 3 quotes to illustrate.	Poor quality. No information about treatment/context. Refers to other literature, but references missing. Journal is peer-reviewed, but several presentational errors and lack of clarity.	Weak conclusion, confirmed women experienced pain. A 2017 paper, same authors and patient cohort, focussed on nursing consultation, not patient experiences, therefore not included in SLR.
Ehlers and Makanjee, 2018	To establish gynaecological cancer patients' expectations, experiences, understanding of HDR brachytherapy treatment procedure.	Purposive sampling, from diverse cultures. N=10. Stopped when data saturation reached.	No data	Not specified	Short duration, 20-30 minutes delivery time, overall time not reported.	Semi-structured interviews based on schedule from Long *et al*. (2016). Probes/prompts where necessary. First author did all interviews, 3 time points, pre-brachy, after brachy, after all brachy completed.	Major challenges, mixed thoughts and feelings, trauma but desire to be healed was fulfilled. Themes: patients wanted to see for themselves; need for more information; benefits of brachy justified painful experiences.	Strengths: one researcher for all interviews, 2nd author helped analysis/write up. Weaknesses: sampling and saturation not explained. Mentioned trustworthiness, credibility and member checking, no method given.	Identified unmet needs of patients. Valuable knowledge for local team, could be applicable to other centres. Short duration procedures with sedation and analgesia, simple ICBT only.
Da Rosa *et al.*, 2021	To know the meaning of brachytherapy in women with gynaecological cancer.	Convenience sampling, consecutive patients. N=32. Stopped at data saturation.	Age range 25-77, average 51	10-11 months	Not specified, some had more than one treatment. 20 had GA induction. Duration not specified.	Semi-structured interviews, last brachytherapy day, closed questions for demographics then two open questions, what did it mean for you to have brachytherapy, what feelings or discomfort arose? Content analysis of transcripts.	5 thematic categories. 3 themes/sub theme categories reported. Description and context of subthemes, numbers of participants contributing to some subthemes.	Strengths: one researcher for all interviews. Good quality data analysis. Similar themes to other studies, good depth of reflection, analysis and theory weaved through results. Weaknesses: unable to member check transcripts or analysis. No reflexivity.	Acknowledged impact of brachy on women and understanding the meaning of experiences. Recommended nurses should be attentive and listen to be able to make appropriate decisions for better nursing care.

Abbreviations: Brachy=brachytherapy; GA=general anaesthetic; ICBT=intracavitary brachytherapy

Table 7 Data extraction for Intervention studies: non-pharmacological

Author/ year	Study aim	Population/ Recruitment	Age (years)	Brachy procedure	Method/ intervention	Results	Quality	Recommendation/ Impact
Kissel *et al*., 2020	To determine feasibility of simple intracavitary implantations for uterovaginal brachy under hypnosis and simple premedication.	N=84 consecutive patients offered hypnosedation or standard anaesthesia	Median=56 (range 36-80)	PDR, but only relevant to insertion time- median duration 30 minutes	Premedication (4 drugs); Nitrous oxide offered/given; Eriksonian technique: suggestion of safety and wellbeing, projection of self to a pleasant situation or memory. Recorded anxiety (validated score), in-house questionnaire to patients and oncologist, pain (VAS) mean and maximum scores before during and after implant, comfort score, conversion to anaesthesia if required, a priori perception of hypnosedation.	N=20/84 selected hypnosedation. 4 converted to anaesthesia due to pain, 80% success rate. Age and pre-op anxiety level associated with failure but not powered for significance. Retrospectively 30% would have preferred a GA, but 90% would recommend to others, could consider success rate as 70%.	Limitations: mean and maximum pain scores given but no ranges. Questionnaires on same day as insertion. Would have been useful to repeat after applicator removal, to give overall comfort scores. Not randomised, no comparison to standard treatment. Strengths: good use of scoring systems and PROs, participants' prior knowledge of hypnosedation, overall satisfaction as well as VAS pain, comfort and anxiety	Author conclusion: Pain scores acceptable, similar to other studies using no anaesthesia. Feasible. Success rate of 70%. May reduce theatre time and avoid anaesthetic side effects. DF conclusion: May not be generalisable, unusual previous experiences e.g. vaginal moulds. Can only offer to suitable patients, if unlikely to experience severe pain, but hard to predict if manipulation of uterus will be painful. Unsuitable for ISBT.
Varnier *et al*., 2021	To assess relevance of VR distraction during uterovaginal brachy applicator removal, as an alternative to nitrous oxide conscious sedation.	N=14 in VR arm, n=21 in reference arm	Mean: VR arm: 53 (range 45–61), Reference arm 51 (range 43–67)	80% had PDR, typically 60 hour duration of whole procedure. HDR, 5 treatments with minimum 8 hour gap, 2 per day, likely 60 hour total time.	During applicator removal: VR arm: 10 minute distraction session, goggles with smartphone/earplugs displaying a virtual dive with a whale, swimming in peaceful environment, invited to slow down breathing to follow movement of whale's tail. Reference arm- standard use of nitrous oxide gas. Recorded: PROs- pain, anxiety; side effects; premedication.	Parallel curves for pain and anxiety except for higher VAS pain value peak in VR group. Side effects of nausea, vomiting and/or dizziness higher in VR group.	Limitations: not randomised, not possible to blind patients or staff. Higher peak pain in VR group, may be related to no analgesic effect of nitrous oxide. Unexpected side effects with VR, no previous reports. VR prevented verbal/eye contact between patients and physicians/nurses during removal, may have been detrimental. Sample too small for inferential statistics.	Author conclusion: acceptable levels of pain and anxiety in both study arms. Definitive study warranted. Alternative could be a programme of breathing, maintaining verbal and eye contact with HCPs. DF: Findings may be relevant where patients are awake for applicator removal. Concerning side effects with VR.

Author/ year	Study aim	Population/ recruitment	Age (years)	Brachy procedure	Method/ intervention	Results	Quality	Recommendation/ Impact
Blackburn *et al*., 2021	To determine if the addition of aromatherapy and foot reflexology to standard care improves pain and anxiety in patients receiving brachy for cervical cancer.	N=41 having ICBT for LACC, 193 ICBT treatments given. N=22 intervention arm, n=19 control arm. Excluded ISBT patients.	Mean: Inter-vention arm: 48 (range 29–77), control arm 55 (range 33–80)	5 x day case procedure, twice weekly. GA 1st time only and Smit sleeve insertion. Total typically 7-9 hours each time.	Patient choice of essential oil, diffuser at head of bed for duration. During rest time waiting for planning (typically 90-120 minutes) reflexologist to ward, 30 minute reflexology. PROs, pain NRS, anxiety short STAI (6 questions) and NRS at 5 time points during procedure. Long STAI (40 questions) at baseline, self-evaluation of both interventions. Drug use.	Average pain 2.9 points lower for intervention group at each time point, greatest difference post reflexology. Average anxiety 2.7 points lower on NRS, 20 points on STAI. Statistically significant difference for pain post reflexology. No difference in drug use between groups. Both interventions highly rated, foot reflexology most helpful, most difference to anxiety.	Strengths: rigorous methods, assessments at 5 time points, powered for significance. Discussed reliability and validity, small number of key staff. Limitations: assessors unblinded. Difference in baseline pain and anxiety levels between groups could be related to self-administered premedication. Reflexologists had to be highly flexible with timing/scheduling due to uncertainties in procedural and imaging times.	Author conclusion: foot reflexology is a viable intervention for improving pain and anxiety, less costly than drugs. DF conclusion: potential intervention to optimise patient experience. Need to investigate feasibility, particularly with timing difficulties when planning start and finish times.

Abbreviations: Brachy=brachytherapy; PDR=pulsed dose rate; GA=general anaesthetic; VAS=visual analogue scale; VR=virtual reality; ISBT=interstitial brachytherapy; ICBT=intracavitary brachytherapy; HCPs=healthcare professionals; LACC=locally advanced cervical cancer; PROs=patient reported outcomes; NRS=numerical rating score; STAI-state-trait anxiety inventory; DF=doctoral fellow

Table 8 Data extraction for intervention studies: medical management/toxicity

Author/ year	Study aim	Population/ recruitment	Age (years)	Brachy procedure	Method/ intervention	Results	Quality	Recommendation/ Impact
Leong *et al*., 2017	To determine the feasibility and safety of outpatient combined ICBT/ISBT for cervix cancer with sedation and LA	N=9, 35 procedures, all cervical cancer, all combined ICBT/ISBT.	Median = 56 (range 40-65)	Usually 4 fractions, 1 patient had 3. Mean duration 4.1 hours (SD 0.95). Day case procedure. Short duration.	All had IV midazolam, propofol, fentanyl and oxycodone and LA to vaginal canal and paracervical block. Recorded sedation score, pain score (11 point NRS), number of needles used and discharge score.	No of needles, median 2 (range 1-4). Median pain scores at 2 time points, 0 (range 0-6) and 0 (range 0-7). Only 3 patients had pain scores >0 at any point and were given IV paracetamol. No adverse effects recorded.	Strengths: Good documentation of drugs, timings and factors which may increase pain. Limitations: small sample size. No evaluation of patient experience, such as fear and anxiety. Authors suggest oncologist evaluation could add to the analysis of benefits.	Author conclusion: moderate sedation and LA appears effective for combined ICBT/ISBT in an outpatient setting. Need to assess patient experience and quantify benefits in future studies. DF conclusion: In UK would still need theatre staff and procedure room, limiting cost benefits.
Nielsen *et al*., 2017	To propose an optimal peri-operative pain management clinical care pathway for interstitial brachy for gynaecologic cancer.	N=23, ISBT with perineal template. 32 implants/ procedures. Gynae cancers- advanced or recurrent cervix, vagina or endometrial.	Mean 55 (range 31-84)	2 or 3 treatments from one implant, some had a 2nd implant. Duration not specified. 1 planned overnight stay per implant. All inpatients except 1. Long duration brachy.	Retrospective data collection/analysis of anaesthesia type (epidural, CS with LA-paracervical block, or CSE), additional drugs given, side effects, pain scores VAS and delayed discharge. GA not possible due to hospital certification restrictions.	Anaesthetic technique decided by clinicians. 74% ASA grade III or IV. 53%: epidural, 34%: CSE, 13%: CS with paracervical block. 52% had post op anxiolytics. PONV in 53% procedures. Pain scores (VAS): CS/local block 3.0; epidural 3.3; CSE 2.6. No statistically significant difference. 5.7 fold reduction in total opioid use with CSE compared with CS/LA, not statistically significant. 22% had agitation, delirium or over sedation associated with basal PCA ($p = 0.03$). 22% had delayed discharge.	Strengths: detailed analysis of drug combinations and side effects. Explanations of pain pathways and neuraxial anaesthesia and local blocks. Limitations: small sample size, many combinations of drugs limiting statistical power. Possible selection bias, anaesthetic type chosen by clinicians (due to patient risk). Needle number/depth not included, may be a confounding variable. Comparison with GA not possible. No patient satisfaction data. VAS and opioid quantity used as proxy for analgesia satisfaction.	Author conclusion: single centre retrospective analysis of effectiveness with many variations in techniques and drugs. Overall low pain scores. CSE appeared to be superior to epidural and CS/local block. High levels of PONV compared with other studies. Recommend giving prophylactic antiemetics early on, but eliminating basal PCA to reduce PONV, avoiding anxiolytics and sedation causing antiemetics. DF conclusion: applicable to other long duration ISBT settings. May not be applicable to short duration or simple ICBT.

Author/ year	Study aim	Population/ recruitment	Age (years)	Brachy procedure	Method/ Intervention	Results	Quality	Recommendation/ impact
Mendez *et al*., 2017	To assess pain and opioid consumption with ISBT in a single institution. Secondary objective: examine associated factors with opioid use.	N=48, gynae cancers, different types, all had ISBT with perineal template.	Median = 63 (range 23-88)	Mean implant duration= 32 hours, 23 had single implant, 25 had 2 implants a week apart. Long duration brachy.	Retrospective analysis of patient records, oral opioid use and IV-PCA converted to oral morphine equivalent dose per day, and by weight. Pain scores taken from nursing charts, 11 point VRS. Number and depth of needles recorded and size of tumour.	IV-PCA pts: over 2 x opioids/day compared with oral opioid patients. Max pain score IV-PCA pts (mean 5.5) vs oral (mean 3.3), statistically sig. P= 0.0007. If 2 implants, 46% more opioids at 2nd implant. Predictors for higher opioid use: previous opioid use and age (inverse association). Not related to number or depth of needles or tumour size.	Strengths: analysis of data, many variables considered. Limitations: greater opioid use potentially due to selection bias. IV-PCA pumps given to patients expected to have poor pain control or requested a pump. No data on well-being, anxiety or distress. Irregular timing of nurse pain scores, but sufficient data to produce pain-score curve with time.	Author conclusion: Age correlation consistent with studies of post-op pain. May not be applicable to ICBT or ICBT/ISBT hybrid techniques as use of perineal ISBT template-needles through perineum and vagina may have different pain mechanisms.
Murata *et al.*, 2021	To investigate the effect of analgesic methods on pain and adverse events during interstitial brachy for gynae malignancy.	N=73, all had ISBT with perineal template for gynae cancers. All had spinals. 3 types of analgesia PCEA (n=32), PCIA (n=9) or conventional (n=32)	Mean and SD: PCEA= 61.2 (±) 13.6; PCIA= 59.8 (±) 17.2; Convent-ional= 58.9 (±) 15.3	All had at least 2 days inpatient stay and at least 4 ISBT fractions. Long duration brachy.	Mean individual pain score, NRS, for 3x12 hour periods, 12-24 hours on first day then 0-12 and 12-24 hours on 2nd day. Additional analgesia and adverse events reported. Anxiolytics given as required. Mean number of needles 14 for PCEA, 14 for PCIA and, 15 for conventional.	NRS significantly lower for all time periods for PCEA and 2nd and 3rd time periods for PCIA compared to conventional analgesia. No significant difference between NRS for PCEA and PCIA. No difference in additional analgesia or adverse events. PCEA and PCIA- lower anxiolytic use. Pruritus 13% more common with PCEA.	Strengths: 5 years of data, good sample size; statistically significant findings. Limitations: retrospective, some pain data missing; may underestimate adverse events as only recorded if patient complained. Unable to determine total analgesia. No patient experience or satisfaction data.	Author conclusion: PCIA and PCEA superior to conventional analgesia techniques for ISBT, although no reduction in adverse events. PCA appears to reduce anxiety levels. Need prospective study to accurately assess pain and adverse events and optimal setting for PCEA and PCIA. DF conclusion: lack of MR imaging compatibility of PCA devices may be problematic for future studies.

Author/ year	Study aim	Population/ recruitment	Age (years)	Brachy procedure	Method/ Intervention	Results	Quality	Recommendation/ Impact
Mahapatra *et al.*, 2021	To compare dosimetry of high-dose-rate ICBT with spinal anaesthesia (SA) with conscious sedation (CS).	Retrospective data for n=56. All had cervical cancer and ICBT. 28 had SA, 28 had CS. Not clear if consecutive or all cases.	SA group, range 31-76, modal range 60-69; CS group, range 35-76, modal range 50-59	Likely all day case brachy but not specified. No duration specified. All had CT scan and simple planning. Once weekly brachy, likely short duration.	Dosimetry for 84 plans, n=28/group. SA group: bupivacaine heavy and fentanyl. CS group: promethazine and tramadol IV infusion. Modified Observers Assessment of Sedation Scale score for depth of sedation, score of 3 considered adequate, then taken to theatre and LA spray. Both groups had ondansetron premedication, CS group added pantoprazole. Pain VAS at end of procedure.	No statistical difference in dosimetry for organs at risk prescription doses. Mean VAS scores for CS group for 1st, 2nd and 3rd fractions were 5.3; 4.8 and 4.5 respectively. For SA group mean VAS was 1.3. Not clear if that was mean for all 3 fractions.	Strengths: large sample size. Useful considerations for high volume caseload if anaesthesia resources are scarce. Limitations: retrospective. Moderate pain in CS group, reduces with subsequent fractions, but no range of pain VAS scores. Only asked patient at end. Lack of detail for SA pain scores for 3 fractions, just one overall score.	Author conclusion: CS a viable option for high volume centres, scarce anaesthesia resources. An option if anaesthesia is contraindicated. DF conclusion: No provision for ISBT techniques, or more complex planning with MR imaging and longer duration. Therefore, may not be applicable in many settings.
Chen *et al.*, 2021	To report applicator insertion-related acute side effects during brachy for cervical cancer patients.	N=125 LACC patients, 407 fractions/ insertions. All had GA.	Median age 54, (range 30-77)	4 x day case procedure Duration 175-336 hours total, mean 218.8	Acute side effects measured at all fractions, during 8 stages of brachy, analysis reported under headings of: anaesthesia-related; mechanical related; infection; pain; vaginal bleeding	Low levels of acute side effects. Positive association between number of needles and vaginal bleeding; also between procedure time and acute side effects frequency. Severe pain in 75/407 fractions, most occurrences at applicator removal (65 fractions), NRS 4.9 (±) 1.6 at removal.	Strengths: large sample size. Weaknesses: no data on variation of acute side effects over time/number of insertions, no post brachy data. Minimal patient experience data.	Author conclusion: Advises reducing procedure time and number of needles used, to reduce acute side effects and enhance patient experience. DF conclusion: Future work could consider which patients need IV-PCA pump and which would manage with oral opioids.

Abbreviations: Brachy=brachytherapy; GA=general anaesthetic; Gynae=Gynaecological; LA-local anaesthetic; IV=intravenous; VAS=visual analogue scale; NRS=numerical rating score; CS=conscious sedation; SA=spinal anaesthetic; CSE= combined spinal epidural; ASA= American Society of Anaesthesiologists; PCA=patient controlled analgesia; PCEA= patient controlled epidural analgesia; PCIA- patient controlled intravenous analgesia;; PONV=postoperative nausea and vomiting; MR-magnetic resonance imaging; DF=doctoral fellow; LACC=locally advanced cervical cancer;

2.3.2 Data analysis and synthesis

Patient experience studies

Three studies examined the lived experiences of patients undergoing brachytherapy through semi-structured interviews, all reporting themes or shared characteristics developed from interview data. Study characteristics are summarised in Table 5 and data extraction and synthesis in Table 6. The number of participants ranged from 10 to 32. Araujo *et al.* (2018) and Ehlers and Makanjee (2018) both described the use of a phenomenological approach, whereas Da Rosa *et al*. (2021) used content analysis of interview data in a descriptive and exploratory approach. Women with different types of gynaecological cancers were recruited to the studies and details of applicator types or the duration of the procedure were unspecified. HDR brachytherapy was reported by Araujo *et al*. (2018) and Ehlers and Makanjee (2018) and dose rate was not specified by Da Rosa *et al.* (2021). Age ranges of participants were similar in two of the studies, with da Rosa *et al*. (2021) commenting that five participants were under 40 and Aruajo (2018) noting that three participants were in their 30s. This was mentioned due to the significance of infertility caused by the treatment. Ehlers and Makanjee (2018) do not specify any age details of participants. Analysis and synthesis of the study findings are summarised under two headings: (1) The meaning of pain and (2) Personal beliefs and the impact of fear.

1. **The meaning of pain**

Araujo *et al.* (2018) interviewed 13 women at two treatment centres in Brazil, to understand the perception and meaning of pain during brachytherapy for cervical cancer. They asked participants one open question about their perception of pain and reported only one category in their results: “Overcoming pain”. They provided seven quotations from only four of the participants, which refer to pain experiences and fear of the treatment and shock at the diagnosis. However, these quotations add little to the understanding of the meaning or perception of pain and the findings are not synthesised with existing literature. Araujo *et al*. (2018) state that the pain women experience is a subjective fact, and that nurses should try to understand the pain and prioritise the relief of the physical pain. They comment that the experience of pain is unique to each person, and advise that culture, age and the extent of the disease need to be considered when assessing pain for these women. Considering the quality of the study, it was noted that this publication appears to be a sub-study into the

benefits of the 'nursing consultation' to provide pre-brachytherapy information (Araujo *et al.*, 2017). The 2017 study referred to the same 13 patient interviews, although it reported different interview questions related to the pre-brachytherapy information provided by a nurse. Araujo *et al*. (2018) contained multiple typographical and grammatical errors which impact upon the overall meaning. Further to this, there was insufficient interview data presented to support the recommendations. Specifically, from 13 interviews with patients, only seven direct quotations from four participants were provided and most of the results and discussion did not relate to these interview data.

Da Rosa *et al.* (2021) presented a study of the experiences of 32 women after brachytherapy at a single centre in Brazil. Participants included 26/32 with a diagnosis of cervical cancer. Although only two guiding questions were reported, the analysis of the data shows interpretive and analytical quality in the development of five thematic categories and relevant examples to illustrate the categories. One of the categories reported is "Pain as the meaning of brachytherapy". In keeping with content analysis methodology, the number of participants who experienced pain is reported, providing a quantitative indication of the significance or importance of the thematic category. In the overall cohort of 32 participants two groups were identified: 12 women who received simple brachytherapy after a hysterectomy (no anaesthesia required) and 20 women who experienced more complex brachytherapy when no hysterectomy had been carried out (requiring anaesthesia for brachytherapy). It might have been anticipated that the simple brachytherapy group would report less pain than the complex brachytherapy group. However, in both groups, pain was reported by most participants. For those having simple brachytherapy 3/12 reported pain before treatment (disease related) and seven reported pain after each brachytherapy session. For those having more complex brachytherapy, 11/20 experienced pain at applicator removal and 9/20 had pain that continued after the end of brachytherapy. Qualitative understanding of the pain experience was provided by the inclusion of quotations from participants. The study results were interweaved through the analysis and discussion, reporting similar findings of painful experiences compared with previous studies. Recommendations were made for anaesthesia to be provided until treatment is completed, or for nurses to stay with patients throughout the procedure, to provide continual pain assessment leading to better pain management.

Ehlers and Makanjee (2018) carried out semi-structured interviews with 10 women from one centre in South Africa at three different time points: before first brachytherapy; directly after first brachytherapy and after completion of all brachytherapy. Questions were based on an interview schedule previously used by Long, Friedrich-Nel and Joubert (2016b). Results reported by Ehlers and Makanjee (2018) were difficult to fully comprehend with headings that did not appear to capture the essence of the text. For example, experiences of pain were mentioned in the results section under the heading: "The machine was hot, but this one is not hot". Some participants had an overall positive experience of brachytherapy, but some found it excruciatingly painful. In the discussion section the authors stated that all participants had some degree of pain. However, they reported that the participants were able to endure the pain because they understood the potential benefit of the treatment, which was to 'heal' them. Following a phenomenological approach, the authors attempted to focus on the meaning of the pain and how women endured it, rather than descriptions of severity or causes of pain. They emphasised the importance of the power of hope, a key message that the participants conveyed during interviews. One of the author's recommendations was to provide higher levels of sedation to women, to reduce the experiences of pain, and better information about the sedation to reduce women's fear of pain.

2. Personal beliefs and the impact of fear

Two of the thematic categories developed by Da Rosa *et al*. (2021) described different aspects of women's fears. They described women's fear of dying and personal beliefs under three subheadings: Religiosity; Treatment as a cure; Motivations for treatment and fear of dying. In this study, ten of the 32 women told the interviewer about their belief in God and how their faith and prayer helped them to cope with the treatment. Da Rosa *et al.* (2021) referred to faith as a "comfort strategy" and an "aid to healing" which women used to reduce anxiety and fear about the discomfort of the treatment. Kolcaba's "Theory of Comfort" was used as a basis for explaining the need for nurses to strive to reduce discomfort, allowing relief, tranquillity and transcendence of the difficult brachytherapy experience (Kolcaba, 2003). Ehlers and Makanjee (2018) also reported that a few participants resorted to their faith in God, praying for help with the treatment.

The impact of the cancer diagnosis, fear of failure of the treatment or cancer returning after treatment were present in the data from all three studies. Ehlers and Makanjee (2018) explained the meaning of their category "Patient's desires" as the participants expressing their desire to be healed and return to normal life. Quotations from participants demonstrated worries about tumour tissue being left behind or the tumour returning. Araujo *et al*. (2018) provided participant quotations related to the shock of the cancer diagnosis, a world being turned upside down and the fear of the treatment itself, including potential suffering. Da Rosa *et al.* (2021) gave examples of women who related fear of dying to concerns about their families. They wanted to live and be cured for their children and grandchildren, and this provided them with the motivation and "stimulus" to cope with the treatment and the cancer diagnosis.

Da Rosa *et al.* (2021) explored women's fear of the treatment and the treatment-related physical and emotional discomfort. Some fears were reported to be due to ignorance about the procedure and the technology being used, and fear resulted in emotional discomfort. Similarly, Ehlers and Makanjee (2018) blamed unfamiliarity with brachytherapy for causing most anxiety among women. They concluded that better information before brachytherapy would alleviate some fears and anxieties and lead to a better experience of the treatment. Ehlers and Makanjee (2018) found that women preferred to "see for themselves" rather than listen to other patients' experiences. They explored the published literature on patient's preferences for information, verbal or written information or both, and the quantity and detail of information to be offered to women. They agreed with an earlier report from Kwekkeboom *et al.* (2009) that patients should be less anxious and afraid as they progress through their treatments as they know what to expect. However, it is not clear if this was supported in their data. Ehlers and Makanjee (2018) found that participants were able to understand their treatment by constructing their own meaning of it, and they explained their understanding of brachytherapy and its purpose at interview. Araujo *et al.* (2018) concluded that the "nursing consultation" is the place where women could learn and be helped to understand the physical and psychological effects of brachytherapy, and that the nurse who already knew the patient was best placed to asess, define and potentially meet their needs.

Shame of exposing their bodies, especially to male medical staff, was linked with emotional discomfort by Da Rosa *et al*. (2021). Women described sadness at their "mutilated body" and loneliness and helplessness when they were alone in the brachytherapy room receiving treatment. This increased their fear of the procedure and hence increased emotional discomfort. Araujo *et al*. (2018) referred to emotional discomfort and "inner/emotional suffering" which they thought may be best managed by a referral to the psychology team.

In summary, with varying levels of depth and quality, the three qualitative studies explored the brachytherapy experiences of women and their understanding and the meaning of the procedure. The meaning of pain, fears about the treatment, fear of death and personal beliefs were identified by the authors as the most important themes.

Non-pharmacological interventions

In this SLR update three studies were identified which examined effects of non-pharmacological interventions; characteristics of the studies are summarised in Table 5 and data extraction and synthesis in Table 7. One study considered the impact of a non-pharmacological intervention throughout the brachytherapy procedure whereas the other two studies considered the effect at specific time points during brachytherapy. The non-pharmacological interventions studied were: hypnosedation (Kissel *et al.*, 2020); virtual reality distraction (Varnier *et al.*, 2021) and foot reflexology and aromatherapy (Blackburn *et al.*, 2021); which could all be classified as types of complementary or integrative therapies.

Two studies carried out in different centres in France examined specific parts of the brachytherapy procedure. Kissel *et al*. (2020) considered applicator insertion while Varnier *et al.* (2021) studied applicator removal. Kissel *et al*. (2020) offered hypnosedation as an alternative to GA during insertion of intracavitary applicators. Hypnosedation in this study followed a classic Eriksonian technique, using indirect hypnosis with the basic principle of suggesting a feeling of safety and wellbeing. The patient would be asked by the therapist to project themselves into a pleasant situation or memory that had been previously established. In this study the hypnosedation was carried out by a radiation therapist who had been trained in the Eriksonian technique. The hypnosedation intervention was accepted by 20 out of 84 patients who were offered it. Clinicians did not offer the procedure to women who were anticipated to have painful procedures, for reasons such as a history of

painful vaginal examinations. The hypnosedation lasted for approximately 30 minutes while the applicators were positioned, but the radiation delivery continued with standard analgesia. Departmental standard premedication was given to all participants, including paracetamol, antispasmodic drug, anxiolytic drug and a small dose of morphine, but no anaesthetic type drug was administered. Mean and maximum pain scores were recorded by participants, along with anxiety and comfort scores on a scale of 0-10. Mean and maximum pain scores were reported as 2.5/10 and 4.9/10 respectively but no details of standard deviations or range of scores were reported. The method mentions that nitrous oxide gas could be used by participants during the applicator insertion, but it is not clear how this would be possible during hypnosedation. No results on the use of nitrous oxide gas were provided. Four of the 20 participants were switched to GA when the procedure became too painful. The authors report 80% success rate, even though one applicator was incorrectly placed and six participants said afterwards that they would have preferred a GA. Whilst hypnosedation helped women to feel relaxed, and was a feasible procedure, it was not acceptable to most patients, considering the number who either declined the study or stated afterwards that they would have preferred a GA.

Varnier *et al.* (2021) used a virtual reality (VR) headset to watch a deep whale dive as a pilot study to see if the use of VR would reduce pain and anxiety during applicator removal. VR was compared with the standard treatment using nitrous oxide gas, called 'conscious sedation' by the authors. However, the level of sedation would have depended on how much nitrous oxide was inhaled and is likely to have been at a lower level than conscious sedation with typically used intravenous drugs such as propofol or midazolam. Rather than reducing pain scores, a higher peak pain score was seen in the VR group and there were concerns regarding unexpected side effects of nausea and vomiting. The authors discussed a possible disadvantage from the use of the VR headset, noting that the loss of eye and verbal contact between healthcare professional and patient during applicator removal may have offset some benefits. They suggest that an RCT would be needed to confirm whether there are benefits of using VR over nitrous oxide gas.

Blackburn *et al.* (2021) carried out a pilot RCT comparing the addition of foot reflexology and aromatherapy to standard care on pain and anxiety levels during short duration day

case intracavitary brachytherapy. Participants received five brachytherapy procedures over a two-and-a-half-week period, with two procedures per week, each procedure typically lasting between seven and nine hours. During each brachytherapy procedure the intervention group received aromatherapy from a travel diffuser using three drops of the patient's choice of essential oil. The diffuser was placed at the head of the patient's bed and scent was diffused until the patient was discharged. The intervention group also received a 30-minute session of foot reflexology while treatment planning was being carried out by the oncologist. All participants had GA for the first procedure, including the insertion of a Smit sleeve[6] (indwelling intrauterine tube) which meant that remaining procedures did not require a GA for applicator insertion. Pain and anxiety were recorded on a numerical rating scale of 0-10. Results showed average pain scores were lower for the intervention group at each time point, with the greatest difference seen post foot reflexology, with an average of 2.9 points lower than standard care. The intervention group also reported lower anxiety scores, with an average of 2.7 points lower compared with standard care. Participants rated the intervention highly, with foot reflexology reported as more helpful than aromatherapy, particularly in relation to reducing anxiety levels. A criticism of the study would be that combing two complementary therapies may have made results more difficult to interpret, therefore it may have been useful to consider just one intervention at a time with three study arms. One problematic aspect noted by the authors was that the reflexologists had to be very flexible with their availability to deliver the intervention, as timing for theatre, imaging and treatment was variable and unpredictable. Feasibility of this service would need to be considered if attempting to provide reflexology in a non-research setting.

In summary, from the three non-pharmacological studies in this SLR update, findings and implications for future practice are variable. Hypnosedation during applicator insertion may be a useful alternative to anaesthesia for a select group of women. For these women, this would avoid side effects caused by anaesthetic drugs and the need for an anaesthetist to be present at applicator insertion (Kissel *et al.*, 2020). Use of a VR headset during applicator removal needs further investigation (Varnier *et al.*, 2021). A pilot study suggested that foot

[6] A Smit sleeve is an indwelling intrauterine tube, typically sewn into position at first brachytherapy and left in place after applicator removal, to assist in the introduction of the intrauterine tube at subsequent insertions and potentially avoid the need for anaesthesia. In current UK practice it is rarely used.

reflexology reduced pain and anxiety during brachytherapy and was potentially inexpensive and safe (Blackburn *et al.*, 2021). Overall, some complementary or integrative therapies warrant further investigation to consider their efficacy and feasibility in different brachytherapy settings.

Medical management and toxicity

In this SLR update there were six studies included which reported investigations of pain medication or toxicity during gynaecological brachytherapy, characteristics summarised in Table 5 and data extraction and synthesis in Table 8.

Short duration brachytherapy

Three studies included in this SLR used short duration brachytherapy techniques with applicators in place for three to four hours or unspecified, with day case or outpatient procedures. A variety of anaesthesia or analgesia techniques were reported. Using a hybrid ICBT/ISBT technique with up to four interstitial needles, Leong *et al*. (2017) carried out a feasibility study of a novel anaesthesia and analgesia technique. This is the only study in this SLR update which examined the efficacy of a paracervical block. For 35 hybrid technique insertions, all nine participants were given intravenous midazolam, propofol, fentanyl, oxycodone, a local (topical) anaesthetic gel to the vaginal canal and paracervical block with a mixture of 1% ropivacaine, 2% lignocaine, and 1:1,000 adrenaline. They reported a median pain score immediately post-insertion and in recovery of 0 (range 0-6) and 0 (range 0-7) respectively. Overall, only three patients had pain scores above zero at any point. They show a highly effective pain management regime for a day case or outpatient procedure with mean duration 4.1 hours (standard deviation= 0.95). The authors considered whether this technique could reduce hospital costs related to GA complications and admissions. They recommended that a further study should be carried out to examine patient experience and the impact of their novel anaesthesia and analgesia technique on patient anxiety or distress (Leong *et al.*, 2017).

A recent retrospective cohort study from a centre in India compared spinal anaesthesia with conscious sedation (Mahapatra *et al.*, 2021) for day case ICBT procedures. Patients for conscious sedation received promethazine and a tramadol IV infusion followed by a local

(topical) anaesthetic spray. Although the primary aim of the study was to compare the radiation dosimetry achieved for patients receiving the different anaesthesia techniques, such as high dose to tumour and low dose to organs at risk, a secondary outcome was to compare pain scores. The inclusion of patient reported pain scores met the inclusion criteria for this SLR. However, there was only one score per patient per procedure in the conscious sedation group, recorded by recovery nurses asking patients for an overall pain score at the end of the procedure. Mean scores for 1st, 2nd and 3rd procedures were 5.3, 4.8 and 4.5 respectively (on a scale of 0-10). For those in the spinal anaesthesia cohort there was only one score reported for all three procedures, with a mean pain score of 1.3. None of the reported pain scores included standard deviations or range of scores. Although the spinal anaesthesia was superior with low pain scores compared to moderate pain scores for conscious sedation, the authors concluded that conscious sedation was a viable option for high throughput centres with limited resources. This was mainly in response to the primary aim as there was no inferiority in the radiation dosimetry achieved in the conscious sedation arm.

Chen *et al*. (2021) analysed applicator insertion related side-effects from brachytherapy. They subdivided side effects into anaesthesia related, such as dizziness, nausea and vomiting; operation related, such as pain, vaginal bleeding and uterine perforation; infection (fever) and 'other'. Although there was little to directly relate these acute side effects to patient experience data, some of the acute side effects are likely to have had a relationship with positive or negative experiences. The study met the SLR inclusion criteria as patient reported pain scores were obtained. Pain was measured using the numeric rating score with a mean pain score at applicator removal of 4.9 (+/- 1.6). Severe pain (score of 7-10) was recorded at applicator removal in 75/407 brachytherapy procedures in 125 patients. There was also severe pain recorded during the waiting time with applicators in place (between imaging and treatment delivery) for 65/407 procedures. Total procedure duration varied from 175 to 336 minutes. Chen *et al*. (2021) found a positive association between number of interstitial needles used and the volume of vaginal bleeding and pain during applicator removal ($p < 0.05$) and a positive association between the frequency of acute side effects and total procedure duration ($p < 0.05$). They recommended that waiting times between imaging and treatment delivery should be reduced as far as practicable and additional

analgesia given when moderate or increasing pain is reported by patients (Chen *et al.*, 2021). They used a mean number of 8.4 needles (range 1-28) with a median depth of 5cm (interquartile range 3-5cm). They also reported a mean vaginal bleeding volume of 44.4 ml (+/- 96.4ml) at the time of applicator removal and concluded that reducing numbers of needles could help to reduce bleeding and pain, but care should be taken to ensure the tumour volume is still adequately covered by the radiation dose.

Long duration brachytherapy

Three studies included in this SLR considered pharmacological management for long duration brachytherapy. They all examined pharmacological management during ISBT alone (Mendez *et al*., 2017; Nielsen *et al.*, 2017; Murata *et al*., 2021). These studies included participants with gynaecological cancers, not cervical cancers alone, as an ISBT technique may typically be used to treat vaginal, endometrial and vulvar cancers in addition to cervical cancers.

Mendez *et al.* (2017) compared pain scores and opioid use for patients receiving standard oral opioid medication versus those given opioids through an intravenous PCA pump. This showed that those with intravenous PCA consumed more than twice the quantity of opioids (calculated as morphine equivalent dose per day) and a statistically significant higher pain score compared with those on oral opioids. However, the authors acknowledged selection bias as those who were anticipated to need stronger analgesia were chosen to have intravenous PCA, rather than showing that the PCA was inferior. They also found that those having a second implant were given 46% more opioids during the second implant compared with the first implant. They examined predictors for higher opioid use and found associations with previous opioid use (prior to brachytherapy) and an inverse association with age. No associations were found relating to number of needles, depth of needles or size of tumour (Mendez *et al.*, 2017a). This contrasts with a study of side effects during short duration brachytherapy by Chen *et al.* (2021) where an association was shown between pain and number of needles used. Selection bias may also have been a factor in the study by Nielsen *et al.* (2017) and shows the difficulty in demonstrating superiority of one technique over another in a retrospective cohort study design where there may be many confounding variables or comparison of dissimilar cohorts. Similar to Mendez *et al.*

(2017), Nielsen *et al.* (2017) reported that the type of analgesia was chosen by the anaesthetist and oncologist "depending on the needs of the case". This would have included consideration of the patient's co-morbidities combined with the number of needles likely to be inserted, the size and position of the tumour and potential for pain. Although duration with needles in situ was not specified by Nielsen *et al*. (2017), it can be deduced that it was long duration brachytherapy as two or three treatments were delivered from each implant, typically with one overnight stay. They reported that a CSE technique gave lower pain scores and lower opioid consumption compared with conscious sedation and local anaesthesia with a paracervical injection or epidural alone, but this did not reach statistical significance.

Murata *et al.* (2017) compared pain scores and adverse events for three types of analgesia after spinal anaesthesia for perineal ISBT implants. The standard technique was using a combination of oral and intravenous analgesia. The alternative interventions were PCA via an intravenous route (PCIA) or an epidural route (PCEA). The mean number of needles used were 14 or 15 for the three groups. The duration was not specified, however two days with four treatments was implied by the data collection time periods. Lower pain scores were shown for the PCIA and PCEA groups compared with conventional analgesia, but no significant statistical difference between PCIA and PCEA. There were no differences in adverse events or additional analgesia other than a higher incidence of pruritus (itching) in the PCEA group. The authors concluded that continuous analgesia was superior to intravenous opioids for this type of brachytherapy implant but consideration may need to be given to MR imaging compatibility of the PCA equipment.

2.4 Discussion

Three patient experience studies included in this SLR update explored women's perception and understanding of their brachytherapy experiences. The nine intervention studies showed pharmacological and non-pharmacological approaches that may be employed to improve women's experiences of brachytherapy through reducing pain and other physical side effects along with reducing the psychological impact.

The study of acute side effects by Chen *et al.* (2021) concluded that reducing waiting time between applicator insertion and treatment delivery and therefore overall procedure time

was desirable to reduce acute toxicity of brachytherapy and patient discomfort. Some centres have examined workflow, reporting decreases in overall time to use less resources and improve safety in brachytherapy planning whilst introducing more complex techniques (Kim *et al.*, 2018; Damato *et al.*, 2015; Mayadev *et al.*, 2014). However, none of these studies mention reducing overall time for the purpose of improving patient experiences of brachytherapy. The development of HDR brachytherapy from LDR techniques was originally welcomed as an improvement which would allow short day case procedures that would be more tolerable for women (Petereit and Pearcey, 1999). Longer duration procedures have arisen due to increasingly complex planning requirements, following the requirements for image-guided adaptive brachytherapy, including MR and CT imaging with requirements to optimise radiation dose to the tumour and minimise dose to the OARs, explained in chapter one (Pötter *et al.*, 2018). Longer treatments such as PDR, multiple HDR fractions per insertion over a number of days or the use of interstitial needles are considered likely to increase pain and therefore anxiety and distress and justify the implementation of continuous analgesia (Janaki *et al.*, 2008). Conversely, some studies of multiple sessions of short duration brachytherapy found that there was no decrease, or sometimes an increase in anxiety for subsequent insertions and raised concerns that contrary to expectations, women did not adapt and were not reassured after their first treatment (Dzaka and Maree, 2016; Kwekkeboom *et al.*, 2009). Therefore, it is possible that multiple day case procedures may lead to a re-traumatisation for women if their first experience of brachytherapy caused distress.

Overall, there is no clear superior fractionation regime in terms of clinical effectiveness, such as local cancer control rates or long-term cancer survival. This has led to a multitude of fractionation options being widely accepted in international clinical practice (Albuquerque *et al.*, 2019). However, it is possible that the large numbers of participants included in the current ongoing multicentre, multinational EMBRACE I and II studies may identify a difference between fractionation regimes in the long-term follow-up. This SLR demonstrated no clear difference in fractionation regimes, in terms of pain, anxiety and distress. It has shown that some centres are attempting to find and implement suitable interventions to address the needs of patients in terms of management of physical and psychological impacts of brachytherapy.

An international survey of practice reported that 97% of 72 respondents used some form of anaesthesia with insertion of brachytherapy applicators (Viswanathan *et al.*, 2012b). From this SLR update and the pre-doctoral SLR, the studies considering pain management can be considered in two categories. Firstly, studies which enhanced pain management strategies, typically aiming to provide continuous analgesia for long duration brachytherapy with applicators in place for more than 24 hours or for interstitial implants likely to cause more pain. Secondly, studies which simplified anaesthesia or analgesia, either to reduce unnecessary side effects from GA or removing the need for any anaesthesia. This was reported in some centres with high numbers of cases and low levels of resources, aiming to reduce dependence on scarce and expensive anaesthetics. Comparisons were made with other simple gynaecological procedures such as hysteroscopy which may be carried out with a paracervical block (Leong *et al.*, 2017; Cooper, Khan and Clark, 2010). Other centres provide a rationale for anaesthesia or analgesia reduction to simplify procedures, reduce physical side effects from the medication and reduce length of hospitalisation. This division in direction is mainly justified by the different techniques and fractionation regimes being used. For example, analgesia for short duration brachytherapy, such as local anaesthetic spray onto the cervix or conscious sedation, would not be suitable or adequate analgesia for long duration brachytherapy, especially if interstitial needles are introduced in addition to intracavitary applicators. Conversely, the use of continuous analgesia with PCA, either IV or epidural, would usually be considered as excessive and unnecessary for short duration brachytherapy. Therefore, rationale for changing anaesthesia and analgesia requirements appears to have variable causes, typically to do with logistics and resources or to avoid unnecessary pharmacological side effects, but rationale does not appear to be related to patient choice or preference. It was noted that compared with the SLR carried out in 2017 (Humphrey, Bennett and Cramp, 2018) there has been a recent increase in the number of studies examining pain management for long duration brachytherapy techniques including hybrid ICBT/ISBT or ISBT alone compared with shorter duration techniques with simpler ICBT applicators. This may be an indicator of the increasing complexity of brachytherapy techniques being developed for the treatment of LACC and the increasing duration of applicators in situ at some centres. This has led to the need to examine pain management techniques for these types of procedures and applicators.

A meta-analysis and systematic review of anaesthetic and analgesic methods by Petitt *et al.* (2020) found 20 relevant articles, eight of which have been included in either the pre-doctoral or 2022 update SLR. Their remaining twelve articles did not include patient reported pain scores or there was no full text available, therefore they did not meet inclusion criteria for this SLR. Petitt *et al*. (2020) found through meta-analysis that neuraxial anaesthesia decreased the frequency in administration of rescue analgesia when compared with GA. This finding was recently confirmed by (Locke *et al.*, 2022). From the Pettit *et al.* (2020) literature review it was concluded that the rate of anaesthesia related complications was comparable between the GA and neuraxial anaesthesia reports. They refer to American Brachytherapy Society guidelines (Viswanathan *et al.*, 2012a) and the critical importance of brachytherapy for primary radiation treatment of cervical cancer, without which mortality rates are significantly worse (Holschneider *et al.*, 2019). However, they state their concerns that anaesthesia and analgesia consideration has not yet been fully described in literature or clinical guidelines (Petitt *et al.*, 2020). The authors present a figure which displays their recommendations for pre, intra and post-operative anaesthesia care. They refer to this figure as their full recommendations for anaesthesia for brachytherapy. Although there is very little detail in the figure, these are the first brachytherapy anaesthetic care recommendations offered. In the text, the implementation of an anaesthetic pre-assessment to develop an individualised anaesthetic plan, the use of premedication, careful monitoring of nausea and vomiting and a plan for rescue analgesia for low, moderate and severe pain are recommended (Petitt *et al.*, 2020). This addresses some of issues identified in the pre-doctoral SLR and this update, relating to the need for clinical care recommendations for cervical cancer brachytherapy, and specifically those relating to pharmacological management for brachytherapy.

Non-pharmacological interventions could be used to supplement the essential pharmacological approaches and potentially provide women with some control over their own wellbeing during brachytherapy. Across the pre-doctoral and SLR updates, relaxation and guided imagery, a music relaxation video and foot reflexology and aromatherapy showed important benefits for women undergoing brachytherapy procedures (Blackburn *et al.*, 2021; Chi *et al.*, 2015; Leon-Pizzaro *et al.*, 2007). They were found to be simple, effective, non-invasive and cheap. Overall, it can be surmised that these supplementary,

complementary or integrative therapies may be beneficial to some women during brachytherapy.

In addition to the studies identified in the pre-doctoral SLR and SLR update, a recent publication on the "Gynae Cancer Narratives Project" reported some patient experiences of brachytherapy (Ashmore *et al.*, 2022). This study did not meet the inclusion criteria for the SLR update because the main focus of the study was not patient experiences of brachytherapy. The "Gynae Cancer Narratives Project" was a collaboration between clinicians and academics at Lancaster University and The Clatterbridge Cancer Centre. They reported 34 patient experiences of radiotherapy for gynaecological cancers through a collection of narrative accounts from written diaries, voice recordings or videos (Ashmore *et al.*, 2022). An anthology of patient narratives was published in June 2022, containing a chapter called "Conversations about trauma". This focussed on gynae brachytherapy experiences of three patients and provided advice for brachytherapy practitioners on appropriate provision of care, in consideration of the sensitive nature of the procedure. Overall, this project demonstrated that every patient journey and experience was unique and encouraged healthcare professionals to read the collection of narratives and to respond to the identified gaps in care by carrying out more open and honest conversations with patients. These findings add further weight to the pre-doctoral SLR and SLR update findings that brachytherapy for gynaecological cancer can cause anxiety, pain and distress.

2.5 Strengths and limitations of the SLR update

The strengths of the SLR update are that the data analysis was much clearer compared with pre-doctoral SLR due to dividing the data extraction and analysis reporting into two separate categories, 1) patient experience and 2) intervention studies. This SLR update repeated the protocol for the pre-doctoral SLR, following PRISMA guidelines (Liberati *et al.*, 2009) including search terms, databases searched and method. The critical appraisal and quality assessment were improved compared with the pre-doctoral SLR through integration throughout the results. Weaknesses of the SLR update were that all steps were carried out by the doctoral fellow without a second researcher to search for literature, apply exclusion criteria, or complete data extraction, synthesis and analysis. However, this was partially

mitigated by use of the same protocol as the pre-doctoral SLR and input from the PhD supervisory team.

2.6 Strengths and limitations of the existing literature

Overall, in both the pre-doctoral SLR and update, existing literature included many studies reporting the technical aspects of brachytherapy procedures for gynaecological cancers, including analgesia and anaesthesia techniques. However, a few studies included patient reported outcomes such as pain, comfort or anxiety or patient satisfaction. There are conflicting directions for developments, either to simplify or reduce the use of anaesthesia, to avoid the need for anaesthetic input and costs or to reduce toxicity and speed up discharge home after brachytherapy. Alternatively, some centres are developing procedures which are increasing complexity in imaging requirements and time taken for planning. The introduction of interstitial needles has led to a search for optimal continuous analgesia to keep patients comfortable with more painful applicators or longer durations. Although different anaesthesia and analgesia techniques are reported and compared, there appears to be no consensus on superior pain management and toxicity profiles, likely to be due to the wide variation in brachytherapy techniques being used and variability in availability of resources.

There were only three qualitative studies of patient experiences in the SLR update and five in the pre-doctoral SLR, which limits our knowledge and understanding of women's experiences of this invasive procedure which is increasing in complexity over time. Only one of these studies was carried out in the UK and with women who had received LDR brachytherapy, published 17 years ago (Warnock, 2005). Since then, all UK centres have switched to HDR or PDR brachytherapy, some with multiple short duration procedures and some with long durations with applicators remaining in place overnight. However, there is no UK generated qualitative data to explore or compare women's experiences of these new procedures. Table 9 shows a summary of the gaps in knowledge identified in the SLR and how these informed the next stages of the doctoral research programme.

Table 9: Summary of identified gaps in knowledge and impact on next stages of research

	Identified gaps in knowledge	Method to address gaps in knowledge
1	Lack of evidence of impact of different regimes on patient experiences (pain, anxiety and distress).	Study two- patient interviews across four UK centres using different regimes.
2	Lack of patient experience data (patient reported pain scores and satisfaction) in anaesthesia and analgesia studies.	Patient care recommendations to include advising centres to record patient experience in future research and audit (study three- development of patient care recommendations).
3	Lack of evidence of superiority of any anaesthesia or analgesia techniques for short and long duration and complex brachytherapy techniques.	Study two- patient interviews across four UK centres using different anaesthesia and analgesia techniques.
4	Lack of anaesthesia and analgesia considerations in clinical guidelines.	Patient care recommendations to include development of protocols for anaesthesia and analgesia (study three- development of patient care recommendations).
5	Lack of qualitative studies reporting patient experiences of modern brachytherapy techniques	Study two- patient interviews across four UK centres using modern brachytherapy techniques.

The aims of the SLR were achieved with discovery of a further 12 studies which reported patient experiences of brachytherapy since the pre-doctoral SLR. Analysis of these 12 studies has added to the knowledge and understanding of women's experiences of brachytherapy, which will assist in future consideration of patient's needs.

2.7 Conclusion

The pre-doctoral SLR and update showed that brachytherapy for gynaecological cancer can cause varying levels of pain, anxiety and distress and evidence to help understand women's experiences of brachytherapy is increasing. Included studies identified a need for better pain management, patient information and support and the development of both pharmacological and non-pharmacological interventions to address these issues. There is evidence that some centres are starting to explore pharmacological and non-pharmacological approaches, especially where applicators are in place for long periods of time or interstitial applicators have been introduced. Pharmacological approaches are being explored and developed, with an aim to minimise pain and discomfort throughout the procedure, some considering specific points in the procedure such as applicator insertion,

patient bed transfers for imaging, waiting between fractions of dose delivery (if multiple doses per insertion) and applicator removal. Some studies addressed the anaesthesia and analgesia requirements for short duration or long duration brachytherapy, with or without the use of interstitial needles. The publication of the American Brachytherapy Society peri-procedural considerations and recommendations for anaesthesia care may be a first step in standardising and improving management of pain and other physical side effects arising from brachytherapy procedures. Alongside optimal management of pain, there is evidence that women's anxiety and distress may be reduced by non-pharmacological interventions. Further development of clinical support guidelines may be able to build on the American Brachytherapy Society considerations and recommendations for anaesthesia and analgesia, incorporating non-pharmacological interventions and psychological support to improve women's experiences of brachytherapy.

Clinical support guidelines or recommendations may be a useful tool to assist audit and evaluation of the quality of service provision, and should therefore include patient satisfaction criteria, especially when new techniques such as ISBT are introduced. Acquiring patient satisfaction feedback about brachytherapy could also give valuable information about which areas are most distressing or satisfactory and which pharmacological or non-pharmacological supports are helpful. This may further promote the development of effective interventions (both pharmacological and non-pharmacological) to improve women's experiences of brachytherapy for LACC.

The summary of literature has identified areas for improvement in brachytherapy for LACC with potential to reduce pain, anxiety and distress. This information directed the development of a programme of research, beginning with an exploration of brachytherapy services for LACC, including provision of patient information and pharmacological and non-pharmacological support.

Chapter Three: UK Survey of brachytherapy practice for LACC (study one)

This chapter presents the rationale, aims, method, results and discussion from a UK survey of brachytherapy practice for LACC.

3.1 Introduction and rationale

A systematic literature review by Humphrey, Bennett and Cramp (2018) showed that brachytherapy for gynaecological cancer can cause pain, anxiety and distress. These findings suggested a need for better pain management and patient information and support, as well as the potential for non-pharmacological interventions to improve experiences.

Surveys of UK brachytherapy practice were carried out in 1998 and 2005 by the Royal College of Radiologists (RCR) to inform national guidelines for brachytherapy service provision. These were published in 2001 and 2007 but have been withdrawn (RCR, 2012). These surveys focused on the delivery of services including the types of cancer for which brachytherapy was being used, numbers of patients treated per year, numbers of staff employed and equipment used in each brachytherapy centre. The findings contributed to the national guidelines on minimum numbers of cases and staff required for safe treatment. In 2012, the RCR published updated guidelines with the addition of quality and safety recommendations (RCR, 2012). These guidelines have recently been withdrawn without explanation and not yet replaced. The RCR survey was not repeated in 2012, but a survey is currently being developed by the European Society for Radiotherapy and Oncology-Health Economics in Radiation Oncology (ESTRO-HERO), and the subgroup Brachy-HERO (Tan, 2017b).

In 2009, the RCR published guidelines specifically for delivery of brachytherapy for cervical cancer (RCR, 2009). These guidelines informed the criteria for an audit that was carried out using a questionnaire to 45 UK radiotherapy departments (Tan, 2011). The questions focused on gaps and delays in treatment and adoption of the new planning strategies,

including MR imaging adaptive brachytherapy, which had been recommended in the 2009 RCR guidelines. As part of the ESTRO Brachy-HERO project, Tan carried out a UK survey on scheduling regimes and planning techniques for common brachytherapy sites in 2017. Findings included data regarding scheduling and anaesthetic provision with responses from 23 UK centres (Tan, 2017a). To date, surveys have not explored women's experiences of brachytherapy or the support provided to help them cope with the potential pain, anxiety and distress experienced. To inform future research it is necessary to develop knowledge of the ways that brachytherapy is currently provided and any existing support offered to women to help them cope with pain, anxiety and distress that may be caused by brachytherapy.

3.2 Aims and objectives

The aim of the survey was to identify current UK service provision for women having brachytherapy for LACC.

The objectives of this survey were:

- To find out current brachytherapy treatment scheduling, and anaesthesia and analgesia provision for women receiving treatment for locally advanced cervix cancer;
- To identify non-pharmacological support currently offered to women before, during and after brachytherapy; and
- To inform the development of a patient interview topic guide and the selection of study sites for subsequent research.

3.3 Method

3.3.1 Study design

A cross-sectional survey was developed to gather information from UK centres carrying out gynaecological brachytherapy for LACC. An internet-based survey was chosen over a postal survey as internet surveys are associated with higher rates of participation when targeting professional groups (Bourque and Fielder, 2003). The Qualtrics survey platform (Qualtrics, Provo, Utah, USA) was chosen as this met the General Data Protection Regulations 2018 required by the University.

The survey questions were informed by research literature (Humphrey, Bennett and Cramp, 2018; Tan, 2017a; RCR, 2009) and developed through discussion with PhD supervisors, local clinical experts from different specialities, and two patient research partners. Examples of ways in which the survey was developed with input from key stakeholders include a consultant anaesthetist collaborator suggesting wording to clarify the meaning of different types of anaesthesia; and a patient research partner suggesting an additional question about adaptations in service provision for patients with special needs such as dementia, learning disabilities and/or victims of abuse.

An initial draft of the survey was piloted with four brachytherapy radiographer colleagues via the Qualtrics survey platform. This enabled a check of effective distribution of the survey via email and that returned data were accessible for analysis. Feedback from the four pilot respondents related mainly to the Qualtrics platform, such as what to do if interrupted during survey completion and how to save work in progress. To address this, it was decided to repeat the instructions from the invitation email within the introduction at the start of the survey. The closing time for the survey was not in Greenwich Mean Time, so this was changed after the pilot. One colleague commented on wording for a question on anaesthetics and this was subsequently changed from "standard care" to "regularly use". Another colleague suggested a wording change to ask what support is available in your centre. A comments box was added after the question about routinely given support with a statement "Please write any comments about your answer to the previous question, especially if there are any support services that are available **on request**, but not routinely offered". Due to a typographical error in an email address, one pilot participant did not receive the survey. The doctoral fellow subsequently discovered how to check on the Qualtrics platform if a survey invitation had not been delivered to the intended recipient and could then be resent to the correct email address.

The invitation email is presented in Appendix 4 and final survey in Appendix 5. The survey consisted of 30 questions covering brachytherapy techniques and scheduling, anaesthetic/analgesia protocols, inpatient/day case treatment and non-pharmacological support such as psychologist input and availability. Most questions were closed with several pre-specified response options provided. Some closed questions were followed by a space

for free text comments, allowing participants to explain or clarify their response. Some open questions were used, requiring participants to provide opinions and comments about service provision such as what worked well and what could be improved. After completion of the survey, participants were invited to email the doctoral fellow if they were interested in their department taking part in the next stage of the study: patient interviews.

Ethical approval was given by the University Health and Applied Sciences Faculty Research Ethics Committee (UWE REC REF No: HAS.18.08.008), see Appendix 3 Letter of approval. A risk assessment and data management plan were submitted with the ethics application. Risks identified were time away from clinical duties and use of display screen equipment for 10-15 minutes. NHS ethical approval was not required for this study as participants were recruited via a special interest group affiliated to a professional body and access to patients' data was not required.

3.3.2 Sample

The survey was sent via the Qualtrics platform to the 44 UK centres reported to be carrying out brachytherapy for LACC as listed on the national cancer statistics database. Potential participant email addresses were obtained from the national special interest group- the Brachytherapy Radiographers Forum. The purpose of the Forum is to provide peer support by sharing clinical expertise and experience to lead improvement and enable development of brachytherapy services in the UK. One of the aims of the group is to promote brachytherapy related research and report progress back to the Brachytherapy Forum. The forum members communicate with each other via an email group which members have opted into by providing their email address. They can opt out of this email group at any time. The lead brachytherapy radiographer was identified as the most appropriate person to complete the survey as they were most likely to have an overview of the brachytherapy service. Whilst oncologists, physicists and nursing staff may have had in depth knowledge about a specific part of the service they were less likely to have been involved across the whole service. The lead radiographers were selected from the Brachytherapy Radiographers Forum members to ensure that only one response was obtained from each department. In most cases the lead brachytherapy radiographer was already known to the doctoral fellow through her role in setting up the Brachytherapy Radiographers Forum and having been a

member for the previous 11 years. For three departments, there was no lead radiographer identifiable through the forum. Email contact was made with these departments and an oncologist or physicist was invited to complete the survey with assistance from nurse or radiographer colleagues. Potential participants were advised by a statement on the introduction to the survey that consent to participate in the study would be assumed by their voluntary completion of the questionnaire.

3.3.3 Data collection

The on-line survey invitation was emailed out and responses collected over a three-month period. For non-respondents a reminder was sent out after one month. Participants' responses were not anonymised, as it was important for the doctoral fellow to be able to identify the department to inform the next stage of the research. The data obtained did not contain personal demographic information although professional opinions were requested. All identifiable features were removed from the data prior to sharing with the full research team. Findings were subsequently reported in aggregate with no individual or department identified. The participants were informed at the beginning of the questionnaire that they would not be identifiable in any presentation or publication of the survey outcomes and confidentiality would be maintained.

Data were stored in adherence with the UWE Bristol Research Data Management Policy on UWE One Drive. Data were remotely accessed from the doctoral fellow's UWE Bristol password protected computer. No paper-based records of the survey results were created.

3.3.4 Data analysis

Data were analysed by the doctoral fellow. The Qualtrics survey software was used to generate a report for each question. From these reports descriptive statistics were generated to identify variance in current UK practice. Respondents' comments were grouped into categories and summarised. There were three open-ended questions inviting participants to provide free text answers which were analysed using content analysis (CA). NVivo software was used to organise the data to assist the CA process (NVivo 12 QSR International, Melbourne, Australia, 2018). The doctoral fellow also analysed the data

without using the NVivo software, coding by hand on a word document, to compare computer assisted and traditional methods.

This analytical method was adapted and applied to help understand the data generated from the survey, rather than the data being collected in a way to meet a specific methodological approach. Duncan (1989) described CA as "a technique which lies at the crossroads of qualitative and quantitative methods" and a method that "allow(s) a quantitative analysis of seemingly qualitative data". Kondracki, Wellman and Amundson (2002) explained that CA consists of coding raw messages (any type of data) and that these codes or content components can then be "subjected to either quantitative or qualitative analysis or both". They report that CA can readily be used to analyse textual data such as open-ended survey questions and that the analysis can be done with either an inductive or deductive approach. For an inductive approach the coding or categorising is done by the researcher without preconceived ideas and by putting any prior knowledge or evidence from literature to one side (Elo and Kyngäs, 2008). The analysis comes from the data upwards and can be described as a "grounded" approach (Berg, 2009). Using a deductive approach, the researcher begins analysis with predetermined concepts or categories, formed from their prior knowledge or literature, and then sorts the data into these categories. This tends to lead to more quantitative results.

Kondracki, Wellman and Amundson (2002) describe how the analysis can be of either manifest or latent content or a combination of both. Manifest is where the words are either present in the text or the meaning is visible at a "surface level", and latent is where there is a deeper meaning implied in the text, however, this can be open to interpretation and therefore subjective. Hsieh and Shannon (2005) describe three approaches in CA, following a naturalistic paradigm as they "interpret meaning from the content of the data". These approaches are Conventional CA (inductive); Directed CA (mostly deductive) or Summative CA (using latent CA to interpret underlying or hidden meaning of content). There were no literature reports to provide a pre-existing theory for analysis of responses to this survey. Unlike interview data, survey data is uni-directional without opportunities for co-creation or shared understanding between the participant and the researcher. This is likely to provide less depth of data for interpretation or development of latent (hidden) meaning. Frequency

of codes or concepts can be counted, to provide some understanding of the overall significance and relevance of the code. Hence the term "quasi-qualitative" data seems to be applicable in this study. Therefore, the analytical method required for this data did not follow one method of CA but instead the doctoral fellow's approach was informed by the methods described previously (Berg, 2009; Elo and Kyngäs, 2008; Hsieh and Shannon, 2005; Kondracki, Wellman and Amundson, 2002; Duncan, 1989).

The data were initially examined by the doctoral fellow by reading and rereading, to "achieve immersion and obtain a sense of the whole" (Hsieh and Shannon, 2005). Analysis began with open coding of responses. NVivo software was used to provide a rigorous approach for counting code frequency. Codes that shared a similar meaning were grouped into categories. This process was overseen by an academic supervisor with experience in inductive CA.

3.4 Results

One of the 44 UK centres invited to take part in the survey was found not to be eligible and did not complete the questionnaire as their brachytherapy services had recently been transferred to another centre. Of the 43 remaining centres, responses were received from participants from 39, giving a response rate of 91%. Responses were received from two centres in Scotland, one in Northern Ireland and 36 in England. No response was received from the one centre in Wales. All 39 respondents confirmed that their department carried out brachytherapy for LACC. Almost all the respondents completed all the multiple-choice questions. Some did not complete all the free text responses. The findings are presented by question, integrating quantitative data from the closed questions and quasi-qualitative data from the open questions and free text comments.

3.4.1 Scheduling and fractionation

It was reported that HDR brachytherapy was used in most respondents' centres (36 out of 39, 92%) and PDR in only four centres (10%), with one centre having both HDR and PDR brachytherapy. Sixteen respondents wrote comments to clarify their selection of inpatient or day case answers. Some respondents chose both options for day case or inpatient

treatment. Some comments indicated that one option was their standard treatment and the other option was for more unusual cases. For example:

"Patients for cervix treatments are day case unless they need to stay over due to complications like bleeding after".

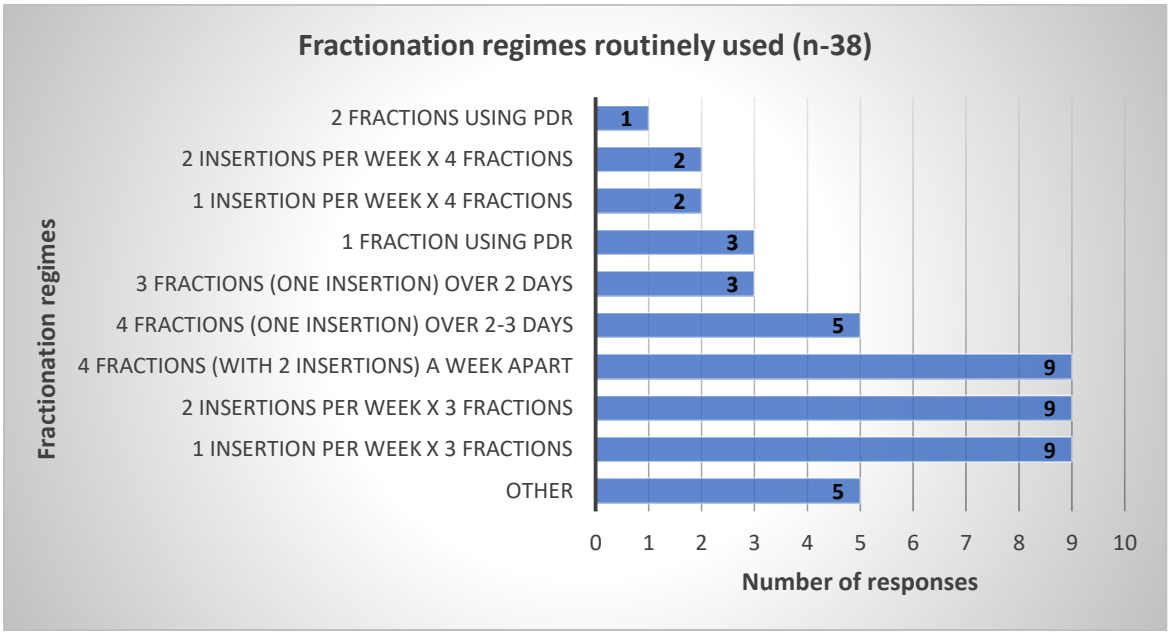
It was therefore possible to deduce which treatment was their standard or predominant schedule. In summary, approximately two thirds (65%) of respondents' centres were giving inpatient brachytherapy as their predominant regime versus one third (35%) delivering day case brachytherapy. It may be useful to note that PDR brachytherapy would only be given as inpatient treatment, due to the long time required for dose delivery, whereas HDR brachytherapy could be provided as inpatient or day case as delivery takes only minutes. Table 10 shows responses for type of brachytherapy, inpatient or day case and predominant inpatient or day case service.

Table 10 Type of brachytherapy and inpatient or day case service

Type of brachytherapy (n=39)	
Intracavitary	16
Interstitial	1
Hybrid	2
Intracavitary + interstitial	4
Intracavitary + hybrid	4
Intracavitary + interstitial + hybrid	12
Inpatient or day case (n=37)	
Inpatient	21
Day case	11
Both inpatient and day case	5
Predominant inpatient or day case (n=37)	
Inpatient	24
Day case	13

Participants were asked to select all fractionation regimes routinely used in their department from a drop-down menu. Figure 10 indicates the fractionation regimes selected by the respondents.

Figure 10 Fractionation regimes routinely used

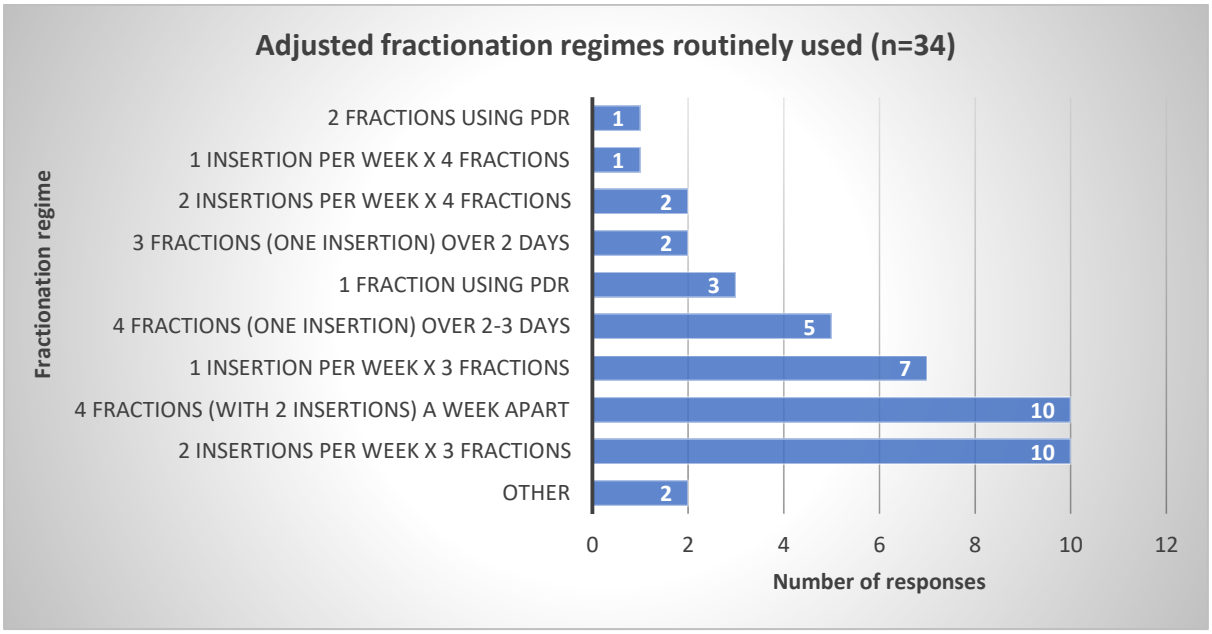


Eight respondents selected more than one fractionation regime from the nine options provided. Four responses were removed from the data as they did not correlate with responses to other questions, therefore likely to be errors of option selection. When the five "other" responses were analysed along with comments about responses to this question, one of the "other" responses was for a regime that was occasionally used, not routinely used, therefore not applicable. One "other" response fitted option "4 fractions (with 2 insertions) a week apart" and one fitted option "2 insertions per week x 3 fractions". Two "other" responses did not fit any option in the drop-down menu. These were:

- "HDR 3 fractions over 2/3 weeks" and
- "3 fractions (one insertion) over 3 days".

Figure 11 indicates the fractionation regimes selected by the respondents adjusted for correction of "other" options and responses likely to be errors removed. In summary eleven different scheduling regimes were reported to be in current use.

Figure 11 Adjusted fractionation regimes routinely used



Analysis of the fractionation responses and clarification in free text comments enabled a deduction of how many insertions are typically carried out in each centre. Table 11 shows the typical number of applicator insertions, including only the first choice or most commonly used regime for each centre.

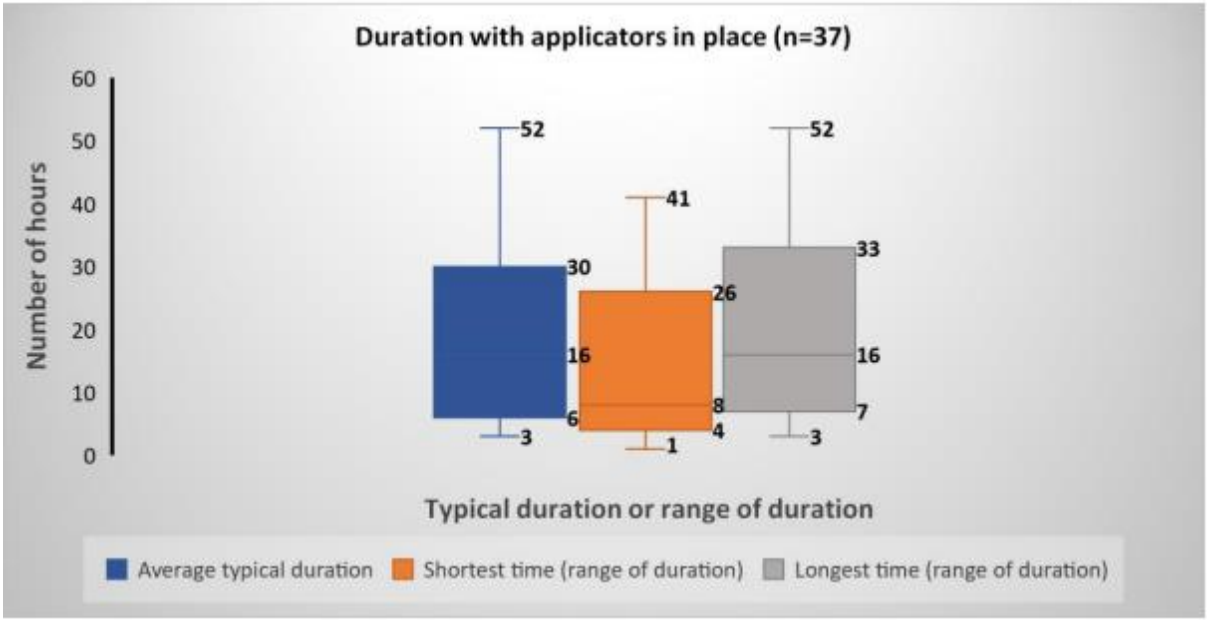
Table 11 Typical number of applicator insertions.

Typical number of applicator insertions	1	2	3	4
Number of respondents (n = 34)	10	7	14	3

3.4.2 Duration of brachytherapy

Participants were asked to indicate average duration of brachytherapy, measured from the start of the applicator insertion to applicator removal, to show an average of how long the applicators remain inside the patient for a typical insertion. From 37 responses the minimum average typical duration was 3 hours and the maximum was 52 hours with a median of 16 hours. Participants were also asked to indicate the range of duration of applicators in place, indicating the shortest and longest typical duration. From 37 responses the shortest duration response ranged from 1 to 41 hours with a median of 8 hours and the longest duration from 3 to 52 hours with a median of 16 hours. Figure 12 shows a box and whisker plot of the responses.

Figure 12 Box and whisker plot for duration with applicators in place



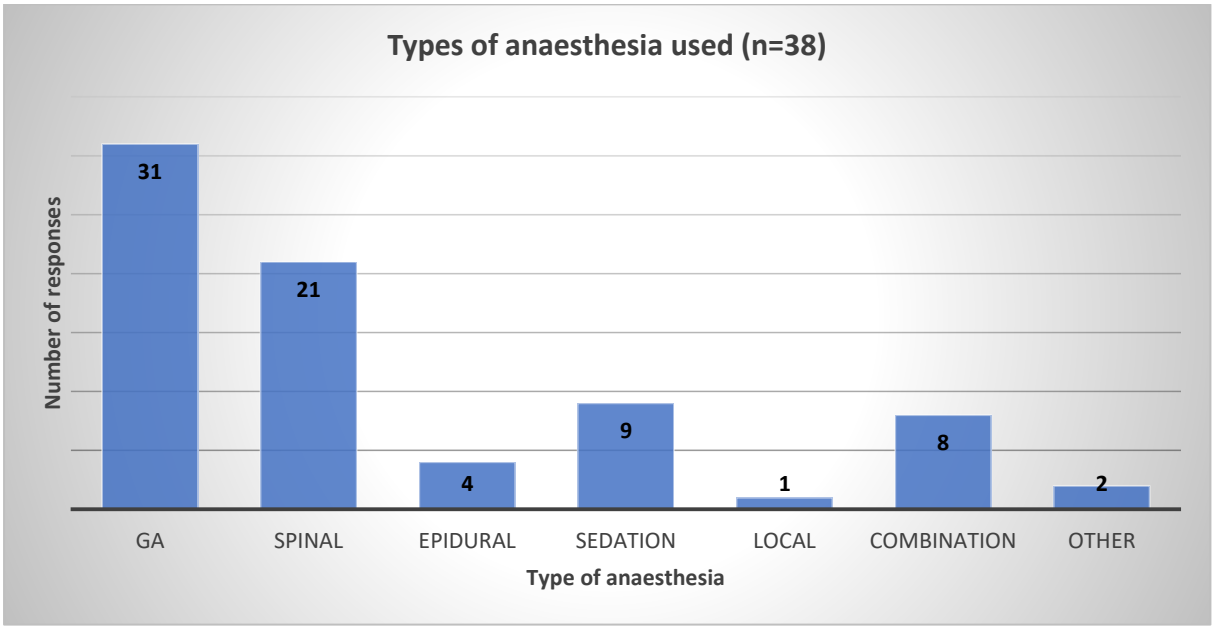
Comments relating to duration were given by 25 participants. In summary, respondents commented that duration was influenced by factors such as scheduling choice, which is dependent on complexity of treatment (may choose multiple fractions for one insertion if very complex) and patient factors such as co-morbidities or contraindications (may choose shorter regime). One respondent stated that duration could be shortened using a Smit sleeve for subsequent treatments, reducing the duration to one to two hours. Another respondent commented that the overall time was reduced if copy plans were used. One respondent stated that duration was reduced when imaging/re-planning were not used before subsequent fractions. Seven respondents commented on delays caused by increased planning time. Reasons given for the increased planning time included increased complexity; new addition of MR imaging/planning; addition of interstitial needles; doctors in training therefore requiring longer for planning (contouring) and limited access to MR scanner. Other examples of causes of delays were limited clinician availability for applicator removal, clinician required if medical complications have arisen; variable time needed in recovery room after GA and the number of cases that day, that is, more cases increases duration.

3.4.3 Pharmacological management- anaesthesia and analgesia

Anaesthesia

The most identified type of anaesthesia was GA, by 82% (n=31) of the 38 respondents. Figure 13 shows the responses for types of anaesthesia routinely used, with many centres routinely using more than one type of anaesthesia.

Figure 13 Types of anaesthesia used



Abbreviations: GA=General anaesthesia

When the two "other" responses were reviewed they referred to the use of PCA which is a type of analgesia, not anaesthesia. Comments or explanations about anaesthesia were given by 18 respondents; five of which mentioned patient choice or preference.

For example:

"Patients are given a choice of GA or spinal. Most prefer a GA but occasionally we have a patient who would prefer a spinal"

Some comments mentioned patient suitability, contraindications or medical reasons for which type of anaesthesia was used. One comment mentioned anaesthetist's preference which could be related to safety/risk or the anaesthetist's own rationale.

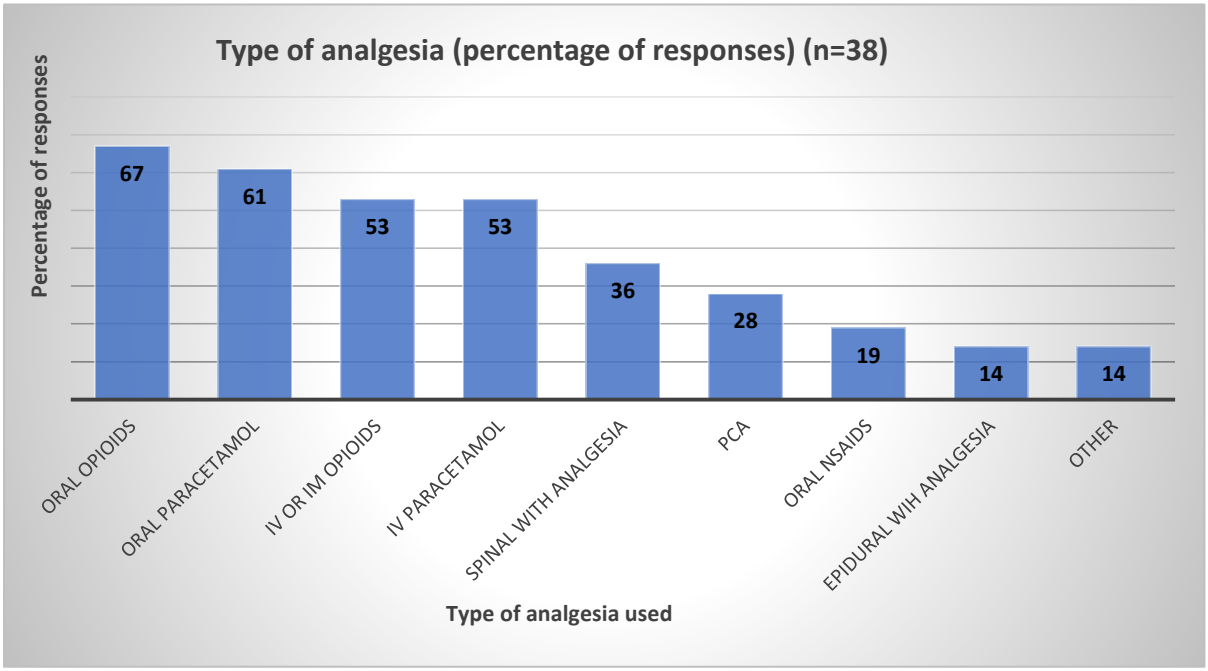
One comment showed a different anaesthetic regime for subsequent fractions:

"We only use general anaesthetic for the first fraction. Lorazepam is given 1 hour before subsequent fractions".

Analgesia

Many different analgesia options were selected, typically four or five options per respondent. Figure 14 shows types of analgesia and percentage of respondents selecting each option.

Figure 14 Type of analgesia (percentage of responses)



Abbreviations: IV=Intravenous; IM=Intramuscular; PCA=Patient controlled analgesia; NSAIDS=Non-steroidal anti-inflammatory drugs

Five respondents selected "Other". These responses are listed in Table 12.

Table 12 "Other" responses about type of analgesia used

"Other" responses	Number of respondents
Lorazepam	2
Nitrous oxide for applicator removal	1
Entonox in GA wears off sooner	1
Diclofenac suppository	1

Comments about analgesia were given by 17 respondents, mostly clarifications or explanations of their selected analgesia options in the previous question. For example, two respondents commented that PCA was routinely used and two respondents said that PCA

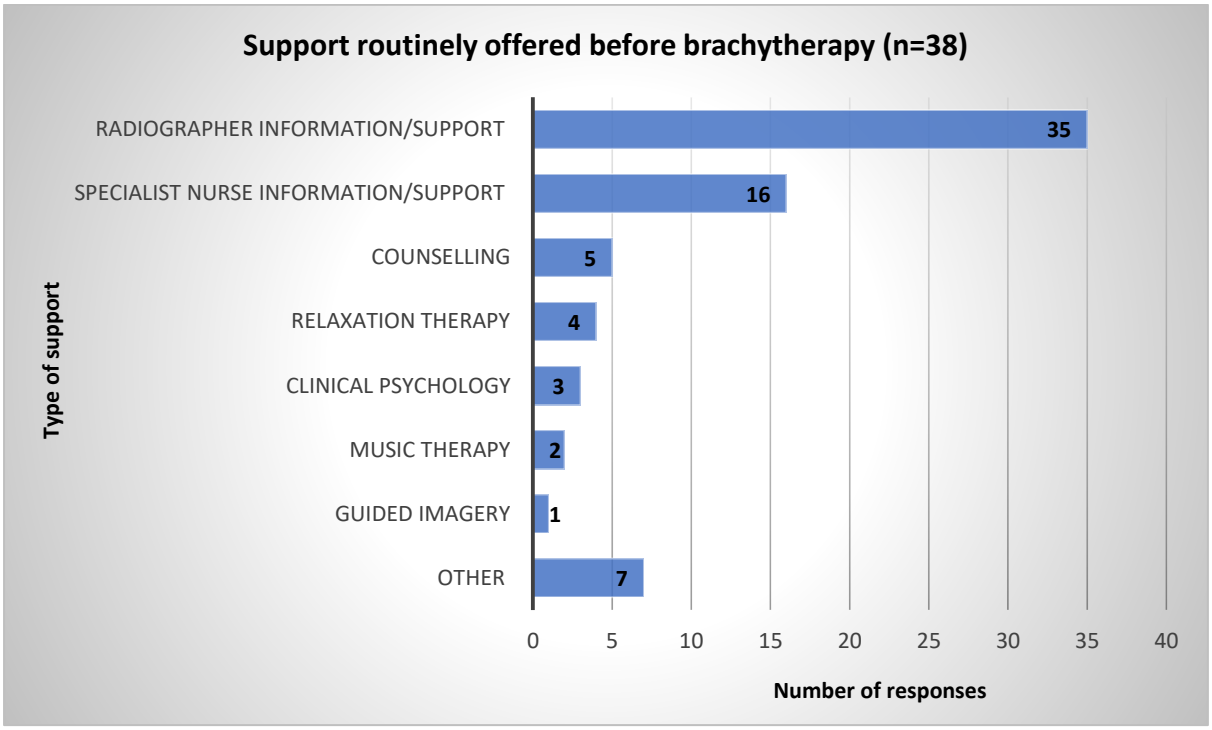
was used if the regional spinal or epidural was contraindicated or failed. Some comments were lists of combinations of analgesia used or stating that many drugs were prescribed. Lorazepam was sometimes given, one of these mentioned it was added if the patient was experiencing anxiety. Two respondents commented that analgesia was dependent on what type of anaesthesia was used. One respondent stated that there may have been other drugs that she was unaware of given by the anaesthetists. One respondent reported that the selection of analgesia depended on the anaesthetist whilst another stated that analgesia was given as required following the World Health Organisation pain ladder. One respondent stated that intravenous paracetamol worked better than oral, but that oral was often given on the ward as it was easier to administer. Intravenous opioids were reported by one respondent to be given in recovery due to patient transfers for imaging.

The use of additional analgesia for applicator removal was reported by 68% of respondents (n=26/38). Details of additional analgesia for applicator removal was provided in a free text comments box by 25 respondents. Nitrous oxide and oxygen gas (Entonox®/gas and air) was the most popular choice with 21 out of 25 responses. Liquid morphine use was reported by 10 of the 25 respondents and three reported the use of benzodiazepines such as midazolam or lorazepam. One response indicated the use of local anaesthetic gel (hydrocaine), one was non-specific, reporting use of "IV or oral" and one reported the use of "Fentora" (Fentanyl buccal tablet).

3.4.4 Support before, during and after brachytherapy

Participants were asked to choose from a drop-down menu of which support services were routinely available to women before, during and after brachytherapy. Participants were asked to select all options that applied. For all three questions, responses were given by 38 participants. Some selected one option only, but many selected multiple options. Figure 15 shows the types of support that were routinely offered before brachytherapy. For the survey, *"before brachytherapy"* was defined as *"the weeks and days leading up to the first brachytherapy procedure"*.

Figure 15 Support routinely offered before brachytherapy

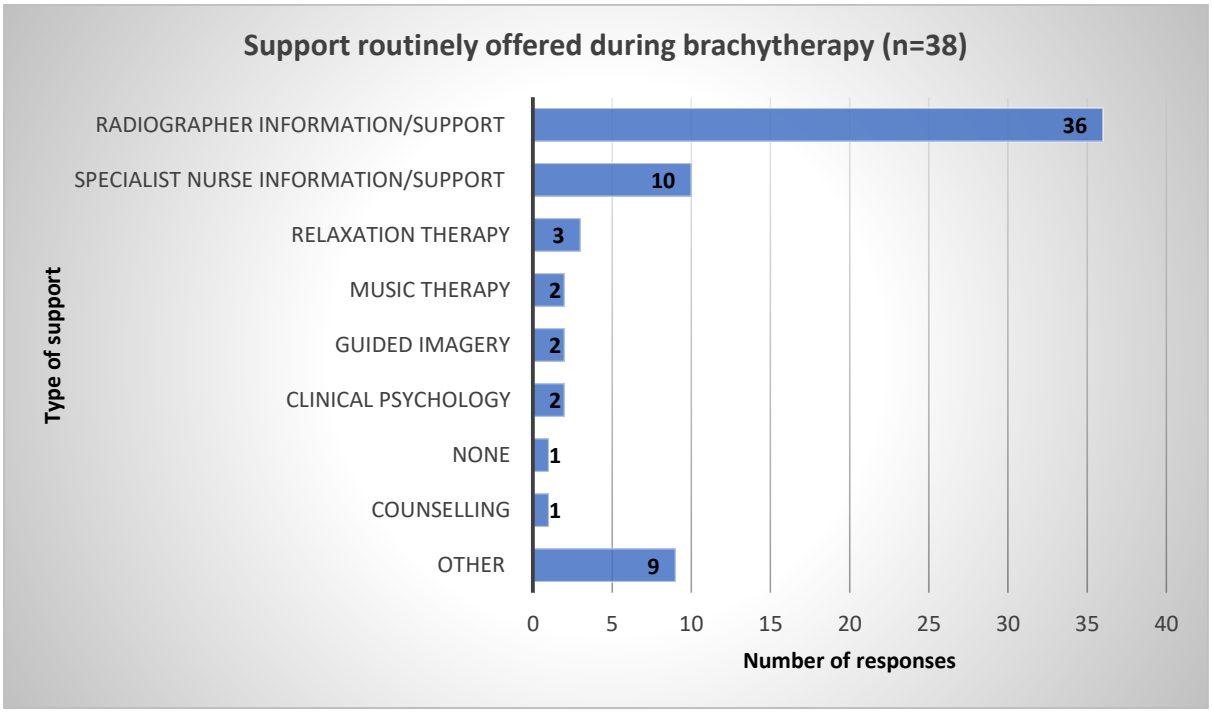


No respondents selected "none". Seven respondents selected "other". Additional comments were provided by 11 respondents. Details included:

- Access to support and information centre or a drop-in support centre with no appointment required
- Clinical psychology offered *"if appropriate",* not offered as a standard but available if required
- Patients invited to a gynaecological cancer support group by CNS team
- Palliative care team referral for all, for pain management and psychological support
- Meeting with brachytherapy radiographers or brachytherapy ward nurse
- Signposting to support centres offering complementary therapies such as relaxation, image and music therapy, counselling, massage, reflexology and reiki

Figure 16 shows the types of support that were routinely offered during brachytherapy. In the survey *"during brachytherapy"* was defined as *"from arrival in hospital for brachytherapy to leaving hospital after brachytherapy"*.

Figure 16 Support routinely offered during brachytherapy



Nine respondents selected "other" and additional comments were given by 11 respondents about support that was available: Details included:

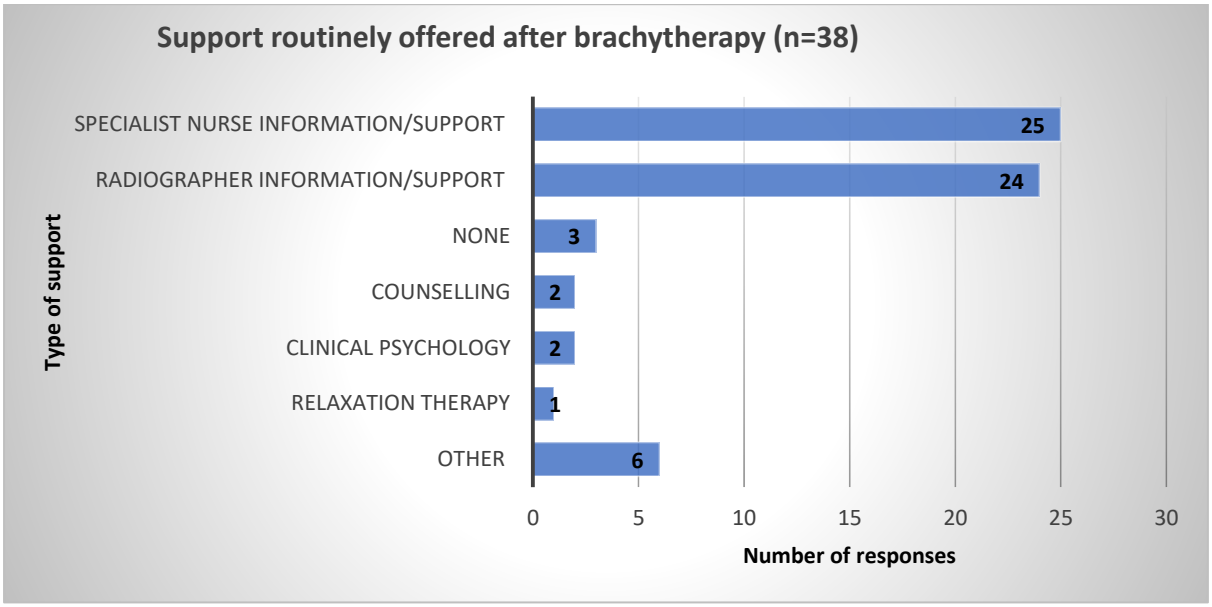
- Scenery screen above the bed and iPod to choose music
- Reiki, Indian head massage, reflexology and hand massage
- Mindfulness, guided imagery and relaxation techniques
- DVD films
- Live windows[7]
- Support and information centre
- Patient advised to bring devices, phone/kindle for reading/music
- Dedicated ward area for brachytherapy
- Staff:
    - Continuity of care (met same staff in previous treatment- chemotherapy)
    - CNS team or nursing support
    - Nurse in brachytherapy suite (four respondents)
    - Brachytherapy trained nurses and radiographers

[7] Live windows refers to a one-way window where patients can see the street outside but people cannot see in.

- Lead brachytherapy radiographer's time
- Brachytherapy radiographer providing a link with pain team and ward staff
- Clinical psychology available if needed/requested

In the survey question *"after brachytherapy"* was defined *as "the days and weeks after completion of all brachytherapy".* Figure 17 shows the types of support that were routinely offered after brachytherapy.

Figure 17 Support routinely offered after brachytherapy

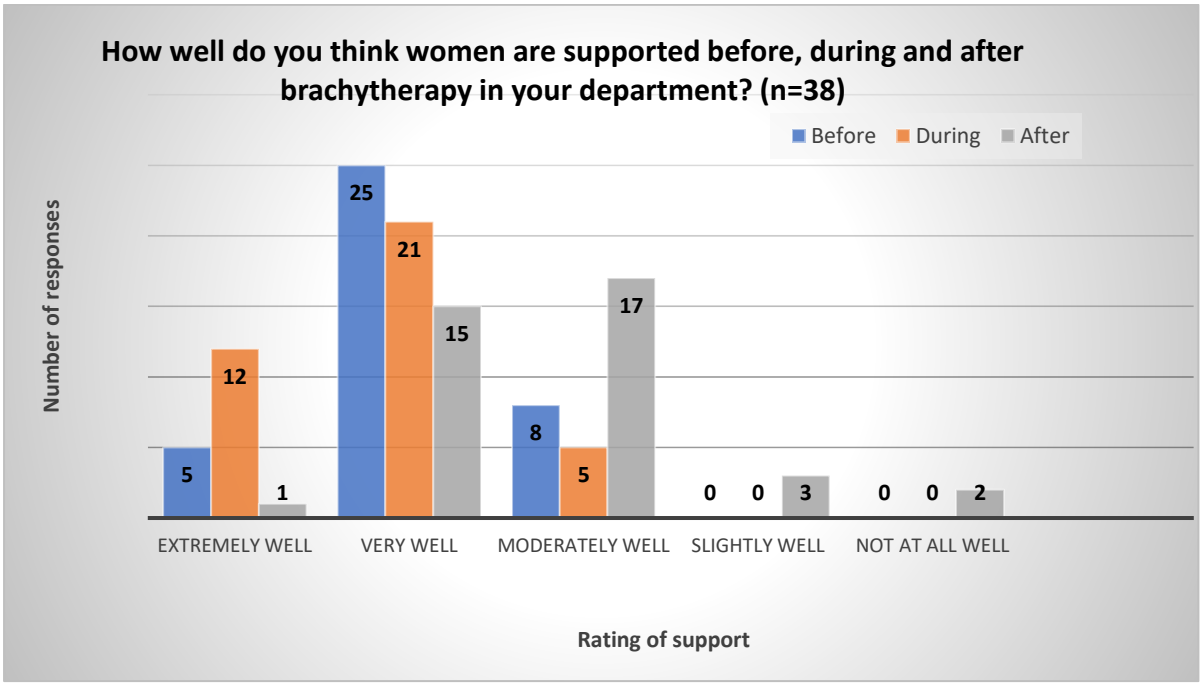


Six respondents selected "other" and additional comments were given by 10 respondents. Details included:

- Follow up appointments or phone calls
- Availability of relaxation and counselling available
- Palliative care team support
- Providing contact numbers for radiographers and oncologist
- Vaginal dilator advice/support
- Signposting to relevant services if required
- CNS team informed when treatment finished

Participants were asked to rate how well they thought women were supported before, during and after brachytherapy in their department. Figure 18 shows the 38 responses.

Figure 18 How well women are supported



3.4.5 Free text responses

In addition to the free text comments that followed some of the closed questions there were three open-ended questions which required free text responses and a general comments section after the final question. The responses were variable in length, mostly one or two sentences, whilst some provided longer paragraphs with multiple comments.

There were 33 responses to the question *"What do you think works well in your department in relation to women's experiences of brachytherapy?"* (85% of participants). These were open-coded and grouped into categories and the number of responses in each category was counted. An example response representing each category is shown in Table 13.

Table 13 What works well: examples from responses

Survey question	Category	Example of response	n*
What works well in your department? Number of responses to question = 33 (85% of total sample)	Consistency of staff	*…knowing the same radiographer from the start of EBRT to brachy support on day.*	19
	Good information from staff	*I feel that we give a lot of information at different times during the EBRT pathway so that patients are well informed about the brachytherapy treatment.*	18
	Experienced, skilled, senior staff	*We have a very focussed female oncologist, 2x CNS and specialist gynae surgical ward nurses plus brachytherapy/review radiographer.*	13
	Appropriate analgesia	*Pain relief is assessed from one week to the next to discuss which drug will best suit the patient in the PCA.*	6
	Service improvements and developments	*MDT team looking for ways to improve patient experience and service developments to reduce pathway length on the day for patients.*	6
	Relationships of trust, rapport and empathy from staff	*They are treated by a small team, all who have met the patient before, so there is already a relationship and a rapport with the patient*.	5
	Good follow up/aftercare	*We do radiographer led calls and follow ups at 3 and 6 weeks for support and to offer advice re dilators. Patients find it helpful to know they can contact us at any time…*	4
	Provision of good facilities	*We have our own theatre which is on the day unit where the patients are cared for and this is a great bonus.*	4
	Patient care on wards	*…dedicated HDR sisters provide one to one care during inpatient stay.*	4
	Good teamwork	*Good relationships and communication between all staff members involved in patient care.*	2
	Access to psychological support	*…ongoing support during treatment and referrals for Psych Onc where appropriate.*	1

**n=the number of open-ended responses in each category*

Key: CNS=clinical nurse specialist; EBRT=External beam radiotherapy; HDR=high dose rate; MDT=multidisciplinary team; PCA= patient-controlled analgesia; Psych Onc=Oncology psychologist.

There were 32 free text responses to the question "*What do you think needs to be improved in your department in relation to women's experiences of brachytherapy?"* (82% of participants). These were open-coded, grouped into categories and the number of

responses in each category was counted. An example response representing each category is shown in Table 14.

Table 14 What needs to be improved: examples from responses

Survey question	Category	Example of response	n*
What needs to be improved in your department? Number of responses to question = 32 (82% of total sample)	Training for different staff groups	*Support for radiographers, ongoing training etc to deal with the emotional side of the treatment experience.*	12
	Follow up and support after brachytherapy	*Patients have a 10 day telephone F/U following completion of Brachy. They have a 3 month F/U in Gynae. I don't feel this is adequate for some women.*	10
	Pharmacological management	*It is being discussed whether to provide GA patients with a spinal block to aid with the control of the discomfort.*	6
	Appropriate allocation of staff	*We have no dedicated brachy radiographer- very physics and technician led…*	6
	The patient pathway	*Access to the MRI facilities at the times required improved to save the waiting time*	6
	Obtain and use patient feedback	*Since introducing hybrid technique (interstitial/intracavitary) we have not got patient feedback.*	4
	Care on wards	*Improvements in the care and understanding of the procedure on the ward.*	3
	Ward facilities	*Although we try and allocate a side room to each patient, it isn't always possible.*	2
	Access to complementary therapies	*Need more therapists to provide relaxation while patients are on the ward.*	2
	Information and support	*I would like to ask some of our patients to consider writing a short paragraph about their experience to show to future patients to alleviate their concerns/provide support before treatment.*	2
	Technical developments	*Patients often report that they are transferred a great deal and the ward is at the opposite end of the hospital to the scanner. If we moved to MRI planning scan only this would reduce the moving.*	2

**n=the number of open-ended responses in each category*

Key: F/U= follow up; GA=general anaesthetic; MRI=magnetic resonance imaging

There were 33 responses to the invitation to comment on *"any adaptations you make for patients with special needs, for example learning disabilities, dementia, victims of sexual abuse or female genital mutilation"* (85% of participants). These were open-coded and

grouped into categories and the number of responses in each category was counted. An example response representing each category is shown in Table 15.

Table 15 Adaptations for patients with special needs: examples from responses

Survey question	Category	Example of response	n*
Adaptations for patients with special needs, for example learning disabilities, dementia, victims of sexual abuse or female genital mutilation Number of responses to question = 33 (85% of total sample)	Access to specialist support	*We have an 'additional needs team' that we can call on if we have patients that need extra help or support.*	14
	Identify and assess individual patients' needs	*Each patient is treated as an individual and everything is tailored to individual needs as far as possible.*	13
	Counselling or psychological support	*We have involved clinical psychologists early on to prep ahead for particularly anxious patients/history of sexual abuse.*	8
	Extra CNS or radiographer support	*Unfortunately that support is limited to CNS and radiographers, we do not have routine counselling services.*	5
	Adaptations to treatment	*Altered fractionation and library plan available for patients unable to tolerate/cope with inpatient procedure.*	5
	Involvement of family/carers	*On occasion we have had family members present in theatre for patients with learning difficulties for example.*	4
	Appropriate information and support throughout	*Information and communication throughout.*	3
	Staff get to know the patient over time	*…we get to know the patient well from first consultation and support them throughout the entire course of treatment.*	2
	Consistency of staff/familiar face	*We also follow the patients through the department from theatre to MRI then CT and back to the ward, so they have a familiar face with them throughout the procedure.*	2
	Extra time	*Allow extra time for information and support meetings with the patients.*	2
	Earlier involvement	*…we would arrange to meet with the patient earlier in their pathway to sensitively address any issues and individualise our approach accordingly.*	2
	Consider gender of staff	*Both male and female staff are available according to the patients … requests.*	2
	Accommodate patient's requests	*I am not sure we have needed it but will always work with requests from patients.*	2

**n=the number of open-ended responses in each category*

Key: CNS=clinical nurse specialist; MRI=magnetic resonance imaging; CT=computed tomography

Access to specialist support staff, not usually part of the brachytherapy team, included:

- Paediatric specialist radiographer
- Young person's team
- Safeguarding matron
- Special Educational Needs champion
- Dementia champion
- Additional needs team
- Accessibility and diversity coordinator
- Social services
- Translator (e.g. staying overnight on the ward)
- Best interest meeting (clinical team and support workers/carers)
- Complementary therapies

Almost all respondents gave specific examples of ways that they had adapted and supported women with a variety of special needs. However, a few respondents made more general comments which were not possible to categorise, such as *"Accommodate patient specific needs i.e. music"* and one respondent said *"None".*

Further Comments

The final survey question invited participants *to "write any further comments you would like to make about brachytherapy for locally advanced cervical cancer".* Responses included a mixture of very short responses and some more lengthy reflections on specific issues in their department or regarding brachytherapy in general. These were grouped into categories and the number of responses in each category was counted. An example from each category is shown in Table 16.

Table 16 Further comments: examples from responses

Survey question	Category	Example of response	n*
Further comments Number of responses to question = 13 (33% of total sample)	Follow up support and late effects	*…I suspect that this type of treatment could have significant mental effect and that survivorship support needs to address this as well as long term physical effects…*	4
	Treatment duration/number of treatments	*The possible option of moving to a 4 fraction technique will have implications- a longer stay or multiple implants (both will be harder for the patient).*	4
	Pain management at applicator removal	*…removal of the applicators using 'gas and air' has triggered thoughts about child-birth and has been described by one as the most horrendous part of her whole treatment.*	3
	Success/survival rates/outcomes	*… it is heart breaking to realise how little there is in place to assist patients who don't have a good treatment outcome.*	3
	Resource heavy- time consuming and labour intensive	*It is a very labour intensive, time consuming process and relies very much on the co-operation of a huge team of people.*	2
	Interstitial needle introduction	*One of our consultants is keen to move towards interstitial needles for these patients, which is something we currently do not offer.*	2

**n=the number of open-ended responses in each category*

3.4.6 Offers to help with the next stage of the study and site selection

Four NHS sites were needed for recruitment of women for the subsequent study. To obtain a range of experiences of brachytherapy, sites needed to represent the range of techniques and pathways in current UK practice. It was possible to identify from the data the centres where brachytherapy was given:

1. As a day-case procedure (repeated three or four times).
2. As an inpatient procedure, with treatment given twice with one insertion then repeated (usually a week later) or PDR with a similar duration.
3. As an in-patient procedure, with treatment given three or four times with one insertion.
4. At a centre which offered non-pharmacological therapies to women during brachytherapy.

Another aim was to select centres already using interstitial or hybrid techniques, to ensure interviews were carried out with participants from centres where modern brachytherapy developments had already been introduced. Also, a mixture of smaller and larger centres was preferred. Three participants sent emails indicating their willingness to take part in the subsequent patient interview study. However, two of these participants were in the same category (2), giving brachytherapy as an inpatient procedure with more than one insertion. A further two potential centres were identified from the data that would provide the cross section of centres required.

3.5 Discussion

This survey produced an excellent response rate of 91% (39/43 centres) from UK centres where brachytherapy for LACC was carried out. This compares favourably with a previous survey of brachytherapy services carried out in 2017 as part of the ESTRO Brachy-HERO project to ascertain current brachytherapy practice in Europe (Tan, 2017a). For the UK part of the Brachy-HERO survey, 50 UK centres were approached and responses were received from 28 centres (56%). Four centres reported that they had no brachytherapy service and one respondent supplied patient numbers for brachytherapy but did not answer the remainder of the questionnaire, so responses could be only be evaluated from 23 centres (Tan, 2017a). An international survey of brachytherapy for LACC was carried out by the Gynecologic Cancer Intergroup (Viswanathan *et al.*, 2012b). They reported that 16 cooperative groups provided 72 usable responses from Japan and Korea, Australia and New Zealand, Europe and North America. However, the number of surveys sent out or number of centres approached and overall response rate was not reported. The RCR carried out a survey in 2011 to assess progress in implementation of image guided brachytherapy for cervix cancer in the UK since publication of the 2009 RCR guidelines (Tan, 2011; RCR, 2009). In the 2011 RCR survey 45 centres known to carry out brachytherapy for cervix cancer were invited to take part (the one centre in Ireland was excluded) and responses were received from 43 centres (96% response rate). They examined the type of brachytherapy machines used (HDR, LDR or PDR), dose prescribed, applicator design and imaging and planning technique. Fractionation and scheduling, inpatient or day case provision, anaesthetics and

analgesia were not surveyed. The high response rate for the current survey has provided a comprehensive overview of brachytherapy service provision for LACC in the UK.

The RCR 2011 survey reported three centres using interstitial needle applicators, less than 1% (Tan, 2011). The Gynecologic Cancer Intergroup survey 2012 reported 3% of respondents carrying out ICBT and ISBT (hybrid technique) and 1% doing ISBT (Viswanathan *et al.*, 2012b), although no overall response rate was reported. The current survey reported the use of interstitial or hybrid technique at 59%, slightly lower than the 70% reported in the UK Brachy-HERO survey (Tan, 2017a), although this could be due to the significantly lower response rate in the UK Brachy-HERO survey. Comparing the findings from the current survey and the UK Brachy-HERO survey (Tan, 2017a) to earlier surveys (Viswanathan *et al.*, 2012b; Tan, 2011) suggests a rapid implementation of interstitial or hybrid (interstitial and intracavitary) brachytherapy in the last eight years in the UK and other developed countries.

Survey responses indicated wide variation in insertion regimes with 17 respondents reporting a predominant use of a one or two applicator insertion regime which involved overnight stays with applicators in place, and 17 reporting three or four insertion regimes of shorter durations. This variation in regime choice has led to the large range of typical duration of applicators in place, from three to 52 hours. The free text comments indicated that this wide disparity had arisen for complex operational reasons, such as access to operating theatres, availability of ward beds, numbers of oncologists and physicists and access to imaging facilities such as MR. There was no evidence of patient input into individual treatment plans or service design, although this information was not explicitly requested in the survey. Brachytherapy for cervical cancer causes patients varying levels of pain, anxiety and distress, and it has been proposed that the duration of the procedure and repetition of the procedure will impact on women's experiences (Humphrey, Bennett and Cramp, 2018). Interstitial or hybrid techniques and use of MR imaging planning has been recommended and widely implemented, with the aim of improving local tumour control (for example: Pötter *et al.*, 2021; Reed *et al.*, 2021; Chargari *et al.*, 2019; Cibula *et al.*, 2018; Haie-Meder *et al.*, 2005). However, decisions on how to implement this development have been left to individual centres, as they have many different logistical factors to consider. Although service users cannot comment on lived experiences of different regimes, it would

be useful to obtain their feedback on the brachytherapy insertion regime that they experienced so their views can be taken into consideration when deciding future fractionation regimes.

It is widely recognised that ISBT is likely to cause patients more pain than intracavitary brachytherapy (Amsbaugh *et al.*, 2016; Viswanathan and Thomadsen, 2012; Janaki *et al.*, 2008). Two studies which reported anaesthesia/analgesia regimes with long durations of ISBT had good outcomes using PCA after a general anesthetic (Wiebe *et al.*, 2011) or a combined epidural medication (Amsbaugh *et al.*, 2016). In this survey six respondents reported no use of PCAs or epidural with long duration regimes. Further research is needed to assess women's experiences of pain with or without the use of continuous pain management (PCA or epidural) and for long duration procedures with interstitial needles.

Applicator removal has been reported to be the most problematic part of brachytherapy. One study reported that instrument removal was "the most physically uncomfortable aspect" and another that "maximal levels of pain coincided with applicator manipulation during insertion and removal" (Bhanabhai *et al.*, 2013; Kwekkeboom *et al.*, 2009). Smith, Todd and Symonds (2002) reported a sudden increase in pain during applicator removal, at a time when other analgesia had worn off. They concluded that inhalation of nitrous oxide gas was appropriate to minimise this short-term discomfort as it is short acting, easy to administer and has a rapid effect due to absorption into the blood stream through lung alveoli. A retrospective five year analysis in a single centre recommended that regional anaesthesia should continue until the end of the brachytherapy, including applicator removal (Benrath *et al.*, 2006). In the current survey almost a third of respondents reported no additional analgesia being routinely offered at applicator removal. Where it was offered, the most popular additional drug at applicator removal was nitrous oxide and oxygen gas (Entonox®/gas and air). For some respondents the use of continuous pain management with PCA or epidural or spinal anaesthetic for short procedures may be considered sufficient for applicator removal. However, there were four centres that did not use continuous pain management techniques and did not routinely offer any additional analgesia at applicator removal. This was corroborated with some free text comments about analgesia needing to

be improved. Therefore, inadequate pain management, especially for applicator removal is likely to be a problem for some patients.

Some respondents indicated little experience of patients with special needs such as learning disabilities, dementia, and victims of sexual abuse or female genital mutilation. This may reflect the low numbers of women having this type of brachytherapy, especially in smaller centres. However, it is important to consider that in the UK the incidence of women who experience domestic violence during their lifetime is one in four, and one in five for sexual assault (Home Office News Team, 2019). Therefore, it may be assumed that clinicians will sometimes be unaware of patients' histories and access to additional support for brachytherapy would not have been sought. However, it is encouraging to see that many respondents in this survey reported that they have access to specialist support services and would assess and adapt their provision according to individual patient needs, assuming that those with special needs are identified.

Respondents rated highly the support given to patients at their centre before, during and after brachytherapy. In relation to what worked well, respondents referred to continuity of care, experienced staff, building trust and rapport and dedicated staff. However, some responses regarding what needed to be improved identified care on the wards and education of ward and other staff. In a previous interview study, many women commented on their "Supportive treatment team (specialized staff members brachytherapy)" (Kirchheiner *et al.*, 2014b). This contrasts with a report of the lived experiences of receiving LDR or PDR brachytherapy, where women reported some negative aspects of care, mostly relating to nursing care on the wards. Some women were distressed by nurses' "lack of understanding of the technology associated with the treatment" and an uncaring attitude or awareness of the ordeal that they were going through. Participants reported inconsistent care in pain management, and a lack of help with basic hygiene and empathy and understanding (Velji and Fitch, 2001). Overall, the literature suggests mixed experiences that may be dependent on the level of knowledge, skill and experience of individual members of the brachytherapy or ward nursing teams and the supportive relationship they develop with patients. Contrasting views were also found in the current survey, with most responses suggesting that patients were well supported and a few indicating that the

provision of care and staff education needed improvement. Inconsistencies in support provided to women were shown in the survey data, and there was evidence that some centres were trying to address this. Further research is therefore warranted to evaluate the provision and uptake of support and explore patients' views of care and support at each stage of treatment.

Survey respondents commented on the good provision of information and frequent opportunities for patients to ask questions. However, Velji and Fitch (2001) reported that despite information provision, women did not feel fully prepared for their experience of brachytherapy. Women said that factual information did not prepare them for how they were going to feel. The effectiveness of information provision in reducing anxiety and distress is therefore questionable. A study of LDR brachytherapy reported women's satisfaction with information provision, but some negative views were caused by a gap between theoretical knowledge and the actual experience of brachytherapy (Warnock, 2005). A study of the informational needs of women having brachytherapy for LACC reported significant unmet needs, such as information about side-effects, sexual intercourse, treatment preparation and appointments (Long, Friedrich-Nel and Joubert, 2016a). Their findings were used to develop patient-centred guidelines for use by multidiscplinary team members, to integrate patient experience into the development process (Long, Friedrich-Nel and Joubert, 2016b). Evaluation of this approach would be helpful to other centres considering similar guidelines.

3.6 Limitations

There are some limitations to this study as questionnaires do not provide an opportunity for the researcher to clarify ambiguities or check that questions have been interpreted as intended. It is also not possible to seek additional information via a questionnaire, although the opportunity for respondents to provide free text comments did add valuable detail. Inconsistencies were noticed in responses from four participants between the fractionation regime selected from the dropdown options, their free text comments and duration of applicators in place. These four responses to this question were removed from the results. For the type of brachytherapy delivered in the centre, one respondent selected "interstitial"

alone, which is likely to be an inputting error as intracavitary brachytherapy is standard treatment. This also raised concerns whether participants had understood the use of the term “hybrid”. A simpler question may have helped, such as: “Are you using interstitial needles for cervix brachytherapy?” or a definition of the term “hybrid” could have been provided.

3.7 Conclusions

The excellent response rate to the survey provided a comprehensive overview of UK brachytherapy service provision for LACC. A wide variability in scheduling regimes and duration of treatment was identified meaning that the experiences of women receiving treatment are also likely to differ significantly. Anaesthesia (GA or spinal) was reported to be used in all centres but analgesia after applicator insertion and for applicator removal was inconsistent. The findings justify the need for further research to explore the experiences of women receiving different treatment regimes and to seek their views on the support that should be routinely offered.

Chapter Four: Women's experiences of brachytherapy for LACC: semi-structured interviews (study two)

This chapter presents the rationale, aims, method, results and discussion for study two, interviews with women who have experienced brachytherapy for LACC.

4.1 Introduction and rationale

Women often experience pain, anxiety and distress related to brachytherapy with some reporting symptoms of post-traumatic stress after brachytherapy (Humphrey, Bennett and Cramp, 2018; Kirchheiner *et al.*, 2014b). Over the last two decades brachytherapy techniques have been evolving, and UK centres have been adapting their scheduling in different ways to be able to implement the new technological advances recommended. In particular, the changes to the scheduling of brachytherapy has increased the duration that applicators are in place, potentially increasing patient discomfort (Humphrey *et al.*, 2021). Also, one of the new techniques includes the use of interstitial needles, which have been shown to cause more pain compared with intracavitary applicators alone (Amsbaugh *et al.*, 2016; Viswanathan and Thomadsen, 2012; Janaki *et al.*, 2008). Brachytherapy centres are having to develop new ways of managing pain and immobilisation for prolonged periods (Brown, 2018; Amsbaugh *et al.*, 2016; Wiebe *et al.*, 2011). International guidelines for the implementation of new brachytherapy techniques (MR image-guided ICBT and ISBT) focus on achieving high radiation doses to tumours and reducing doses to normal pelvic tissue (Sturdza *et al.*, 2016; Lindegaard *et al.*, 2013; Viswanathan and Thomadsen, 2012; Viswanathan *et al.*, 2012b; Pötter *et al.*, 2006, 2007, 2011; Haie-Meder *et al.*, 2005). Whilst the guidelines advise that anaesthesia and analgesia are required they do not provide any suggestions relating to the patient experience of treatment (Amsbaugh *et al.*, 2016; Viswanathan and Thomadsen, 2012; Janaki *et al.*, 2008).

Study one (Chapter three) identified the non-pharmacological support available to women receiving brachytherapy across the UK, as reported by health professionals. To complement this, it was deemed important to explore women's experiences of treatment to identify potential aspects of brachytherapy that could be improved. Two different time points were

chosen to carry out patient interviews to explore women's views about their brachytherapy experience soon after treatment and one year after treatment, to consider the shorter and the longer-term impacts. As treatment can vary by centre it was also important to capture women's views from a range of sites.

4.2 Aims and objectives

The aim of this study was to examine women's experiences of brachytherapy for LACC.
The objectives were:

- To explore women's experiences of brachytherapy immediately post brachytherapy and one year post brachytherapy through recruitment of two distinct samples;
- To understand women's experiences of brachytherapy in different UK centres that employed different treatment schedules;
- To explore ways to improve women's experiences; and
- To inform the development of an intervention(s) to reduce distress caused by brachytherapy.

4.3 Method

4.3.1 Study design

Qualitative research is typically used to understand or explore an issue or a phenomenon in depth (Creswell, 2013). It is often used to develop theories or understanding when quantitative measures are unable to capture the complexity of an issue or its' meaning (Creswell, 2013). It can be used to describe both the technique (for data collection and analysis) and the research framework or paradigm, that is, the beliefs and values of a community (Braun and Clarke, 2013). In the qualitative paradigm, it is not assumed that there is only one correct version or observable truth, but instead that there are "multiple versions of reality", even in the same person (Braun and Clark, 2013, p.6). It can be used to make sense of and interpret data which is related to a specific context (Braun and Clarke, 2013). Therefore, a qualitative research approach was deemed to be appropriate to explore and make sense of women's accounts of their lived experiences of brachytherapy, to meet the study aim and objectives.

A number of different methodological approaches where considered for this exploratory study of patient experiences. Phenomenology is considered to be a philosophical method which explores the common meaning for a group of individuals, to understand the nature of the phenomenon through their lived experiences of it (Creswell and Poth, 2018). There are multiple schools of phenomenology with a requirement to adhere to a strict set of principles or guidelines, dependant on which school of phenomenology is being followed (Norlyk and Harder, 2010). One key principle in phenomenological approaches is the need to 'bracket' the researcher's prior knowledge of the phenomenon, suspending judgement, also known as phenomenological reduction (Dörfler and Stierand, 2021). This involves putting aside all personal experience and theoretical knowledge to avoid influencing interpretation of the data (Giorgi, 2008). With over 30 years of clinical experience in radiotherapy and brachytherapy, the doctoral fellow considered that 'bracketing' this experience would potentially detract from data interpretation and could be detrimental to develop an in-depth understanding of the lived experiences of brachytherapy patients.

Qualitative Case Study Methodology was also considered. It is a form of empirical enquiry which can be used to develop in-depth knowledge about a real-world issue or phenomenon, with one or more cases and often multiple methods of data collection to facilitate triangulation of data (Yin, 2014). It has been described as a flexible methodology which can incorporate different epistemological and ontological paradigms, research designs and methods (Hyett, Kenny and Dickson-Swift, 2014). However, this flexibility has led to some criticism in research publications due to the lack of consistency in its application and whether it is a method or methodology (Priya, 2014). There is no consensus regarding the design and implementation of case study methodology and Yazan describes three widely differing approaches to case study methodology set out by authors Yin, Merriam and Stake (Yazan, 2015). They have different views on epistemological stance, definition of case and case study, use of mixed quantitative and qualitative data or qualitative data alone and the number of evidence sources required to facilitate triangulation of data, potentially problematic for a novice researcher to navigate. The use of multiple data collection methods to understand patient experiences of brachytherapy, such as observational fieldwork, document analysis and interviews, would not have been practical across a number of NHS inpatient and day case settings with multiple procedures in operating theatres, imaging,

treatment delivery and multiple and sometimes unknown overnight stays in a hospital ward. A pragmatic approach, considering access and feasibility, led to a case study approach being ruled out.

Overall, reflexive thematic analysis (RTA) was considered to be a more appropriate approach which would make best use of the doctoral fellow's extensive knowledge and experience of brachytherapy. This approach is explained in section 4.3.6 Data analysis.

There are many different qualitative data generation or collection methods including interviews; observational fieldwork; focus groups; documentary sources; diaries; qualitative surveys; and story-completion tasks (Barbour, 2014a; Braun and Clarke, 2013). For this study individual semi-structured interviews were chosen to facilitate an understanding of brachytherapy from a patient's perspective in the context of their personal history. Given the potentially highly sensitive and personal nature of the topic, focus groups were rejected as participants may have been reluctant to disclose such information in a group setting (Guest *et al.*, 2017). Interviews have been reported to be best suited to "exploring understandings, perceptions and constructions of things that participants have some kind of personal stake in" and can "generate rich and detailed responses" to experience-type research questions (Braun and Clarke, 2006, p.81) and were therefore appropriate for this study.

A semi-structured interview approach was chosen to allow some prompts and probing questions, through building rapport with the participant whilst remaining within the boundaries of the research aim (Braun and Clarke, 2013). It was recognised that having flexibility in the wording and order of questions rather than following a rigid script would allow adaptations for the context and the need for the interviewer (doctoral fellow) to be "responsive to the participant's developing account" (Braun and Clarke, 2013, p.78). Another advantage of this flexible approach is that the questions can be refined during and between interviews based upon sequential analysis of data, allowing the researcher to pursue emerging avenues of inquiry (Pope, Ziebland and Mays, 2017).

A face-to-face interview data collection method was chosen in preference to remote interviews due to the potential for personal and emotive disclosures. It was thought that rapport and a trusting relationship developed through face-to-face contact would facilitate more in-depth disclosure of emotional responses, including any distress caused by the experience of brachytherapy. The use of remote video interviewing has previously been criticised due to the risk of technical glitches at key moments of emotion (King and Horrocks, 2010). Concerns have also been raised about the potential to lose the "rapport and richness" of a face-to-face interaction (Rowley, 2012, p.265) and loss of intimacy due to the lack of direct contact, making personal and sensitive subjects more difficult to discuss (Seitz, 2016). Paralinguistic or non-verbal cues, such as gestures and facial expressions, can all be used to convey meaning and emotion (Park, 2007) and these visual cues would be lost in telephone interviews and possibly compromised in video interviews if images were blurry or delayed due to poor internet connection. However, some evidence comparing telephone to face-to-face interviews reported little difference in data quality with advantages and disadvantages of each method identified (Irvine, 2011; Novick, 2008; Sturges and Hanrahan, 2004). Participants may even open up more and talk for longer in telephone interviews, especially if they are shy or reserved and interviewed in a familiar, comfortable environment (Seitz, 2016; Deakin and Wakefield, 2014; Hanna, 2012). It has been reported that Skype interviewing was as good as face-to-face interviewing and in some cases better (Lo Iacono, Symonds and Brown, 2016). Many consider face-to-face interviews to be the 'gold standard' interview mode in qualitative research due to the ability to observe visual or non-verbal cues and employ active listening , helping to create a personal connection, to build rapport and trust (Fontana and Frey, 2005; Gillham, 2005; Rubin and Rubin, 2012; Braun and Clarke, 2013; Barbour, 2014). Based upon the researcher's preference it was initially decided to carry out the interviews face-to-face.

The interview schedule was informed by relevant research literature and survey responses, and developed through discussion with PhD supervisors and two patient research partners. The patient research partners provided key insights including the suggestion to signpost participants to national charities which provide help and support to women after a cervical cancer diagnosis. The final interview schedule included an introduction to the study aims and confirmation of consent (Interview schedule- see Appendix 6). Interview questions were

used by the doctoral fellow to invite women to talk through their brachytherapy experience including what helped them to cope and with hindsight what they thought could have helped. If participants reported experiencing pain or psychological distress, this was explored in more detail and all participants were asked for any ideas for improvements. As suggested by the patient research partners, the interview concluded with signposting participants to local and national support services.

Four recruitment sites were identified from the UK survey of practice (study one). Selected sites represented a range of brachytherapy techniques and pathways, including recently adopted techniques such as interstitial needles. The selected sites included two small and two large radiotherapy centres. In the selected four recruitment sites brachytherapy was given:

1. As a day-case procedure (repeated three or four times)- one site.
2. As an in-patient procedure, with treatment given twice with one insertion then repeated (usually a week later)- two sites.
3. As an in-patient procedure, with treatment given three or four times with one insertion- one site.
4. At a centre which offers non-pharmacological therapies to women during brachytherapy- one site.

University Hospitals Bristol and Weston NHS Foundation Trust was excluded as the doctoral fellow may have been involved in the clinical care of potential participants, which may have influenced the researcher-participant relationship and the participant's ability to speak freely about their experiences.

To be able to explore women's experiences of brachytherapy at different time points after the treatment, two distinct sampling groups were identified:

Group one: up to 20 patients were to be interviewed up to six weeks after completion of brachytherapy. A short recall period was considered optimal for participants to recall events and their experiences of the procedure. However, it was considered important not to interview too soon after the brachytherapy, to allow time for acute treatment related side

effects to settle down, such as fatigue, which could affect the interview if the participant was too tired to concentrate for the duration of the interview.

Group two: up to 20 patients were to be interviewed at one year post brachytherapy (range of 10-14 months post brachytherapy). The purpose was to see if they were experiencing any distress or anxiety that may relate to their previous experience of brachytherapy and if this had any impact on their longer term wellbeing. Recollection of positive experiences that helped them with the treatment were also explored.

4.3.2 Sampling strategy and recruitment

By approaching consecutive eligible women, it was anticipated that those being invited to participate would represent the typical demographic of patients with this specific cancer diagnosis and brachytherapy treatment. Access to participation was facilitated by avoiding the use of jargon in an easy-to-read Study Flyer (Appendix 7) and Participant Information Sheet (PIS) (Appendix 8). One of the patient research partners contributed to the design of the Study Flyer. Specific suggestions included having a yellow background and black text to make it easy to read and eye-catching to potentially tired women at the end of their cancer treatments. Attempts to avoid potential bias in participant selection was made by encouraging healthcare staff to approach all eligible women, without making assumptions about who would be likely to agree or be a useful or interesting participant.

The option of incentivisation was considered to promote recruitment but there were concerns that this could be counterproductive by reducing 'intrinsic altruistic motivation' (Zutlevics, 2016). Therefore, no payment to participants was offered other than reimbursement for travel and parking costs for face-to-face interviews.

Eligibility Criteria

Women who had received brachytherapy for LACC in one of the four participating centres were considered for their eligibility. The brachytherapy team or site-based research radiographer checked inclusion and exclusion criteria below before offering a study pack to potential participants.

Inclusion criteria

- Women who had received brachytherapy for LACC and were available to be interviewed either up to six weeks (group one) or 10-14 months (group two) after brachytherapy
- Over 18 years old
- Able to communicate verbally in English
- Have capacity to consent to take part in the study

Exclusion criteria

- Had brachytherapy for any other conditions or had a hysterectomy
- Lacking capacity to consent to take part in the study
- Had received brachytherapy in a centre not taking part in the study
- Previous diagnosis of a major psychiatric disorder
- Group two: diagnosis of progressive or metastatic disease since brachytherapy

Participants from group one were excluded from being interviewed a second time in group two.

Size of sample

Many researchers use the concept of data saturation to determine when to stop data collection, based on the model of grounded theory and theoretical saturation (Guest, Bunce and Johnson, 2006). However, a saturation concept to determine sample size may be problematic if extended to apply in other qualitative approaches and has become a controversial topic (O'Reilly and Parker, 2012). Guest, Bunce and Johnson (2006) advise interviewing a minimum of 12 participants in a homogenous group, to reach saturation of data. However, homogeneity may be more complex than just considering demographics such as age, treatment type or socio-economic status of participants. Homogeneity may also depend on the specificity and the breadth of the research topic. Crouch and McKenzie (2006) recommend no more than 20 participants for a researcher to remain close to the data, that is, to prevent a dataset becoming too large and unwieldy for the resources available for analysis. Explanations of how data saturation determines sample size is poorly

described in literature and reported to be impractical to carry out (Malterud, Siersma and Guassora, 2016). Braun and Clarke (2022) suggest that a sample size should not be decided upon in advance, as this is a purely quantitative research concept which assumes that capturing a representative sample is desirable. They prefer to use the concept of 'information power', described by Malterud, Siersma and Guassora (2016). This model includes a continuous assessment of the quality of the data and how it meets the study aims, to decide on the sample size during the data collection phase. Consideration of sample size is often a requirement in the planning phase of the research, to quantify cost and resource allocation for funders and reviewers. Therefore the 'information power' approach can be used to estimate the possible number of interviews required to enable planning, costing and resources needed for a study. Malterud, Siersma and Guassora (2016) suggest that sample size decisions should consider the following factors:

- the aim of the study,
- sample specificity,
- use of established theory,
- quality of dialogue, and
- analysis strategy.

For this study, the sample was considered to be highly specific for the study aim, as all the participants' experiences of brachytherapy were relevant within the relatively narrow topic. Quality of the dialogue was difficult to predict in advance, although consideration was given to the novice research status of the doctoral fellow mitigated by supervision provided by experienced researchers. There was some available theory from literature and the doctoral fellow was an experienced clinician with extensive knowledge of the subject. A cross-case analysis was proposed. Taking this pragmatic 'information power' approach, it was estimated that between 12 and 20 interviews in each group would be appropriate for this study.

It was intended to interview a minimum of three and maximum of five patients from each of the four recruitment sites for group one and group two, that is a maximum of 10 patients from each site, between 12 and 20 patients in each group giving a total of 24-40 patients.

The quality of interview data and how it met the study aim was continuously reviewed during the recruitment period so that sufficient 'information power' was ensured.

4.3.3 Ethical considerations and approvals process

Ethical issues were considered in relation to the potential risk of harm versus the likely lack of benefit for interview participants. They would be giving their time to recall and retell their experience of a procedure that may have been upsetting or distressing at the time and interviews could potentially cause re-traumatisation. The possible benefits would be that talking through the experience may be therapeutic, like a debriefing session, or that they may be comforted by thinking that they may help other brachytherapy patients in the future. The doctoral fellow provided mitigation against the risk of causing distress or re-traumatisation by preparing appropriate signposting with each recruitment site team, confirmed during the site initiation visit. At the end of each interview, the doctoral fellow drew the participants' attention to the available support from their clinical team and local and national support services. The doctoral fellow acknowledged that they may not always recognise participants' distress, or that it may be hidden by the participant or may occur after the interview had finished, therefore signposting to support services was included at all interviews. Consideration was given to the risk that the doctoral fellow could be affected by distressing accounts from participants. Supervision from the PhD supervisory team and a clinical psychologist colleague were available to the doctoral fellow, if required. Other considerations were for the doctoral fellow's safety as a lone worker if interviews were taking place away from NHS premises. The doctoral fellow followed the sponsor's (UWE) Safety for Social Researchers guidance.

Ethical issues regarding inclusion and exclusion criteria were carefully considered. For example, the decision to exclude potential participants who would need a translator. The cost for translation services were not the deciding factor, but more importantly that the doctoral fellow would not be able to confirm the accuracy of translation both during the interview and the transcription process. Inclusion of potential participants with disabilities was considered, and recruitment site teams were encouraged to be as inclusive as possible, for example reading out and summarising the PIS to those with learning disabilities, reading difficulties or visual impairments.

Between November 2018 and May 2019 documents were prepared for Health Research Authority approval and uploaded to the Integrated Research Application System (IRAS), see Table 17 and Appendices 8, 9, 13 and 14. The application was submitted with authorisations from the Director of Studies, first Academic Supervisor and the UWE Faculty of Health and Applied Sciences, Associate Dean for Research. The NHS Research Ethics Committee (REC) review took place on 23rd May 2019 with the doctoral fellow participating by teleconference. One minor amendment to the PIS was requested. REC favourable opinion was received on 29th May 2019 and Health Research Authority approval was received on 24th June (see Appendices 9 and 10).

- REC reference: 19/WS/0080
- Protocol number: HAS-AHP-18-005
- IRAS project ID: 256311

UWE Health and Allied Sciences (HAS) Faculty Ethics approval was received on 27th June 2019 (see Appendix 11).

- UWE REC REF No: HAS.19.06.206

NIHR Clinical Research Network Portfolio application was submitted in March 2019 and portfolio approval received in May 2019. Access to the Clinical Research Network South West support services was subsequently initiated. Recruitment data were confirmed monthly by the doctoral fellow on the Central Portfolio Management System.

Table 17 Documents submitted to IRAS (study two)

Research protocol	Study flow diagram
Participant information sheet (PIS) (Appendix 8)	Statement of Events
Consent form (Appendix 12)	Statement of Activities
Study flyer (Appendix 7)	Risk assessment (UWE)
Research data management plan (UWE)	Letter to GP (Appendix 13)
Interview schedule (Appendix 6)	Organisation Information document
UWE indemnity letters	Delegation log for each NHS site

Capacity and capability assessments were carried out at each of the four NHS recruitment sites and took between one and six months to complete. The doctoral fellow attended a

departmental research committee meeting at one of the four sites to present a study outline and answer their questions about the study. The doctoral fellow also attended site initiation visits at each site, meeting key staff and providing training in the recruitment requirements as stated previously. Identification of roles of recruitment site staff were discussed with each team and delegation logs completed. As the doctoral fellow was already an NHS employee a 'Letter-of-Access' rather than a 'Research Passport' was provided by each of the NHS Trusts acting as recruitment centres to allow them to interview their patients. Throughout the recruitment period, the doctoral fellow had regular email contact with the principal investigator at each recruitment site, to monitor, encourage and support recruitment efforts.

4.3.4 Data Collection

For group one, patients were invited to participate in an interview up to six weeks after completion of brachytherapy.

For group two, patients were interviewed between 10 and 14 months post brachytherapy.

Recruitment and consent

Eligible patients for group one were identified by the local brachytherapy teams and given a study pack, comprising a Study Flyer, PIS and stamped addressed envelope. The study pack was given out by brachytherapy radiographers when discussing end of treatment and follow-up arrangements or at a follow-up clinic appointment with their clinical oncologist. Eligible patients for group two were identified by research radiographers and given the study pack at routine follow-up clinic appointments. The Study Flyer included a tear off slip where patients could indicate their consent to be contacted about the research, their contact details and preference for being contacted by telephone or email (see Appendix 7). On receipt of the tear off slip the doctoral fellow contacted the potential participant, gave them the opportunity to ask questions about the study, checked eligibility, took verbal consent for interview with audio recording and made arrangements for the interview. Written informed consent was obtained prior to commencement of the interview. The original Consent Form was signed and dated by the participant and the doctoral fellow, filed

in the patient's medical notes at the recruitment site and a copy kept in the recruitment site file. With the consent of the patient their GP was notified of their participation in the study in case the patient wanted to discuss with their GP any issues raised during the research interview.

For each face-to-face interview, a convenient venue for the participant was agreed. Interview venues needed to be private to allow sharing of experiences of a personal and intimate nature and quiet enough for good quality audio recording to take place. Participants were given a choice of interview venue including a hospital clinic room; a patient support centre; hospital research facility; their own home or any other appropriate negotiated venue. Maintaining participants' privacy and avoiding interruptions and background noise was discussed before the start of the interview.

Conducting the interviews

Recruitment and interviews were carried out over a 20-month period. Interviews commenced in September 2019 and were completed in April 2021. Prior to commencing the interview, the participant's recruitment number, age, recruitment site, group one or two, date of interview and whether they would like to be informed about the findings of the research and whether by email or by post was documented. All interviews were carried out by the doctoral fellow and audio-recorded using a pin code protected and 256-bit file encrypted digital voice recorder (Olympus DS-9500). The doctoral fellow recorded field notes after each interview, including observations and personal reflections on thoughts and feelings, reflecting on areas where the interview went well or could have been improved, to assist in the reflexive process. For example, consideration of whether the doctoral fellow had missed following up lines of enquiry, used leading questions or closed questions. A summary of each interview was written from the field notes and interview transcript data and used to inform the supervisory team of progress and discuss with the Steering Group at the annual meeting.

4.3.5 Impact of COVID-19 pandemic

From March 2020, the COVID-19 pandemic prevented travel to potential interview venues. The risk of transmission of COVID-19 through a face-to-face interview was unacceptable for research purposes, especially for patients still immunosuppressed from anti-cancer therapies. In addition, all UK NHS non-COVID-19 research was suspended and the study was paused for four months. The doctoral fellow was required to return to full-time clinical duties for four months from April to August 2020.

Initially the doctoral fellow considered switching from face-to-face interviews to remote interviews but was concerned that remote interviews might reduce the quality of the data due to less opportunity to build rapport and a trusting relationship. The advantages and disadvantages of face-to-face interviews compared with remote interviews and the rationale for face-to-face interviews has previously been described in section 4.3.1. However, the COVID-19 pandemic meant that alternative options had to be considered. These included: waiting for travel and face-to-face interviews to be allowed (potentially with social distancing and wearing face masks in large, ventilated rooms); abandoning the research; or switching to remote interviews. On balance it was decided that switching to remote interviews was the best option.

For interview recruitment, the switch to mainly remote oncology clinic appointments during the COVID-19 pandemic made approaching patients face-to-face more difficult so some were approached by telephone by a research radiographer and study packs sent out by post.

4.3.6 Data analysis

Reflexive Thematic Analysis

Thematic analysis is considered by many to be a highly flexible approach to qualitative analysis as it is possible to adapt the method to use with many different types of research study (Nowell *et al.*, 2017; Braun and Clarke, 2013; Braun and Clarke, 2006). The Reflexive Thematic Analysis (RTA) method allows a theoretical or epistemological flexibility and reflexivity of the researcher and is relatively simple to learn and put into practice, even by

novices to thematic analysis (Nowell *et al.*, 2017; Braun and Clarke, 2013; Braun and Clarke, 2006).

The six-step process described by Braun and Clarke (2006) has become one of the most well-known and frequently cited papers in qualitative research methodology with over 100,000 citations to date. However, Braun and Clarke (2006) point out that the process they have described needs to remain fluid and flexible and that the six steps do not mean that the process is unidirectional and linear. They encourage users of this method to understand that the process should move between the steps iteratively, and it is therefore impossible to define exactly when analysis should stop (Braun and Clarke, 2019; Braun, Clarke and Hayfield, 2019). In these more recent publications, Braun and Clarke have explained the development and clarification of their ideas on thematic analysis and named their approach 'Reflexive Thematic Analysis' (Braun and Clarke, 2019; Braun, Clarke and Hayfield, 2019). This acknowledges that the way that a researcher collects, understands and interprets the data will depend on their own experiences (professional and personal), their values, interests and insights (Starks and Trinidad, 2007). Therefore, no two researchers would look at the same data and generate the same understanding and interpretation. There is no right or wrong answer, but the key is in the reflexivity, the understanding, acknowledgement and insightful account of the researcher's own background and epistemological position (Braun and Clarke, 2019; Braun, Clarke and Hayfield, 2019). Researchers are encouraged to be "honest and vigilant about their own perspectives, pre-existing thoughts and beliefs and developing hypotheses" when they are carrying out and describing the process of thematic analysis (Starks and Trinidad, 2007, p1376). It is important that a researcher begins their reflexivity before starting interviews and throughout the interviews and subsequent analysis, to develop "a habit of awareness and critical thinking" (King, 2004, p 20). The inclusion of reflexivity in the account of analysis is thought to help the reader weigh up the credibility of the interpretation, whether it fits with their views or experiences and therefore may add to the trustworthiness of the findings (Starks and Trinidad, 2007; Tobin and Begley, 2004).

Another choice to be made about the analysis is whether it should be carried out through an inductive or a deductive approach (Braun and Clarke, 2013). An inductive approach is

grounded in the data, with limited prior assumptions about the phenomena being researched. A deductive approach would fit data to confirm or challenge a pre-existing theory or framework. The inductive approach fits well with exploratory research, where there is little existing knowledge or understanding of a complex phenomenon. Kidder and Fine (1987) explore the option to use a 'small q' approach which aligns more closely to a (post) positivist and traditionally quantitative stance, versus use of a 'Big Q' approach which aligns more to a contextualist or critical realist approach. Kidder and Fine (1987, p60) explain that the concept of 'small q' and 'Big Q' and deductive versus inductive are not necessarily either/or approaches, but more 'as end points on a continuum' within a qualitative paradigm. Braun and Clarke's (2022) RTA sits firmly towards the Big Q end of the continuum, where coding and theme development are driven by the data, not by existing theories. Due to the obvious lack of a single truth, reality or understanding across women's experiences of brachytherapy and aiming to generate nuanced insights rather than confirming or refuting a hypothesis, the study aligns more naturally with a contextualist or constructionist approach and more towards the 'Big Q' and inductive ends of the qualitative spectrum. However, the doctoral fellow is aware that as a novice researcher, the requirement to be interpretive and creative with RTA may be an aspiration which is limited by both experience and ability.

Reflexivity- information about the doctoral fellow

My professional background

I am a therapeutic radiographer and have been working in radiotherapy for 35 years, having specialised in brachytherapy 18 years ago. Although this can be a highly technical job, I have throughout my career had a particular interest in patient care and the psychological impact of a cancer diagnosis and treatment. I have undertaken training in counselling skills and theory and tried to use this knowledge and skills to support patients during radiotherapy. My move to specialise in brachytherapy allowed me to spend more time with patients, with some procedures taking a whole day compared with 10 minutes for simple EBRT. My treatment review radiographer role provided me with education, practical training and the opportunity to support patients during radiotherapy for gynaecological cancers and provide information in preparation for brachytherapy. I trained as a non-medical prescriber so that I

could support patients in pharmacological management of treatment related toxicities. A qualification in applied pharmacology helped to increase my knowledge and understanding of anaesthesia and analgesia techniques. As a theatre manager I gained experience in managing patient safety, risk assessments, theatre finances and staff resources. I have carried out some patient experience research interviews in the radiotherapy department. As part of the doctoral fellowship education programme, I attended a short course on qualitative research interviews including theory and practical workshops (University of Oxford).

My personal background

I am female, married and a mother of three grown up children. I have had no serious illnesses in my life, but like most others I have experienced the loss of a close family member and the devastating effect of a cancer diagnosis and treatment on a close friend and a close family member. These experiences have had a significant impact on my understanding of what it is like to be a cancer patient and cancer survivor, and the carer of a cancer patient or survivor. I believe that the uniqueness in the way people cope with and process the fears and worries for their future can never be underestimated, or generalised, and I constantly strive to improve my understanding so I can provide better support.

Impact of me being me on study two: patient interviews

As an experienced clinician, I became aware even before the doctoral fellowship started that I was a very novice researcher. I worried about my ability to carry out the research interviews and the need for me to switch from a clinician and therapeutic relationship with patients to that of a researcher. Would I be capable of developing in-depth, probing discussions about sensitive topics with women who I had not previously met? I discussed with my supervisory team whether to disclose my professional background to participants. My research partners told me that they thought that participants would want to know that I was a clinician, knowledgeable and experienced in brachytherapy. I felt comfortable with this honest and transparent approach and therefore informed participants of my professional background and current research role. However, it was important for me to acknowledge and consider how my professional and personal background influenced the

researcher-participant relationship and whether this had an impact on participant responses and reactions.

My experience and views on brachytherapy for LACC have been shaped by my experience working in brachytherapy in one centre, but in addition through reading literature and working with multi-disciplinary groups at national and international level. Involvement with the Brachytherapy Radiographers Forum has raised my awareness of the disparity between brachytherapy service provision across the UK. I have heard concerns from colleagues about pain management and poor patient experiences as brachytherapy has become more complex and increased in duration over the last 15 years. As a member of an international working party on development of planning guidelines for brachytherapy and a European working party for development of quality indicators for cervical cancer radiotherapy, I am aware of the global variation in service provision. This is particularly noticeable in developing countries where resources are fewer but incidence of cervical cancer much higher than in developed nations. My clinical experience is with day case brachytherapy. Due to a lack of availability of ward beds, a day case service was developed to avoid any reliance on ward beds, otherwise treatment could be delayed with a detrimental effect on cancer outcomes. I have observed the resource heavy workload of carrying out four day case procedures per patient. The required staff resources- physicists, oncologists, radiographers and theatre team and imaging resources with a need for up to four CT and MR scans per patient over a two week period. However, I have also observed the benefits for patients, going home after each procedure with no overnight stay. I have visited some UK brachytherapy units and in one centre worked in brachytherapy with an honorary contract to cover staff shortages, helping with long duration inpatient brachytherapy. Having read extensively to develop a research proposal, I became aware that there are many benefits for longer duration brachytherapy, including patient experiences, as there may be less re-traumatisation and less analgesia required if repetition of procedures is reduced. I have been aware of the need to constantly reflect on and scrutinise my thought processes, questions and prompts to interview participants, and to remain honest and true to the data. I wrote reflexive notes after each interview, to document my thoughts and feelings after each interview, to assist the reflexive data analysis.

Data analysis methods

Interview data were analysed by the doctoral fellow using the six-stage inductive RTA (Braun and Clarke, 2019; Braun, Clarke and Hayfield, 2019; Braun and Clarke, 2022).

Phase 1: Familiarising yourself with the dataset

Familiarisation began with preparation of the interview transcripts. Audio files were sent by encrypted and secure email to a professional General Data Protection Regulations 2018 compliant and university approved transcription service. The audio data were transcribed following strict or true verbatim, capturing everything the interviewer and participant said. This included filler words such as “um” or “ah”; sounds such as sighs or throat clearing; incomplete sentences; pauses and annotation of tone/texture of voice or reactions such as laughter or crying. The doctoral fellow checked the transcription against the audio data for accuracy, making corrections for errors, where possible adding words that the transcriber had documented as incomprehensible and anonymising for participant names, names of friends or relatives, names of members of healthcare staff, names of hospitals and geographic locations. The transcription and checking process was considered as the start of the analytical process (Braun and Clarke, 2013) as the doctoral fellow became familiar with the data by listening and relistening to the audio and checking the transcript several times. After each interview, the doctoral fellow wrote up field notes with reflections on how the interview went and notes of thoughts and feelings and any interesting features of the interview.

Phase 2: Coding

Interview transcripts were imported into NVivo 12 Pro. NVivo software was used to organise and store the data and collate coded text for analysis. Participants were allocated a unique identification number which indicated which NHS site they were recruited from and in which order. For example, the fifth participant from the fourth recruitment site was allocated a research ID of 4-05. For the purpose of reporting the findings, including verbatim quotations, pseudonyms were assigned to each interviewee and interview numbers in chronological order. For each transcript, the doctoral fellow inductively generated codes (or units of meaning) and allocated sections of transcript text to each code, using NVivo

software, that is, there was no pre-formulated codebook used in this process. Some codes (referred to as nodes in NVivo) were allocated as 'parent' codes and subgroups within the parent nodes were formed, that is child codes or nodes, so that in effect some codes became grouped under heading codes. As more transcripts were analysed, some codes generated from previous transcripts were able to be re-used and some new codes were generated. As coding progressed some codes were renamed or subdivided into child codes in an iterative process.

Phase 3: Generating initial themes

The transcript from one interview was reviewed by two academic supervisors with thematic analysis expertise and discussed with the doctoral fellow. Focus of the discussion was on what was interesting about the interviews, consideration of possible underlying or latent meanings and reflection on the complex and traumatic nature of their experience. This assisted the doctoral fellow in considering the transitions from coding to themes. For the purpose of writing and submitting abstracts for conferences, the doctoral fellow conducted preliminary analysis after the first 19 interviews (see Abstract 3, Appendix 33). The doctoral fellow examined the codes they had generated at this point and searched for patterns of meaning across the data. Codes that shared a core concept or type of experience were identified and clustered together. These were named as candidate or initial themes. Care was taken to avoid defining themes by subject or topic, particularly in relation to the questions asked, but instead to look across the data at concepts that would help to answer the research question. This was repeated after 31 interviews had been completed, to be able to write and submit another conference abstract (see Appendix 34).

Phase 4: Developing and reviewing themes

The candidate themes were discussed with the supervisory team. Some candidate themes were revised, amalgamated or split into sub-themes. A thematic map was developed to demonstrate the numerous interrelations between themes and sub-themes.

Phase 5: Refining, defining and naming themes

The themes and sub-themes were named and described in a short synopsis. A revised thematic map was developed. During the writing of the analytic report the themes were discussed again with the PhD supervisory team and further refined and renamed.

Phase 6: Writing up

Using NVivo software, tools such as grouped coded data, 'coding stripes', 'text query function' and cross referencing with field notes were used to find data extracts which best illustrated each theme and sub-theme. Using these data an analytic commentary was developed to form a report relating the thematic analysis to the research question and literature.

4.3.7 Non-substantial amendment

Eligible patients were likely to be in the "extremely vulnerable category" and in self-isolation for 12 weeks or more at the start of the first lockdown in March 2020 due to lowered immune system from cancer treatments. It was not certain at the time of submission of a non-substantial amendment in May 2020 when travel and face-to-face interviews would be able to resume, or what additional risks this may pose to those in the extremely vulnerable category. Due to uncertainties from the impact of COVID-19 restrictions on recruitment, the time frame for interview was extended to six months post brachytherapy for group one and up to 18 months for group two. Therefore, a non-substantial amendment, submitted through IRAS (see Appendix 14) requested the option for remote interviews, and extend the time frame for recruitment and overall duration of the study. A list of revised documents submitted to IRAS is shown in Table 18.

The amendment was allocated by IRAS to 'Category A'. This meant that all four NHS recruitment sites were notified of the amendment and had to approve the changes before the study could continue. This took a further three months to process the approvals in the NHS sites. In addition, each site had to extend the duration and reissue the 'Letter-of Access'. The study was re-opened in all four recruitment sites in August 2020 after a four month pause.

Table 18 Revised documents submitted to IRAS (study two)

Research protocol v1.1
Risk assessment (UWE) update
Research data management plan (UWE) update

4.3.8 Carrying out remote interviews

Potential participants were given the choice of video (using Skype for Business or Microsoft Teams) or telephone interview. The selected videoconferencing platforms were supported by the University. The video/audio recording function was not used as it would have prevented maintenance of participant anonymity during the transfer of files for transcription. Therefore, the voice recorder was used to record the telephone and videoconferencing interviews and the files sent to transcription services were anonymised audio files.

For remote interviews, the participants were asked to be in a quiet and private room where they would not be interrupted.

Consent forms were signed by the participant and returned before remote interviews and signed by the doctoral fellow prior to commencement of the interview, when consent was confirmed. The consent forms were subsequently posted to the NHS recruitment site for their records.

Following the switch to remote interviews additional safety checks were included at the start of the interview. The doctoral fellow confirmed the participant's location and whether there were others present, in case of an emergency such as the participant becoming unwell. This information was destroyed immediately after the interview.

4.3.9 Feeding back findings to participants

A newsletter summary of the study results was developed and distributed to participants (see Appendix 15). This included numbers of interviews completed; median age of participants; median duration of interviews; overarching and sub-themes; and the impact of

COVID-19 on the interview type (face-to-face, telephone or video-conference). Participants were thanked for taking part and informed of plans for the next phase of the research.

4.3.10 Practice interview

A patient on clinical follow-up after brachytherapy at the doctoral fellow's workplace was approached by her clinical oncologist to consider being interviewed as a practice interview for this study. She was selected as an appropriate interviewee by the clinical oncologist as she seemed to have coped well with brachytherapy, did not appear to have distress or trauma associated with brachytherapy at follow-up appointments, had recently MR imaging showing no residual disease and lived close to the hospital so there would be little inconvenience for her to travel for an interview. The interview was observed by a PhD supervisor with experience of carrying out qualitative interviews. With consent from the interviewee, the interview was recorded on a digital voice recorder, with the understanding that the doctoral fellow and supervisor could review the recording, make notes to assist feedback and then delete the recording. The interview duration was 32 minutes and followed the interview schedule (Appendix 6). After the interview the PhD supervisor shared observations, comments and feedback with the doctoral fellow. This included observing points in the interview where there were missed opportunities for follow-on questions, to probe further to try and understand the experience being described or encourage the interviewee to examine or reflect more. Overall, the interview schedule worked well as a structure for the interview, but opportunities to encourage reflection to capture richness and depth in the responses could have been enhanced. The interviewee was invited to give verbal feedback directly following the interview. She reported that she had felt comfortable with the questions and interview style but had been surprised at the emotions generated by reflecting on her experiences in the context of her cancer treatment and close relationships.

4.4 Results

Thirty-five interviews were conducted with 20 participants in group one and 15 in group two. The first six interviews (four cohort one and two cohort two) were face-to-face and took place in a variety of settings including hospital clinic or research rooms, the home of a patient's relative and a hired room in a community centre. After a four month pause due to COVID-19, the study restarted with remote interviews. Twenty-nine further interviews were

carried out with seven by telephone and 22 via a videoconferencing platform (16 cohort one and 13 cohort two). Telephone interviews were undertaken due to lack of availability or confidence in using a computer, tablet or smartphone, not wanting to download an App that they had not used before or just preferring the telephone. If participants were unsure about their ability to use the available videoconferencing platform (Microsoft Teams or Skype for Business), they were offered a practice meeting. Those that chose a videoconferencing interview were sent an invitation and online link via email.

By April 2020, six participants had been recruited from site one, nine from site two and 10 from both sites three and four. Two recruitment sites were unable to identify any further eligible patients for group two, who had not previously been approached or interviewed in group one. The doctoral fellow and PhD supervisory team agreed that sufficient data had been collected to meet the 'information power' assessment criteria for group one and two, therefore recruitment ended at this point.

Recruitment to the study began slowly after delays in approvals at two of the four sites, due to low staffing levels in research management teams. The doctoral fellow was unable to ascertain how many potential participants had been approached and given the study information at each recruitment site. One recruitment site numbered the study packs so the doctoral fellow could see from the returned reply slips that at least 33 packs had been given out with 10 participants recruited. Two of the recruitment sites were smaller centres with low numbers of patients with LACC receiving brachytherapy, typically 10-15 per year.

The age of the participants ranged from 28 to 87 years with a median of 65 years. Interview duration ranged from 22 to 78 minutes with a median of 42 minutes. Each participant was allocated a unique study number, relating to recruitment site and interview number in chronological order. A pseudonym was allocated to each participant (see Table 19).

Table 19 Recruitment and participant demographic data (study two)

Interview number	Study ID	Group	Duration (minutes)	Interview format	Pseudonym	Age
1	2-01	1	41	Face-to-face	Diane	72
2	2-02	2	37	Face-to-face	Laura	31
3	3-01	1	78	Face-to-face	Amy	37
4	3-02	2	37	Face-to-face	Anita	66
5	2-03	1	36	Face-to-face	Caroline	66
6	1-01	1	65	Face-to-face	Dawn	61
7	4-01	2	36	Telephone	Gina	77
8	2-04	1	34	Videoconference	Nicola	69
9	1-02	1	38	Videoconference	Rebecca	47
10	2-05	2	37	Videoconference	Anna	37
11	1-03	2	45	Videoconference	Ruth	69
12	4-02	2	53	Videoconference	Hazel	43
13	1-04	1	38	Telephone	Dorothy	66
14	2-06	1	64	Videoconference	Charlotte	51
15	1-05	1	52	Videoconference	Rita	70
16	1-06	1	22	Videoconference	Elsie	72
17	3-03	1	56	Videoconference	Annie	41
18	4-03	1	31	Videoconference	Bethany	56
19	3-04	2	58	Videoconference	Vicky	28
20	3-05	2	38	Videoconference	Monica	87
21	3-06	2	48	Videoconference	Eleanor	85
22	3-07	1	67	Telephone	Marion	77
23	4-04	2	58	Videoconference	Claire	65
24	3-08	2	60	Videoconference	Rosie	32
25	2-07	1	41	Videoconference	Joanna	77
26	2-08	2	45	Videoconference	Theresa	75
27	2-09	2	42	Telephone	Linda	46
28	4-05	2	39	Videoconference	Maureen	76
29	4-06	1	39	Videoconference	Molly	30
30	3-09	1	51	Telephone	Bridget	57
31	4-07	1	47	Videoconference	Juliet	59
32	4-08	1	43	Videoconference	Lucy	42
33	4-09	2	34	Videoconference	Justine	58
34	3-10	1	49	Videoconference	Lilian	75
35	4-10	1	41	Telephone	Karen	68

4.4.1 Reflexive thematic analysis

An analytic report has been developed to illustrate the analysis process, including the understanding and interpretation of interview data. This is presented in order of themes and sub-themes with data extracts to illustrate and provide evidence for the analytic claims.

Across the dataset, women's reports included difficult and traumatic experiences of brachytherapy with periods of severe pain and poor nursing care on the wards. However, some women described more positive experiences, reporting what had gone well. A thematic map was developed by the doctoral fellow (version 1 Figure 19) with five overarching themes and subordinate or sub-themes. This was subsequently amended following discussion with the supervisory team to reduce to three overarching themes (version 2 Figure 20). Discussions with the supervisory team during the analytic report writing led to a further refinement and renaming of the themes (final version Figure 21). Development of themes was a difficult and problematic process for the inexperienced doctoral fellow. It was a struggle to find central organising concepts and to avoid the pitfall of collecting data into themes by subject, known as 'bucket themes' (Braun and Clarke, 2006). The PhD supervisors, with more experience of qualitative research and RTA, encouraged the doctoral fellow to use themes to portray the impact of the brachytherapy experience on participants rather than simply grouping experiences as themes. The final overarching themes are distinct and discrete, as well as mutually influential and interlinking as they represent the complexities of the physical, emotional and psychological experiences that participants described.

Some participants in group one (soon after brachytherapy) had poor recall of their brachytherapy whilst some in group two recalled very clear memories of the experience. When analysing across the dataset it was found that themes developed from group one and two data were indistinguishable and therefore they have been integrated and reported as a whole.

To assist the reader and minimise inclusion of words that do not add to the point being made, the quotations taken from the interview transcripts have been annotated with "…" for a short pause or "….." for a gap where sections of words have been removed.

Figure 19 Thematic map- version 1

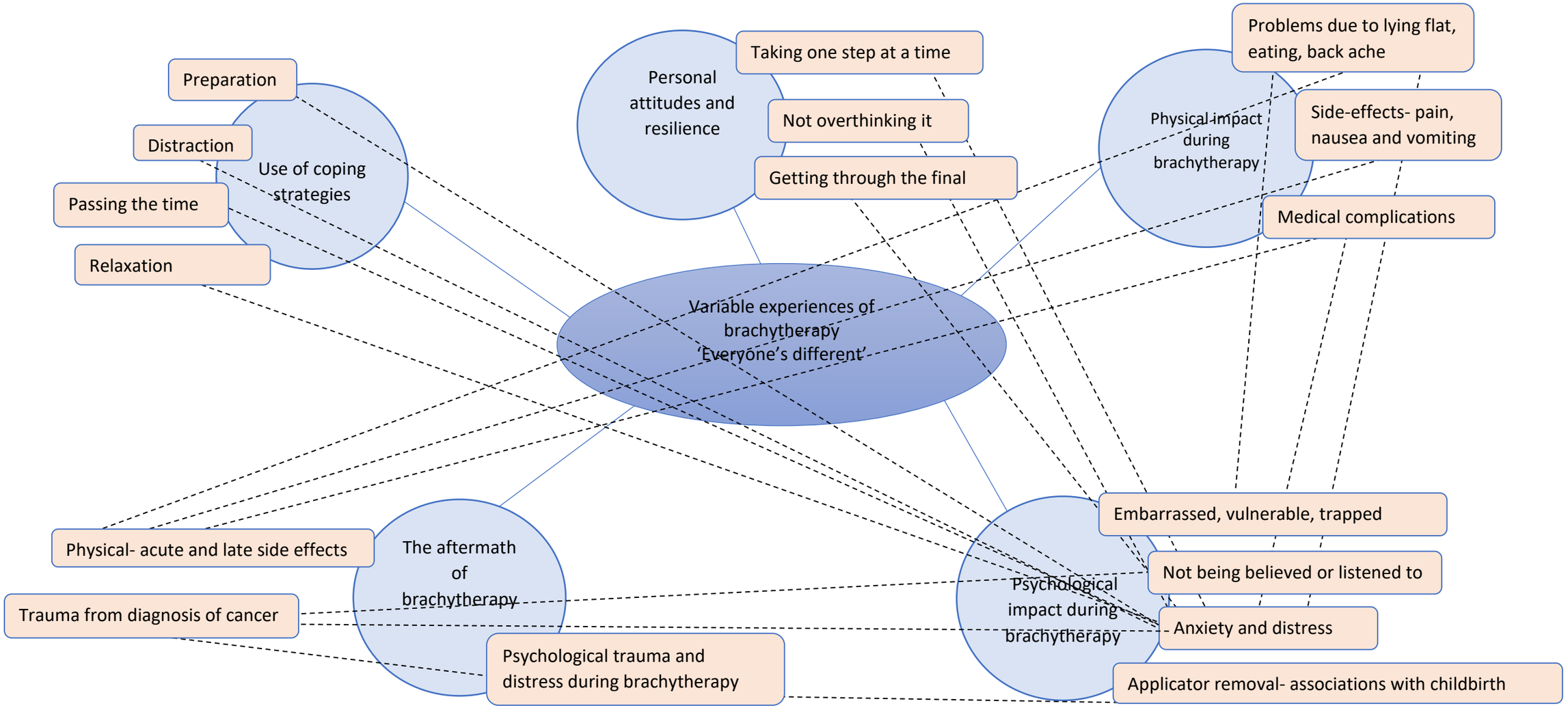


Figure 20 Thematic map- version 2

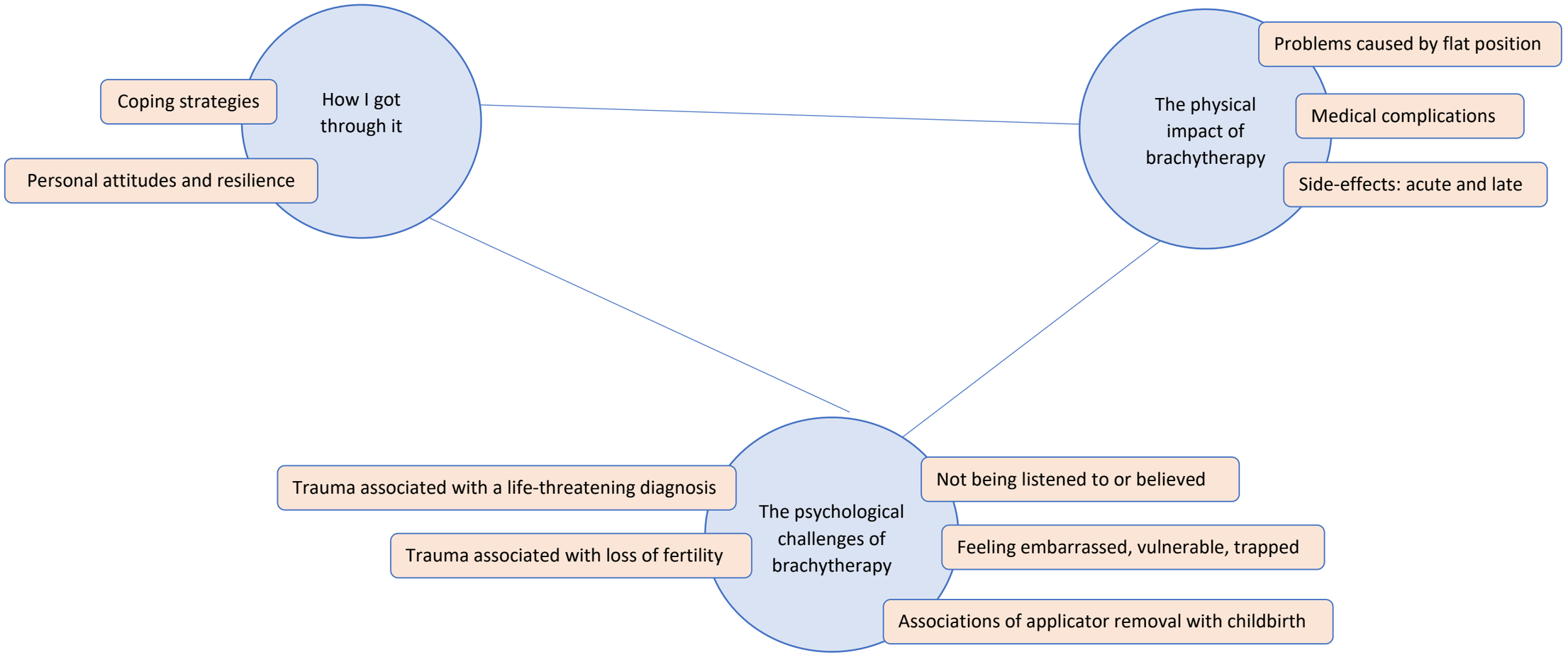
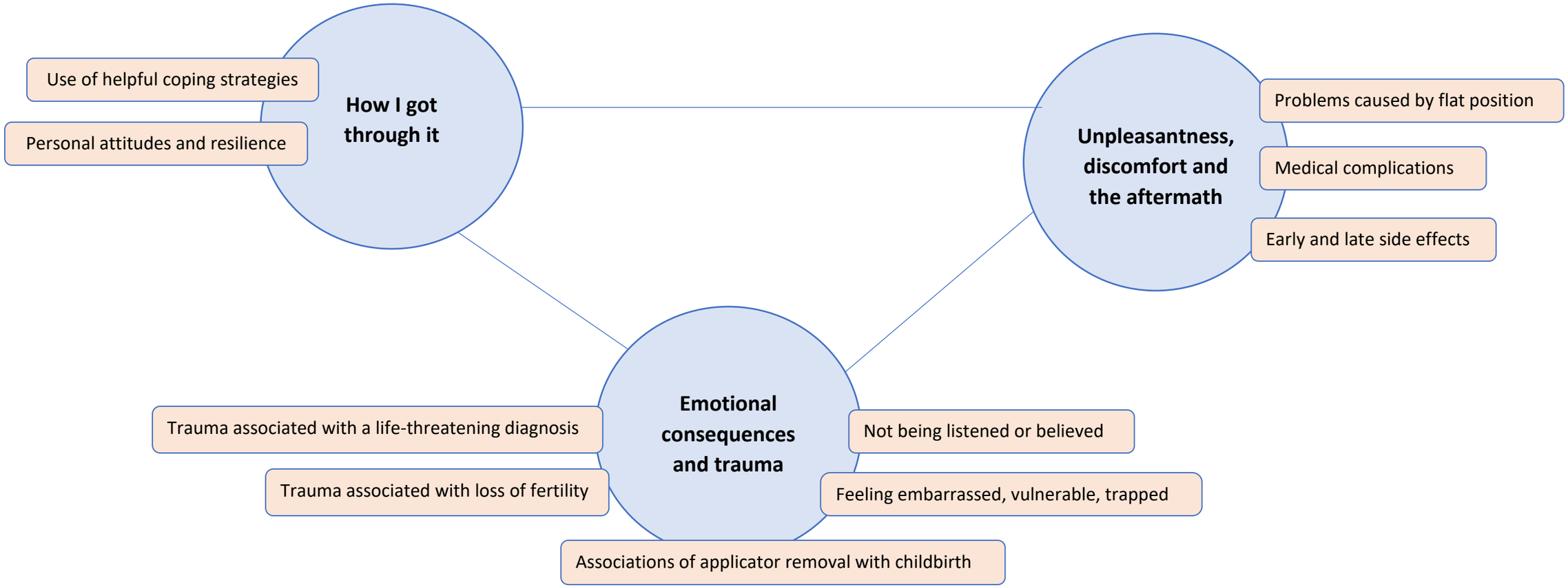


Figure 21 Thematic map- final version



4.4.2 Analytic commentary

Theme 1: How I got through it

Many participants described the fears and worries that they had before brachytherapy and reflected on the ways that they managed to get through the treatment. To distinguish between coping methods that women used to help them get through brachytherapy and the participants' views on their helpful pre-existing inner strengths, two subthemes were developed:

A) **Helpful coping strategies**
B) **Personal attitudes and resilience**

Subtheme A: Helpful coping strategies

Aids for passing time or distraction

Due to the requirement to lie flat for long periods of time, many women had been advised and encouraged to bring items into hospital to help pass the time and help to distract them on the ward or recovery room, such as reading material, audio books or music playing devices and headphones. Without distraction there may have been a greater likelihood of women becoming bored or frustrated with the length of time lying flat, waiting many hours for treatment. The procedure might also have been less tolerable with nothing to distract them from the physical discomfort of the applicators. Some women said they had not been given advice on what to take into hospital and some forgot or decided not to take any items. Some of the suggested items were reported to be difficult to use while lying in a totally flat position, however others found them quite useful. Laura said she was in too much pain during her first brachytherapy procedure to be able to use any distractions, but on her second admission she was more prepared. Many participants made suggestions about what items future patients should be advised to distract or occupy them during brachytherapy procedures.

"I think just being prepared and taking stuff, cos the second time I had my book, I had music and time went a little bit quicker." [Laura, interview 2]

Amy found that using large headphones served a dual purpose, being able to listen to music and to block out what was going on around her on the ward, especially when she was

finding it annoying (lots of visitors to other patients) or upsetting (seeing very sick patients on the ward). Anita found that listening and reading was helpful, even when she was in pain and unable to get to sleep.

Nicola had taken in an iPad but had not been able to find out how to get internet access. She reported that she was bored, but also sleepy for a lot of the time and unable to read her books. Hazel said that she had worked out how to use the hospital Wi-Fi when she was coming for daily radiotherapy, so she was already prepared when she came in for brachytherapy. She recalled making sure that her phone was fully charged each time she went in for her brachytherapy so that she could listen to music. She said it was important for her to be able to use her phone to help pass the time. Vicky reported that music and reading helped her to relax and pass the time.

"I used to put my headphones on with the music and read at the same time. So, you know while I relaxed with the other [music], then if I didn't [read] I just tried to relax and tried to rest as much as I could. I thought the quicker I rest, the quicker I can go home." [Vicky, interview 19]

Some participants thought that an iPad was too heavy to hold for a long time while lying flat and preferred to use their phone instead. One participant suggested that hospitals could provide an angled tray for devices so that you did not need to hold them while lying flat. Another participant had a tablet with headphones and her own stand but found that she did not have sufficient concentration to watch anything. Another participant reported that using a Kindle was useful and quite manageable as it was lightweight, and some said that iPads and phones were invaluable to help pass the time. Joanna had been advised to bring in books but said that she was unable to read anything because of poor concentration and her flat position. Gina also found the lying flat position too difficult to use the tools she had brought in with her to help pass the time. Lucy was having short duration (day case) brachytherapy and managed to read a book in the recovery room when she was propped up a little.

"They did lift me up slightly, ever so slightly because I couldn't sit fully up…I just had it [the book] sort of up in the air so I could read it, or to one side, but it was fine, it passed the time, and it didn't feel like three and a half hours." [Lucy interview 32]

Some women were in a single room without a television and others were close to a television but not in a position to see the screen. Some did not have access to the television as the hospital device needed a bank card payment. One participant was annoyed that no-one had helped her to access the bedside television and was unable to make the payment while lying flat in bed with applicators in place. Another participant could not watch the television as she was feeling nauseous and watching the screen made her feel worse. Another participant in a single room found it comforting to have the television on throughout the night as this was something that she was used to doing at home as it helped her to relax.

People watching

Some participants found that 'people watching' or 'watching the world go by' helped them pass the time and was a useful distraction when they were unable to concentrate on reading or listening to music.

"They put me in a side room off of the main ward so I was pretty much opposite the desk where the girls were, so being the nosey person I am I was more interested in watching what was going on." [Caroline, interview 5]

"As I say, your concentration is rubbish, you are drifting in and out of consciousness quite a lot of the time…so just having a little buzz of conversation going on that you can dip in and out of…" [Linda, interview 27]

Joanna found the combination of drugs (opiates) and being in a strange environment with lots of other patients fired her imagination and she began to make up stories in her head about the patients around her. She described the ward experience as intriguing and not at all boring and found herself ***"slipping into parallel universes" [Joanna, interview 25].***

Talking to other patients

Many participants found that being able to talk to other patients helped to pass the time and was sometimes a supportive exchange when they were also going through brachytherapy. Some participants were on the ward with women they had already met during radiotherapy or chemotherapy and they found that helpful and supportive. Lilian who had two admissions for inpatient brachytherapy said:

"The lady next door was having the same treatment, we got to know each other…..so we were chatting and, so that was nice, you know, that we could share what was going on…because I'd already been through it, so um, she didn't know what to expect…" [Lilian, interview 34].

Withdrawing or disengaging

Not all participants wanted a connection or closeness with others, some preferred to withdraw or disengage as their way of coping.

"I didn't want to talk to anybody. I wasn't being rude, I just didn't want to engage in conversation. I just didn't want to see the lounge, I hate cannulas, I don't like injections, I just didn't want to know… I didn't want to be there, how ridiculous, it's like going to school, you have to go, you have to go to work." [Juliet, interview 31]

"It just seemed like an awful long time…I remember trying not to watch the clock…the main thing I remember is just trying to shut my eyes and shut everything out and try and think about somewhere else I'd like to be, you know." [Theresa, interview 26]

Thoughts, reflections and making plans

Some participants described the passing of time being helped by going into their own thoughts or making plans.

"I felt like I was lying there, you know, just reflecting on, really, what I'd been through really, and what I was still going through. And just thinking about my little girl really, more than anything." [Anna, interview 10]

"So I did spend quite a lot of time thinking, right, what do I want to make sure for Christmas we have, so having something that was enough in advance that I could think…so I sort of listened to music and think about what shall I buy for Christmas presents or like what should we have, that's slightly different this year, or that kind of thing did help quite a bit." [Amy, interview 3]

Time seeming to pass quickly due to sleepiness or grogginess

Being sleepy and groggy helped many participants as the time seemed to pass more quickly, although some said that their sense of time was altered.

"Yeah, groggy with painkillers…..quite often I did fall asleep…..cos at night-time, you're lying on your back, you can't get comfy, and with being awake at night-time and sleeping in the day-time and, it's the whole routine kind of changed completely…it just kind of all blended into itself." [Anna, interview 10]

Theresa talked about time becoming blurred while she was lying flat for so long, unable to move.

"…day and night morphed into one". [***Theresa, interview 26]***

Relaxation techniques, prayer and complementary therapies

Some participants used relaxation such as breathing, mindfulness, visualisation and yoga. Maureen had practiced yoga in the past and found yoga breathing exercises could help her in times of anxiety and stress. She reported finding this useful while having a spinal anaesthetic procedure for brachytherapy.

"Yes, but the breathing is so important, well I still do it now, you know, if you feel a bit anxious about anything and I'm doing it for, you know, I do sleep well, but occasionally I can't get to sleep and I still do breathing exercises. Yeah, that might just be a mental thing isn't it, I'll do my breathing exercises, and I'll be okay, if you just have to have something don't you? Something you can go to when things aren't the way you want them to be." [Maureen, interview 28]

Laura was distressed and traumatised at her first applicator removal and sought support from a counsellor before going in for her second inpatient brachytherapy procedure. At her second applicator removal she said she knew more about what to expect and was able to use breathing techniques to help her get through it.

Claire said that she had used prayer to take her mind elsewhere when she was lying flat for radiotherapy and brachytherapy.

"I prayed a lot (chuckling). Yeah, yeah, I mean not so much with, but certainly on the flat bed, we'd start with the Lord's prayer and move on… and err it's a fairly recent thing actually, but it's helped a lot, and it helped a lot for me to know that people were praying for me as well…I did yeah, because you're on your own, it's the only thing that comes with you if you like… and I must say it was, it was helpful. So, it's a bit like a mantra of some sort." [Claire, interview 23]

Theresa tried to avoid watching the clock and sometimes used visualisation to take her mind elsewhere, such as the seaside.

"…a lovely beach, the waves flapping in, (chuckling)." [Theresa, interview 26]

Some participants from one NHS site reported that they were offered complementary therapies while on the ward during their admission for brachytherapy. They reported experiences of foot massage, reiki and reflexology. They were very positive about their experiences with complementary therapies, reporting that it was relaxing and comforting. Some had complementary therapy sessions at each admission for brachytherapy. Others only received the therapy once and would have preferred to have more sessions, but therapists were not available. Some were not sure exactly when they had the therapy, whether it was with applicators in or after applicator removal. Participants from the other three NHS sites did not report any experience or offers of complementary therapies, and one participant had been told they could not have any therapies due to the need to lie flat and still.

Finding humour

Some women were able to have a joke and a laugh with staff which helped them to keep positive as well as being a way of coping with embarrassing situations, such as bodily functions.

"Yeah, and so I had a laugh, any time the nurses came in or whatever, I would have a laugh with them, so that was fine, you weren't isolated, there was somebody coming in every hour you saw somebody." [Bridget, interview 30]

Supportive staff

Many participants talked about the great care and support from specific hospital staff during their brachytherapy. There were many examples of praise, gratitude and appreciation for theatre staff, brachytherapy treatment staff (radiographers), ward nurses, porters and cleaners and some participants singled out their clinical oncologist for special recognition. For example, Maureen said that her oncologist was ***"absolutely amazing"*** and ***"exceptional"***. Many participants talked about the kindness, and caring attitudes of the staff and that they did their best to make them as comfortable as they could, in the circumstances. Karen found that a member of staff chatting to her throughout the insertion procedure in theatre took her mind off what was being done.

"…the anaesthetist sat with me, and she kept me mind off everything, she sat and chatted to me, the whole time." [Karen, interview 35]

Theresa had one admission for all four of her brachytherapy treatments. She found the radiographers in the brachytherapy treatment unit really cheerful and said that she almost looked forward to being taken down to the treatment unit each time. Some participants appreciated the continuity of care, for example, seeing the same staff during brachytherapy as during EBRT, building up a rapport with them and the importance of being remembered by them.

Subtheme B: Personal attitudes and resilience

Although brachytherapy was reported to be a daunting prospect, some talked about how they set their mind to get through it. They knew that the brachytherapy was an important

part of their treatment for a life-threatening condition. Some women talked about their personal attitude which helped them to cope with the procedure and others explored what attitudes they believed would help other women.

The fight for life

The importance of fighting for survival was mentioned by some participants. Some said that this gave them the sheer determination and perseverance to push on through to the end of the treatment. Anita said she was going through a process, the treatment process, and her rationalisation of the necessity of the process helped to convince her to go back for the second brachytherapy admission, even after an initial difficult and painful experience.

"It was very, very hard for me going back that second time. All the way on the train going to [name of Radiotherapy department], I was thinking, "Why are you doing this? Why are you doing this?" I'm doing it because I'm in a process, I want to get better…I'm not ready to die yet." [Anita, interview 4]

Anna described her frame of mind before her brachytherapy began and her understanding of how she got through it.

"And I just think you've kind of got to go with what you're told by the specialist…and kind of belief in yourself that you can, if you can get through this, you can get through anything." [Anna, interview 10]

Ruth rationalised the need to complete treatment by reminding herself that each brachytherapy only lasted two days, a relatively small amount of time for the potential benefit of surviving cancer.

"But, um, yeah, I think that was the only thing is that I felt that oh, I could've done something but in…at the end of the day it's just…it's just, you know, 48 hours…and I got through it…twice [laughs]." [Ruth, interview 11]

Bethany described her need to ***"set her mind to it"*** even though she was very scared of an internal treatment, having always refused cervical smears.

"…just the thought of having some things inserted up you, you know, just all that, and the impersonal thing about it all just, just the thought of somebody being up, up your vagina with things and instruments…and just, you know, the whole internal scenario because that's why I'm in this position 'cause I haven't had any smear tests 'cause I was scared…I was petrified. I mean I've had no children. Doctors, dentists, hospitals, anything, I'm absolutely, I'm a big baby…as the time got nearer, the night before they did give me some diazepam to, you know, so I could sleep because it were just, and I [sighs] my partner drove me to the hospital and walking from the car into the hospital I don't know how I made it, my legs were just absolute jelly and you know, he can't come with you, you're just on your own and I just had to, I just knew if I want to live I've got to do it…so I just did it. Well, I had to do it, every stage I've had to go through I have to do it to live, so if I want to live I've got to do it and that's how I put my, put it in my mind." [Bethany, interview 18]

Charlotte described her arrival at hospital for the first of her two brachytherapy admissions and her resolve to get through it. Visitors were not allowed into the hospital due to COVID-19 restrictions.

"So, um went back out to the car, saw my husband, said "Goodbye", but I was just, I just felt this determination take over. And I felt, right this is it, I can do this." [Charlotte, interview 14]

The final hurdle

As brachytherapy is usually the last part of many months of intensive cancer treatment, many participants talked about just needing to get to the end of the treatment. They talked about the desire to complete the course, to get over the final hurdle or reach the finish line.

"But, to be honest, by that stage, I just, the only thing in me head was, just get it over and done with…just get to the end of it all…cos I'd not been well with the radiotherapy and chemo, so I just felt, I'll do anything, just to get to the end of it all." [Karen, interview 35]

Dorothy kept her focus on the end goal during applicator removal for the second and last time.

"Well I think you've just gotta realise that it's you know, it's gonna be over soon and you've just gotta listen to what you're being told and just you know, just concentrate I suppose in the moment and, and hope…and just knowing then the second time that was, it was all finished then, the brachytherapy was finished". [Dorothy, interview 13]

One day or one step at a time

Molly reflected on experiencing anxieties about loss of fertility before the treatment started and after it finished, but during the course of treatment she put this to one side.

"I think when I was having the treatment it was just a case of getting through each day." [Molly, interview 29]

Breaking down the procedure and taking it 'one step at a time' was a strategy used by some women.

"I think that I had in that week prior to Brachy, like a couple of moments where I was quite, extremely tired, like I hit a little bit of a wall…and I was just kind of like "one step in front of the other, just get through it"." [Amy, interview 3]

Life experiences leading to resilience

Some women described health beliefs or past experiences which had empowered them with skills and tools to complete brachytherapy. Lilian put her resilience down to her previous difficult life experiences, giving her the inner strength to cope with a second cancer diagnosis and treatment.

"I'm seventy-five now, my life has never been easy, um, I've grew up, I mean my mother had eight children, um, I lost my dad when he was thirty…I had to look after all the children, I, I lost my husband, you know, I mean, life has just been one thing after the other, I lost my daughter. Life throws everything at you, and you have to be resilient, otherwise, you'll go under...I've had cancer before, so, I got through that, so I think about being positive, but I've got it now, I'll get through it again, you know what I mean?" [Lilian, interview 34].

Resignation or acceptance of the procedure

Many women described an acceptance of brachytherapy as a belief that there was nothing they could have done to change or improve their experience.

"Well, it was just a procedure I had to go through, and there was no point feeling about it. Because I had cancer, I'd been told that I was going to have this procedure, and I was told they believed this procedure was going to cure me…So it was just something you have to go through… So I was in a process. I mean, everybody knows that cancer treatment is not nice…You don't go into cancer treatment to have a ball, you go into cancer treatment to cure yourself. And it worked." [Anita, interview 4]

Resignation or acceptance was sometimes described in terms of 'handing yourself over' to the health professionals and having a belief or confidence in them.

"everyone deals with it in a different way. And I just think you've kind of got to go with what you're told by the specialist…" [Anna, interview 10]

Theme 2: Unpleasantness, discomfort and the aftermath

Many participants described their experiences of brachytherapy in terms of the difficulties that they had endured during and afterwards. Some of the unpleasantness or discomfort arose from the insertion of applicators during a theatre procedure with different types of anaesthesia, the length of time that the applicators were in place and having to lie flat for a long time, removal of applicators at the end of the procedure and the multitude of medications required to try and combat the side effects of the procedure, chemotherapy and radiotherapy. Some described how badly they were affected after brachytherapy was completed and how long and difficult their recovery was. These experiences have been included in the analytic commentary to demonstrate the severity and duration of the physical impact of brachytherapy, in combination with EBRT and chemotherapy, and reflects the desire of participants to share this aspect of their experiences at interview.

Three subthemes were developed to demonstrate the breadth and variety of the participants reports of the unpleasant physical aspects of brachytherapy:

A) **Problems caused by flat position**
B) **Medical complications**
C) **Early and late side effects**

Subtheme A: Problems caused by flat position

For day case brachytherapy most women lay flat for four to five hours with applicators in place and this procedure was repeated three or four times over a two to three week period. For inpatient brachytherapy, they lay flat for just over 24 hours if two treatments were delivered or up to 52 hours if four treatments were delivered. For the purpose of reporting results in this thesis the procedures are categorised as short, medium or long duration brachytherapy. Physical problems reported due to lying flat included build-up of abdominal gas, backache and difficulty with eating and drinking. Overall, the impact of lying flat for long periods of time was generally more pronounced and negative in the reports from participants who had medium and long duration compared with short duration brachytherapy.

Build-up of gas

Some participants talked about the embarrassment of passing wind, particularly when in a general ward. Trapped wind could also cause severe pain and loss of appetite or nausea. Dawn had two admissions for medium duration brachytherapy and explained what the gas build-up felt like.

"The mattress I have to say, I know they kept saying it was a special mattress and it was the best mattress for that thing, it was the most uncomfortable mattress I'd ever laid on.....the ridges in the mattress were actually underneath my shoulder blades and so…the wind was actually in my back, so I got the wind in my back and then these ridges were like really digging in to my shoulder blades…It was, very painful, very painful." [Dawn, interview 6]

Although the ward staff tried to alleviate the wind and the discomfort with medication, nothing seemed to help.

"I actually couldn't eat anything all day on Wednesday…'cause the, the wind, it, it was really uncomfortable. That actually stands out more in my mind, being uncomfortable with the wind and not being able to eat because of the wind, and trying to take the tablets, because you're laid down." [Dawn, interview 6]

One woman explained that she was careful with her food choices to avoid bowel and gas problems. For short duration brachytherapy some found that an enema before each procedure helped to prevent faecal accidents and bowel gas.

Backache

Backache was a common experience for individuals when they were lying flat with applicators in place. Some reported that opiates, such as morphine, helped. Some thought that the only thing that would have helped would be to stretch or change position, which they said was not allowed or may have risked moving the applicators and giving incorrect treatment. Some had anticipated difficulties which created anxiety, especially if they had pre-existing back problems. Diane [interview 1] anticipated that the long duration brachytherapy would be problematic for her back but gained some relief from morphine. Amy had backache with her first medium duration brachytherapy, but due to developing a pulmonary embolism she was propped up by an angled wedge under her back for the second procedure.

"So the first one, I had pelvis and my back hurt from the lying flat. But with the wedge in [second admission for brachytherapy], I didn't have pelvis pain or…um backache at all." [Amy, interview 3]

For medium duration brachytherapy Vicky found the long duration lying flat was difficult to tolerate and more uncomfortable than the applicators inside her.

"The pain was worse, towards like the end of the time you were laying down, the pain I was getting was the back. Where I'd been laid down for so long and they were good, they did try and like move me around a little bit, put pillows under me each side and stuff. It was, that was the worst, like I couldn't wait to get up yeah. Because the backache, but um, yeah, the applicators, yeah to me, that didn't really bother me." [Vicky, interview 19]

Bridget had medium duration brachytherapy and complained of back pain which medication from the PCA pump did not relieve. She did not want to inconvenience the nurses by asking for additional pain relief.

"…the first night, into the second day my back started to kick up badly and I never have problems with my back, but it was the pain was really bad in my back…and the morphine didn't do anything for it, it really didn't…it's very difficult with your back, if you have pain in your back, honestly, I don't know anything that really kills the pain, you know…I dunno whether it was because I was in the one position for so long that my back, started to act up." [Bridget, interview 30]

Bed transfers

After applicator insertion in the operating theatre and a short period of time in recovery, patients were taken for imaging for treatment planning purposes. Some women had CT and MR imaging and typically the CT would be repeated before each subsequent dose delivery to check that applicators had not moved and to allow for recalculation of doses to organs at risk. Many women described the experience of being wheeled around the hospital, flat on their backs and being transferred numerous times from bed to trolley or CT/MR imaging couch as problematic. Amy found the transfers for CT and MR imaging quite difficult due to not being in control and worrying that she might fall or the applicators might move out of position.

"…one of the things that I would say I found quite difficult was the complete lack of control in terms of when they were doing the rolls and the slides on and off the MRI and CT and stuff, um I wouldn't say that I'm a control freak, but feeling so out of control in that particular scenario is quite…Um it was more that I was really, really concerned that I might move and move the applicators which…They, everybody kept on saying to me "You won't, you'll be fine, like it's fine, don't worry about it", um, but also because obviously like the beds for the MRI and the CT are quite narrow. And I know that I'm quite wide (chuckling), I was like, really worried I was gonna…yeah, was I gonna fall off it…..Yeah, was kind of like, actually for both sets of the brachy, that was kind of one of the main things." [Amy, interview 3]

Some women experienced pain or discomfort during the transfers.

"Yeah, they slid me, yeah, they slid me across on the board. From my bed I was in on to the CT scanner, I remember that hurting, that it sort of moved it about a bit. Like everything's a stabbing pain..." [Annie, interview 1]

Some women reported an increasing level of pain as the effect of the spinal anaesthetic wore off, which was particularly noticeable during bed transfers.

"Um, yeah, I found, I found that more problematic later on, um as in, each time I was having my treatment, I think in the beginning it, it was okay because where I was still quite numb. Um, but as the treatments went on, it became more and more uncomfortable, each time they had to slide me across." [Rosie, interview 24]

However, some women did not recall any pain during transfers and were quite accepting of this part of the process.

Problems with eating and drinking

Eating, drinking and swallowing tablets when lying flat was a problem reported by many participants. Visitors were often asked to leave the ward during mealtimes to allow patients to get adequate nutrition. However, Laura needed help to eat her food which her parents could have supported if they had been permitted to stay. An elderly, frail patient on the same ward offered to help Laura, but as a young and usually independent woman this seemed all wrong to her, so she declined.

"So my dinner would come, put on my tray, I would be sat there, my parents were told they weren't allowed to come during dinner time, so they didn't even come and feed me, so then they weren't there. And then like it just sit there for forty-five minutes and someone come and clear it, and I'd be like "fucking starving here". [Laura, interview 2]

Laura reported that she had not been given any advice about types of food to choose, what would be manageable when lying flat and suggested that hospital staff should give recommendations to choose solid foods such as finger food, and/or to allow visitors to stay and help at mealtimes. However, for some participants this was not a problem and they

adapted well to the restrictions due to lying flat. Caroline said that she used her 'common sense' and ordered sandwiches as she thought that would be easier to manage. Another participant said that sandwiches were the only food she had for three days whilst lying flat for long duration brachytherapy. Nicola took in some extra supplies of 'emergency food', but then could not reach it and did not like to ask for it. With the hospital food she requested help from the nurses to avoid getting it all over herself.

Rebecca described her difficulty in eating and drinking when lying flat and reported that she vomited when she sat up after applicator removal at both brachytherapy admissions. She thought it was as if the food had not gone down properly or was not digested due to her positioning. Her advice for other women would be to take in supplies of sweets as that helped her when she was not feeling very hungry.

Vicky had a good appetite throughout her admission for brachytherapy and asked her mum to feed her, but really objected to her loss of independence. She talked about how awful it would have been to have to ask a nurse to feed her. The experience had later impacted her work as a carer in a nursing home as she now better understood how it feels to be helpless and has made her feel more compassionate and sympathetic when she feeds people at her workplace. She also mentioned eating a lot of sandwiches over her two admissions for brachytherapy. Marion was frustrated that her food was left out of her reach and out of her sight as she was lying flat and on her own in a side room. However, for her second admission Marion was in a shared ward, and she thought that this led to more attention from the nursing staff. Her food was placed within reach and she was frequently offered cups of tea and coffee, so she felt that she was not forgotten. Theresa complained that her food and drink was always placed out of reach and that ward staff did not seem to notice or care that she did not eat or drink.

"I actually went, the five days I was in there, without food or any drink. The food was brought to me and it went away untouched…nobody noticed..." [Theresa, interview 26]

Overall, Theresa was very critical of the ward nursing care and lack of compassion. She attributed the lack of nutrition during brachytherapy to her need for readmission a couple of days after brachytherapy due to weakness, fatigue and being unable to eat anything.

Some women reported that eating was less of a problem than trying to drink while lying flat. Gina reported that there was a knack to drinking while lying flat, which she learned during her stay on the ward.

"But it, it was the drinking really you know, and I love a cup of tea, but I didn't have one, in case I spilt it over me, so I had a cold drink, but I did get how to hold the carton with me head turned, and the straw. And I did learn to do it that way, so I was fine, yeah…Yeah I got the hang of it yeah." [Gina, interview 7]

Nicola was given a special cup with a lid and straw when one of the radiographers noticed that she was struggling to drink from a normal cup. She said she would advise other women to take in a sports bottle. Anna had to ask the nurses to give her an appropriate cup. Some participants were more positive overall about their eating and drinking and some reported that they were given advice on food choices and help to eat. Charlotte asked the ward staff what to choose from the menu and was offered some advice. She was offered help with cutting up food and suitable beakers and straws for drinking. Molly had short duration brachytherapy three times and did not find eating and drinking too much of a problem.

"Yeah, so they can raise your head slightly, erm, they brought me a drink with a straw in so that I could do that and eating wasn't too bad, they just leave things, sort of close and accessible for you so that you can do that yourself. Erm, but yeah so that wasn't too bad." [Molly, interview 29]

This example was quite typical for those having short duration brachytherapy, lying flat for only four or five hours each time. Overall, most seemed to manage with drinks and a light snack such as tea and toast and then had more to eat once the applicators had been removed and they were allowed to sit up fully.

Subtheme B: Medical complications during and after brachytherapy

For this analytic commentary, a distinction has been made between medical complications (subtheme B) and side effects from radiotherapy, chemotherapy and associated supportive medication (subtheme C). Overall, the severity of medical complications experienced during the brachytherapy procedure were more evident in the reports from participants who had medium and long duration compared with short duration brachytherapy. Development of

emboli, pressure sores, allergic reactions or collapses were only reported by those who had medium or long duration brachytherapy.

Pulmonary emboli/deep vein thromboses

Amy developed multiple pulmonary emboli which was diagnosed when she became short of breath after removal of intracavitary applicators and interstitial needles at her first brachytherapy procedure. She was given reassurance from medical staff and only later became aware of the potential risk to life. For her second brachytherapy the interstitial needles were not used (due to increased risk of bleeding), she was given a continuous intravenous anticoagulant and she had to be propped up at an angle to help her breathing. This was a life-threatening complication which was concerning to Amy when she reflected on the seriousness after the event. She said:

"Um so there was, I think quite a lot of stuff going on, behind the scenes that I wasn't necessarily witness to at that point. They didn't necessarily play it down, like they told me that I'd got the PE and they were like you know, obviously this affects your treatment etcetera, but I don't think I'd realised at that point how bad it was… Like they told me it was, you know, like there's definitely more than one, but it's not too bad, don't panic, um but I think it was quite bad (chuckling). Um so I stayed in hospital between my first set of treatments and my second set of brachy." [Amy interview 3]

Monica developed a deep vein thrombosis at around three or four months after her brachytherapy. Lilian developed severe chest pain at about three or four months after brachytherapy, also about two months after COVID-19 infection. These reports of embolic complications during or after brachytherapy were from patients in one NHS centre, carrying out medium duration brachytherapy.

Pressure sores

Some participants reported skin changes during or after brachytherapy that are likely to have been grade one or two pressure ulcers. Anita had medium duration brachytherapy and described painful and sore areas on her ***"bottom"*** but thought they were a ***"friction blister"*** as she said she was too fat to get pressure sores and they were not over bony areas. Nicola

discovered that she had developed pressure sores when she got home after completing brachytherapy. She had lain flat for long duration brachytherapy, but the nurses had not moved her while the applicators were in place. She remembers lying on a special air mattress throughout her admission.

"Well, I had some bedsores, um, which were a right nuisance, um, and I didn't find lying on my tummy comfortable um. And I didn't find lying on my back, it was very difficult to find anywhere, where the bedsores weren't quite painful, basically." [Nicola, interview 8]

Rita, Anna and Joanna all described the development of pressure sores on sacral/coccyx area after long duration brachytherapy and Rita said the community nurses were visiting and dressing the pressure sores for three weeks after brachytherapy. Marion had a severe skin breakdown over her coccyx which may have been a pressure ulcer and/or a radiation reaction or a combination of both after her second brachytherapy admission. She described severe pain and broken skin and that her neighbour heard her crying out and called an ambulance for her. She was admitted and stayed in hospital for three or four days for administration of antibiotics and analgesia.

"…and it felt quite bobbly, as though it was … I had spots and things, the skin had broken on it…..it was like hot pokers going through the spine, and going on the nerve endings, it was awful." [Marion, interview 22]

Allergic reactions

Some women described experiences of allergic reactions during their brachytherapy. After Vicky's first brachytherapy she tried to stand up after applicator removal and she collapsed. She also experienced severe itching and made her skin bleed by scratching.

"Yeah, I was really like, with the Morphine as well, I was so itchy that I made my skin bleed…So, where I was itching so much, so I had to have like antihistamines and stuff like that, so I think we came to the conclusion that maybe Morphine just does not agree with me…..Yeah the Morphine, that, that scared me a little bit, because like when, when they said "Oh stand up", I said "I can't, I can't stand up", and then I was like "Oh I'm gonna be

sick" and then everything was spinning, and then I don't remember three hours after that, I woke up, so I literally lost three hours of my life." [Vicky, interview 19]

Marion discovered that she had a sensitivity to morphine and was also switched to oxycodone for her second brachytherapy admission.

"***I can't put any of that into any kind of sequence on the Wednesday, because er, I had … I think I had a bit of a drug reaction, er, because I was … I was sick, I was nauseous and then I was sick, and I was incredibly sleepy that … that second day, after my last brachytherapy treatment…..I had to stay another night or two because of that … my reaction to the drug, which I think was a form of morphine…" [Marion, interview 22]***

Anita reported an allergic reaction to the plaster that was put over her spinal/epidural site.

"Well, I can remember…the first time, I was massively uncomfortable because, unbeknownst to everybody, I'd had an allergic reaction to the plaster that had been put on my back to hold the epidural in place. So when the epidural came off, my back was one mass of plasters, of blisters." [Anita, interview 4]

This led to a change in management for her second brachytherapy as no spinal anaesthetic or epidural was possible, so a general anaesthetic was given and interstitial needles were not used.

Other medical complications

A few patients collapsed during or after brachytherapy, with several potential causes. Anna collapsed in the shower while she was trying to get ready for discharge after her first brachytherapy, due to development of neutropaenic sepsis, a known risk when white blood cell counts have been significantly affected by chemotherapy.

"***So they, um, they gave me a shower and I kind of collapsed. I said I didn't feel very well, and I felt really, really hot and dizzy. And I collapsed. And then, the only thing I can remember from that, and will never, ever forget it, is, there was, I was, obviously, I had shower gel on me, I had shampoo in my hair…And the next thing I can remember is six nurses, a towel being wrapped round me, me being put onto a bed with the oxygen mask.***

And then, everything kind of happened; there were doctors in, consultants in. And they found out it was sepsis. Neutropenic sepsis." [Anna, interview 10]

This led to an extra three nights in hospital and significant personal complications with arranging extra childcare and transport home as Anna was a single mum and received brachytherapy in a centre a long way from her home. Theresa was readmitted to hospital a few days after completion of long duration brachytherapy due to severe weakness and fatigue. Elsie developed breathlessness, later found to be due to congestive cardiac failure, and was unable to complete brachytherapy. She received one treatment and then applicators had to be removed so that she could sit up and breathe more easily. She thought the breathlessness was due to inhaling water while trying to drink while lying flat. This was early in the COVID-19 pandemic and Elsie was moved to a COVID ward until heart failure was diagnosed and a second negative COVID-19 test was received. She was upset that her husband had been contacted by hospital staff and told she was on a COVID ward, struggling to breathe and he was warned that she might die.

Subtheme C: Early and late side effects

Many participants reported physical effects during brachytherapy which may have been related to their recent EBRT and/or chemotherapy or due to the anaesthesia and analgesia medication given at brachytherapy. Some participants experienced physical side effects after completion of brachytherapy. These were sometimes acute effects from the radiation, where acute effects are defined as occurring up to three months after any radiotherapy dose (Maduro *et al.*, 2003). Some participants reported late effects from the radiation, where late effects are defined to occur from three months after any type of radiotherapy (Maduro *et al.*, 2003). Overall, severity of some of the side effects experienced during the brachytherapy procedure were more apparent in reports from participants who had medium and long duration compared with short duration brachytherapy. For example, multiple episodes of nausea and vomiting, uncontrolled pain and feelings of lethargy and drowsiness were reported exclusively by those having medium or long duration brachytherapy.

Nausea and vomiting

Nausea and/or vomiting during and soon after brachytherapy was commonly reported, however, the severity or level of distress it caused was variable. Some women described a single episode of nausea or vomiting and some reported multiple or continuous episodes. For some this was particularly frightening as they were lying flat and not allowed to sit up. Others reported vomiting after applicator removal, or on their journey home. Dorothy had a problematic time with nausea and vomiting at brachytherapy, which may have been related to the ongoing side effects from chemotherapy. She had been experiencing intermittent nausea and vomiting for many weeks before brachytherapy. She had tried lots of different antiemetics which sometimes helped but sometimes had no effect. She commented on the difficulty with vomiting while lying flat for brachytherapy and her complete loss of appetite.

"So, I, I mean, I was even being sick, when I was flat on my back on the trolley you know. I did, um, I did have a lot of sickness and it was really, um that was the worst part of it actually, the whole treatment I thought. The sickness and not being able to eat properly you know." [Dorothy, interview 13]

She also spoke of her embarrassment especially when she was not in a single room and was being sick in front of other patients. The nurses drew the curtains around her bed to give her some privacy. Dorothy said that overall, she had ***"great care"*** during her brachytherapy, but was critical of the management of her nausea and vomiting when her medication was being given orally and she was vomiting every five minutes. Anita experienced vomiting during applicator removal at her first brachytherapy procedure and was constantly sick throughout her second brachytherapy procedure. She thought this may have been related to her use of "gas and air" at her first brachytherapy and may have been related to increased opiates at her second brachytherapy as she was unable to have an epidural.

"Well, they tried to give me 'laughing gas' when they were removing the applicators, and I started being sick…..And the second time I was sick constantly. But the really difficult, the really massive change for me would have been to give me a bowl without a rim on it. Because the hospital bowls for vomiting tend to have, they're like upside-down bowler

hats…..Well of course, when you're lying flat on your back and you're trying to vomit over a rim, it's impossible…I mean, that was probably the worst thing…" [Anita, interview 4]

Rosie had experienced significant nausea and vomiting throughout her chemotherapy. She spoke about weighing up whether to press her PCA button to relieve her pain but knew the morphine would increase her nausea. She was unable to watch the TV to pass the time as this made her nausea worse.

"Um, err I struggled with it quite a lot, I was still, I still hadn't really, it had only been a week since I'd had my last chemo, um, I was still kind of having the…the effects from that, um but it was quite bad, so, I, I had a bit of a balancing act, so, I think my pump, it was morphine, um but that was making me feel sick as well. So, I was trying to manage what was worse, the sickness or the pain? So, I didn't, I tried not to use it too much because it just made me feel…really sick, um." [Rosie, interview 24]

Pain

Participants described a range of pain experiences during brachytherapy. This included an overall feeling of pelvic pain where the applicators were in place, back pain, pain from the urinary catheter and pain at a cannula site. There were key time points identified where pain occurred or was exacerbated, such as the interval between a spinal anaesthetic wearing off and intravenous or oral analgesia taking effect; during transfers for scans; and most commonly at applicator removal. Descriptions of pain varied from some who said they had no pain, or manageable pain to those who described it as unbearable or their worst pain ever.

General pain experiences

Some women developed pain early in the brachytherapy process, when the spinal anaesthetic was wearing off and before oral or intravenous analgesia was given or became effective.

"It was still numb when I woke up, it was only when I went for the MRI afterwards that it started, the feeling started coming back. That was quite uncomfortable, I wish it had like lasted a little bit longer than the MRI. Cos it was very uncomfortable on my back." [Linda, interview 27]

Hazel and Molly both had spinal anaesthetics for day case procedures and found that the length of time waiting for treatment varied, and when waiting longer the spinal anaesthetic had worn off more compared with shorter waiting times, therefore it was more uncomfortable or stressful for them, especially at the point of applicator removal.

"Yeah, so the second and the third time my spinal had worn off by the time I went in for my treatment. Erm, even though I went in earlier, I think, but the spinal I must have had earlier, so it didn't sort of cover me till the end. So before I actually got into the treatment room I was in quite a lot of discomfort." [Molly, interview 29]

Alternative names for pain

The women described pain in different ways, with Charlotte describing an ***"intense pressure".***

"They said that they had to place the rods quite high up and it felt like it was sort of, (sighing), I don't, I don't know, not like it's pressing on my bowel, it felt, it just felt like intense pressure….but by the evening, early evening, it really was very, very intense the pain, very intense. Um and I would like, I think I've got quite a high pain threshold, but I just couldn't get comfortable." [Charlotte, interview 14]

Some women used the word 'soreness' rather than 'pain', and some used 'pain' and 'soreness' interchangeably. Claire experienced pain on her third day case brachytherapy procedure that was different to her other procedures.

"(Sighing), um, it was more, rather than the kind of, cos I started to expect the kind of period type pain, and it was more discomfort type, you know, the actual, you know, as though someone had had a good scrape around or something. Um, it was more sore, than, than, than the sort of steady type pain, um." [Claire, interview 23]

Rosie described her pain as an ***"intense ache"*** through the night:

"Um, it felt pretty uncomfortable, I think because, because I'd been so, sick during the night, I was really trying not to use the morphine too much so, it, (sighing), it just um, it, I

find it quite hard to describe, because it's painful but in some ways it was more of an ache, it was just a really intense ache, um." [Rosie, interview 24]

Uncontrolled severe pain

Laura had been scheduled for long duration brachytherapy with four treatments over two and a half days but found the pain so unbearable that she asked for the applicators to be removed after the second treatment.

"…then as it started wearing off, it was just, it felt like someone was like just stabbing me and I kept saying to the nurse, "This isn't right", I'd read about people saying "It's uncomfortable, it's annoying", this isn't like, I've got pains in my ribs, I've got high pain threshold, like this…..and they said "Well we'll give her paracetamol and ibuprofen, and then we'll do this", and I was just like "Just give me something to take it away"….."But I am telling you, I am ten out of ten in pain, paracetamol and ibuprofen, ain't going to fix it" and it took them ages to get my pain medication right and even when they had me on the highest doses of everything, I was pressing the button all the time, to get extra shots throughout the night, it was just excruciating, um and I kept saying "It's not right, it feels like it's pressing in the wrong place, it doesn't feel right" and every time they tried rolling me, it was just like, the worst pain I have ever felt in my life." [Laura, interview 2]

Annie had pain as the spinal/epidural was inserted, during applicator insertion in theatre and when she was transferred for imaging. When back on the ward she developed severe pain.

"…and I was literally screaming for help. I was like "Please, please somebody help me", and I was just, they, they wouldn't even come back and explain to me what they were trying to do, or what they were gonna be doing long term. I was just, I was literally screaming the ward down, asking for help…..But this was just constant like, like something was squeezing my insides really tight and then punching me at the same time, no that's how it felt, like I was being punched from the inside and stretched and like finger nails clawing at my insides…" [Annie, interview 17]

The intense pain continued for an hour until her consultant oncologist arrived. She was then given gas and air and later the epidural was switched back on.

No significant pain overall

Although many women experienced mild, moderate or severe pain during their brachytherapy, it is important to note that some women said they had not had any pain, or just a bit of discomfort. Gina had always been too frightened to have smear tests and was extremely anxious before she had brachytherapy. She was surprised how well she coped with day case brachytherapy procedures, carried out three times, with a spinal anaesthetic each time, and was able to reassure other prospective patients.

"I couldn't understand it was so, so different to what I expected, I, I just never felt a thing at all, in through it all…after that [first brachytherapy] I had no fear of having it done. I had to have another two and it didn't worry me one little bit…..I was very relaxed all the way through, very relaxed, yeah (chuckling) it was just a funny feeling that I couldn't move anything from my waist down. It didn't hurt." [Gina, interview 7]

Vicky had medium duration brachytherapy twice and said that it was far less painful than she had expected.

"I thought it was gonna be hell, and it, like, and I thought it's gonna be actual physical, I thought there's a reason they're gonna give you a Morphine drip, because it's gonna be absolute agony, but it really wasn't." [Vicky, interview 19]

Pain at applicator removal

Pain at applicator removal was often experienced. Dawn gave a detailed descriptive account of the removal of vaginal packing and applicators:

"…and I have to say the packing was like razor blades coming out of there, so there, apparently there was two lots of packing, erm, it did, that was horrendous…..I could feel sort of like it unravelling, erm, sort of up inside, I could feel that, the unravelling, but it felt just like really sort of like, erm, like tough, really like hard, erm…..Yeah, the two lots were

knotted together, so when they were pulling them out, I mean it just went, it seemed to go on…forever this packing coming out and I was really, I was crying I was really in pain, I was, that was…..so I'd had the morphine, the gas and air, the instillagel, no, it, it, I think it dried out…..Yeah, and it was more like a razor blade rather than soft packing as I was imagining the packing to be, but it wasn't soft…..then I literally had to give birth to the applicators and so that, that's how I would explain getting those applicators out. So taking some really good long breaths of the gas and air and then holding and then pushing while they pulled, and that was like, whoa…..I just wasn't expecting it. I felt like a plunger being pulled out, you know…..and then, when they pulled them out it was like, whoa, that was not very nice." [Dawn, interview 6]

Vicky had been very sleepy during her first brachytherapy procedure and therefore had not pressed the PCA many times before applicator removal. She also declined to use the gas and air for the first removal.

"I wasn't pressing it a lot no, and then but when, the first week, when they took the applicator out, they didn't give me any pain relief, whatsoever, so literally they ripped it out, with nothing…..(Sighing), so like, like somebody was literally ripping my insides out, it was horrendous, but it's because I said stupidly, "Oh when I had my son, the gas and air made me sick"." [Vicky, interview 19]

At her second brachytherapy she asked for extra medication before removal and used the gas and air during removal and had a much less painful experience.

No pain at applicator removal

Conversely, some women said they could not feel the applicators being removed as some were still numb from their spinal anaesthetic.

"It's as I say, when they, when they pulled the, the things out and the, and the packing that they'd put in, you, you couldn't feel that at all, so whether, all my legs I could move completely by this time, err, it, the numbness had gone completely by this time, err, but I didn't feel anything of them pulling anything out. So whether it was still very, just a bit slightly numb inside there, I don't know." [Gina, interview 7]

For those who had medium or long duration brachytherapy where a spinal anaesthetic would no longer have been effective at applicator removal, some women reported no significant discomfort or pain.

"And they tried to … they tried to give me oramorph. And I said, "No. I don't want that." I don't respond particularly well to a lot of drugs that are sedative. So, um, I said, no we'll get it out and I … and they literally … it came out with relative ease. They thought it was amazing that I didn't need, you know, oramorph but it's a … it's short. Do you know what I mean? It's a couple of minutes of discomfort. I wouldn't say pain. I'd say discomfort and once it's out that's the end of it." [Ruth, interview 11]

Anna and Charlotte both had long duration brachytherapy with one applicator removal after two and half days and reported no pain at removal and much easier than they had expected.

Medieval torture

Some women likened the brachytherapy process to medieval torture. For Diane, this was how she described the experience.

"…but when the packing came out I felt they were pulling my entrails out…..I can't even describe it properly, either, and you just think of someone in a torture chamber in a very medieval way when they used to hang, draw and quarter people. Um, and um, I think I've also read about some practices where women are punished with some instrument that draws out from down below, yet it was, I just relate to that after that." [Diane, interview 1]

Before having brachytherapy, Claire saw some diagrams in an information booklet and became very worried about what was going to happen. After that she decided to stop reading any information as she thought it might be better not to know or think about it anymore.

"I was joking to people that I was going to be like Henry the second, you know, it sounded like kind of um, you know, the hot, the hot coals, the hot poker approach." [Claire, interview 23]

Presumably, Claire was referring to the historical legend of *Edward II* who is alleged to have been murdered by having a red-hot poker inserted into his anus, possibly as a punishment for homosexuality. However, Claire's experience did not live up to her fears, having visualised a kind of ***"cauterisation"*** treatment. Instead, she coped well with the procedure and joked about the way she visualised it afterwards.

"It was just, it just seemed, you know, it was Barbarella, it wasn't Edward the second at all, um, the Orgasmatron, um (chuckling) just, just surreal really, I thought."

It is likely that her reference to the "orgasmatron" relates to an imaginary sexual stimulation machine from the 1968 film, Barbarella, and the fictional orgasm-inducing device from the 1973 Woody Allen film, Sleeper. Juliet [interview 31] said that she was worried that the brachytherapy part of the cancer treatment sounded ***"really kind of medieval to me, torturous you know".*** However, her experience was nothing like she had imagined.

"…my impressions were dispelled after the first one. I'm not saying that err, um, I, I embraced or liked the treatment thereafter, but I was a lot clearer about why the anaesthetic was spinal, and um, a bit more confident about the people that were doing this." [Juliet, interview 32]

Therefore, for some women their preconceptions of brachytherapy being like a medieval torture were unfounded, but for Diane her brachytherapy experience led to her likening the treatment to medieval torture afterwards.

Anaesthesia and analgesia experiences

Most of the study participants had received a spinal anesthetic or an epidural prior to applicator insertion. One recruitment centre routinely gave a general anaesthetic to brachytherapy patients, but due to COVID-19 restrictions for aerosol generating procedures, they switched to spinal anaesthesia for several months. Therefore, two participants from this centre had spinal anaesthesia. Conversely two patients at centres that routinely gave spinal anesthesia had general anaesthetics due to medical complications which prevented the use of spinal anaesthesia. The term 'spinal' or 'epidural' seemed to be used interchangeably by some participants and it was difficult to determine which procedure

they had. As far as the doctoral fellow is aware, only one of the four recruitment sites used both spinal anaesthesia and epidurals, with selection typically determined by the type of applicators to be inserted; that is use of interstitial needles would indicate the need for an epidural. A few participants were surprised by the effect of the spinal anaesthetic or epidural, including leg numbness, loss of sensation and immobility. Anita explained how she had felt unprepared for the loss of sensation.

"I hadn't really had what happens to you when you have an epidural explained to me, so I wasn't expecting to be totally paralysed….. I knew I was going to have an epidural, I didn't know that an epidural meant I was paralysed and couldn't move." [Anita, interview 4]

Rosie described the sensation as the "oddness" of not being able to feel her legs. Marion found that gradually losing sensation in her lower body was quite unpleasant the first time, but not so bad the second time when she knew what to expect. Amy was annoyed by the two hourly use of a cold spray to check the level of spinal block, especially the pre-test on her shoulder.

"Oh the cold spray that they used for the epidural, (sighing), like, got quite tedious, quite quickly, and the, and any time it was a different nurse that did it, they wanted to do it on my shoulder. Yeah and I was like, "I know exactly what it feels like", so I was probably a little bit grumpy about that, at a couple of points….Yeah, and I know that they were trying to do it, to be like you know, it's probably how they've been trained to do it, but that was, rubbish." [Amy, interview 3]

Many participants reported that they were anxious or frightened about the spinal/epidural, worried about risks of paralysis or nerve damage. For example, Hazel said that she was quite scared when the spinal anaesthetic was being put in as she was aware of the potential for harm. Overall, most participants found it an effective form of anaesthesia/analgesia, especially during the insertion of the applicators in theatre, and were very relieved to feel no pain.

"But unfortunately, it was part of the treatment um, and it just seemed like a very complicated process, you know, needles, wires, internally in the cancer, and because I

didn't have an epidural before, I just didn't realise just how painkilling it actually was when you had it…..my impressions were dispelled after the first one, I'm not saying that err, um, I, I embraced or liked the treatment thereafter, but I was a lot clearer about why the anaesthetic was spinal, and um, a bit more confident about the people that were doing this." [Juliet, interview 31]

Participants described being awake throughout applicator insertion and mostly this was not a problem as the staff were good at explaining what was happening. Molly said it was helpful to be given progress updates during the procedure and was glad that she was awake for this part. Some participants reported that the staff were good at distracting them through conversation. Some described feeling a pulling or pushing sensation but no pain. Some women were highly anxious throughout the theatre procedure and wanted medication to sedate or relax them as well as the spinal or epidural. Administration of sedatives was variable between participants and procedures. Bethany said that she had a cocktail of drugs for her nerves and that this had been described to her as being like a ***"gin and tonic"*** **[Bethany, interview 18]**. Lucy had three theatre procedures and was given sedation on her final time.

"They didn't the first two times actually, but on the third occasion, um, it [the anxiety] didn't get any better each time I had it to be fair, but that's me, I'm not saying that was anything to do with the procedure. Um, and on the third occasion, she said look, I can give you a little bit of something if you want to, she said, it's not … it's not um, you know, it's not going to harm or affect you. She said if you want something, just to relax you a bit, um, she did. I don't know if it was sedation, I know she gave me a drug, um, she put something in. And um, I didn't feel particularly spaced out, but …. But it 100% did relax me. I did feel better on that third occasion, and it really, really did help." [Lucy, interview 32]

Juliet found out that another patient had been given sedation and asked for it on her last procedure as she was tired and still very anxious. Overall, there were mixed experiences with the spinal anaesthetic or epidural, mostly with good analgesic effects. However, some

women would have preferred to be asleep throughout the theatre procedure and this was not always offered or given, even when patients were highly anxious.

Drugged up, sleepy or lethargic

Some of the participants who had medium or long duration brachytherapy described feeling very sleepy or lethargic during their procedure.

"Um so I was a bit bored, I mean, the first day I was reading my books and all that sort of stuff, but I really didn't feel like it after that. So I do remember being fairly bored, but also being half asleep a lot of the time. Um, which I was obviously quite, quite, I dunno if it's just the Morphine or if they gave you, I think they gave, they gave you sleeping stuff, I had sleeping stuff as well they gave me. Um, and I think that, so I had that, so I think probably I felt that made me feel dopey for most of the rest, you know, quite a lot of the time. So I do remember feeling pretty dopey for the last couple of days anyway." [Nicola, interview 8]

Vicky reported that she slept though most of her admissions; having to be woken up to take her medication and to be taken for her radiation treatment but then she slept through that. She believes she slept through a reflexology session as she had been advised that it had been given but has no recollection. She was very tired after five weeks of radiotherapy and chemotherapy and appreciated the permission to fall asleep without having to worry or feel guilty about her son.

"so it was nice just to, as horrible as it sounds like, because obviously I love my son and that, it was nice just to have that time, where I, I know that all I can, no one's gonna tell me off if I just fell asleep." [Vicky, interview 19]

Diane was unsure if her relatives had visited her or not as she was in and out of sleep for long periods of time. Amy was perhaps less sleepy and described herself as ***"dopey"*** but without the ***"oblivious sleep"*** due to the hustle and bustle of a busy general ward. In general women found that being sleepy helped to pass the long periods of time and lying flat in bed between treatments.

Side effects after brachytherapy, the 'aftermath'

Some side effects developed after completion of brachytherapy and may relate to any of the treatments, not just brachytherapy. However, they were described by participants in the context of their overall brachytherapy experience. Many participants expressed dissatisfaction with the information and support given about side effects after brachytherapy and would have liked more information when they were being discharged from the hospital.

Bowel and bladder side effects

Women talked about bladder side effects, especially pain passing urine (dysuria) after brachytherapy. Molly complained that she had two hospital admissions with urinary tract infections after her day case brachytherapy procedures. Some participants had urinary pain the evening after day case brachytherapy, when they had arrived back at home. Some had urinary pain after every procedure, and a few said they had not been warned in advanced and therefore were not expecting this to happen. Linda had a few episodes of urinary incontinence after brachytherapy, but this passed off after a week or so. Some participants had bowel side effects which seemed to last a little longer than the bladder side effects. Eleanor had initial bowel and bladder incontinence that developed into a longer-term bowel problem. This led to faecal urgency which she manages well by making sure she knows where toilets are situated when she goes out. Bridget also complained of softer stools and urgency for four weeks after brachytherapy. Following discharge home after brachytherapy with cardiac complications, Elsie had episodes of urinary and then faecal incontinence for two days, which she found very distressing.

"That was the most upsetting thing I'd say. It's going to upset...it's going to affect different people differently surely. But that was a big, big thing for me." [Elsie, interview 16]

Seven or eight months after brachytherapy Justine developed radiation proctitis and commented that she could not remember being warned about this potential side effect.

Fatigue

Participants talked about their experiences of fatigue after brachytherapy, such as, feeling extremely physically weak or tired and excessive sleeping or sleepiness. Bridget was still experiencing fatigue four weeks after brachytherapy and coped by pacing herself.

"I didn't have the energy that I had before any cancer, it was like, I would get everything done in the morning up to about three o'clock and after that then I would just slow right down, like my batteries were doing dead." [Bridget, interview 30]

Justine said that she was sleeping so much that she had to rely on her parents to look after her, to cook for her and support her recovery for the first few weeks. Maureen said she ***"could sleep on a clothesline"*** for many months after her treatment finished, and even a year after treatment thought that she was sleeping more than normal. Juliet reported that she had ***"never ever been so physically weak"*** in her life during the first week after brachytherapy, but that she started to improve in the second week.

Loss of appetite and weight loss

During and after their cancer treatment loss of appetite, taste changes and weight loss were reported. Rita said she lost two stone over the whole process of diagnosis and treatment. Joanna had no appetite, complained of a ***"peculiar taste"*** and went down by two dress sizes but started to improve about two weeks after treatment. Juliet lost weight due to her poor appetite and nausea and vomiting after chemotherapy and Linda said that it was a month after treatment before she could eat normally. Karen suffered from loss of appetite and lost 10% of her body weight during treatment but this had started to improve a couple of weeks after her treatment finished.

Insufficiency fractures

This rarer symptom of pelvic bone pain due to insufficiency fractures was reported by Eleanor and Maureen but it is unknown if this was related to their cancer treatment. Maureen would have liked more information or advice about insufficiency fractures after treatment as she was unsure how much exercise to do and did not want to exacerbate her condition.

Vaginal stenosis

Due to vaginal stenosis Justine was unable to use the vaginal dilators and her oncologist was unable to carry out vaginal examinations at her follow up appointments, to check for tumour recurrence. Whilst this did not concern her from the perspective of sexual intercourse, it was important to her that the cancer follow-up could be conducted. Rita was unable to use the second size of vaginal dilator as it was too tight, but she suspected that this may have always been the case and not related to the treatment. Her oncologist and radiographer had encouraged her to try and use the vaginal dilators.

Lymphoedema

Justine reported experiencing lymphoedema, which developed approximately one year after treatment. Bridget mentioned that her fear of developing lymphoedema motivated her to resume exercise after treatment finished.

Absence of complications/side effects

A few participants reported that they had no complications or side effects during all or some of their brachytherapy procedures. Joanna was surprised that having lain flat for two and a half days for long duration brachytherapy, that she had no pain and was able to get up and walk out of the hospital.

"I am slightly puzzled, how I'd gone from feeling, err having no sensation and then being able to get up, get dressed, gather my stuff together and then walk out of the ward, down to a door. Um, and wait for my daughter to come and pick me up and I am, I am, this is the bit that has puzzled me….but in that space of a few hours, I had gone from feeling nothing, to being able to get up and walk." [Joanna, interview 25]

Theme 3: Emotional consequences and trauma

Women's stories of their brachytherapy included many psychological challenges as the treatment was being delivered in the context of a recent cancer diagnosis; specifically, an inoperable LACC. Some of the younger women were also dealing with the fact that treatment would make them infertile. Regardless of age or previous experience of childbirth, the removal of brachytherapy applicators was likened by some women to childbirth. Lying in a hospital bed for hours or days with applicators inside their uterus and

vagina made some women feel vulnerable and some were embarrassed due to the personal nature of the disease and treatment. The spinal anaesthesia or epidural meant that they were unable to get out of bed or walk away from the procedure, causing some to feel trapped. In addition, the knowledge that any movement may move the applicators and make their treatment inaccurate was of concern to women and in some cases, this added to their feeling of confinement. Some were also upset by experiences of pain and not being listened to, understood or believed when they complained or asked for help. Five subthemes were developed:

A) **Trauma associated with a life-threatening diagnosis**
B) **Trauma associated with loss of fertility**
C) **Associations of applicator removal with childbirth**
D) **Feeling embarrassed, vulnerable, trapped**
E) **Not being listened to/believed**

Subtheme A: Trauma associated with a life-threatening diagnosis

For many participants their cancer diagnosis was a significant and impactful event that they referred to in their descriptions of their experiences of brachytherapy. Charlotte [interview 14] said that she was so shocked and traumatised when she received her diagnosis that she had fallen apart and was not able to speak for two weeks. Participants talked about their worries that the treatment might not eradicate the cancer or that it would come back in the future. Bethany talked about her last brachytherapy, remembering staff asking her about ringing the 'End of treatment bell', suggesting that she celebrated with streamers and whistles, but in her mind, she was consumed with fear for her survival, uncertain whether the cancer would return.

"you know, in my head I'm still thinking, well nothing's set in stone, nothing, you know, just 'cause it's my last treatment it, it's not, I might still have got, got it, you know…there's nothing that's said it's, I'm cured and I know, you know…Yeah, so, I mean they're all thinking really positive, even when I went and had my last chemo they were saying, "oh, we wish you all the best, it's your last one" and this that, and you know, they're all so nice

and positive, but deep down in, inside my head I'm going out thinking what if, what if, what if?" [Bethany, interview 18]

Younger participants in particular, talked about their fear of dying and worries about their young children. Some women referred to having been emotional or 'tearful' during or after their brachytherapy and the retelling of these events generated emotional points during the interview, with tears and apologies for getting upset. Vicky reported symptoms of PTSD, having flashbacks of when she was initially told she had cancer. This led to panic attacks at follow up appointments where she was convinced that she was going to be told bad news. Receiving her diagnosis had been a shocking experience, which seemed at odds with her expected life trajectory, and she had become unable to move on. She was interviewed over one year after brachytherapy during which she had received increasing doses of antidepressant medication and regular counselling.

"Every time I go to the hospital, I just literally lose it, because I think, bad news, bad news, they're gonna give me bad, and I just, yeah and everyone's around me, going "Why are you getting so worked up for? They're not gonna say anything", but you're not in my brain, because you weren't the one sat in that chair at twenty-six years old, when they turned round and said "You've got cancer", you weren't that person. So, in the nicest way possible, don't comment, because you don't understand. I never thought at the age of twenty-six I'd be sat with, with somebody saying, you know, you could die." [Vicky, interview 19]

Vicky also talked about how difficult it was to cope with the uncertainty and that if she had not had a cervical smear test, she could have left her son without a mother.

"But all the time I'm like keeping busy, it doesn't get to me, it's when I stop, and I'm on my own, and you've got your thoughts, and they're dangerous, my head, my head's a dangerous place to be, I think." [Vicky, interview 19]

Participants talked about the anxious wait for results after treatment was completed, and the feeling of being 'in limbo' whilst they waited to find out if the cancer had gone or if they

would need further treatment. Lucy spoke of the relief she felt to finish treatment and the subsequent concern about whether it had worked.

"…and I think the adrenaline of having all the treatment and everything and it was like you know, I'm getting up having this done and they're treating me, it's going to get better but I think afterwards, once it's all done, it's you start to worry again, about you know, has it worked, and the rest of it, so … I can fine, talking like I have been to you, quite openly and everything, but then something, anything, just bizarrely, might just trigger me to you know, to obviously get upset about it again." [Lucy, interview 32]

Some patients received information about visible tumour regression during their brachytherapy which boosted their determination to complete the treatment. Molly had some positive news at her last brachytherapy procedure, that the tumour was no longer visible, which made her feel relieved but also quite emotional. She described the physical and emotional exhaustion at the end of treatment.

"…it was a mixture really. I was so tired, erm, and quite uncomfortable still, but my husband came to pick me up so I was telling him what the doctor had said so it was quite ... I was like again, like relieved but still quite worked up from sort of the anxiety that had built up. Erm, and I think I fell asleep on the way home, I think I was just so exhausted." [Molly, interview 29]

Some participants talked about finding it hard to understand or accept that they had cancer, that it was not real or not happening to them.

"…going back to the very beginning, erm, when I was told that I had the cancer, erm, I, I don't quite think that I believed them. I wanted it not to be, not to be happening." [Eleanor, interview 21]

Juliet said she did not want to engage with her follow-up appointments and admitted that she had not yet come to terms with her cancer diagnosis. Her interview took place four weeks after treatment. She said she was very grateful for such good treatment and felt she was being ***"infantile"*** or even ***"churlish"*** to not want to attend future appointments. She

wanted to put the experience behind her and try and forget all about it or pretend it had never happened. Claire was interviewed a year after treatment and talked about distancing herself from the experience.

"I think it was the brachy because, I, I don't, the cervix, it, it's like it's not happened to me, does that make sense? I, I've always felt as though I've been on the ceiling the whole time watching what was going on. And then I'm still not quite sure that it has, and for that reason, I think sometimes, I don't, I don't want to just be the person that's got cervical cancer. Whereas some people seem to be, want to be part of the club all the time, and it's almost a club I'm, I'm a bit reluctant to be a member of (chuckling)." [Claire, interview 23]

Subtheme B: Trauma associated with loss of fertility

The issue of loss of fertility was raised at interview by all participants under the age of 40 regardless of whether they already had children. Vicky had a young son at the time of diagnosis.

"That completely broke my heart, because it wasn't even the case of maybe I wouldn't have had any more children, I don't know, it's the fact of that got taken away from me…..But you know, when you're told you can't have something, you want that so much more. When you're told you can't have it, and that's it, it's grieving, I'm literally grieving it, I'm grieving the fact that, of the children I could have had in the future, nobody understands that." [Vicky, interview 19]

Vicky had to decide between harvesting eggs (for future surrogacy) or delay starting her cancer treatment. Weighing up this choice was particularly difficult as she said had to make the decision alone. In the year following treatment her sister became pregnant and she said she had tried not to let her sadness affect the happiness she felt for her sister. Molly had a young daughter who had been conceived naturally after many unsuccessful attempts at IVF treatment. She would have liked her daughter to have a sibling but decided against egg harvesting/surrogacy as she rationalised that it was more important for her to be there for her daughter and was not prepared to risk worse outcomes by delaying treatment. Anna had a daughter and said she would have liked another child, but again did not want the added risk caused by delaying treatment. Amy was single at the time of diagnosis, had not

had any children and found it hard when seeing friends with their children or pregnant. She was tearful recounting how she had received a text from a friend while she was lying in a ward bed with brachytherapy applicators inside her. She was upset by the irony and sadness of the position she was in as the text contained the news that her friend was pregnant. She talked about friends or acquaintances making comments that she found upsetting or unhelpful, like ***"miracles can happen"*** and thinking to herself ***"no they can't"***. She had recently been upset by seeing news reports about developments in fertility treatments.

"You, you're, like things catch me unawares every now and again, like the news sort of thing [sounding upset at this point]. Yeah, maybe cos I was like, at least you guys can have a chance, even when it's only, it's only twenty four per cent [sounding upset at this point]…" [Amy, interview 4]

Rosie had not had children and said it made her sad when so many of her friends were having children in the year since her cancer treatment. Laura talked about having counselling after treatment finished, to work through the feelings of loss and grief as the treatment had made her infertile. Annie, already a mum, had found out that she had cervical cancer when she was pregnant. She explained that she had to make a choice between a significant delay to her treatment (until it was safe to deliver the baby) or to have a termination. She was upset and emotional during the interview, recounting how that baby was wanted and loved, but she said she was told *"It's the baby or you"* and had chosen termination [Annie, interview 17]. She was then upset and angered by an insensitive comment by a healthcare professional who called the termination an "abortion".

Subtheme C: Association of applicator removal with childbirth

Many women recalled experiences of applicator removal using words related to childbirth. For some women this was just a way of describing a physical experience, but for some it was retold as a more upsetting or traumatic analogy. Almost all participants recruited from one centre recalled being told by a healthcare professional to push the applicators out, like giving birth. For women who had experienced childbirth this may have been a helpful instruction, however Rebecca said that she had no idea how this was going to feel as she had never given birth, had no children, and thought this was an insensitive instruction. At her first removal she was surprised that it was quick and not too uncomfortable. However,

her second removal was painful as she was more sore throughout this procedure. Reflecting on this, even though it only took a few seconds to take the applicators out, she would have liked a general anaesthetic for this procedure. Diane said she felt after applicator removal like she had felt after giving birth, as if something large had come out and stretched her. Ruth likened the experience to when she had a forceps delivery and Hazel said the pulling sensation was similar to when she had a caesarean section. Both Claire and Linda likened the sensation to when they had experienced contractions during childbirth. Annie described the sensation during applicator removal and said that it was not as bad as she had expected.

"I had the gas and air, and um, they took it out and it was like a slithery sort of wet feeling, a bit like when you deliver a baby and you know that, yeah you feel the slithering and the, the wet, it felt like that." [Annie, interview 17]

The treatment for cervical cancer causes infertility and for some women who had not had children, the association of applicator removal with childbirth had caused prolonged upset including flashbacks and intrusive thoughts. Laura had not experienced childbirth herself but had been a birth partner for her friend, so had witnessed a delivery and the use of gas and air.

"…I now can't have children and I've never had children and when they removed the packing, it was a sensation of what I would imagine giving birth was like, um, sorry, I'm getting quite emotional, and that kind of like really traumatising, more so than the pain [sounding very upset at this point] um…Yeah because they were giving me gas and air, so I was there with my legs up and they were kind of and I think it was because they were pulling all the packing out and it was like, that vacuum of you know, totally with my friend when she was like giving birth and it just, in that room and looking at the nurses there, and gas and air, it just and I said, I did say to them afterwards, I said "that was really, really traumatising for me", and they didn't understand why [sounding very upset at this point]." [Laura, interview 2]

Rosie, who had not had any children, said that using the gas and air and being told to breathe, made her think of childbirth in that moment.

"…but you know, that in my head I've managed to like link those things, um, and it did feel really sad, you know, you're in this big room, just you and two other people, getting this applicator out, um, and it was, you know, a really unpleasant experience, and you just think oh well this is it, this is the closest I'll come to um, being able to relate to the experience that maybe, you know, my friends etcetera…..Um and yeah I, I do think in the back of my head, every time I think about the thought of giving birth, I, like just even if it's only for a split second, I, I think of that, having the applicators removed." [Rosie, interview 24]

Subtheme D: Feeling embarrassed, vulnerable, trapped

Participants described feeling vulnerable during their brachytherapy procedures, often associating this to having applicators inside an intimate part of their body and a sense of loss of privacy or dignity and embarrassment. Sometimes the vulnerability related to having to lie flat with applicators in place for long periods of time. The inability to sit up or get out of bed, for fear of moving the applicators and hurting themselves or making the treatment inaccurate, left some women feeling trapped or helpless.

Vulnerability caused by embarrassment, loss of dignity or privacy

Vicky talked about feeling embarrassed during her EBRT, especially when having vaginal bleeding and needing to be undressed from the waist down, and male radiographers delivering or lining up the treatment. However, she said that they were very kind and caring to her and that this helped to reduce her feeling of embarrassment as she got further into the five weeks of daily radiotherapy. The diagnostic investigations and the brachytherapy however were more invasive.

"Like it felt like everybody, in like a ten-mile radius is having a look up there, do you know what I mean (chuckling)? It feels like, I literally had lost, I thought you lost all your dignity when you had a child, but I think cervical cancer, is when you lose all your dignity, because that was worse. It is constant. Yeah, and it's not like, I don't like to moan about it, because as I said, they, they were saving my life, but it, it was all just really personal, and I thought to myself, trust me to have cancer in the most delicate, sort of place for a woman." [Vicky, interview 19]

Vicky described an upsetting episode where she was lying on a trolley, waiting for a scan, and thinks she was in a staff room where members of staff were getting things out of their lockers. She said this situation felt **"surreal"** and made her feel **"undignified"**.

"But I was thinking, but there's somebody in their locker and I'm left here in this bed, with this, this thing up inside me." [Vicky, interview 19]

Dawn was particularly embarrassed by her problems with trapped wind and needing to pass wind when on a ward with other women.

"But you feel embarrassed because there was three other ladies in the same room with you, and there were their visitors there as well…and your wind is building up and building up and…do you know what, in the end I just thought it's got to come out, it's coming out and that's it, I don't care. But there was the kind of feeling that I shouldn't be doing that, not in front of all those people, you know [laughing]." [Dawn, interview 6]

Hazel was embarrassed at her first applicator removal that there was a male radiographer doing the procedure and she coped by looking up at the ceiling, taking her mind away from what was going on with her body. But she said he was very good at his job, removing the applicators very carefully and without causing pain, so she felt less embarrassed the next time. After applicator insertion, whilst waiting for her MR imaging, Annie became concerned for her dignity.

"Yeah, that was um quite an experience, cos there's just people waiting there for their normal like radiotherapy treatment, and you're there like, oh my God, can people see me like downstairs bits…" [Annie, interview17]

Conversely, Marion said she was not embarrassed at all when she had applicators inside her.

"…my privacy wasn't invaded at all to be honest, it wasn't, it was all handled beautifully, no, no, no way, I wasn't embarrassed, and I wasn't self-conscious about any of it, to be honest, I wasn't." [Marion, interview 22]

Vulnerability caused by lying flat, immobile and feeling trapped

Many women talked about the position they were in, lying flat for hours or days, and how that made them feel vulnerable and helpless due to their total dependency on others for basic functions. Juliet talked about feeling vulnerable at applicator removal.

"…then you go down to the, and then the, the brachy area, pellet administration, and they start unscrewing you. But it's just weird, because you just can't move and you're, you're so vulnerable aren't you." [Juliet, interview 31]

Both Dorothy and Charlotte explained that the feeling of vulnerability was because they could not move, they were not allowed to sit up, and that this meant that they felt trapped. Dorothy also talked about it being a new experience, being in hospital and wanting to be in a single room as she was a very private person. Vicky said that her feeling of vulnerability was due to being completely reliant on others for everything, which could be interpreted as a sense of helplessness. She did not want the ward nurses to provide any personal care or to help her as this would be ***"invasive"*** or ***"degrading"*** and instead relied on her mum to help her when she visited. She also said that being hospitalised and lying in bed for days, brought home the reality that she was a cancer patient and was seriously ill.

"I just felt like I was just a lost little girl, just wanting their mum and dad, that's how I felt…I think it's also the fact is, not only are you in hospital fifty minutes away from your mum and dad, and you know, your son and that, you're also in there for cancer and that makes it all the more scary. It's not just you're in there, you're in hospital like, oh you're having your appendix out or something. You're in there with, with a life-threatening illness." [Vicky, interview 19]

Annie said she had been promised one to one care on the ward, but described feeling alone, vulnerable and let down by the staff.

"And they made me all these promises, that people would always be there with me, and I was thinking, I'm at my most vulnerable and at a time when I needed medical professionals more than ever, there was just nobody, they just all left me, like." [Annie, interview 17]

Rosie was glad that she was in a single room on the ward as this helped maintain some privacy. She would have felt embarrassed if she had been on a general ward when nurses regularly checked the applicator position and applied soothing gel to the area. However, the downside of the single room was that she felt very alone at night, unable to see out of the door as she was lying so flat, not able to see the nurses. Claire talked about feeling alone and vulnerable when she was having the radiation delivered. The applicators were connected to the machine with the radioactive pellet inside, then all the staff left the room. She said she felt trapped and wondered later what would have happened if there had been a fire or an intruder. Ruth talked about having anxiety caused by being trapped in bed, and just counting down the hours.

"So it was, for me, 48 hours of boredom…..I think that's the things for me, was the worst thing. Not being able to get out of bed." [Ruth, interview 11]

Subtheme E: Not being listened to/believed

Some participants were distressed by experiences of healthcare staff not understanding their pain. They felt they were not listened to or believed when they were in severe pain and calling out for help. At Laura's first brachytherapy she was shocked by the amount of pain she was experiencing and told the nursing staff she wanted the applicators removed.

"…and I was like "I don't think this is right", and then all night I was just up in pain um, and then there, on the second day when I was going to have my second treatment, I kept saying "This isn't right, I want it out, I want it out", um I'd rung my mum and they live in [Town name] and I was like "Please come up, please come up, I want it out, they're not listening to me"…and they said "Well we'll give her paracetamol and ibuprofen, and then we'll do this", and I was just like "Just give me something to take it away…..and it took them ages to get my pain medication right and even when they had me on the highest doses of everything, I was pressing the button all the time, to get extra shots throughout the night, it was just excruciating…" [Laura, interview 2]

After the second treatment was delivered the applicators were removed, so Laura was unable to complete the planned four treatments at that admission and was readmitted for a second brachytherapy a week later. However, the impact of not being listened to led to her

losing trust in the healthcare professionals. She tried to find out why it had hurt so much and whether the applicators were in the right place and was not happy with the explanations she was given. After all the treatment was completed, she wrote a formal complaint which led to an investigation of the incident. Caroline experienced an intense and constant pain from the urinary catheter and was upset by the amount of time it took for the nurses to give her some sedation and more painkillers. The nurses called her oncologist who suggested they gave the extra medication.

"Yeah, I, yeah I think they may have thought there was some kind of, I was overreacting." [Caroline, interview 5]

Annie experienced problems with pain from the very start of the procedure, as the epidural was being inserted.

"…and I kept saying to them, "It's hurting" and the one thing I remember them telling me was "If you're in pain, you need to let us know, so we can do something about it", and um, it really hurt, and no one was doing anything about it….] I almost felt like I was being um, I almost felt like they were trying to say "Oh stop being silly", like, I don't think my view of how much it was hurting was taken into account at all, which we'll find that is an ongoing theme with my brachytherapy." [Annie, interview 17]

Annie recalled that later in the day she was unable to feel or move her legs, so the epidural and PCA were switched off, at which point the pain became more intense. She explained that she was crying and shouting out for over an hour, due to the severe pain, until her oncologist arrived and the epidural and PCA were restarted. She was told by the oncologist that she was experiencing 'total pain' due to her previous trauma with delayed diagnosis and loss of her baby. However, Annie disagreed with the oncologist's explanation of her severe pain and said it was not in her mind. She believed that it was physical pain which only subsided when the applicators were removed. Her loss of trust had begun a long time before brachytherapy, with repeated visits to doctors eighteen months before her cancer diagnosis. She had been complaining of unexplained vaginal bleeding then intermittent bleeding early in her pregnancy. She thought her cancer might have been diagnosed at an earlier stage if she had been listened to. She stated that she was angry that doctors do not

listen to women, and that often women know their own bodies best and know when something is wrong.

Variations in brachytherapy provision across the four recruitment centres

Table 20 shows a summary of the brachytherapy service provision at the four recruitment sites for this study.

Table 20 Summary of recruitment centre approaches to brachytherapy for LACC

Site	Typical brachytherapy regime	Complementary therapies usually offered	Interstitial needles used (when required)	Typical anaesthesia for insertion	Typical analgesia
1	Inpatient procedure, treatment twice with one insertion, usually repeated a week later: MEDIUM DURATION	No	Yes	General Anaesthesia	Oral and IV given in recovery and on ward, extra before removal
2	Inpatient procedure, three or four treatments with one insertion: LONG DURATION	No	Yes	Spinal anaesthesia	PCA set up in recovery
3	Inpatient procedure, treatment twice with one insertion, usually repeated a week later: MEDIUM DURATION	Yes (but less during COVID-19)	Yes	Spinal anaesthesia	Epidural or PCA set up in recovery
4	Day case procedure, three times, a week apart: SHORT DURATION	No	Yes	Spinal anaesthesia	Oral offered and extra before removal

Variations in themes across the fours recruitment centres

Differences in themes were only identified for Theme 2: Unpleasantness, discomfort and the aftermath and are summarised in Table 21. Explanations for these variations are explored in the following Section 4.5 Discussion.

Table 21 Differences in experiences across the centres

Theme 2: Subtheme	Differences in experiences
A: Problems caused by flat position	Centres 1, 2 and 3. More pronounced and negative experiences in centres using medium and long duration regimes. Examples: Build-up of gas, backache, problems eating and drinking.
B: Medical complications	Centres 1, 2 and 3. Some complications were only reported by those who had medium or long duration brachytherapy. Examples: development of emboli, pressure sores, allergic reactions or collapses.
C: Early and late side effects	Centres 1, 2 and 3. Severity of some side effects were more apparent in reports from participants who had medium and long duration compared with short duration brachytherapy. Examples: multiple episodes of nausea and vomiting, uncontrolled pain and feelings of lethargy and drowsiness were reported exclusively by those having medium or long duration brachytherapy.

Impact of COVID-19

COVID-19 was not developed as a theme or sub-theme in this RTA, but it is important to document how it impacted on interviews and experiences of brachytherapy during the pandemic. The first six interviews were carried out before March 2020 and the first lockdown and were face-to-face. The remaining 29 interviews took place remotely after March 2020, although 14 were in group two, being interviewed between 12 and 18 months after brachytherapy, therefore their brachytherapy occurred before the pandemic. Rebecca had completed brachytherapy a week before the first lockdown and commented on how the lockdown had affected her recovery from treatment and that working from home had been helpful. Not all participants who received brachytherapy during the pandemic mentioned impact due to COVID-19. Key impacts reported by participants included:

- Nicola had brachytherapy in the weeks after the first lockdown. She reported that staff were in a panic about COVID-19, new rules, increased distancing between patients and whispering about a suspected COVID-19 case on the ward. Staff seemed very stressed and were not operating at their best. She witnessed arguments between staff about theatres being converted into COVID wards.

- Some participants reported that wearing a face mask during ward admission was uncomfortable and made communication with staff more difficult, especially when lying flat for brachytherapy.
- Dorothy and Elsie reported being transferred from an oncology ward to a COVID-19 ward during brachytherapy due to having a cough or shortness of breath. Both women said they knew they did not have COVID-19, so it was more an inconvenience and upheaval for them to be moved and cared for by ward staff who may have had little knowledge of brachytherapy.
- There were fewer patients on a ward compared to pre-COVID-19 as the space between beds was increased to comply with infection control guidance. This was reported as a positive aspect of COVID-19 as patients appreciated having more space around them.
- Rita and Annie reported a change to their brachytherapy regime due to COVID-19. All brachytherapy treatments were given in one admission instead of two with a week's gap between them. This was to avoid the need for a second theatre procedure and second hospital admission. Annie was surprised at the last-minute change and worried whether it would be too painful to have an extra night with applicators in place, but both Rita and Annie appreciated getting all the treatment over and done with in one admission.
- Annie had to book hospital transport for brachytherapy admissions as no friends were allowed to provide transport due to the need to self-isolate before brachytherapy and after chemotherapy. She reported that this increased her feeling of isolation from the support of family and friends.
- Rita was given a spinal anaesthetic instead of a GA. She said this was to get her out of the theatre and recovery area more quickly. However, this may have been due to a GA being considered as an aerosol generating procedure and staff requirements for full personal protective equipment, additional room ventilation and extra time needed for aerosols to disperse after an aerosol generating procedure. She did not mind the spinal anaesthetic as she did not feel pain for a long time afterwards.

- Some participants mentioned that visitors were not allowed on the ward. This was described as a negative impact as they felt more lonely, isolated and vulnerable and missed the distraction of chatting to a visitor.
- Lilian blamed the COVID-19 pandemic for the lack of nursing care on the ward. She thought that the nurses were avoiding spending time with patients to reduce their risk of contracting or transmitting COVID-19. Having been promised one-to-one care, she felt disappointed and let down.
- Some participants reported that complementary therapies were unavailable during brachytherapy due to COVID-19 restrictions and were disappointed by this lack of support.

Doctoral Fellow reflections on impact of COVID-19 and remote interviewing

At the time of the first lockdown in March 2020, I was informed that all research that was not related to COVID-19 related research had to be suspended. I returned to full-time clinical work for four months. Getting back into a research frame of mind was not too difficult as I was raring to go with the interviews. The thought of carrying out remote interviews was daunting, but the only alternative option was to abandon the research and that was far more frightening. I decided that I needed to embrace the changes. I was worried about the IT; whether I had the skills to make it work and whether participants would struggle and potentially give up if there were problems with the videoconferencing. However, dummy runs with participants worked well and gave me and the participants reassurance. Reflecting on the differences between face-to-face, telephone and videoconference interviews, I found the telephone interviews the most difficult. Being unable to see any visual or non-verbal cues was frustrating and becoming accustomed to this took some time. On the telephone, there were more instances of talking over each other, or extra-long pauses to make sure I wasn't talking over the participant. One participant was exceptionally talkative on the telephone, and I struggled to get a word in to stop her when she was going off on a tangent. Comparing face-to-face and videoconference modalities, I was pleasantly surprised that they seemed remarkably similar. On screen I was able to observe the body language of the participant and pick up on non-verbal cues, such as particularly emotive issues and I could respond appropriately. When I could see that participants were thinking I could give them time without jumping in to fill a silence. There

did not seem to be any loss of rapport and personal connection when compared with my experiences of face-to-face interviews. I was also aware how much time I was saving by not having to travel to meet participants across the UK. On reflection, remote interviews may have helped improve recruitment to the study. Before the first lockdown recruitment was quite slow, with only six interviews over seven months, but after re-opening the study I managed to carry out 29 interviews over nine months. It is possible that potential participants were more comfortable with volunteering for a remote interview, especially as so many people had learned how to use videoconferencing to keep in touch with family and friends during COVID-19 lockdowns. Overall, I was amazed at how many participants managed to cope with using Microsoft Teams, with some needing just a little support.

Doctoral Fellow reflections on participants' questions

During interview, some participants asked how brachytherapy was done elsewhere, whether I had seen other women with the same side effects as them and advice on management of their side effects. Where possible I suggested that we talked after the interview, for an informal debrief and an opportunity for them to ask me questions about the research. This was quite challenging at times as it needed considerable thought and care, to explain differences in treatment regimes without raising concerns or disappointment with the treatment that they had received, and not to undermine the confidence and trusting relationship that they had with their clinical team. Some women expressed surprise at the variation in brachytherapy regimes being used and at the lack of standardisation. Some said they would not have wanted brachytherapy with a different regime, short or long duration, and some said they would have preferred the alternative regimes. Many women were unable to imagine having a different regime, staying overnight with applicators in or having to have theatre procedures repeated three or four times. For any clinical concerns raised, we explored the issues, and I guided them back to their clinical team.

4.5 Discussion

This study has provided a new understanding of women's experiences of brachytherapy across four UK treatment centres using modern brachytherapy techniques including interstitial needles and MR image-guided planning. Across the four recruitment centres brachytherapy was delivered using different regimes including day case and inpatient stays of different durations. Thirty five women were interviewed at two time points after treatment with 20 in group one, soon after brachytherapy and 15 in group two, a year after brachytherapy. Six participants were recruited from site one, nine from site two and 10 from sites three and four. Key themes developed were (1) How I got through it; (2) Unpleasantness, discomfort and aftermath; and (3) Emotional consequences and trauma.

Early in the data collection phase the variability in women's experiences of brachytherapy became clear. A similar finding was reported in an interview study of 32 women after LDR brachytherapy (Warnock, 2005) with variation in the incidence and severity of problems. This variation can present challenges for those providing care (Warnock, 2005). Velji and Fitch (2001) found that the quality of the women's experience depended on the nursing care received, the information received prior to brachytherapy and stresses related to context and environmental factors. A better understanding of these factors could be used to inform development of interventions to improve the care and support for women receiving brachytherapy.

A study of 51 women following brachytherapy identified three independent pre-treatment variables that were predictive of PTSD (Kirchheiner *et al.*, 2014b): a history of sexual violence; poor physical performance status; higher depression score and lower emotional functioning score. No socio-demographic factors were found to be related to levels of PTSD. Kamer *et al.* (2007) investigated anxiety levels in 146 women before and after brachytherapy. They found that marital status and number of pregnancies influenced anxiety levels before first brachytherapy. Married women had lower anxiety compared with unmarried or widowed women and those having had three or more children had lower anxiety compared with none to two children. Age, menopausal status, disease, prior operations and educational level were not shown to have any association with anxiety level (Kamer *et al.*, 2007).

Wilson *et al*. (2021) found that younger age and higher body mass index was associated with increased use of opioids with intracavitary applicator insertion when using conscious sedation for short duration HDR brachytherapy. They considered that the body mass index association may be due to pharmacokinetic factors, and age association possibly due to a combination of physiological changes related to aging, such as increased sensitivity to opiates and polypharmacy in older people (Wilson *et al.*, 2021). For ISBT with a longer overall procedure duration, Mendez *et al.* (2017a) also found an inverse association between age and opioid use. They noted that with repeated brachytherapy procedures there was a 46% mean increase on previous opioid use but number of needles and depth of needles was not a predictive factor for opioid use (Mendez *et al.*, 2017a). The brachytherapy pain experiences appear to be similar to findings in more general surgery with younger patients requiring higher opioid levels post surgically (Ip *et al.*, 2009). Dzaka and Maree (2016) interviewed 16 women after HDR brachytherapy and found that pain management was not 'best practice', stating that procedural pain can be anticipated and predicted, unlike other types of cancer pain. However, this may be an over simplistic criticism as the brachytherapy (procedure) is being given in the context of the presence of a locally advanced tumour arising in the cervix in combination with the psychological aspects of a life-threatening diagnosis and fears for survival. Therefore procedural pain may not always be accurately predicted due to the variability and complexity of the context (Raja *et al.*, 2020)

Velji and Fitch (2001) interviewed 10 women following LDR brachytherapy. Their findings indicated that the discomfort experienced by women during the procedure was perceived as *"a totality of symptoms, including but not limited to pain"* that was not always relieved by medication. The women's experiences were unique to each participant and included reports of diarrhoea, heartburn, flatulence, dizziness, nausea and vomiting and fatigue. These findings were similar to the current study suggesting individual variation in severity and distress caused by the physical effects of brachytherapy. Another theme developed by Velji and Fitch (2001) reports that women's experiences were *"embedded within the complete context*" of the treatment, where the context included personal, environmental, and treatment-related factors. This resonates with the findings from the current study

supporting an interconnection between the context of women's life experiences and coping strategies (theme one), with the physical and psychological impact of the treatment (themes two and three). Overall, it appears that women's experiences are influenced by a combination of the brachytherapy context, including the cancer diagnosis and the environment, along with the interrelation of physical and psychological aspects of brachytherapy. An example of this is the experience of pain and the need to lie flat in bed for many hours, knowing that sitting up or getting up would be physically harmful to the individual and reduce the chance of getting rid of the cancer. Other examples are the experiences of women who reported not being listened to or believed when in severe pain, and those that received insensitive comments relating to loss of fertility. These women are likely to have lost trust in those providing their care, potentially leading to increased trauma.

'Total pain' was mentioned by a participant who experienced severe pain and the term was referred to by her oncologist to explain why her pain was so difficult to manage. This participant disagreed with the use of the term 'total pain' as she thought the oncologist was saying that the pain was in her head, but to her it was a real and physical pain. The concept of 'total pain' was first introduced by Dame Cicely Saunders, founder of the modern hospice movement and the discipline of palliative care. This concept suggests that distress (including pain) may have emotional, social and spiritual dimensions, not just the physical (Mehta and Chan, 2008; Saunders, 2000). In 2020, the International Association for the Study of pain (IASP) published a revised definition of pain which aims to convey the nuances and complexity of pain in their definition (Raja *et al.*, 2020). The key notes defined in the IASP definition include that:

> *"Pain is always a subjective experience that is influenced to varying degrees by biological, psychological, and social factors…Through their life experiences, individuals learn the concept of pain and its applications…A person's report of an experience as pain should be accepted as such and respected…Although pain usually serves an adaptive role, it may have adverse effects on function and social and psychological well-being"* (Raja *et al.*, 2020, p.7).

Some of these nuances and the complexity of pain were demonstrated in the narratives of the participants in this study. For example, some women explained how they coped with pain during brachytherapy in the context of a cancer diagnosis and previous health experiences. Another example is seen in the impact of their pain not being understood or believed by their carers. It is therefore important that healthcare professionals caring for brachytherapy patients have a good understanding of the complexity of causes, experiences and descriptions of pain and can use appropriate language to demonstrate their acceptance and respect for those reporting pain. Additional training may be needed so that healthcare professionals can provide appropriate pain management with consideration for the emotional, social and spiritual as well as physical aspects.

The introduction of more complex brachytherapy techniques, with the addition of interstitial needles and planning using MR imaging, has been accompanied by the development of more advanced anaesthesia and analgesia techniques (Petitt *et al.*, 2020). The use of interstitial needles has been reported to cause more pain compared with intracavitary applicators alone; possibly due to the more invasive nature of the procedure and the increased duration with applicators in place (Petitt *et al.*, 2020; Amsbaugh *et al.*, 2016; Janaki *et al.*, 2008). In this study all four recruitment centres had access to complex or hybrid techniques (intracavitary and interstitial applicators) and would have chosen the applicator type depending on tumour size and response to EBRT, recommended by international guidelines (Pötter *et al.*, 2018; Fokdal *et al.*, 2013). From women's accounts of brachytherapy, it was not possible to distinguish which of them had intracavitary applicators or the more complex hybrid applicators including interstitial needles with potential for higher levels of pain, as most participants did not know which type of applicators had been used for their procedures. It may be seen as a limitation of this study that differences in the experiences of women may have been related to the type of applicators used and may need further exploration in future studies.

Many studies have shown superior analgesia during brachytherapy with neuraxial anaesthesia, demonstrated in a meta-analysis and systematic review by Petitt *et al.* (2020). Neuraxial anaesthesia includes epidural, spinal and CSE techniques. Some studies have reported effective pain relief by using intravenous or epidural PCA for longer duration

brachytherapy procedures (Brown, 2018; Mendez *et al.*, 2017a; Shankar *et al.*, 2016; Xu-Welliver and Lin, 2013; Wiebe *et al.*, 2011). Some studies state that continuous analgesia is essential for ISBT (Amsbaugh *et al.*, 2016; Janaki *et al.*, 2008). There are a number of reports which state that there is no standard approach to anaesthesia and analgesia, even when more complex interstitial techniques are being employed (Amsbaugh *et al.*, 2016; Janaki *et al.*, 2008) and this lack of consistency is demonstrated across the four recruitment centres in this study. One recruitment centre in this study did not routinely use neuraxial anaesthesia. Their standard approach was GA followed by intravenous and oral analgesia, without the use of continuous or PCA. The other three recruitment centres used neuraxial anaesthetic techniques as standard treatment, and two of these centres also used PCA or a syringe driver with opiates for medium or long duration brachytherapy with overnight stays. One of these two centres was also able to provide epidural analgesia for long duration brachytherapy. For some participants it was difficult to ascertain which type of anaesthesia and analgesia had been used as terms such as spinal and epidural seemed to be used interchangeably. Participant's use of terminology for PCA, syringe driver or epidural was also unclear with some referring only to a 'pump'. Not knowing which type of anaesthesia and analgesia had been used for each interview participant may be seen as a limitation to the study as it was not possible to establish whether this related to their experiences. Future work would be needed to see what impact specific anaesthesia and analgesia regimes have on patient experience. Future work could be done to improve patient experience by exploring optimal anaesthesia and analgesia along with specific applicator types and duration of applicators in place.

Many interview participants spoke of the excellent treatment and care that they had received and expressed their gratitude for having been given a curative treatment. However, some participants gave examples of poor nursing care or a lack of consistency in care, especially those who had experienced overnight stays with applicators in place. This is similar to findings of inconsistencies in care between nurses, such as pain management and assistance with basic hygiene reported by Velji and Fitch (2001). Duncan, Mason and Thirlwell (2015) found a lack of standardised practice and variations in practice leading to inconsistent and fragmented care. Warnock (2005) gave examples of unhelpful care such as poor management of pain and inaccurate information about the duration of treatment.

Lying completely flat for long periods of time was problematic for some participants. One participant mentioned being given a 'wedge' after developing a pulmonary emboli with shortness of breath and it is possible that this could be explored for other patients and incorporated into a protocol for patient positioning. In an online discussion forum, UK brachytherapy radiographers discussed the use of the Oxford Help® pillow (known as an 'Oxford wedge') for obese patients or those having difficulty breathing. This is a 25 degree wedge-shaped head and shoulder support used in anaesthesia (Onrubia *et al.*, 2020) and may be beneficial to those having difficulty coping with lying flat including eating and drinking in a supine position. If a 25 degree angle is too steep for standard brachytherapy a lower angled wedge could be developed. Personal care was mentioned by some participants as lacking, not being offered help to wash face, hands or cleaning teeth. Some even developed pressure sores despite the use of an air mattress. This is likely to have been due to the lack of turning during brachytherapy reported by some participants. These findings suggest that there is scope to improve women's experience of brachytherapy through the development and implementation of standardised minimum care protocols. For example, ward staff making sure that food and drink are placed in reach, in suitable receptacles and offering help to patients where required.

Dzaka and Maree (2016) found participants had different views of the caring and supportive behaviours of healthcare professionals, with some experiencing the nurses and doctors as caring and comforting whilst others found them to be uncaring. Velji and Fitch (2001) found that some patients experienced nurses with an uncaring attitude and a lack of understanding about the 'ordeal' of LDR brachytherapy. In the current study there were examples of participants reporting a lack of compassion from some healthcare professionals. For example, one interview participant said the ward nursing staff showed an uncaring attitude and lacked compassion. Her justification for this judgement was that no-one noticed that she did not eat for three days during her inpatient stay for brachytherapy. Whilst it was only a small number of participants in the current study that reported dissatisfaction in the attitude of healthcare professionals, it is important to use these findings to ensure that future supportive care is consistently of an acceptable standard. It is not known whether the participant's negative experiences were related to insufficient allocation or under prioritisation of staff resources to meet the needs of brachytherapy

patients, or general staff shortages or deployment of bank or agency staff with less experience in caring for brachytherapy patients. It would be interesting to determine from a staff perspective what barriers to patient care exist and further research could be carried out to explore this aspect. The provision of additional healthcare professional's training in care and compassion to support patients and an understanding of the difficult nature of the treatment may be warranted to try to improve consistency of care. However, allocation of sufficient numbers of appropriately trained staff may also be an important factor which can impact on patient's experiences of care on the ward.

Some participants were reluctant to voice dissatisfaction during treatment as they felt indebted to the staff who were providing potentially curative cancer treatment. This dilemma has previously been identified in a study of women receiving HDR brachytherapy where it was reported that being thankful for receiving a potentially life-saving treatment inhibited open communication with the doctors about problematic experiences of brachytherapy (Kirchheiner *et al.*, 2014b). So and Chui (2007) identified 'growth' as an emergent theme in their study, suggesting personal growth as a way to cope with adversity, possibly achieved by reflecting on physical and emotional wellbeing after a difficult experience. They recommend a debriefing session is provided after brachytherapy, so that stress experienced during brachytherapy can be processed and to give an opportunity for patient growth. Considering the findings from this study, it may be beneficial to invite patients to give verbal feedback during brachytherapy so that improvements or changes to care can be made at the time. A debriefing session may help patients to process a problematic experience and provide an opportunity for healthcare professionals to learn from their feedback to improve services for future patients.

Many of the participants referred to resignation or acceptance of a procedure that they did not really want to have but knew was essential to get the best possible outcome. Brennan (2001) suggests that acceptance and resignation are helpful coping responses which cancer patients may draw upon to adjust to a diagnosis or endure a treatment. It is therefore important for the brachytherapy team to show understanding of this reluctant consent as patients have no real alternative for a cure from cervical cancer. Dzaka and Maree (2016) reported that having hope for the future was important to women going through

brachytherapy and this was also reflected in the resilience, determination and hope for curative outcome shown by many participants in this study.

The overall aim of this study was to examine women's experiences of brachytherapy. This included interviewing participants in two distinct groups, soon after brachytherapy or at one year after brachytherapy, to consider the impact of time on their views of treatment and recalled experiences. Within both groups there were some participants with poor recall and some were able to provide highly detailed accounts of their experiences. Comparing narratives and theme development, there was no distinguishable difference between the two groups. Experiences were variable, with both groups reporting positive, negative and mixed impact of brachytherapy on their recalled experiences. Current literature includes studies where interviews take place immediately after brachytherapy and Kirchheiner *et al.* (2014b) includes some interviews at three months after brachytherapy. However, examining experiences reported a year after brachytherapy in this study has given new insight into women's recall and longer term view of their brachytherapy experiences.

A study objective was to explore how treatment scheduling impacted on women's experiences. Participants were recruited from four UK sites where brachytherapy was delivered in different ways. This included centres using short duration (day case) regimes or long duration (inpatient) regimes including overnight stays with applicators in place for a longer time. In terms of medical complications and side effects during the procedure, the longer duration of brachytherapy appeared to negatively impact women's experiences. This was likely related to the need for more nursing and medical interventions over a longer time frame with applicators in place. For medium and long duration brachytherapy, patients spent considerably more time immobile, lying flat in a ward bed with applicators inside them and therefore there would have been greater requirements for nursing and medical care, including pain management and personal care. This may have provided more opportunities for these interventions to be inconsistent or suboptimal on some occasions, for some participants. Previous literature did not include patient experiences from more than one centre or where brachytherapy was delivered using different scheduling regimes. The findings from the current interview study therefore provide novel insights relating to the impact of different durations of brachytherapy procedures.

A further study objective was to explore ways to improve patient experiences of brachytherapy. Many participants provided suggestions of types of care or support that would have helped them cope better with brachytherapy or that they thought could potentially help other women having brachytherapy in the future. For example, ward staff, volunteers or visitors providing more help with eating and drinking while lying flat. Another example was sedation to help reduce anxiety during the theatre procedure or applicator removal. The breadth of suggestions for improvements has not previously been reported in the literature.

The original aim of this doctoral fellowship was to develop an intervention to reduce distress caused by brachytherapy for LACC. The participants' suggestions for improvements, along with descriptions of their lived experience of brachytherapy and published research data have shown that there is not one single intervention that would provide universal benefits or reductions to distress caused by brachytherapy. It has been found that distress caused by brachytherapy is due to complex interrelations between pain, anxiety and the wider context of the cancer diagnosis and treatment pathway. However, benefits could be provided through patient care recommendations or protocols for brachytherapy, to advocate for the delivery of consistent and standardised minimum care. Similar findings were reported in an information needs study and thereafter the development of guidelines for quality patient-centred care for South African women receiving HDR intracavitary brachytherapy (Long, Friedrich-Nel and Joubert, 2016a). Patient care recommendations could include a wide range of factors such as regular audits of pain and discomfort; development of specific anaesthesia and analgesia protocols to cover the key time points where pain may be increased; personal care, nutritional support and prevention of pressure sores and staff training needs.

Doctoral fellow reflections on interview experiences and data analysis

During data collection, I found the most distressing or disturbing narratives were from women who were younger and significantly impacted by loss of fertility. This was noticeable for those who already had children as well as for those who had no children. It is difficult to know if this was because the distress caused by loss of fertility resonated particularly

strongly with me, as a birth mother of three children, and a radiographer who had witnessed distress of younger patients during brachytherapy. It would be interesting to know whether these narratives would have the same impact on others hearing or reading about these experiences. Younger women potentially have more years of life to fight for, so a life-threatening diagnosis may have seemed to me to be more traumatic for younger people. However, a desire to get through the cancer treatment and a will to live was commented on by many participants, regardless of age. It is also possible that younger participants were more willing or able to express the impact of the procedure on their lives in terms of trauma distress. Their distress was shown in emotional language and tearfulness, which has been documented in the interview transcripts, and had an emotional impact on me as the interviewer. I considered contacting a clinical psychologist colleague who already provided clinical supervision in the clinical workplace, to explore any potential impact on my wellbeing, but then decided that it was not necessary. However, I found it helpful to discuss some of these interviews with my PhD supervisors, which provided me with an opportunity for debriefing and helped me to acknowledge my feelings in response to witnessing emotional narratives.

Reviewing the analytic commentary, I am aware that I have been less interpretive than I had initially hoped, coming perhaps unconsciously from a desire to stay close to the narratives of the participants, to avoid being too interpretive for fear of misunderstanding or misrepresenting the meaning of their words. This is more in keeping with a critical realist perspective, not as far along the continuum as the RTA interpretive and creative analysis described by (Braun and Clarke, 2019, Braun and Clarke,2022). Throughout the research process I have struggled with my tendency towards “positivism creep” , while at the same time striving to develop a “qualitative sensibility” so that I can carry out RTA effectively (Braun and Clarke, 2022, p.270). However, it is important to acknowledge that Braun and Clarke (2022) encourage and support some variations of RTA, emphasising that they are providing guidelines, not rules. Within their explanation of RTA, they accept variation along a continuum between inductive and deductive orientation to data, semantic to latent focus of meaning, experiential to critical in the qualitative framework and realist to constructionist in theoretical framework. They describe this variation as all contained within a Big Q orientation and following the RTA guidelines (Braun and Clarke, 2022, pp.4-24). To analyse

my own use of RTA, I would position myself towards the inductive end of the spectrum in relation to the data, with coding and theme development being driven by the data rather than existing theories. I tend to veer towards the semantic rather than latent focus of meaning, aiming to remain true to the narrative of the participants rather than interpreting underlying meaning. In the qualitative framework I tend to steer closer to the experiential end of the spectrum, aiming to portray participants' perspectives and understandings of their experiences. I find that I have naturally or unconsciously steered towards the realist rather than constructionist theoretical frameworks, to capture the reality expressed in the data rather than interrogating or interpreting the realities in the data.

4.6 Strengths and limitations

Completing 35 interviews with recruits from four NHS recruitment sites where brachytherapy is given with different regimes and across two different time frames after brachytherapy has led to a large dataset which demonstrates a wide range of participants' experiences and is a strength of this study. On analysis the doctoral fellow has found a richness and depth in the interview data from face-to-face and remote interviews. For qualitative research this is considered a substantial body of work which has led to a better understanding of women's experiences of brachytherapy in these UK settings.

A limitation to this study is that findings relied on participant recall. This could have led to a greater focus on the more distressing narratives which were more memorable, and may have implied a more negative patient experience. This tendency for better recall of negative or emotional experiences is referred to in research literature (for example Kensinger 2009; Baumeister *et al.*, 2001). It was clear from the interviews that there were some parts of brachytherapy that participants were unable to remember, indicating incomplete recall. However, interviews are commonly used to elicit patient experiences and memory of experiences are recognised as their interpretation and understanding of events. It is important to acknowledge that there was a diversity of experiences described and a spectrum of positive and negative experiences, even in the narrative of an individual participant. Inviting consecutive eligible patients to interview and carrying out interviews at

two discrete time points after brachytherapy was appropriate to ensure trustworthiness of the data.

A lack of member checking could be seen as a limitation to this study. However, as themes were developed across the whole dataset of 35 interviews, member checking would have been inappropriate as the themes would not necessarily reflect or resonate with the experience of an individual participant (Braun and Clarke, 2022). Member checking may also raise issues about how to respond to feedback, whether the doctoral fellow's completed analysis should be altered in light of feedback (Braun and Clarke, 2022). Instead, a summary of themes was sent to all interview participants, and some wrote back either confirming that the findings were similar to their own experience or that they felt lucky that their experience was not as bad as others had described.

A lack of data on anaesthesia and analgesia and type of applicator used for each participant may be seen as a limitation of this study, as it was not possible to relate experiences to these potentially contributing factors. However, this could have taken focus away from participants' experiences and been beyond the remit for a qualitative study.

A lack of data on ethnicity or other minority characteristics of participants may be seen as a limitation of this study. The recruitment strategy was to invite consecutive patients, chosen as the optimal way to recruit participants who represented typical demographics for patients having brachytherapy for LACC. The doctoral fellow's focus for recruitment and message to recruiting healthcare professionals was to be as inclusive as possible, to avoid excluding or not inviting people with disabilities, such as learning disabilities, hearing or visual impairments. Inclusivity was discussed with the Research Ethics Committee and approval for this recruitment strategy was given. Participant ethnicity data were not collected as there were concerns about the relevance to the research question and the information governance principle to only collect essential data was followed. No attempt was made to deliberately recruit participants from diverse ethnic backgrounds. At interview, one participant informed the doctoral fellow of her Eastern European origin, however her use and understanding of English language appeared excellent and there was clearly no need for a translator (an exclusion criteria). The doctoral fellow was not aware the ethnic

backgrounds of the remaining 34 participants. No data were collected on sexual orientation of participants, and no participants disclosed this information at interview. It may be considered as a limitation of the study that data regarding ethnic diversity and other minority group characteristics of the participants were not collected. Therefore it would be difficult to know whether experiences for these potentially under-served populations could vary from the recruited participants.

4.7 Conclusions

Through exploration and examination of interview participants' experiences, this study has described a new understanding of patient experience for modern brachytherapy in the treatment of LACC. This has included participants' experiences with intracavitary and interstitial techniques, different anaesthetic and analgesic techniques and day case and inpatient regimes with a range of procedure durations. A variability of experiences has been described, dependant mainly on information received, the quality of the care received and stresses related to contextual and environmental factors. This new understanding of these factors has provided a foundation on which to develop recommendations for patient care in brachytherapy for LACC.

Overall, patient experiences were reported to have been more problematic for those who had medium or long duration brachytherapy, likely to be related to the requirement for more medical intervention over the time spent immobile and lying flat with applicators in place. Consistent standards of care and support for the whole duration of the brachytherapy procedure are needed to improve patient's experiences and this may be helped through development and implementation of patient care recommendations for brachytherapy. The data from the interviews have indicated a wide range of factors that need to be considered for inclusion in future recommendations including pain management, personal nursing care, nutritional support and psychological support. Further work is warranted to inform the development of recommendations for consistent standards of care for women receiving brachytherapy.

Chapter Five: The development of patient care recommendations in brachytherapy for LACC including nominal group technique workshops (study three)

This chapter presents the rationale, aims, method, results and discussion for study three, the development of patient care recommendations in brachytherapy for LACC, including the use of nominal group technique (NGT) workshops.

5.1 Introduction and rationale

The SLR and update (chapter two) contains analysis of the evidence relating to women's experiences of brachytherapy. The UK survey (study one, chapter three) provided an overview of service provision, demonstrating the introduction of technological advances in brachytherapy and variations in scheduling and duration of brachytherapy. The semi-structured interviews with women who had received brachytherapy for LACC (study two, chapter four) provided a new understanding of women's experiences of modern brachytherapy techniques and highlighted episodes of inconsistent and suboptimal patient care. From the data, it was clear that clinical protocols or guidelines were needed to inform the delivery of consistent, quality standards of care for women receiving brachytherapy for LACC. The international guidelines and recommendations for the implementation of new brachytherapy techniques (MR image-guided ICBT and ISBT) focus on achieving high radiation doses to tumours and reducing doses to normal pelvic tissue (Mahantshetty *et al.*, 2019; Lee *et al.*, 2012; Viswanathan and Thomadsen, 2012; Viswanathan *et al.*, 2012a; Pötter *et al.*, 2006; Haie-Meder *et al.*, 2005; Nag *et al.*, 2002). However, none of the guidelines provide any detail about optimising patients' experiences of care whilst delivering these improved technologies. Therefore, the development of patient care recommendations in the context of advancement in brachytherapy techniques was warranted.

The development of clinical protocols and implementation of protocol-based-care was promoted by the Department of Health in The NHS Plan (2000) as a means of modernising the NHS and creating a high quality service (Rycroft-Malone *et al.*, 2010). Clinical protocols are an umbrella term for statements of clinical processes, including guidelines, care

pathways, procedures or codes of practice (Ilott *et al.*, 2006) and have been identified as an essential component for providing quality healthcare (Heymann, 1994). They may be introduced where evidence based information is lacking, and there is a need for a set of standards, rules or guidance for healthcare staff to follow in a specific setting (Heymann, 1994). They may be considered as descriptions of healthcare activities which identify the right thing to do and when it is appropriate to do it. They should be developed by the staff who are going to use them, ideally through a multidisciplinary collaboration (Heymann, 1994). The benefits of having clinical protocols include facilitation of shared care, by specifying which healthcare professionals are expected to provide a specific type of care for a patient and when it should be provided. Clinical protocols may assist in medico-legal protection by indicating minimum standards of care, and therefore it is advised that protocols should be written in a way which indicates realistic rather than idealistic standards (Heymann, 1994). They can be used for clinical audit, by measuring compliance with and variance from a protocol. There is also value in the process of developing of a protocol, requiring healthcare professionals to reach a consensus for a common approach, and encouraging multi-professional collaboration and agreement on shared goals (Heymann, 1994).

Clinician's views about the use of clinical guidelines and protocols remain highly controversial. Numerous limitations and potential for harm have been reported in the literature. Woolf *et al*. (1999) describe the potential harm to patients, clinicians and healthcare systems if guidelines are incorrect as well as the potential for them to lead to ineffectual or wasteful interventions. Multiple causes of harmful, ineffective or wasteful interventions are identified, particularly where there is a lack of high quality evidence, and guidelines are overly influenced by the opinions of individuals on a guideline group (Woolf *et al.*, 1999). Spence (2008) is highly critical of the proliferation of clinical guidelines, likening them to a set of IKEA flat pack instructions, with success dependent on who writes the instructions and who reads them. Some guidelines can be criticised for not supporting individualised care, sometimes viewed to be blanket recommendations rather than a menu of possible options. Some consider clinical guidelines to be too prescriptive, limiting shared decision making or allowances for patient preferences. Spence (2008) considers that overdependence on guidelines leads to 'mass production medicine', reducing clinical

judgement and discretion to a set of algorithms. Clinicians may have concerns that protocols will be used to performance manage them, with unfair judgements made by auditors or managers if protocols have not been followed (Woolf *et al.*, 1999). There are also concerns that guidelines can easily become outdated if they are not regularly updated in light of developments in practice and research evidence.

Canino, Baglioni and San Giovanni Battista, (2008) suggest that guidelines should be viewed as "handrails, not handcuffs", created to support healthcare professionals, patients and healthcare systems rather than shackling them with constraints and limitations. This view is reinforced by Bury (2008), who encourages clinicians to see guidelines as a '*guide',* aiding the inexperienced to follow best practice, and emphasising that they are not supposed or expected to be applicable for all patients or all situations.

Regardless of the quality or flexibility of clinical protocols or guidelines, their effectiveness will also depend on how well they are implemented in routine care (Rycroft-Malone *et al.*, 2010). Facilitators and barriers to implementation of guidelines were reported in a systematic meta-review (Correa *et al.*, 2020). Barriers to implementation included lack of credibility in the evidence, lack of clarity, and lack of a leader, teamwork or disagreement between colleagues. Clinicians reported a lack of knowledge or confidence in themselves along with lack of time or financial support. Facilitators to implementation included consistent leadership, team commitment and administrative support (Correa *et al.*, 2020). The review authors concluded that early consideration of potential barriers and facilitators should be undertaken to inform the development of implementation strategies when aiming for improvement in professional practice and health outcomes for patients.

In England, NICE is responsible for the development of evidence-based guidelines and recommendations, through committees which include expert clinicians along with lay people, and consultation with stakeholders. NICE also develop quality standards to indicate where service improvements are required and indicators to measure outcomes. In 2006, NICE published an interventional procedures guidance for HDR brachytherapy for cervical cancer (NICE, 2006). The guidance reported the safety and efficacy of HDR brachytherapy compared to LDR brachytherapy, along with indications for use and a brief description of

the brachytherapy procedure. The guidance endorsed the use of HDR brachytherapy for cervical cancer. However, the publication contained little detail about the procedure itself, and since 2006 there has been no update. There are no other NICE guidance documents relating to brachytherapy or radiotherapy for cervical cancer.

In 2014, it was reported that the NHS had been collecting data about patient experiences for over 10 years with a lack of translation into real improvements for patients (Coulter *et al*., 2014). Surveys such as the Friends and Family Test and the National Cancer Patient Experience Survey provide large quantities of data about NHS services and specifically cancer treatments. However, Coulter *et al*. (2014) reported no co-ordination of the patient experience data collected and difficulty tracking changes which were made in light of patient feedback. Knowledge mobilisation (KM) is a term that refers to the process from development of research or evidence to its assimilation into practice. KM refers to how these different forms of knowledge can be used in the real world, to change and inform practice or to justify decisions or policies. KM is most effective when it employs a collaborative approach, involving and engaging all the relevant stakeholders (Greenhalgh *et al*., 2016). Langley, Wolstenholme and Cooke (2018) describe KM in terms of 'collective making' as it provides opportunities for collective engagement leading to ownership of the outcomes.

Co-design is a term used to describe a collaborative, connective or co-operative approach to knowledge generation and implementation (Zamenopoulos and Alexiou, 2018). It may also be referred to as co-creation, participatory design or collective making (Sanders and Stappers, 2008). All these terms indicate a creative, dynamic and adaptive process in a community-academic partnership, where the community may be considered to be the key stakeholders (Langley, Wolstenholme and Cooke, 2018). The key principles are the recognition of the valuable knowledge that different stakeholders can contribute and the importance of equality or lack of hierarchy of the participants (Smith, Bossen and Kanstrup, 2017). The potential benefits to researchers, practitioners, research processes and research outcomes from the use of co-design in healthcare research are reported to be due to the prioritisation of research topics and refinement of research designs (Slattery, Saeri and Bragge, 2020). A spectrum of stakeholder engagement has been described, ranging from

limited engagement in decisions about research questions (such as a consultation exercise only) to participation in the "challenging, messy and unpredictable research co-production" process (Slattery, Saeri and Bragge, 2020, p.9). For this study, engaging with relevant stakeholders was recognised as an important component in the development of patient care recommendations to facilitate future implementation.

The key stakeholders identified for this study were brachytherapy service users (patients) and service providers (healthcare providers). Their participation in the decision making or prioritisation process for developing patient care recommendations was planned to be part of the project's KM strategy, to support the implementation of changes and service improvements. A co-design approach involving service users and providers has been shown to enhance implementation (Greenhalgh *et al.*, 2016; Chalmers and Glasziou, 2009). The principles of co-design are well suited to health services research, especially patient experience projects, where service improvement projects can benefit from the knowledge and experience of patients from their input throughout the whole research process.

Options such as Evidence Based Co Design (EBCD) and consensus methods such as the Delphi Technique and NGT were considered. EBCD has a good track record for leading to health service improvement and implementation, especially in cancer services (Donetto, Tsianakas and Robert, 2014). For example, EBCD was used to identify and implement patient-centred improvements during chemotherapy for head and neck cancers (Brady, Goodrich and Roe, 2020) and in breast and lung cancer services (Tsianakas *et al.*, 2012). However, the EBCD six-stepped approach is a rigid and lengthy process, usually confined to one clinical site, placing emphasis on the use of filmed interviews to promote the need for service improvements and typically taking 18 months to complete (Donetto, Tsianakas and Robert, 2014). With the exploratory stages of this programme of work already completed, video recordings of patient and staff interviews were not available and a programme in one clinical site would have been restrictive.

The Delphi Technique uses an expert panel to vote on issues/questions through repeated rounds of questionnaires to obtain a consensus view (McMillan, King and Tully, 2016; Cantrill, Sibbald and Buetow, 1996). This consensus method does not provide the

opportunity for interactive group work and is more appropriate for healthcare research seeking the views of an expert panel of healthcare professionals (Taylor, 2020). The remote nature and lack of interaction and opportunities for clarification and discussion between participants in a Delphi process may limit engagement in the knowledge mobilisation part of co-design, and therefore hinder the future implementation of the recommendations.

NGT is considered to be a mixed method approach, using qualitative techniques to obtain quantitative results (O'Neil and Jackson, 1983). It involves individual activity or expression of individual opinions within a group setting and is therefore known as a 'nominal' group technique. It is a consensus method which aims to obtain general agreement or converge opinion from people about a particular subject or problem, usually where insufficient evidence exists (McMillan, King and Tully, 2016). It is a useful tool in developing consensus guidelines (Jones and Hunter, 1995) and is one of the consensus methods recommended by Murphy *et al.* (2013) for creating clinical guidelines in evidence based healthcare. NGT can be used in healthcare to generate ideas for a solution to a question or help to determine priorities (Jones and Hunter, 1995). It involves highly structured meeting(s) of a group of 'experts' providing balanced participation from members of the group so that all voices and opinions can be heard. The 'experts' can be invited from relevant stakeholder groups and for this study, service users and healthcare professionals were considered the most appropriate. NGT is well suited for research that includes both health professionals and service users, since it allows for the free exchange of opinions and the generation of ideas within a structured and non-hierarchical discussion forum (Allen, Dyas and Jones, 2004). Therefore, NGT was chosen for this study, to enable interactive service user and healthcare provider involvement, following the principles of co-design and co-creation by aligning research with service improvement to optimise impact (Jones and Hunter, 1995).

NGT involves the use of workshops where participants are invited to individually rank items or issues before explaining and clarifying their choices in a 'round robin' stage, allowing all participants an equal voice (McMillan *et al.*, 2014; Potter, Gordon and Hamer, 2004; O'Neil and Jackson, 1983). One of the benefits of NGT when compared with focus groups is that the highly structured group work prevents dominance of louder voices and encourages quieter members to fully participate (McMillan, King and Tully, 2016). It is thought that

mixed groups of healthcare professionals and service users benefit from hearing each other's views (Allen, Dyas and Jones, 2004). This co-design approach prevents patient-only groups suggesting improvements that are not feasible and healthcare professional groups from making assumptions about what patients want and suggesting improvements that are not relevant or meaningful to patients (Allen, Dyas and Jones, 2004). The NGT has been used successfully for the development of national priorities in critical care (Vella *et al.*, 2000). The NGT ranking method was found to increase the level of consensus between participants compared with using questionnaires (Vella *et al.*, 2000). NGT was considered by Vella *et al.* (2020) to be beneficial through increasing polarisation, with participants voting more strongly for or against topics after discussion compared with pre-discussion voting. Vella *et al*. (2020) reported that some insights into reasons for lack of agreement were useful to the researchers.

In addition to the quantitative ranking data from the NGT workshops, Potter, Gordon and Hamer (2004) consider that the inclusion of qualitative data analysis can add valuable meaning and explanation of the quantitative results, through insights shared by the participants. Patton (2002) suggests the use of inductive content analysis to enable verification of the information from the meeting. Content analysis can be used to count numbers of comments to provide some quantitative account of the importance of the comments, such as how many participants expressed the same view. However, in a group situation counting or quantifying becomes problematic as it is not possible to determine how many participants agree with a stated view or opinion from another participant. For this study, with a workshop setting, inductive content analysis without quantitative data was considered appropriate.

NGT has been shown to be adaptable and versatile and it was anticipated that online workshops rather than the traditional face-to-face method would be an effective adaptation in view of the ongoing restrictions caused by the COVID-19 pandemic. There has been limited research literature about the use of online NGT workshops, however the recent COVID-19 pandemic has prompted researchers to begin to explore and assess feasibility. Michel *et al*. (2021) reported use of online NGT workshops as an effective method to achieve consensus from an international collaboration on developing a COVID-19

vaccination training programme in a timely and cost-efficient manner. In the light of the COVID-19 pandemic, Boland *et al*. (2021) carried out a rapid review of the use of videoconferencing in qualitative group research. They found many advantages of videoconferencing compared with face-to-face research, such as increased cost-effectiveness due to reduced travel costs and increased access to disparate participants. They also found literature detailing several potential disadvantages of using online NGT, such as difficulty building rapport, technical problems, privacy issues, extra planning requirements and the issue of equity of participant access to the required technology. Solutions to minimise potential disadvantages were suggested, such as online rapport building techniques, the use of headsets and muting microphones, promoting ground rules at the start of the meeting and careful facilitation such as clear instruction on taking turns in speaking. For this study, it was anticipated that online workshops would enable recruitment of service users and service providers from across the UK. With uncertainties of future COVID-19 restrictions, it was expected that online workshops would prevent any additional infection risks to participants from attending a face-to-face workshop and would be more convenient and appealing to some people.

For this study, to highlight the involvement of key stakeholders and the selected co-design method, the terms 'service user' and 'service provider' have been deliberately used instead of 'patient' and 'healthcare professional'. This is in contrast to the interview study where the term 'patient' aligns better with the collection of patient experience data and recruitment through NHS services.

5.2 Aims and objectives

The aim of this study was to develop and then prioritise potential recommendations for the care of patients receiving brachytherapy for LACC.

The objectives were:

- To draw up a list of potential patient care recommendations in brachytherapy for LACC.
- To consult with service users and service providers to develop useful, feasible and relevant recommendations.

- To consult with service users and service providers to review, refine and prioritise the list of potential recommendations.

5.3 Method

NGT workshops with key stakeholders were the main data collection method for this study. In phase one, a list of potential recommendations was developed, informed by the data from the literature review, study one and study two and with input from the supervision team and patient research partners. In phase two, the NGT workshops were carried out with key stakeholders.

5.3.1 Phase one: Drawing up a list of potential patient care recommendations

To be able to consult with key stakeholders, a list of potential recommendations was needed as a starting point for prioritising and refining. In an iterative process, the doctoral fellow used the survey and interview data, informed by the research literature, to begin development of a list of patient care recommendations. Using field notes from interviews, summaries of the 35 interview participants' experiences were written to systematically categorise all experiences which highlighted areas requiring improvement. This included cross checking and integrating with relevant coding categories in NVivo, such as coded excerpts for "suggested improvements". These findings were tabulated to display positive and negative experiences; helpful and unhelpful interventions; explicit suggestions for improvements and implied improvements inferred from interview participants' narratives. The full table developed from interview study data is shown in Appendix 16. The table contents were then converted into a standard or recommendation that might lead to the required improvement and reformatted as a list of points of recommendation, grouped under topic headings such as "information and support" or "facilities" or "nursing care on wards". The free text comments from the UK survey question in study one "*What do you think needs to be improved in your department in relation to women's experiences of brachytherapy?"* were amalgamated into the list of points of recommendation derived from the interview data. Previous doctoral research carried out by a clinical psychologist at the Medical University of Vienna and University Hospital Vienna included development of a new standard operating procedure to optimise tolerability of brachytherapy for LACC at the

Vienna brachytherapy centre (Kirchheiner, 2014). This standard operating procedure and published research literature were considered in the development of the points of recommendation. As day case and inpatient experiences led to different problematic experiences, the list was subdivided into "widely applicable" recommendations and "inpatient specific" recommendations. At this point, there were 37 potential recommendations for patient care. Following consultation with the supervisory team and patient research partners, some recommendations were broken down into shorter and simpler wording, leading to 51 potential recommendations. For the purpose of polling, these were renamed as short duration (day case) brachytherapy recommendations, with 29 recommendations, and long duration (inpatient) brachytherapy recommendations, with 51 recommendations. The short duration brachytherapy list was a subset of the long duration list (Appendices 24 and 25).

5.3.2 Phase two: NGT study design

The classic NGT involves four key stages (O'Neil and Jackson, 1983):

1. Silent generation (of ideas or individual responses to questions),
2. Round robin to state ideas, recorded on a flip chart (or whiteboard),
3. Clarification- facilitator checks their own and the participants' understanding and
4. Participant voting (ranking or rating).

The online platform Zoom was chosen due to its functionality (for example, whiteboard and voting) and widespread public use during the COVID-19 pandemic meaning that some participants would be familiar with it already. A University Zoom account was available to use where there was justification that other platforms were not suitable.

5.3.3 Sampling strategy and recruitment

Recruitment was purposively designed to include individuals with experience of brachytherapy from the patient or healthcare professional perspective. Service users who had previously taken part in the interview study (study two) were excluded as it was considered preferable to obtain wider experiences of brachytherapy. Service providers who had taken part in the survey (study one) were not excluded as this would have prevented most brachytherapy radiographers from participating.

Eligibility Criteria

Service users and service providers with experience of brachytherapy for LACC.

Inclusion criteria

- Service providers: Healthcare professionals with experience of working in brachytherapy for LACC in a UK setting at any time during the previous five years. It was anticipated that they would be from the following professions:
    - Clinical oncologists
    - Therapeutic radiographers
    - Nurses (ward, theatre, recovery or CNSs)
    - Anaesthetists
    - Clinical psychologists
- Service Users: Members of the public who had experienced brachytherapy for LACC in the last five years in a UK hospital, over 18 years old and able to communicate verbally in English
- Able to complete the online survey, able to access Zoom with use of both video and audio in a private space for the NGT workshop
- Having capacity to consent to take part in the study

Exclusion criteria

- Under 18 years old
- Lacking capacity to consent to take part in the study
- Unable to communicate verbally in English
- No experience of brachytherapy for LACC in the UK in the last five years.

Healthcare professionals were invited to take part in the study through professional contacts, for example through the Brachytherapy Radiographers Forum.

With the UK lifetime incidence of cervical cancer currently standing at one in 142, with approximately 3200 new cases per year (Cancer Research UK, 2022) this would not meet the definition of a rare disease, that is, incidence less than one in 2,000 in the general

population (Department of Health and Social Care, 2021). However, with UK annual incidence of new cervical cases at approximately 3200 per year and a third of cases presenting with locally advanced disease requiring radiotherapy including brachytherapy, LACC could be considered a low-incidence disease (Cancer Research UK, 2022). The significance of the low-incidence rates on recruitment is that advertising for research recruitment through print, radio and television would be unlikely to improve participation rates and likely to be costly (Fenner *et al.*, 2012). The use of social media has been shown to be a useful method for recruitment of under-served groups, such as those with low-incidence diseases and especially useful in engaging young women in health research (Gelinas *et al.*, 2017). The research steering group considered the options for recruitment strategies in light of the low prevalence of women with recent experience of brachytherapy and that the use of social media could be an effective recruitment tool.

The national charity 'Jo's Cervical Cancer Trust' displayed the study details including contact information on their website and in their monthly newsletter, 'Jo's Voices'. The Pelvic Radiation Disease Association (PRDA) emailed study information to their contacts who had expressed an interest in radiotherapy related research. Twitter was also used to advertise the research, using tags to alert some cancer charities to the tweet. This recruitment strategy used a combination of passive and active online recruitment. The placement of flyers and tweets is considered passive whereas charities emailing the research information to their members may be considered as active online recruitment, although not all their members would be eligible for the study (Gelinas *et al.*, 2017).

Service users and service providers with an interest in the research could contact the doctoral fellow by email. The subsequent reply included a hyperlink to a short survey via the Qualtrics survey platform to confirm eligibility. The survey included an online consent form (Appendices 22 and 23). The Qualtrics survey platform was chosen as this met the requirements for General Data Protection Regulations 2018 required by the University. The email also included the PIS (Appendices 20 and 21) and privacy notice.

Size of sample

The plan for each NGT workshop was to have up to four healthcare professionals and four service user participants. In the literature, the size of a NGT group varies from two to 24 participants (Wood *et al.*, 2021;, Mc Sharry *et al.*, 2016; McMillan, King and Tully, 2016), however typically between six and twelve participants are recommended (Harvey and Holmes, 2012; Pastrana *et al.*, 2010; Jones and Hunter, 1995; O'Neil and Jackson, 1983) and some warn against exceeding ten participants (Cantrill, Sibbald and Buetow, 1996; O'Neil and Jackson, 1983). It has been proposed that less than six participants could limit the reliability of group judgements or decisions, with potential for outcomes to be overly influenced by unusual or individual opinions or experiences, although there is little evidence to demonstrate this in practice (Murphy *et al.*, 2013). However, the reliability of group judgements could be increased by holding multiple meetings with small numbers of participants, to increase the pool of views or experiences included overall (Cantrill, Sibbald and Buetow, 1996). Conversely, too many participants could make it difficult to monitor individual participation, for either face to face or online workshops (Mc Sharry *et al*., 2016). The larger the number of participants, the longer the duration required to allow all members to contribute in the 'round robin' stage. To provide a balance of service providers and service users and enough participants for an effective group that would be manageable using an online meeting platform and an acceptable meeting duration, eight members per workshop were chosen for this study. However, if any members were unable to take part at the last minute, the workshop would still go ahead with a minimum of four members and an uneven number of service providers and users would be accepted. If less than four members were available, it was planned that the workshop would be rescheduled.

To enable a meaningful analysis of voting or ranking data, total numbers of participants can be increased by running sequential groups where questions are refined or changed for the different groups (Wood *et al*., 2021; Tillett *et al*., 2017). For this study, up to four sequential NGT workshops were planned to provide contributions from up to 32 participants, to include a reasonable representation from across the healthcare professions involved in providing brachytherapy services and from service users across the UK. This was not aiming for statistical representativeness, but an attempt to include participants with a range of

views and experiences of brachytherapy. The final number of participants and workshops was determined by the number of potential participants completing the online Qualtrics questionnaire including consent form, their availability to attend a workshop at the same time as other participants and the required combination of service users and service providers from different professions to enable an effective workshop.

If numbers permitted it was proposed to select participants from across the professional groups to be evenly represented in workshops, to include services users with a range of ages and to have separate workshops for day case and inpatient brachytherapy techniques.

For similar reasons given in the qualitative patient interview study (study two, chapter four), the doctoral fellow and PhD supervisory team considered the option of incentivisation, to promote recruitment, but there were concerns that this could be counterproductive by reducing 'intrinsic altruistic motivation' (Zutlevics, 2016). As participants would not incur any travel expenses, no payment was offered.

5.3.4 Ethical considerations and approvals process

There was a low risk of harm to service user participants that by recalling their experience of brachytherapy, they may become upset or distressed during or after the workshop. The doctoral fellow provided mitigation against the risk of causing distress or re-traumatisation by including signposting at the end of each workshop to support from their clinical team and local and national support services. The only potential benefit for service user participants was the altruistic reward of being involved in a study which aims to improve services for future brachytherapy patients. There was no anticipated risk to healthcare professionals taking part in the workshops, other than use of their time and using a Visual Display Unit while taking part in the online meeting. A risk assessment was carried out and the mitigation plan submitted with the ethics application.

Ethical issues regarding the equity of the recruitment strategy were considered. The doctoral fellow and supervisory team were aware that recruitment through cancer charities and social media may lead to potential participants coming forward from a younger age group or those with more socio-economic resources, as they might be more likely to access

online support from charity run websites and social media (König, Seifert and Doh, 2018). However, this was balanced by the need for participants to be able to use a videoconferencing platform for the workshop, to interact effectively in the four step NGT process including online polling. Topolovec-Vranic and Natarajan (2016) reported a rise in people accessing social media sites with increasing numbers of older people using Facebook. They acknowledged the potential for successful recruitment to research studies through social media, including under-served groups, low-income populations and those with a specific medical condition. However, overall effectiveness of recruitment through social media was found to be variable, depending on multiple factors including age and sex (Topolovec-Vranic and Natarajan, 2016). Layi *et al*. (2011) found social media to be a highly effective tool when recruiting cancer survivors to an intervention study, with participant mean age of 52 and 82% female. However, Gelinas *et al.* (2017) reported that there was no specific regulatory guidance for recruitment through social media and little information regarding potential ethical issues. The main ethical issues that they suggested were respect for the privacy of social media users and investigator transparency. For this study, care was taken to avoid social media users being identified by their medical condition. The methods of online recruitment required individuals to contact the doctoral fellow directly and their eligibility was checked through a secure online mini questionnaire, so privacy and data security was ensured as far as possible. The nature of the online support group with service user membership limited to those with a diagnosis of cervical cancer meant that privacy about their cancer diagnosis and investigator transparency may have been an issue. However, for this study the patient research partners and one study recruit posted the research information on support groups where they were already members. The doctoral fellow did not attempt to join any support groups.

Due to the use of videoconferencing in a group setting, consideration was given to the maintenance of the privacy of workshop participants. Participants and facilitators were advised to find a quiet and private location for taking part in the workshop, avoiding others being able to see their screen and using headsets if not in a private room. Participants were informed that they could type in a pseudonym on arrival at the Zoom meeting, if they wanted to remain anonymous to other participants. They were informed that their names and locations of where they had treatment or worked in brachytherapy would not be

included in any workshop reports. At the start of each workshop, all participants were reminded of workshop ground rules, including that participants' names and brachytherapy centres should not be mentioned outside of the workshop. A data management plan was completed, documenting how participants' identities would be protected and data stored and maintained, following UWE Bristol research governance policies.

The Qualtrics survey asked potential participants at which centre(s) they had experience of brachytherapy, so that service users would not be allocated to the same workshop as healthcare professionals who may have cared for them. This was seen as a potential ethical conflict as it may cause distress to a service user or lead to participants feeling uncomfortable speaking about their experiences of brachytherapy. The research steering group agreed that this should be avoided when allocating participants to specific workshops and clearly stated in the recruitment information and PIS that this would be avoided.

Health Research Authority and NHS Research Ethics Committee (REC) approval was not required as the service user participants were not recruited through the NHS and healthcare professionals were recruited through their membership of a relevant profession. Between June 2021 and October 2021 documents were prepared for application to UWE Health and Applied Sciences (HAS) Faculty Research Ethics Committee (FREC). UWE HAS FREC approval was received on 1st December 2021, UWE REC REF No: HAS.21.10.020 (FREC letter of approval-see Appendix 17). A list of documents submitted is shown in Table 22.

Table 22 Documents submitted to UWE Faculty ethics committee (study three)

Ethics application form
Research protocol
Participant information sheet (PIS) for service providers (Appendix 20)
Participant information sheet (PIS) for service users (Appendix 21)
Recruitment information for service providers (Appendix 18)
Recruitment information for service users (Appendix 19)
Service providers Qualtrics survey, including consent form (Appendix 22)
Service users Qualtrics survey, including consent form (Appendix 23)
Privacy notice
Risk assessment (UWE)
Research data management plan (UWE)
Draft recommendations for short duration brachytherapy workshop (Appendix 24)
Draft recommendations for long duration brachytherapy workshops (Appendix 25)

A script for the NGT workshop was developed including an introduction, explanation of ground rules and the planned schedule.

Consent

A consent form for the NGT workshop was included in the Qualtrics survey (Appendices 24 and 25). At the start of the NGT workshop participants were reminded that they had consented to take part in the study, asked for verbal consent for the workshop to be recorded and given an opportunity to withdraw from the study at this point. Consent for both audio and visual recording was obtained as the Zoom platform does not enable separation of these at the point of recording.

5.3.5 Data collection and analysis

NGT workshops were completed using the online videoconferencing platform, Zoom. In advance of the meetings, the workshop members were sent an email outlining the NGT process, ground rules around confidentiality, respect and protection of participants' identity. Workshop members were provided with a list of the potential recommendations developed from the exploratory data. These were grouped under headings in a similar format to the polls that were used in the Zoom meetings, including some explanatory notes about some of the potential recommendations. Workshop participants were asked to read through the list of potential recommendations prior to the meeting and make notes on any suggestions for amendments to wording or additions of new recommendations. The workshops were facilitated and led by the doctoral fellow and supported by the research partners. The workshops were audio and video recorded through the online platform to assist in the accurate documentation of outcomes. Each workshop was two hours long with a scheduled short comfort break.

The following process was followed at each NGT workshop:

- Stage 1- initial voting and silent generation
    - Participants were shown up to 10 recommendations at a time and asked to carry out initial voting on the importance of each point of recommendation, ranking them using a 4-point scale: 1. Not important/not relevant; 2. Slightly important; 3. Important; 4. Very important. Polling was carried out using the

Zoom polling function. The participants were given the opportunity to ask questions at the start of each section of voting.

  - Participants were asked to make a note privately of any suggestions for additional recommendations (silent generation of ideas).

- Stage 2- round robin
  - The results from the initial voting were shared with the group.
  - In a round robin process participants were asked if they wanted to add or amend recommendations, ensuring all voices were heard and diverse opinions sought and documented.
  - The doctoral fellow made notes of suggested changes.
- Stage 3- clarification
  - A discussion on the potential recommendations was facilitated by the doctoral fellow and patient research partner(s), including checking understanding of each recommendation, any amendments needed to the wording used and any new recommendations added. Care was taken to ensure all participants were given an opportunity to contribute. During a short break the doctoral fellow amended the polling questions to reflect the changes made during the discussion stage.
- Stage 4- prioritisation by participant ranking
  - A new list of potential recommendations (from previous voting and new ideas) was presented to the group.
  - Participants were asked to vote again on the new list of recommendations using the same 4-point scale as before (intra-group ranking) via the Zoom polling function.

Participants' contributions using the online voting tools were saved within the Zoom software and subsequently transferred to a Microsoft Excel spreadsheet. As new ideas were generated in each workshop, these were incorporated into that workshop's final ranking of potential recommendations, so the list of potential recommendations presented to the next workshop could be slightly different to the previous workshop, becoming part of an iterative process to refine the list. Voting outcomes/rankings were summed across all the NGT workshops to derive the rank order at the inter-group level, following examples in the

literature (McMillan *et al.*, 2014; Hiligsmann *et al.*, 2013; Sanderson *et al.*, 2010; Van Breda, 2005). Data are presented as a percentage of the maximum possible priority score (number of participants × 3 points x 100).

The Zoom video recordings were reviewed by the doctoral fellow and notes taken of the key points made by all participants at each stage of the workshop. The notes were tabulated, and inductive content analysis carried out by the doctoral fellow through identification of patterns of meaning and consistencies in the data. It is important to recognise that the qualitative data reported here is an adjunct to the quantitative data captured through the voting stages. The inclusion of inductive content analysis has allowed an optimisation of participants' contributions to the workshops, using all the available data. The qualitative data reported in the results section represents the thoughts and reflections of the doctoral fellow arising from standing back from the data, rewatching the workshop recordings with an analytical stance.

5.3.6 Pilot workshop

A pilot workshop was carried out to test the NGT process, for example, to check the Zoom polling function; the generation and accessibility of data; time the duration of each NGT phase and obtain feedback from pilot participants. Prior to the pilot workshop the potential pilot participants were sent an email invitation with an explanation of the aim of the pilot workshop, the study PIS and privacy notice and hyperlink for a pilot version of the short survey to check eligibility and consent via the Qualtrics survey platform. Eight individuals were invited to take part. Four of the eight worked with the doctoral fellow including: a radiographer; an oncologist; an anaesthetist and a clinical psychologist; two were radiographer colleagues from other UK centres and two were patient research partners who had agreed to take on the role of service users for the pilot workshop.

Pilot workshop results

Seven of those invited successfully completed the short survey, showing that eligibility and consent could be verified though the Qualtrics survey platform. There was no response from the remaining individual. The survey options for ascertaining availability of participants showed that finding a suitable time to schedule the pilot survey would be problematic.

There was no day of the week or time identified when all seven participants could be available. After numerous emails with potential participants and several proposed and cancelled dates, a date and time was agreed where six potential participants were available. On the day of the workshop one potential participant withdrew due to a last-minute recall to clinical work. Five participants took part in the pilot workshop.

The use of the long duration brachytherapy recommendations with 51 patient care recommendations was chosen for the pilot workshop, to indicate the maximum time needed to complete polling. Some stages of the workshop took longer than anticipated with some informal chatting and a delay due to difficulties for one participant joining the meeting and another participant having problems with audio. The round robin stage inadvertently merged into the discussion stage as some participants and the doctoral fellow responded to individual comments before the discussion stage began. The Zoom polling function worked, with editing recommendations being completed by the doctoral fellow during the scheduled break, in time for the repeated polling after the break. Wording changes for four recommendations were suggested. Inviting participants to write on the whiteboard during the discussion stage did not work well. One participant could not access the writing tools. Participants could not see the list of recommendations unless they were using two screens or had printed them prior to the workshop. This led to an unsystematic approach when making changes to the list of recommendations. There was not enough time to complete the full set of second polling, due to the late start and previous stages overrunning. Data from both polls were recorded on an excel spreadsheet and were accessible from the Zoom cloud. The video and audio recording were downloaded to the UWE OneDrive and were shared with the PhD supervisors.

Feedback from pilot participants and PhD supervisors

There were some discussions during the pilot workshop about the large amount of time taken for polling. Questions arose regarding the relevance of the second polling and whether participants should be influenced by the workshop discussion when completing the second poll. The doctoral fellow discussed these questions with PhD supervisors and concluded that the initial and final polling were both essential and that the influence on voting that may occur during the discussion stage was a key component of the NGT process.

One participant suggested clarification in the wording of the recommendations to indicate who they were aimed at, the brachytherapy team or wider service providers. It was suggested that the invitation email should suggest that participants may find printing the list of recommendations prior to the workshop a useful aid or consider using screen sharing of the list instead of the whiteboard function. The draft script, list of recommendations and workshop instruction email were amended to incorporate this feedback.

Doctoral fellow reflection on pilot workshop

Overall, I felt that the pilot workshop had gone well. Although I was nervous, especially about the online technology, I managed to get the polling and editing functions to work. I decided to practice with the whiteboard function prior to the first workshop and consider the screen sharing as an alternative option to document any suggested changes during the discussion stage. I realised that I would need to improve my facilitation skills through being firmer regarding timing, sticking to the schedule and not allowing participants and facilitators to voice their comments during the round robin stage, as this had contributed to the overrun. I also needed to be mindful of not adding my own comments! After the pilot workshop I scripted some phrases that I could use to politely bring participants back to task or move on to another participant.

5.4 Results

Three NGT workshops were carried out over a five-week period during March and April 2022. A total of 13 participants took part in the workshops. Numbers of service providers and service users per workshop are shown in Table 23. The service providers were from three different healthcare professions: one clinical oncologist; three nurses and four radiographers. At the first workshop two patient research partners co-facilitated with the doctoral fellow. The five service users had received brachytherapy at four different UK brachytherapy centres, with two having experienced short duration and three long duration brachytherapy with at least one overnight stay with applicators in place. The eight service providers had worked in six different UK brachytherapy centres, four having delivered short duration and four long duration brachytherapy. Overall, participants had experience of brachytherapy at nine UK brachytherapy centres. At the following two workshops, one patient research partner co-facilitated with the doctoral fellow.

Table 23 Workshop service user and service provider participant numbers

	Workshop 1	Workshop 2	Workshop 3	Total
Number of service users	2	2	1	5
Number of service providers	3	2	3	8
Total number of participants	5	4	4	13

Service user recruitment took place over a four-month period, beginning in December 2021 with research information being advertised on Jo's Cervical Cancer Trust website and monthly newsletter emailed out to members. This resulted in only one service user enquiry. In January 2022, the doctoral fellow tweeted the research information which was then retweeted by Jo's Cervical Cancer Trust. This created a cascade effect through retweets and Facebook posts by several cancer charities and their followers, leading to a wider reach. For example, the cancer charities Jo's Cervical Cancer Trust, Shine Cancer Support, GO Girls (Gynae-Oncology), The Eve Appeal, and Grace Charity (Gynae-oncology, Research and Clinical Excellence) retweeted the original tweet which some of their followers retweeted. This led to 22 email enquiries from potential service user recruits. Some enquiries were from service users who were ineligible for the study for a variety of reasons, such as having brachytherapy in non-UK centres, too nervous to join a group, too nervous to use Zoom, brachytherapy was more than five years ago or had a hysterectomy before brachytherapy. Ten potential service user workshop participants completed the consent form via the online Qualtrics survey. One survey respondent was a service user who had brachytherapy in the centre where the doctoral fellow provides clinical care and was therefore informed by email that this would be a potential ethical breach, meaning that she could not take part in a workshop. Of the nine remaining individuals, four were unable to take part in a workshop due to time limitations from their work commitments, being unwell with COVID-19, colleagues being absent with COVID-19 or not feeling mentally strong enough to take part. There were some last-minute changes of availability or withdrawals which led to workshops being rescheduled or cancelled on the day. Completed online survey responses were from service users who had received brachytherapy in England, Scotland and Northern Ireland. Final workshop service user participants were from England and Northern Ireland.

Service provider recruitment took place between January and March 2022. Overall, 24 service providers completed the consent form on the Qualtrics survey with 22 complete responses. Two responses were incomplete, with no name or contact email address and were therefore unusable. The respondents were from a variety of healthcare professions. Two responses were from clinical oncologists, 12 radiographers, six nurses, one operating department practitioner and one anaesthetist. Seven respondents were from a single brachytherapy centre and four respondents from another centre. Survey responses were from service providers working in brachytherapy centres in England, Wales and Northern Ireland. Final workshop service provider participants were from England and Northern Ireland.

Scheduling workshops with up to eight participants, with a maximum of four service users and four service providers from different professions was problematic. Service providers generally indicated very few time slots for their availability during typical working hours and many did not indicate any availability at evenings or weekends. Many of the service users indicated more availability at evenings or weekends with less availability during typical weekday working hours. Some potential service provider participants provided brachytherapy at the same centres as some of the potential service user participants, so care was taken to avoid inviting them to the same workshop, further limiting potential availability of participants. Over a four-week period, between seven and eight potential participants were invited to one of three proposed workshop dates and times with as close a match to their indicated availability as possible. For workshop one, seven participants confirmed availability for a late afternoon meeting on a specified date and a pre-workshop email was sent (Appendices 18 and 19), including Zoom workshop joining instructions, guidance on maintaining privacy and confidentiality and the list of patient care recommendations for long duration brachytherapy (Appendix 25), PIS (Appendices 20 and 21) and privacy notice as attachments. Two potential participants did not join the workshop. For workshop two the process was repeated with six potential participants confirming availability for an evening meeting on a specified date. Two potential participants did not join the workshop. For the third workshop, an early afternoon meeting was planned with six participants including two service users. The day before the workshop one service user withdrew, leaving only one service user. This potential participant decided to withdraw as

she was not confident being the only service user at the workshop. The workshop was rescheduled for a week later when two other service users would be available. On the day of the rescheduled workshop, one service user withdrew, but the remaining service user was happy to continue with the workshop regardless of being the only service user. It was not possible to schedule workshops with participants who all had experience of short duration brachytherapy or long duration brachytherapy, so all workshops had a mixture of short and long duration participants. Therefore, the long duration patient care recommendations were used for the initial and final polling for all workshops.

Polling

The first workshop began with participants rating 51 potential patient care recommendations. At this workshop, four additional recommendations were agreed by the participants, so the second polling included the additional recommendations. Wording amendments or further text for clarification were added to 15 recommendations. The new list of 55 recommendations was used for initial polling at workshop two. At this workshop, wording was amended to one recommendation and no new recommendations were developed. This amended recommendation list was used for the second poll. The amended list of recommendations from workshop two was used for the initial polling at workshop three. Wording amendments or text for clarification for three recommendations were agreed at workshop three and were taken forward for the second polling (see Table 25 for new and amended recommendations).

Polling results from the second poll at each workshop were summed and calculated as a percentage of the maximum score possible. Three points were allocated for *"very important"* responses; two points for *"important"*; one point for *"somewhat important"* and no points for *"not important/not relevant"*. Over the three workshops, 25 recommendations received a score of 100%, the maximum possible score, showing that all participants across the three workshops voted *"very important"* for these 25 recommendations. Overall, 46 recommendations received a score of 90% or above and nine recommendations received a score of less than 90% with the lowest score of 74%. On further analysis it was found that scores stayed the same between poll one and two for 39%, 42% and 65% of recommendations in workshop one, two and three respectively. The scores increased

(greater importance indicated) between poll one and two for 55%, 47% and 29% of recommendations in workshop one, two and three respectively. The scores decreased (lower importance indicated) between poll one and two for 6%, 9% and 5% of recommendations in workshop one, two and three respectively.

When votes from second polls across the three workshops were grouped by participant type, service users versus service providers, there was no significant difference seen in voting patterns. There was a maximum of 0.5 points difference by participant type, when scores were averaged across the service user group and compared with the service provider group. Sixteen recommendations were scored slightly higher by the service user group compared with service provider group, but this averaged at only 0.24 points difference between the groups. Seven recommendations were scored slightly higher by service providers but averaged at only 0.28 points difference between the participant groups. The recommendation with the largest variation between service users and service provider scoring was Recommendation 5.2, regarding training for nurses in nutrition requirement for patients during brachytherapy. Service users gave this recommendation 17% higher scores (more important) compared with service providers (see Appendix 27).

When votes from second polls across the three workshops were grouped by brachytherapy type, short duration experience versus long duration experience, there was no significant difference seen in voting patterns. There was a maximum of 0.9 points difference by brachytherapy type, when scores were averaged across the short duration brachytherapy group and compared with the long duration group. Sixteen recommendations were scored slightly higher (more important) by the long duration brachytherapy group compared with short duration group, but this averaged at only 0.29 points difference between the groups. Eight recommendations were scored slightly higher (more important) by short duration brachytherapy group but averaged at only 0.16 points difference between the groups. The biggest variation in results between short and long duration brachytherapy groups was seen for recommendations 4.6; 7.7 and 7.4. Recommendation 4.6 was scored 17% higher by short duration brachytherapy participants compared with long duration brachytherapy participants and related to provision of information about support groups after brachytherapy. Recommendation 7.4 was scored 17% higher by short duration

brachytherapy participants compared with long duration brachytherapy participants and related to provision of complementary therapies during brachytherapy. Recommendation 7.3 was scored 18% higher by long duration brachytherapy participants compared with short duration brachytherapy participants and related to provision of ward facilities such as an angled tray to read and iPad. See Table 24 for polling results for the second poll at each workshop. For first and second poll results see Appendix 26. For poll results by short duration versus long duration brachytherapy experience see Appendix 28.

Of the nine recommendations which received overall scores lower than 90%, six recommendations were in poll 7, relating to facilities on wards. For example, offering a choice of a single or shared wardroom, complementary or relaxation techniques and facilities to help women pass the time while lying flat for long periods of time.

Table 24 NGT Workshop polling results (2nd poll)

Original recommendation wording, with additional recommendations denoted by *

Number of participants at WS 1 = 5; Number of participants at WS 2 = 4; Number of participants at WS 3 = 4 Scoring 4-point scale: 1. Not important/not relevant = 0 points; 2. Slightly important = 1 point; 3. Important = 2 points; 4. Very important = 3 points		WS 1 % Score	WS 2 % Score	WS 3 % Score	Mean % Score
Poll 1: Pain management					
1.1	Each centre should have a protocol for anaesthesia for applicator insertion, including options for anaesthesia for different types of applicators and adaptations to meet the needs of individual patients.	100	100	100	100
1.2	Each centre should have a protocol for pain management in theatre recovery, including options for pain and relaxant medication for different types of applicators and to meet the needs of individual patients.	100	92	82	91
1.3	Each centre should have a protocol for pain management on the ward for the duration with applicators in place, including options for continuous flow or patient-controlled pain medication and breakthrough pain to meet needs of individual patients.	100	100	100	100
1.4	Each centre should have a protocol for pain management for applicator removal to meet the needs of individual patients (fully informed of procedure).	100	100	100	100
1.5	Each centre should provide individualised advice on short term pain management before discharge from hospital.	100	100	100	100
Poll 2: Medication for anxiety and distress/Management of anxiety and distress[8]					
2.1	The protocol should include consideration of medication or other interventions to reduce anxiety while staying on the ward or at home the night before brachytherapy.	100	92	100	97
2.2	The protocol should include consideration of patient request or need for drugs or other interventions to reduce anxiety and distress when coming into theatre.	100	100	100	100
2.3	The protocol should include consideration of patient choice or need for drugs or other interventions to reduce their awareness of the theatre procedure.	100	92	100	97
2.4	The protocol should include consideration of patient choice or need for drugs or other interventions to help patients sleep when on the ward for long duration brachytherapy.	100	67	100	89
2.5	The protocol should state the minimum frequency or threshold for pain, anxiety and distress to be reviewed by senior brachytherapy clinicians or senior ward clinicians.	93	100	92	95
2.6	The protocol should include frequency of ward rounds with oncologist and nursing staff for regular review and management of pain, anxiety and distress, in addition to personalised reviews at times needed by the patient.	93	92	100	95
2.7	The protocol should Include consideration of patient request or need for drugs or other interventions to reduce anxiety and distress during applicator removal.	100	100	100	100
2.8	The protocol should include consideration of patient choice or need for drugs or other interventions to reduce their awareness of applicator removal.	100	92	100	97

[8] The title of poll 2 was changed during workshop 1

Number of participants at WS 1 = 5; Number of participants at WS 2 = 4; Number of participants at WS 3 = 4 Scoring 4-point scale: 1. Not important/not relevant = 0 points; 2. Slightly important = 1 point; 3. Important = 2 points; 4. Very important = 3 points		WS 1 % Score	WS 2 % Score	WS 3 % Score	Mean % Score
Poll 3: General medical management					
3.1	Each centre should have a protocol for prevention and treatment of nausea and vomiting, including additional medication options and adaptations when medication does not work, and consideration of non-medical options.	100	100	100	100
3.2	Each centre should have a protocol for prevention of severe infection, including the level of blood count where preventative antibiotics should be given and the level of infection risk with different applicator types.	100	100	100	100
3.3	Each centre should have a medical pre-brachytherapy assessment protocol, including when doctors should discuss individual cases to weigh up the risks and benefits of brachytherapy and any adaptations needed.	100	100	100	100
3.4	Senior brachytherapy clinicians should consider change of regime/technique or no brachytherapy if there are significant medical or psychological trauma risks.	100	100	100	100
3.5	Each centre should provide a late effects service, to help with possible long term side effects of treatment such as pain, bowel, bladder and sexual problems in the months and years after completion of treatment.	100	100	100	100
3.6	Each centre should have a protocol regarding patient positioning and where possible to avoid keeping patients in a totally flat position.	100	83	92	92
3.7	Each centre should have a protocol for prevention of blood clots, including risk assessments, how often to re-assess risk and the use of preventative medication and mechanical devices (such as stockings or alternative devices).	100	100	100	100
3.8	Each centre should provide training for brachytherapy clinical staff on pain assessments and understanding individual pain experiences, including the impact of psychological trauma and mental health history, previous pain and analgesia history.	100	100	100	100
3.9	Each centre should have a strategy for prevention of pressure sores.	100	92	100	97
Poll 4: Information and support					
4.1	Each centre should allocate appropriate time/resources to patient-centred pre-brachytherapy information and support, including a realistic explanation of the procedure and range of experiences of those who have had it.	100	100	100	100
4.2	Each centre should provide training for the brachytherapy clinical team on potential psychological trauma of cervical cancer diagnosis and triggers for trauma during treatment, especially for brachytherapy.	100	100	100	100
4.3	Individual risk assessments to be carried out for potential trauma during brachytherapy, considering factors such as age, social history, previous pain/medication history, mental health, coping mechanisms, and adaptations/access to specialist support.	100	100	100	100
4.4	Each centre should provide written and verbal advice at the point of discharge from hospital on management of post treatment side effects and information on accessing help and support.	100	100	100	100
4.5	Each centre should provide support to patients after completion of brachytherapy, such as a telephone call a few days after discharge home, offering a debriefing session to talk through what happened and offering advice on management of aftereffects.	100	100	100	100

Number of participants at WS 1 = 5; Number of participants at WS 2 = 4; Number of participants at WS 3 = 4 Scoring 4-point scale: 1. Not important/not relevant = 0 points; 2. Slightly important = 1 point; 3. Important = 2 points; 4. Very important = 3 points		WS 1 % Score	WS 2 % Score	WS 3 % Score	Mean % Score
4.6	Each centre should provide information about patient support groups that the individual can access after completion of cancer treatment.	100	94	100	94
4.7	Each centre should provide assessment of the need for psychological support after brachytherapy and be able to provide this or refer patients as needed.	100	100	100	100
4.8*	Pain management, methods, and potential side effects should be discussed with patients before, during, and after treatment, with level of detail and choices offered as appropriate.	93	100	100	98
Poll 5: Patient care/ward nursing care					
5.1	Ward nurses should offer advice and support in relation to eating and drinking while applicators are in place.	100	100	92	97
5.2	Ward nurses should receive training about nutrition requirements and the need to monitor patients during brachytherapy to ensure they are supported to eat.	100	92	75	89
5.3	Wards should provide access to someone for the patient to communicate with when lying flat with applicators in place, especially if visiting is restricted.	100	100	83	94
5.4	Ward nurses should check in on patients at regular frequent intervals and provide support through the night if patients are unable to sleep due to pain/discomfort/distress.	100	92	100	97
5.5	Ward nurses should offer help and support with personal care.	100	100	100	100
5.6	Ward nurses should provide close supervision of patients after applicator removal to avoid risk of falls and monitor the effect of medication wearing off.	100	100	100	100
5.7	Ward nurses should help patients to prepare for discharge home, including washing, dressing and mobilising.	93	92	100	95
5.8	Ward staff should receive training on awareness and identification of drug reactions, especially for long duration brachytherapy or high levels of opiate use.	100	100	100	100
5.9	Ward staff should receive additional training in the nursing care and compassion needed to support patients during brachytherapy.	100	100	100	100
5.10	Centres should provide specialised care standards for brachytherapy patients on ward, i.e. fewer patients that one nurse should be allocated to look after, therefore a greater allocation of nursing time to brachytherapy patients.	93	92	75	87
Poll 6: Communication, logistics and staffing					
6.1	Each centre should ensure that there is effective communication between referring centres and brachytherapy teams, especially where plans change including dates for treatment or centre for brachytherapy.	93	100	100	98
6.2	Each centre should offer transport for patients to attend brachytherapy and return home after brachytherapy, if there are no family/friends able to provide.	93	92	92	92
6.3	Each centre should carry out regular service evaluation to check that staffing levels are appropriate throughout the brachytherapy pathway, including contingency planning for absence of key staff.	100	100	100	100

Number of participants at WS 1 = 5; Number of participants at WS 2 = 4; Number of participants at WS 3 = 4 Scoring 4-point scale: 1. Not important/not relevant = 0 points; 2. Slightly important = 1 point; 3. Important = 2 points; 4. Very important = 3 points		WS 1 % Score	WS 2 % Score	WS 3 % Score	Total % Score
6.4	Each centre should implement a service evaluation programme for obtaining patient feedback about their brachytherapy services, including patient reported pain and distress, especially after adaptations to service delivery are made or new services introduced.	100	83	100	94
6.5	Each centre should ensure that patients do not experience delays to treatment or unnecessary transfers	93	92	92	92
6.6*	Ward bookings for long duration brachytherapy should include the option to stay the night after treatment finishes, to allow sufficient recovery time if needed.	93	83	100	92
6.7*	Pregnancy checks before theatre procedures and radiation delivery should be handled with sensitivity where previous treatment has prevented this possibility.	100	100	100	100
Poll 7: Facilities on wards					
7.1	Centres should where possible offer patients a choice of a single room or shared wardroom, considering individual preferences for privacy or company/distractions.	80	58	83	79
7.2	Centres should provide clear information to patients about access to facilities such as TV, internet and music to help pass the time.	73	75	92	80
7.3	Centres should provide access to facilities such as an angled tray for reading and/or iPad to optimise patient comfort and enable access to facilities when lying flat for a long period of time.	80	75	92	82
7.4	Centres should offer complementary therapies during admission for brachytherapy.	73	82	67	74
7.5	Centres should provide information and support to help patient's use of relaxation techniques during admission for brachytherapy.	80	67	92	80
7.6	Centres should provide pre-brachytherapy information to patients including detail of ward facilities, what to bring in, what to expect and to offer to show patients around in advance of brachytherapy.	100	92	100	97
7.7	Centres should offer patients a choice of brachytherapy regime, where possible and equally effective.	87	100	83	90
7.8*	Consideration should be given to the location of brachytherapy ward facilities and where possible avoid entry and exit routes near sensitive areas such as maternity units.	93	75	83	84

Colour coding: 100% score between 90 and 99% score less than 90%

Abbreviations: Workshop 1 (WS 1); Workshop 2 (WS 2); Workshop 3 (WS 3)
*Denotes new recommendation added at WS 1 after first poll

NGT Stage two: Round robin comments on rationale for initial voting

Participants were asked in turn to comment on their reasons or justification for their choice of ratings in the initial voting round. Many participants commented on how important all the recommendations were and that ideally, they would all be included in future recommendations. However, some participants explained their rationale for voting choices providing a multitude of reasons.

NGT Stage three: Clarification and discussion stage

Participants were invited to put forward suggestions for changes to wording of recommendations or additional recommendations they would like considered, and to discuss this within the group. The Zoom screen share function was used to display and edit the recommendation list, reflecting the group decisions on changes and additions required. Additional recommendations and wording changes at each workshop are shown in Table 2.

Table 25 New and amended recommendations

Workshop 1: New recommendations[9]		
Poll number and title	**New recommendation**	**Comments**
Poll 4: Information and support	*4.8 Pain management, methods, and potential side effects should be discussed with patients before, during, and after treatment, with level of detail and choices offered as appropriate.*	Suggested by a service user who had not had pain management and opiate side effects explained to her and reported suffering from paranoid thoughts likely to have been caused by high levels of opioid use via the PCA.
Poll 6: Communication, logistics and staffing	*6.6 Ward bookings for long duration brachytherapy should include the option to stay the night after treatment finishes, to allow sufficient recovery time if needed.*	Suggested by a service user who had been encouraged to leave hospital when she did not feel ready. She suggested that patients should be given a choice, whether to stay on the ward for an extra night after brachytherapy was completed.
Poll 6: Communication, logistics and staffing	*6.7 Pregnancy checks before theatre procedures and radiation delivery should be handled with sensitivity where previous treatment has prevented this possibility.*	Suggested by a service user who had found the frequent questions about the possibility of pregnancy was upsetting and insensitive when treatment had caused infertility.
Poll 7: Facilities on wards	*7.8 Consideration should be given to the location of brachytherapy ward facilities and where possible avoid entry and exit routes near sensitive areas such as maternity units.*	Suggested by a service user who had to walk through a maternity unit to reach the ward for her brachytherapy admission. She found this upsetting and insensitive and hoped it might be considered when designing future services.
Workshop 1: Recommendation amendments		
Poll number, title, recommendation number	**Original Recommendation**	**Amended recommendation**
Poll 1: Pain management Recommendation 5	Each centre should provide individualised advice on pain control before discharge from hospital.	Each centre should provide individualised advice on *short term pain management* before discharge from hospital.
Poll 2: Medication for anxiety and distress Recommendation 1	The protocol should include consideration of medication to reduce anxiety while staying on the ward the night before brachytherapy.	The protocol should include consideration of medication or other interventions to reduce anxiety while staying on the ward *or at home* the night before brachytherapy
Poll 2: Medication for anxiety and distress Recommendation 5	The protocol should state the frequency that pain, anxiety and distress will be reviewed by senior brachytherapy clinicians.	The protocol should state the *minimum* frequency that pain, anxiety and distress will be reviewed by senior brachytherapy clinicians.
Poll 2: Management of anxiety and distress Recommendation 6	The protocol should Include frequency of ward rounds with oncologist and nursing staff for regular review and management of pain, anxiety and distress.	… and management of pain, anxiety and distress, *in addition to personalised reviews at times needed by the patient.*

[9] Four new recommendations were suggested by two service users and agreed by the group.

Poll number, title, recommendation number	Original Recommendation	Amended recommendation
Poll 2: Medication for anxiety and distress	Poll title: Medication for anxiety and distress	Poll title: *Management of anxiety and distress*[10].
Poll 2: Medication for anxiety and distress **Recommendations 1, 2 3, 4, 7 and 8**	…need for drugs…	Six recommendations had *"or other interventions"* added, to read: need for drugs *or other interventions.*
Poll 3: General medical management **Recommendation 1**	Each centre should have a protocol for prevention and treatment of nausea and vomiting, including additional options and adaptations when medication does not work.	…when medication does not work, *and consideration of non-medical options.* *Explanatory notes: non-medical options may include herbal remedies such as ginger, or relaxation techniques, music therapy or massage.*
Poll 3: General medical management **Recommendation 5**	Each centre should provide a late effects/long term side effects service, to help with bowel, bladder and sexual problems in the months and years after completion of treatment.	Each centre should provide a late effects service, to help with possible long term side effects of treatment such as pain, bowel, bladder and sexual problems in the months and years after completion of treatment.
Poll 4: Information and support **Recommendation 7**	Each centre should provide assessment of the need for psychological support after brachytherapy.	Each centre should provide assessment of the need for psychological support after brachytherapy and *be able to provide this or refer patients as needed.*
Poll 5: Patient care/ward nursing care **Recommendation 9**	Ward staff should receive additional training in the care and compassion needed to support patients during brachytherapy.	*Explanatory notes: This may include training such as advanced communication skills and a need for clinical supervision sessions or debriefing for staff*
Poll 6: Communication, logistics and staffing **Recommendation 3**	Each centre should carry out regular service evaluation to check that staffing levels are appropriate throughout the brachytherapy pathway.	Each centre should carry out regular service evaluation to check that staffing levels are appropriate throughout the brachytherapy pathway*, including contingency planning for absence of key staff.*
Poll 7: Facilities on wards **Recommendation 1**	Centres should offer patients a choice of single room or wardroom, considering individual preferences for privacy or company/distractions.	Centres should *where possible* offer patients a choice of a single room or *shared* wardroom, considering individual preferences for privacy or company/distractions.[11]

[10]Following a group discussion about the benefits of non-pharmacological management of anxiety and distress in addition to medication

[11]In workshop 1, this was the only suggestion made by a service provider. All other changes were suggested by the two service users.

Workshop 2[12]: Recommendation amendments		
Poll number, title, recommendation number	**Original Recommendation**	**Amended recommendation**
Poll 5: Patient care/ward nursing care **Recommendation 10**	Centres should provide intensified care standards for brachytherapy patients on ward, i.e. fewer patients that one nurse should be allocated to look after, therefore a greater allocation of nursing time to brachytherapy patients.	Centres should provide *specialised* care standards for brachytherapy patients on ward, i.e. fewer patients that one nurse should be allocated to look after, therefore a greater allocation of nursing time to brachytherapy patients.
Workshop 3[13]: Recommendation amendments		
Poll number, title, recommendation number	**Original Recommendation**	**Amended recommendation**
Poll 1: Pain management **Recommendation 4**	Each centre should have a protocol for pain management for applicator removal to meet the needs of individual patients.	Each centre should have a protocol for pain management for applicator removal to meet the needs of individual patients *(fully informed of procedure).*
Poll 2: Management of anxiety and distress **Recommendation 5**	The protocol should state the minimum frequency that pain, anxiety and distress will be reviewed by senior brachytherapy clinicians.	The protocol should state the minimum frequency *or threshold* for pain, anxiety and distress to be reviewed by senior brachytherapy clinicians or senior ward clinicians.
Poll 5: Patient care/ward nursing care **Recommendation 9**	Ward staff should receive additional training in the care and compassion needed to support patients during brachytherapy. *This may include training such as advanced communication skills and a need for clinical supervision sessions or debriefing for staff.*	Ward staff should receive additional training in the *nursing care* and compassion needed to support patients during brachytherapy. *This may include training such as advanced communication skills and a need for clinical supervision sessions or debriefing for staff, and management of complex pain.*

[12]One wording change to one recommendation was suggested by a service provider and agreed on by the group.
[13] Wording changes to clarify the meaning of some recommendations were suggested by service users and providers and agreed upon by the group.

Content analysis of qualitative data from stage two and three

The verbal data for each workshop was summarised in note form in a word document. Using a content analysis method, data from all workshops were then grouped into themes and the themes were organised into overarching categories and reported here in Table 26. Frequency of responses were not counted, as it was not possible to verify how many of the participants agreed or disagreed with comments made by other participants in the workshop setting.

Table 26 Content analysis of qualitative data from NGT workshops

ROUND ROBIN INDIVIDUAL COMMENTS AND DISCUSSION OF PROPOSED PATIENT CARE RECOMMENDATIONS FOR BRACHYTHERAPY AT THREE WORKSHOPS TOTAL NUMBER OF PARTICIPANTS = 13 [SERVICE USERS = 5**;** SERVICE PROVIDERS = 8]	
CATEGORY	**EXAMPLES OF VERBAL RESPONSES**
RATIONALE FOR VOTING	All proposed recommendations are important
	Pain management, information and psychological support are most important
	Some recommendations are not required as they should be standard care
	Some recommendations are not necessary as already in place
	Feasible recommendations are most important
	Feasibility should not be the main driver of prioritisation
	Complementary therapies are relatively less important
PAIN	Patients have fear of pain before brachy
	Inadequate pain management was experienced
	Some experienced or provided good pain management
	Severe pain significantly impacts on patient experience
PATIENT INFORMATION AND SUPPORT	Patient centred, timely and accurate patient information is very important
	Inaccurate or unrealistic information reported
	Patient information about aftereffects and aftercare is very important
	Patient information about ward facilities is helpful
	Patient information before discharge home is very important
	Distress was caused by poor timing of brachy information
	Poor patient information impacts patient experience
WARD CARE AND TRAINING	Inconsistent and poor care on wards reported
	Some good nursing care reported
	Brachytherapy training of ward nurses/HCPs needs improvement
	Guidelines for ward brachy nursing care are needed
	Inconsistent staff allocation reported
	Nutrition and hydration support need improvement
	HCPs need training in complex pain
	Need to help patients to access time passing strategies whilst lying flat
	Guidelines to minimise pressure sores and DVTs are needed
	Ward nurses need advanced communication skills training
	Need to improve ward medication administration
	Brachy trained ward staff gives more consistent good care
	Lack of training can lead to poor patient experiences and complaints

FACILITIES	Inappropriate ward location for brachytherapy patients
	Providing single rooms is not always feasible
	Single bay inpatient bed available in some centres
	Appropriate logistical resources needed, such as individualised transport
	Should offer patient choice for length of inpatient stay
PHYSICAL EFFECTS OF BRACHYTHERAPY	Excess side effects from medication
	Offer pharmacological and non-pharmacological for nausea and vomiting
	Flat position for brachy is problematic
	Total reliance on help from partner/relative to eat and drink
	Poor management of side effects reported
LATE EFFECTS	Late effects service provision is really important
	Experience of late effects reported and poor information and support.
PSYCHOLOGICAL ISSUES	Need to increase sensitivity and awareness of HCPs to fertility loss and impact
	Emotional or psychological impact of brachytherapy reported
	Psychology expert advice needed for debriefing recommendation
	Management of anxiety needs improvement
	Patients experience stress and anxiety before, during and after brachy
	Report of feeling vulnerable and disempowered due to flat position
SHORT DURATION VERSUS LONG DURATION BRACHYTHERAPY	Good care experienced for short duration brachy
	Increased duration can be for complex reasons, hard for patients to tolerate
	Different views on duration of brachytherapy
	Day case brachy gives better experiences than inpatient (long duration)
	Would have preferred day case brachytherapy
	Preferred all brachytherapy in one admission
ANAESTHETICS	Lack of consistency of care in anaesthesia reported
	Having experienced anaesthetists is important
PATIENT-CENTRED CARE	HCPs need to know patients well deliver patient-centred care
	Building rapport helps to identify patients with higher risk of trauma
MISCELLANEOUS	Care delivered differently in centres
	Patient feedback is used to improve their next brachy experience
	Patient experienced good support and care in theatre
	Staff work hard to try to make patient experiences tolerable
	Good communication between centres is essential
	Need to improve logistics for pre-assessment
	Radiographers provide ward nursing care too
	Some patient experiences are good
	Patient choice is important
	Patient comfort needs to be improved
	Privacy versus companionship was discussed

Abbreviations: HCPs=Healthcare professionals, DVT=deep vein thrombosis, brachy=brachytherapy

Doctoral fellow reflections on qualitative data and examples for illustration

Overall, service users and providers were very supportive of the list of proposed recommendations. One service provider said:

> **"*Every single step is really important as we need to get every step right"* [Service provider, workshop 1]**

This was corroborated by a service user who commented:

> ***"All of it I kind of think is really important, what you have included [in the list of potential recommendations] and it will be brilliant to see this, and it will make such a massive difference if this is done, for the consistency across treatment centres. To have that continuity and consistency will be fantastic."* [Service user, workshop 1]**

One service user described the proposed recommendation list as being

> ***"…like a wish list of everything, and I'm so envious of anyone who gets any of this."* [Service user, workshop 1]**

Re-watching and reflecting on the workshop recordings, the doctoral fellow observed a discrepancy between the experiences of service user and service provider participants. In general, service users were more negative than service providers about their experiences of brachytherapy, especially regarding nursing care standards, consistency of care, management of pain and other physical side effects. All the service users spoke unprompted about their pain experiences and strategies they used to manage the pain. Three service users had experienced poor pain management with long duration brachytherapy. Pain at applicator removal had been particularly problematic for two of these three participants and pain after completion for one of the three participants. One of the long duration brachytherapy service users had experienced dreams and flashbacks of applicator removal and described it as ***"barbaric"*** and ***"cruel"***. The other two service users had short duration brachytherapy and reported no problem with pain other than at applicator removal after the third brachytherapy procedure for one of the two participants. Service users spoke of experiencing some aspects of good care, but also that care was inconsistent and poor at times. In contrast, some service providers said that brachytherapy training of ward staff was taking place in their centre, that good care and provision of good pain management was standard practice.

The service users highlighted many of the recommendations that resonated with negative experiences of brachytherapy, such as problems with pain, nausea and vomiting, lying flat, reaching food and drinks, feeling wobbly after applicator removal. They reported that their voting was an affirmation of the importance of recommendations to improve these negative experiences. In contrast, some service providers voted more strongly in favour of recommendations that would be feasible or more important in their centres. A service provider in workshop one said that all recommendations were important but that in relative terms, patient preparation through information and support or pain management "trumps" services such as complementary therapies. Therefore, her rationale for voting was to acknowledge the prioritisation of essential services over those that would be nice for patients, but not essential. Other service providers said that some proposed recommendations were not required, or less relevant in their centre, as those aspects were already in place. In workshop three, a service provider said that she voted 'important' or 'somewhat important' for recommendations that may be less feasible to implement, or not within their control, such as offering brachytherapy patients a choice of a single or a shared ward room. She said that at her hospital they had a major problem with bed capacity, so they were often very grateful to get a ward bed at all. Also, that the location of the ward could only be considered if you were setting up a service from scratch. She therefore voted "very important" for recommendations which she thought her team had the ability to implement, such as recommendations relating to nursing care standards or pain management protocols. She commented on the problems she experienced with lack of ward nursing staff and that the brachytherapy radiographers needed to "settle patients" on the ward after treatment, and that specifying a higher ratio of nursing staff to brachytherapy patients may not be feasible. However, she acknowledged that the existence of guidelines may help them to access more resources. Another service provider in workshop three echoed the same concerns about resources and that some recommendations were aspirational but not currently possible. She also commented on the provision of one-to-one nursing care in her centre with some recommendations, such as pain management protocols, seeming less important as she believed that the brachytherapy trained nurses already knew what to do.

Two of the service users were registered nurses, both working in acute surgical areas, and they commented on the impact that their professional experience had on how they had processed their brachytherapy experiences and viewed the potential recommendations. One commented on the need to include non-pharmacological options in protocols for management of pain and nausea and vomiting. She endorsed the inclusion of protocols to reduce risks of pressure sore development and prevention of blood clots. In contrast, she had reservations about the protocolisation relating to the frequency of pain assessments or reviews on the ward, as in her experience, when a time frame was set for a pain review there was a tendency for staff to wait for the review time and not give personalised and timely care.

Service users emphasised the importance of the recommendation relating to the provision of 'late effects' services. One service user could not rate this highly enough and it was her personal mission to make sure all centres provided this service in the future. One service user thought the information leaflets provided by hospitals gave "false information" about late effects of treatment and she no longer had any faith in the NHS information websites. In contrast, service providers did not comment on late effects services or the proposed recommendation, but this recommendation received 100% maximum score for importance at all workshops.

Some service providers expressed their appreciation for the participation of service users at the workshop and the importance and impact of hearing the patient voice. One service provider participant provided feedback via email after the workshop:

"I thoroughly enjoyed the workshop and found it very informative to hear what other clinics are doing and the patients' perspective was particularly valuable."

5.5 Discussion

Overall, three NGT workshops were carried out with thirteen participants comprised of five service users and eight service providers. The initial 51 patient care recommendations were added to by participants in workshop one and 55 recommendations were voted on by the thirteen participants. Minor wording changes were made to recommendations at each

workshop. In general, recommendations were positively received with 25 recommendations scoring maximum points (very important/3 points) by all thirteen participants. An importance score above 90% was given to 46 of the recommendations with nine recommendations receiving scores between 74 and 90%. No recommendations scored lower than 74%.

Service users commented on the value of the proposed patient care recommendations due to their resonance with problems they had experienced during brachytherapy and a desire to see the recommendations implemented in clinical practice. Service users placed particular importance on the need for pain management at key time points, accurate and realistic information before brachytherapy and the provision of radiotherapy late effects services. National guidelines for management of acute pain include standards relating to the need for individualised analgesia plans which are appropriate to the patient's medical condition, stating that the analgesia plan should be "effective, safe and flexible with planned review" (Faculty of Pain Medicine of the Royal College of Anaethetists, 2021, p.85,). UK survey data by Rockett *et al*. (2017) has shown that there is a lack of consistency in approach to acute pain management and highly variable service provision. The need for recommendations for pain management during brachytherapy arose from patient interview data, and this finding was reinforced by comments from service users in the NGT workshops.

Late effects services were an important issue for all the workshop service users. This may have been related in part to the nature of service user recruitment via charities such as Jo's Cervical Cancer Trust and the PRDA. Some of the workshop service users had personal experience of late effects of radiotherapy and were keen to see a higher prioritisation of improving awareness and knowledge and better service provision for treatment. Morris and Haboubi (2015) state that pelvic radiation disease has been under reported and sub-optimally treated over many years, with an over emphasis on survival rates and a neglect of short- and long-term toxicity of treatment. National service specifications for radiotherapy include requirements for both local management and provision of specialist late effects centres (NHS England, 2019) and there is recent anecdotal evidence that late effects services are being developed on a more equitable and less sporadic basis. In the doctoral

fellow's radiotherapy network, three new posts for late effects healthcare professionals were created in 2022. In 2020 the Society of Radiographers founded a special interest group for radiotherapy late effects, to provide a network of support for therapeutic radiographers to share clinical experience and expertise.

Two of the four new recommendations related to patient choices. Firstly, recommending that full information about potential side effects of pain medication should be given so that informed choices could be made by patients. Medication prescribing recommendations state that prescribing healthcare professionals should advise patients on adverse effects and potential harm and involve them in shared decision making (Faculty of Pain Medicine of the Royal College of Anaethetists, 2021). Importance is placed on providing sufficient information so that patients have "realistic expectations" and can make informed decisions about their medication (Faculty of Pain Medicine of the Royal College of Anaethetists, 2021, p.105). For brachytherapy, this information provision and discussion would ideally take place in the pre-operative assessment setting to inform patients about potential pain and likely analgesia requirements. Secondly, patients should be given a choice about whether to stay the night after brachytherapy. With the limited availability of ward beds, some service providers were not sure if this would be possible in their centres.

The other two new recommendations suggested by service users related to the need to improve sensitivity around infertility, which had been caused by the treatment. Distress had been caused through being asked multiple times during radiotherapy and theatre procedures for brachytherapy if there was any possibility of pregnancy and having to walk through maternity areas to access radiotherapy or brachytherapy services. Although service providers commented that relocating current services may be difficult, all participants agreed that this should be considered in future service design. Ionising Radiation Medical Exposure Regulations require referrers (oncologists) and operators (radiographers) to enquire about pregnancy status before delivering a medical exposure (UK Parliament, 2017). However, recent Royal College of Radiologist guidance for checking pregnancy status in radiotherapy clarifies that:

> "It may not be considered relevant to ask an individual if there is any possibility of pregnancy who is known to have had a TAH[14] or is *undergoing medical treatment resulting in infertility* or arrested ovulation." (The Radiotherapy Board, 2020, p.65)

For operating theatre procedures, National Institue for Health and Care Excellence (NICE), 2016, p.6) advise that all women of "childbearing potential" should be sensitively asked about the possibility of pregnancy, without any caveats for infertility, leading to different interpretation of the meaning of 'childbearing potential'. If it is clearly documented by an oncologist that there is currently no 'childbearing potential' for a patient, a standard operating plan could be used to specify that these patients do not need to be asked about the possibility of pregnancy, avoiding distress to those recently made infertile by cancer treatment whilst meeting the legal requirements for patient safety.

Recommendations in Poll 7 (Facilities on wards) received the lowest scores overall and included six of the nine recommendations with less than 90% scores. Both service users and service providers discussed the difficulties of resource allocation, such as access to complementary therapies, support for relaxation techniques and facilities to help women cope with lying flat for prolonged periods of time. Offering a choice of a single room or a shared wardroom was commented on by some participants as being unrealistic due to the limited availability of beds. However, several service providers remained keen for aspirational recommendations to be included, to support subsequent requests for better resource allocation. Using patient experience feedback to drive service improvements has been recommended by many organisations over a long period of time (National Institute for Health Research, 2019b; NHS Institute for Innovation and Improvement, 2013), putting patients at the centre of developments. However, it has also been recognised that patient experience feedback can be difficult to integrate with clinical effectiveness and safety improvements which are often driven by healthcare professionals and managers. However, integration of both patient experience feedback along with staff experiences improvements, has been demonstrated though initiatives such as 'Experience Based Co-Design', driving improvements that are relevant and feasible (Robert *et al.*, 2015).

[14] TAH = Total Abdominal Hysterectomy

Research partner involvement

During the planning stages for study three the research partners were involved in designing the workshops, reviewing documents, and discussing the relevance of the study two interview findings, as part of the steering group and pilot NGT workshop. They also contributed to the NGT workshops as co-facilitators.

5.6 Strengths and limitations

The use of a co-design research method was a strength of this study. Enabling service users and providers to come together to discuss patient care recommendations and share their experiences had impact and was of value to the workshops. This was demonstrated by comments in workshop participant feedback. Although it was problematic to schedule the workshops to meet the needs of service users and providers, it was a worthwhile ambition and a strength of the study. The NGT online format worked well, as it created structure which ensured fairness and equity between service users and service provider participants, through equal allocation of time and the use of polling.

The number of participants was lower than originally planned and could be seen as a limitation of this study, potentially reducing reliability of results, as larger participant numbers could have included a broader range of views, experiences and knowledge from both service user and service providers. However, the small number of participants enabled detailed discussion of the 55 proposed recommendations as there was more time for each participant to explain their views.

Overall, the aims and objectives of the study were met as service users and providers were able to discuss, refine and prioritise the potential patient care recommendations, leading to the verification of useful, potentially achievable and relevant recommendations.

5.7 Conclusions

Proposed patient care recommendations were discussed and voted on at three workshops that included both service user and service provider participants. Of the 55 potential recommendations, all participants considered 25 recommendations to be very important,

receiving the maximum possible score of 100%. Scores of 90% or above were given to 46 of the 55 recommendations. Verbal comments from participants confirmed that all the recommendations were relevant and important. The 55 patient care recommendations could be used as a starting point for future development of recommendations or patient care guidance, for subsequent implementation into clinical practice. The aim of the guidance would be to improve consistency of care and patient experiences of brachytherapy across different centres and brachytherapy techniques.

Chapter Six: Summary and discussion

This chapter presents a summary of the key findings of the doctoral research, the contribution these findings have made to original knowledge, implications for clinical practice and research, and the doctoral fellow's personal reflections. Finally, the strengths and limitations of the research are considered, followed by conclusions.

6.1 Introduction

At the outset, the aim of this programme of research was to develop an intervention to reduce distress caused by brachytherapy for LACC. However, as the research progressed it became apparent that service provision and care were widely variable, and this impacted significantly on patient experiences. Improving service provision to meet patients' basic support needs was identified as a greater priority than the development of new interventions. As a result, the overall purpose of the research was adapted following the initial stages to the development of recommendations to support best practice in the clinical care of patients undergoing brachytherapy for LACC. The clinical care recommendations developed through this programme of research could be considered a complex intervention, where a range of education and behaviours of different healthcare professions are required within a complex health setting (Skivington *et al.*, 2021). The overarching research question was: *What are women's experiences of brachytherapy and how can we improve them?* The research question has been answered through the programme of research, with the development of recommendations found to be the most appropriate means to address patient experiences of brachytherapy.

6.2 Summary of research programme including aims, key findings and original contribution to knowledge

6.2.1 Summary of literature review

An SLR explored women's experiences of brachytherapy for cervical cancer to inform the programme of research. The findings showed that women experienced varying levels of pain, anxiety and distress related to brachytherapy. In addition, the findings suggested that better pain management, the provision of patient information and support through non-

pharmacological interventions may improve women's experiences of brachytherapy. The SLR was updated in 2022 and it was notable that the number of relevant studies published per year had increased, particularly those reporting different pharmacological approaches for pain management for long duration brachytherapy and interstitial needle techniques. There were indications that some non-pharmacological interventions may reduce anxiety and distress and warrant further exploration. The SLR update also showed that some centres were developing procedures with greater complexity in imaging requirements, number of applicators used, and time taken for planning. There appeared to be no consensus on optimal pain management and toxicity, which reflected the wide variation in brachytherapy techniques being used and resources available.

The SLR update provided new knowledge and understanding of women's experiences of brachytherapy relating to the meaning of pain, fear about the procedure and fear of death and the impact of their personal beliefs. However, the three patient experience studies in the SLR update were not from centres where *modern* brachytherapy techniques were used, such as MR image-guided and ISBT or multiple treatments per insertion. Over the last 10 years, all UK centres have developed MR image-guided brachytherapy, some with multiple short duration procedures and some with long durations with applicators remaining in place overnight and many centres using interstitial or hybrid techniques. Therefore, there was a need to explore women's experiences of modern brachytherapy to identify whether any additional support is required.

6.2.2 Summary of study one: UK Survey of brachytherapy practice for LACC

A survey of current UK service provision of brachytherapy for LACC was carried out. In addition to closed questions, participants were asked to provide free text comments about what worked well, what could be improved and how they supported brachytherapy patients with special needs in their centres.

Responses were received from 39 of the 44 UK brachytherapy centres providing a comprehensive overview of brachytherapy service provision for LACC in 2018. Treatment scheduling was found to be widely variable with 11 different regimes identified and duration with applicators remaining in place ranging from three to 52 hours. Although analgesia and anaesthesia were reported to be available in all centres, the provision of analgesia for

applicator removal was found to be inconsistent. The findings provided new knowledge about UK brachytherapy service provision and informed the development of an interview schedule and the selection of four UK NHS sites for the patient interview study that followed.

6.2.3 Summary of study two: Patient interview study

Interviews were carried out with 35 women after brachytherapy for LACC. The women had received treatment in one of four UK centres where brachytherapy is delivered in different ways, some receiving multiple short duration day case procedures and some with inpatient stays with applicators remaining in place for long durations. Participants were invited to retell their brachytherapy story and explore views on their care and ideas for improvement.

Women's experiences were widely variable including reports of difficult and traumatic experiences with periods of severe pain and poor nursing care on the wards. In contrast, some women described positive experiences, reporting what had gone well. The data indicated that there was a need to develop patient care recommendations to improve patient experiences of brachytherapy for LACC rather than developing a specific intervention.

6.2.4 Summary of study three: NGT workshops

Data from the literature review, UK survey of practice and patient interviews informed the development of a list of potential patient care recommendations. These recommendations were rated for importance at a series of three online NGT workshops. The workshop participants included a mix of brachytherapy service users and service providers in an approach informed by principles of co-design. The initial 51 proposed recommendations were increased to 55 at workshop one, and 25 recommendations were identified as very important by participants at all three workshops. Verbal comments from participants confirmed that all the recommendations were relevant and important.

Summary of new knowledge from this programme of research is shown in Table 27.

Table 27 Summary of key research papers and new knowledge form thesis work

Key research papers	Summary of research	Similarities with thesis work	Differences compared with thesis work	Area of new knowledge identified from thesis work
Velji and Fitch, 2001 (Canada)	Exploration of lived experience of women receiving LDR or PDR brachytherapy.	Includes patient experiences of long duration brachytherapy, 10 patient interviews.	LDR and PDR, isolation issues different to HDR. Simple techniques used. Only 6 interviews with cervical cancer patients. 4 had post-operative endometrial cancer brachytherapy (a shorter, simpler treatment compared with LACC). Recruitment from one centre.	All interviewees had HDR brachytherapy for LACC, using modern complex techniques and some had interstitial needles (when required), from 4 recruitment sites. Therefore patient experiences of modern complex brachytherapy reported.
Warnock, 2005 (UK)	Exploration of patient descriptions of their experiences of brachytherapy through questionnaires and interviews.	Includes patient experiences of long duration brachytherapy. Similar themes: fear, anxiety, discomfort, immobility, variability in experiences, challenges for staff.	LDR brachytherapy, some experiences related to isolation, not the same as for HDR . Simple techniques, not interstitial needles. Only 6 patient interviews. Recruitment from one centre.	35 patient interviews completed across 4 UK sites, HDR brachytherapy with complex techniques including interstitial needles and different durations.
So and Chui, 2007 (Hong Kong)	Exploration of experiences of women undergoing brachytherapy for cervical cancer.	Telephone interviews with 8 women after LDR brachytherapy. Long duration brachytherapy. Recommendations to tailor nursing care and better prepare patients.	Isolation from LDR not applicable to HDR techniques. Simple techniques, not interstitial needles. Small number of interviews. Recruitment from one centre.	Large number of interviews, mix of face to face, and mostly videoconference. Using 4 NHS sites with different regimes, includes short, medium and long duration regimes.
RCR, 2007 and RCR, 2012 (UK)	Survey of UK brachytherapy services and recommendations for brachytherapy for cervical cancer.	Survey: Details of number of UK sites and types of cancer treated. Recommendations: Guidelines for cervical cancer brachytherapy including introduction of complex techniques.	Survey: not specific to cervical cancer. Recommendations: refers to planning and imaging requirements, not patient care and support, fractionation regimes, analgesia or anaesthesia.	Study one: Comprehensive survey of UK brachytherapy service provision for LACC. This informed the development of an interview schedule and the selection of 4 UK NHS sites for study 2.
Kirchheiner *et al.*, 2014b (Austria)	Investigation of psychological consequences of HDR brachy with 2 treatments in 1 application under spinal/epidural anaesthesia.	Includes 50 patients during and after brachytherapy for LACC. Complex techniques and some with interstitial needles. Similar findings of variable levels of pain and trauma.	Only one centre included, carrying out medium duration brachytherapy, 1 insertion with 2 treatments, repeated a week later.	Interviews with patients from 4 UK centres, different regimes including short, medium and long duration brachytherapy with different number of overnight stays and day case procedures.

Key research papers	Summary of research	Similarities with thesis work	Differences compared with thesis work	Area of new knowledge identified from thesis work
Dzaka and Maree, 2016 (South Africa)	A descriptive summary of experiences of women having HDR brachytherapy for cervical cancer.	Includes 16 interviews. Similar findings: pain, trauma, poor information and variable levels of care and support. Similar recommendations: individualise care, improve pain management and information.	All patients had short duration brachytherapy with multiple visits, but duration and number not given. Recruitment from one centre.	Interviews with patients from 4 UK centres, different regimes including short, medium and long duration brachytherapy with different number of overnight stays and day case procedures.
Long, Friedrich-Nel and Joubert, 2016b, (South Africa)	Identification of informational needs through patient interviews, to develop guidelines for quality patient-centred care.	Includes 28 patient interviews, all had brachytherapy for LACC. Four themes emerged, similar to thesis findings.	Four themes developed from interview data but only one theme reported: informational needs. Recruitment from one centre.	Focus on all emerging themes across the dataset from 35 patient interviews. Breadth and depth of data for a specific brachytherapy procedure.
Ehlers and Makanjee, 2017 (South Africa)	Exploration of gynaecological cancer patients' expectations, experiences, understanding of HDR brachytherapy procedure.	Includes 10 patient interviews, all HDR brachytherapy. Similar findings of trauma and pain, resignation to the treatment, desire to be healed.	Recruitment from one centre. Very short duration- not complex imaging/planning or use of interstitial needles.	Includes patient experiences of different durations of brachytherapy, including complex and interstitial techniques.
Da Rosa *et al.*, 2021 (Brazil)	Exploration of the meaning of brachytherapy in women with gynaecological cancer.	Includes 32 patient interviews, all had HDR brachytherapy	Recruitment from one centre. Only 20 interviewees had not had hysterectomy, therefore 12 had simpler brachytherapy not requiring anaesthesia. Simple techniques (no CT or MRI), short duration regime likely.	Includes patient experiences of different durations of brachytherapy, including complex and interstitial techniques.
Ashworth *et al.*, 2022 (UK)	The Gynae Cancer Narratives Project.	Contains some patient experiences of brachytherapy in UK centres (quotes from 3 patients in the report). Reports of trauma caused by brachytherapy.	Focus on radiotherapy experiences, very little data on brachytherapy for gynaecological cancers.	Focus on brachytherapy experiences for treatment of LACC. Study two: depth and breadth of experiences in 35 interviews. Data led to development of patient care recommendations for study 3.

Key: LDR = *low dose rate; PDR = pulsed dose rate; HDR = high dose rate; LACC = locally advanced cervical cancer*

6.3 Implications for future clinical practice

Patient interview data clearly demonstrated that negative experiences were frequently related to aspects of inadequate patient support. This included reports of periods of severe pain, nausea and vomiting, difficulty managing eating and drinking, and backache caused by long durations lying flat. For some participants this was compounded by trauma associated with a life-threatening cancer diagnosis, loss of fertility and not being listened to or believed by healthcare professionals. The data showed that improving standards and consistency of care for women receiving brachytherapy should be a priority for healthcare providers, with a potential to positively impact patient experiences of brachytherapy. Similarly, Kirchheiner *et al*. (2014b) found that changes were needed to improve patients' tolerability of the treatment and identified areas for improvement. Overall, a wide range of factors were considered for inclusion in the development of patient care recommendations.

6.3.1 Pain management

Some healthcare professionals in the UK survey (study one) and at NGT workshops (study three) indicated that pain management protocols were in place in their centres, whereas others indicated that improvements were needed. Some service users (study two interviews and study three workshops) reported inadequate pain relief with episodes of severe and uncontrolled pain. This indicated that pain management was not consistent or adequate for all patients throughout their brachytherapy pathway, justifying the need for pain management recommendations.

The recommendations that have been developed through the programme of research advise centres to implement pain management protocols at each stage of the brachytherapy pathway. That is, at applicator insertion, in the recovery room, on the ward, and during applicator removal. In addition, advice should be offered to patients at the point of being discharged home. Some centres may have informal guidance, with an understanding of "this is what we do", or more formally documented in a written protocol, work instruction or standard operating procedure. A key component of protocols for these key time points is that there should be options specified for adaptations to pain management for different types of brachytherapy procedures as it has been shown that

some applicators are likely to cause more severe pain (Locke *et al.*, 2022; Chen *et al.*, 2021; Janaki *et al.*, 2008). The protocols that are developed need to allow individualised pain management, depending on how much pain is experienced and how each woman responds to pain medication, as experiences of pain are widely variable (patient interviews; study two). Protocols also need to allow for the variability in duration that applicators are in place and scheduling of brachytherapy (UK survey of practice; study one).

It is anticipated that the implementation of the proposed recommendations will facilitate more consistent pain management for patients during brachytherapy and as a result lead to a better overall experience of the procedure.

6.3.2 Management of anxiety and distress

It was clear from the SLR that brachytherapy causes anxiety and distress. Further to this, the primary data collected from this programme of research (patient interviews; study two and service user feedback; study three) indicated that anxiety and distress were important issues that were not always managed effectively.

It was therefore recommended that centres implement protocols for the management of anxiety and distress at key time points during the brachytherapy pathway: the night before brachytherapy; immediately prior to theatre; during theatre procedures; at frequent intervals whilst on the ward; and at applicator removal. Interventions may include the use of medication to reduce anxiety or retention of memories of the procedure, indicated by patients' experiences of requesting, but not receiving sedation (study two). Interventions may include non-pharmacological strategies such as relaxation or distraction techniques, reported by some patients to have been useful (study two), and evidenced in the literature (Blackburn *et al.*, 2021; Chi *et al.*, 2015; Leon-Pizzaro *et al.*, 2007). Although some of these recommendations were not rated as 'very important' by all participants at the NGT workshops, due to higher prioritisation of recommendations regarded as essential, all received high levels of endorsement. Strategies to reduce anxiety and distress would need to be highly individualised to meet the variation in patients' needs, as demonstrated in the patient interview study (study two).

6.3.3 General medical management

The SLR findings and patient interview data (study two) showed the range of side effects and medical complications that can arise from chemoradiotherapy, brachytherapy and the anaesthetic and analgesic medication given during brachytherapy. From the patient interview data (study two), it was evident that these side effects have a negative impact on wellbeing and overall experiences of brachytherapy. Therefore, protocols need to be in place to avoid or minimise the impact of these wide-ranging side effects.

The proposed recommendations received high importance scores at all the workshops, with seven of the nine recommendations rated as very important in all the workshops. The recommendations encompass prevention of nausea and vomiting; severe infection; blood clots and pressure sores. They also include the provision of pre-brachytherapy assessments and the need for individualised adaptations to techniques to minimise risks of medical or psychological trauma. Ip *et al.* (2009) advised using individualised medical and psychological risk assessments to identify patients at high risk of experiencing pain; for example younger patients, those with a history of significant pain, and those with high anxiety levels (Wilson *et al.*, 2021; Mendez *et al.*, 2017b; Ip *et al.*, 2009). Data from patient interviews in study two and Kirchheiner *et al*. (2104b) indicated that knowing a patient's history, such as their experiences of childbirth, miscarriage, domestic violence, sexual abuse or anxiety and depression, may help to identify those who need additional support before, during and after brachytherapy. Increased psychological support could then be targeted towards those at greatest risk. Kirchheiner *et al*. (2014b) suggested that individuals identified to be at risk of PTSD prior to brachytherapy could be offered psychosocial support. It is not clear what psychosocial support they propose, but possible that involvement of a clinical psychologist before brachytherapy could help an individual to identify and develop coping strategies to be used during brachytherapy. Liaison between a clinical psychologist and the brachytherapy team could facilitate better support for the patient during brachytherapy, ensuring that identified coping strategies are understood and supported by the whole clinical team. If more than one brachytherapy procedure is planned, then patient consultation with the clinical psychologist after the first procedure could feedback the effectiveness of coping strategies and enable discussion with the brachytherapy team about

potential changes or adaptations for the next procedure. Further research is needed to determine the optimal support for patients to address the psychological impact of brachytherapy. Implementation of the proposed recommendations would potentially provide a more consistent and higher standard of medical management, minimising and helping women to cope better with side effects, reducing trauma and improving their overall experience of treatment.

Late effects services were identified by service user participants in the NGT workshops as being 'very important' and from their experiences had been lacking. Late effects services have been described as rehabilitation after radiotherapy (NHS England Specialised Commissioning, 2019). This may be in the form of local management of common late effects, with referral to appropriate specialists such as gastroenterologists, urologists, dietitian, therapeutic radiographers or nurse specialists (Pelvic Radiation Disease Association, 2022; NHS England Specialised Commissioning, 2019). However, some more complex late effects may need specialised support from a regional or national rather than a local service provider. The NHS England service specifications for radiotherapy state that it is the responsibility of radiotherapy providers to ensure that late effects services are available and accessible (NHS England Specialised Commissioning, 2019). At the time of writing, work was being undertaken in the NHS to develop late effects services which would be accessible to all patients. Specifically, Macmillan were supporting work through the Cancer Networks to deliver late effects services. In October 2022 the Pelvic Radiation Disease (PRD) Best Practice Pathway was launched by the PRDA at their annual conference (Pelvic Radiation Disease Association, 2022). The PRDA charity worked with UK experts on pelvic radiation late effects to develop this world first document.

6.3.4 Information and support

Although many healthcare professions in the UK survey (study one) and NGT workshops (study three) said that the information and support they provided was good, there were many reports from patient interviews (study two) and service users at NGT workshops (study three) that information and support was inaccurate or inadequate. This resonates with the inconsistency in information provision that has been reported by participants in previous studies (Ehlers and Makanjee, 2018; Dzaka and Maree, 2016; Long, Friedrich-Nel

and Joubert, 2016b; Warnock, 2005; Velji and Fitch, 2001). Although it may appear obvious, this highlights again that provision of information and support is reliant on good communication and appropriate timing. Healthcare professionals need to ensure that wording, format, level of detail and quantity of information are appropriate to the individual and delivered at the right time and in the right environment for each patient. To achieve this, the health professional needs to be able to recognise when the patient may be in a receptive frame of mind and be able to process the information. A recent study examined the usability of a graphic narrative discussion guide to provide patient information prior to brachytherapy for gynaecological cancer (Avila *et al.*, 2023). Clinicians liked the graphic narrative guide and thought it would help understanding and memorability of the information as well as reduce patient anxiety about brachytherapy. However, it appears that the guide was developed by clinicians and designers, without involvement of patients or carers, and their research did not include patients or carers. Further work is therefore needed to ascertain the opinions of patients about the information and the format that they would find helpful.

The recommendations developed in this programme of research advises centres to provide individualised patient centred information and support. The recommendations specified key time points, such as pre-brachytherapy, at the point of discharge home and soon after brachytherapy. There were also recommendations about training for healthcare professionals around the potential psychological trauma from brachytherapy and the need for individual assessments to identify those at high risk of trauma. All of these recommendations received maximum possible scores at all three workshops being rated 'very important' by all participants.

Psychological support was a key component in the proposed recommendations, reflecting the experiences reported by patients (study two) and their suggestions for improvements. Incorrect or inadequate information led to increased fear and anxiety, and insensitive comments by healthcare professionals increased the distress from fertility loss caused by the cancer treatment. Some interview participants and workshop service users wanted staff to be more aware of triggers for distress, such as proximity to maternity services and some associating applicator removal with childbirth. Therefore, training to improve staff

awareness of distress triggers is needed to facilitate better support for patients and improve experiences of brachytherapy.

6.3.5 Care on the ward

Although some healthcare professionals in the UK survey (study one) and service providers in NGT workshops (study three) thought the patient care at their centre was good, others reported that care for patients when they were on the ward needed improvement. A key component was said to be the need for ward staff to be given brachytherapy specific training, to increase their awareness of the physical and psychological needs of patients. High turnover of staff, or changes in the usual wards being used for brachytherapy patients, sometimes caused by COVID-19 restrictions, led to care being provided by staff that were untrained in brachytherapy patient care having to provide support for patients. Some qualitative literature reports poor patient care during brachytherapy (Dzaka and Maree, 2016; Warnock, 2005; Velji and Fitch, 2001) which resonates with the patient interview data (study two). It was surprising, and at times shocking to hear the narratives of inconsistent care, lack of compassion from healthcare professionals and some of the most basic support needs not being met while patients were on the wards.

The developed recommendations cover aspects of care identified as lacking or inconsistent (SLR; study one and patient interviews; study two). Development of bespoke brachytherapy training, repeated at regular intervals to include new staff, should ensure that all ward staff caring for brachytherapy patients are adequately trained and aware of the needs of patients. This may include bespoke training for ward staff, delivered by therapeutic radiographers or oncologists to explain to ward staff the types of applicators used for gynaecological brachytherapy and the importance of lying flat and still. Anaesthetists or members of the Acute Pain team could explain the management of complex pain, the need for regular pain reviews and recognition of adverse drug reactions. Clinical psychologists could raise awareness of the psychological impact of brachytherapy, especially in the context of trauma caused by loss of fertility and a life-threatening illness and the risks of PTSD. Ideally, the training would be designed by a multi-disciplinary team and include input from service users with lived experience of brachytherapy for LACC.

Skill mix and number of nursing and allied health professional staff have been reported to be a key factor in ensuring safe, effective and high quality patient care on inpatient wards, leading to the development of safe staffing guidelines (National Institute for Health and Care Excellence, 2014). The National Quality Board (2018) provide guidance on establishing safe staffing levels depending on multiple patient factors, such as the acuity and dependency levels of the types of patients being cared for. As brachytherapy patients must lie flat with applicators in place for long periods of time, sometimes for up to 52 hours (UK survey, study one), they are particularly vulnerable as they are unable to self-care. Therefore, healthcare staff to patient ratios need to reflect the high dependency of these patients, during day and night shifts as there were some reports of severe pain at night and patients feeling alone, abandoned, and let down. Kirchheiner (2014) reported development of a standard operating procedure which advocates a ward nurse to brachytherapy patient ratio of one to two or three. Implementation of the proposed ward patient care recommendations should lead to more consistent high standards of care and better patient experiences for those patients having long duration brachytherapy with overnight stays with applicators in place.

6.3.6 Communication, logistics and staffing

In study two, some participants reported staff shortages or absence of key staff, and poor communication between referring centres and brachytherapy centre. This was confirmed by some service users at the NGT workshops. Appropriate staffing levels and access to support staff such as interpreters or psychologists were identified as requiring improvement in the UK survey (study one).

The proposed recommendations covered organisational aspects such as patient transport, communication between centres, ward bed allocation, and appropriate staff allocation. A recommendation for regular service evaluation was included to obtain patient feedback, including reports of pain and distress management, especially when services are changed or new services introduced. This is particularly important when centres introduce techniques which may cause higher levels of pain, such as interstitial or hybrid brachytherapy, or multiple treatments requiring applicators to be in place for longer. These suggestions are in

agreement with Kirchheiner (2014b) who recommended that treatment (brachytherapy) outcomes should include measures of patients' distress and pain. Chen *et al.* (2021) proposed reducing waiting time between applicator insertion and treatment, to minimise toxicity and patient discomfort whilst other researchers have considered time reductions for reasons unrelated to patient care (Kim *et al.*, 2018; Damato *et al.*, 2015; Mayadev *et al.*, 2014). These study findings propose that every step of the patient pathway is examined to ensure maximum efficiency, and minimal time with applicators in place. For example, Kim *et al*. (2018) suggested that streamlining imaging services and better coordination between physicists and oncologists is needed to minimise transition time between tasks. Damato *et al*. (2015) used process mapping to enable a redesign of planning procedures, including parallel rather than sequential planning, where an oncologist contours brachytherapy images at the same time as a physicist or radiation therapist works on the applicator modelling. This may require the purchase of additional computer hardware, planning software including licences and allocation of adequate staff resources. Mayadev *et al.* (2014) emphasised the need for a skilful and well-coordinated team approach to optimise safety and efficiency. Implementation of the proposed recommendations may improve the patient pathway, offer patients choice in the duration of their ward stay and access to additional support. Shortening the duration of the procedure may lead to less pain, distress and anxiety and thereby improve experiences of brachytherapy. Velji and Fitch (2001) identified distress caused by treatment disruption or interruptions which prolonged overall duration and this resonated with comments made by service users (study two) and healthcare professional (study one). The developed recommendations include the need to review staffing levels and avoid unnecessary delays. Examination of workflow or process mapping could be used to explore efficiencies to reduce overall duration.

6.3.7 Facilities on wards

In study one, patients commented on the ward environment. Several patients indicated that they would have preferred a single room, providing greater privacy during this invasive procedure. Some said they enjoyed or preferred a shared ward as it provided company and a useful distraction from the procedure they were experiencing. Some interview participants (study two) and service users at NGT workshops (study three) were unaware that brachytherapy regimes varied between centres, and would have liked a choice between

short duration day case and long duration inpatient brachytherapy schedules. At the NGT workshops, service providers commented on the limited availability of beds restricting choice. Proposed recommendations included the aim to offer a choice of single or shared rooms and adequate and accurate information about ward facilities, so patients knew what to bring with them and what to expect.

Some interview participants (study two) reported the beneficial impact of complementary therapies such as reflexology, foot massage or reiki during their inpatient stay for brachytherapy. However, only a few interview participants recruited from one centre had been offered complementary therapies. The recommendation to offer complementary therapies was the least well supported at the NGT workshops. Some workshop participants commented that this was not an essential component of brachytherapy, and they had prioritised the essentials such as pain management in their rating of recommendations.

Overall, recommendations on ward facilities were the least well supported, which may be due to the perception that they would be less likely to be implemented in an overstretched NHS. From the UK survey (study one) and NGT workshop (study three) it was shown that some healthcare professionals believed that their centre met all the essential requirements but indicated that they may want to consider these extra steps to improve patient experiences and be a recognised centre of excellence. As reported in the SLR, foot reflexology and aromatherapy, a music relaxation video and relaxation and guided imagery benefit women undergoing brachytherapy procedures and would be worth consideration if resources were available (Blackburn *et al.*, 2021; Chi *et al.*, 2015; Leon-Pizzaro *et al.*, 2007). These RCTs demonstrated significant reductions in pain or anxiety when compared with control conditions and warrant feasibility testing to see if these non-invasive interventions could be used in routine clinical practice, rather than in a setting of a clinical trial.

6.3.8 Overall impact of proposed recommendations on clinical practice

The 55 proposed patient care recommendations provide a starting point for the co-development of clinical protocols and possible intervention strategies to improve patient experiences of brachytherapy. This will need to be followed by a programme of implementation and evaluation.

6.4 Indications for future research

To improve standard care in brachytherapy for LACC, the proposed patient care recommendations will need further refinement before they can be considered ready for implementation into clinical practice. After this, methods need to be explored to find which would be the most effective implementation route. The proposed patient care recommendations include assessing and identifying those most at risk of poor experiences. However, further research is needed to investigate ways to assess patients to be able to identify those at most risk of poor brachytherapy experiences. If they can be identified, then targeted interventions or resources can be used to improve their experiences in a targeted approach.

6.4.1 Development and implementation of patient care recommendations

It has been found that it takes an average of 17 years for research findings to be translated into clinical practice (Balas and Boren, 2000) and there have been consistent failures to bring research outcomes into policy (Ferlie *et al.*, 2012; Grimshaw *et al.*, 2012). This highlights the importance of considering implementation strategies and knowledge mobilisation as part of the research process.

To evaluate and improve implementation of new knowledge, many theories, models and frameworks have been developed from a broad range of philosophical backgrounds. They can be categorised into five main theoretical approaches: Process models; Determinant frameworks; Classic theories; Implementation theories and Evaluation frameworks (Nielsen, 2015). A better understanding and use of these theoretical approaches may help to reduce the research-practice gap.

Clinical practice guidelines (CPGs) have been defined as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” (Committee to Advise the Public Health Service on Clinical Practice Guidleines. Institute of Medicine, 1990, p.8). For many years the quality of CPGs have been criticised for not reporting sufficient detail of their guideline development processes or not following robust, transparent processes (Hou *et al.*, 2022; Alonso-Coello *et*

al., 2010; Shaneyfelt, Mayo-Smith and Rothwangl, 1999). Clinical guidelines produced specifically by specialty societies were also found to be unsatisfactory and it has been recommended that methodological criteria should be established (Grilli *et al.*, 2000). Tools and checklists have been developed for the appraisal of guidelines, such as the Appraisal of Guidelines, Research and Evaluation (AGREE) II tool and Reporting Items for Practice Guidelines in Healthcare (RIGHT) checklist (Chen *et al.*, 2017; Brouwers *et al.*, 2010). Tools and checklists can help to assess the quality or credibility of CPGs in healthcare, however Schünemann *et al*. (2014) reported that there were few practical guidelines to help clinicians or organisations to develop and implement CPGs. They devised a comprehensive checklist of 18 topics and 146 items for CPG development including the stages of planning; formulation, implementation and evaluation. For example, deciding guideline group membership, processes, target audience, and what evidence to consider (Schünemann *et al.*, 2014). There is also guidance on the rating and grading of evidence to be used in development guidelines (Guyatt *et al.*, 2008; Atkins *et al.*, 2004). Guidelines based on theoretical frameworks and following defined processes have increased since 2015 (Peters *et al.*, 2022; Gagliardi and Alhabib, 2015). Theoretical frameworks include the Theoretical Domains Framework and Social Cognitive Theory and analysis of barriers, which it is thought may lead to improvements in the impact of guidelines through effective implementation strategies (Peters *et al.*, 2022).

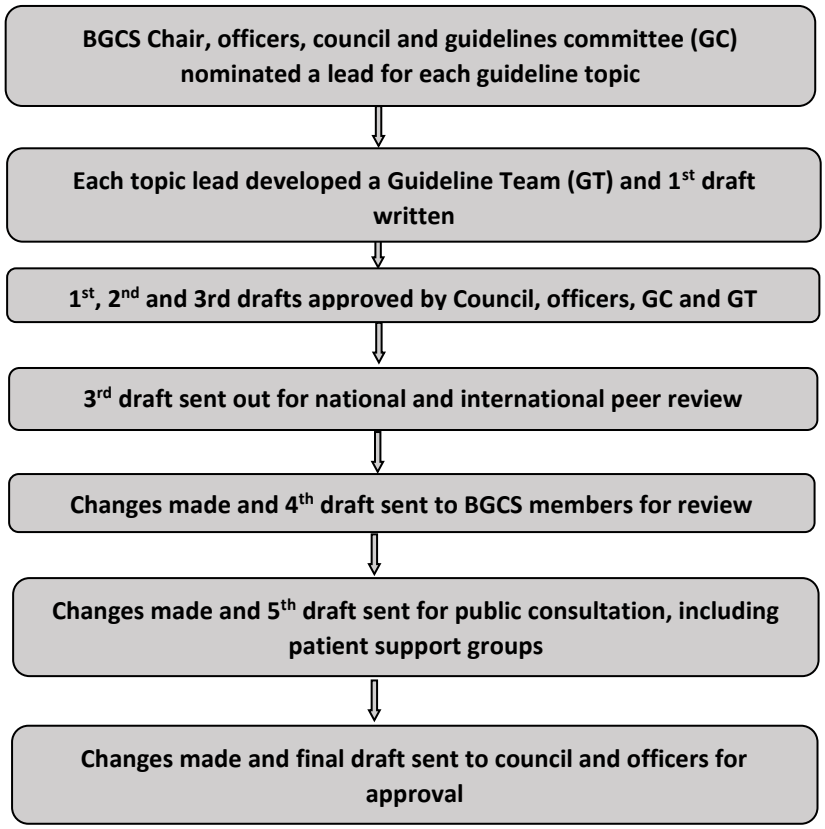
A number of different approaches through specialty organisations may be considered as part of a post-doctoral programme to develop CPGs for patient care in brachytherapy for LACC, which could be followed by an implementation phase.

National development of CGPs for patient care in brachytherapy

The UK survey of brachytherapy practice (study one) showed a clear picture of current provision for scheduling, anaesthesia and analgesia and support for patients during brachytherapy. The NICE guidelines relating to brachytherapy for cervical cancer were published in 2006 and focus on efficacy of this interventional procedure as LDR techniques were replaced by HDR. Since 2006, NICE have not developed any further guidelines or recommendations relating to brachytherapy for cervical cancer. In 2009 the RCR published guidelines for implementing image guided brachytherapy (RCR, 2009), but these guidelines

were withdrawn by the Clinical Oncology Professional Support and Standards Board in May 2017 without explanation. More recently, the British Gynaecological Cancer Society (BGCS) has produced guidelines about radiotherapy for gynaecological cancers and brachytherapy (Reed *et al.*, 2021). However, to date there are no guidelines relating to patient care in brachytherapy for cervical cancer. NICE, the RCR and BGCS are key stakeholder organisations that could contribute to further development of the patient care recommendations developed in this programme of research, and contribute to future implementation. The most recent work on UK cervical cancer guidelines was carried out by BGCS and this would align well with development of the proposed recommendations from this research programme. The method used in development of the BGCS 2021 guidelines is summarised in Figure 22. This includes consultation stages, firstly through national and international peer review, followed by BGCS members then public consultation including patient support groups.

Figure 22 The BGCS guideline development process (2021)

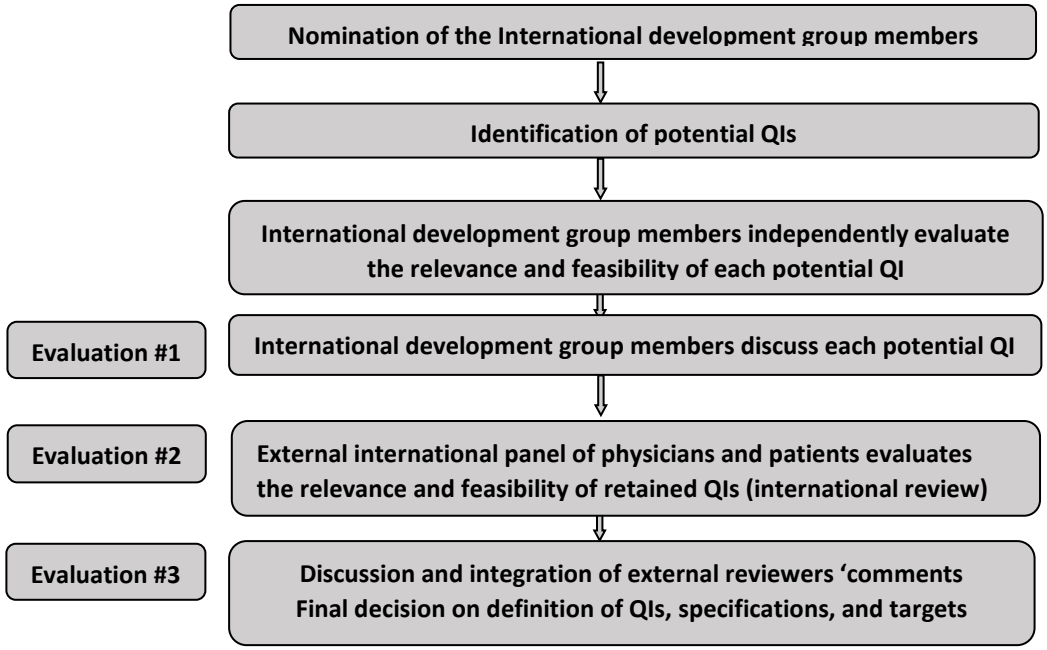


If a similar method were to be applied for development of recommendations for patient care in brachytherapy for LACC, a potential strength would be the use of an established collaboration of UK clinical experts, although reassurance would be needed that this included sufficient *brachytherapy* experts. Another strength would be the involvement of public and patient feedback, although it is not possible to know what changes were made as a result of the BCGS radiotherapy guidelines public consultation as this is not reported in the publication.

International development of CGPs for patient care in brachytherapy

From 2021 to 2022 the doctoral fellow was involved in a working party formed through a collaboration between the ESGO and ESTRO to develop quality indicators (QIs) for radiotherapy for cervical cancer. The working party comprised an international multi-disciplinary team of radiation/clinical oncologists, gynaecological-oncology surgeons, a methodologist and one therapeutic radiographer (the doctoral fellow). The process adopted by the working party is displayed in Figure 23.

Figure 23 The ESGO-ESTRO guideline development process (2021-2022)



The QI development work has recently been completed and in October 2022 the manuscript was submitted for simultaneous publication in leading international surgical and oncology journals (Chargari and ESGO and ESTRO International Development Group, 2023, article in press). The manuscript contains 20 QIs, three of which relate to patient outcomes (local recurrence rate; major late complications and patients offered a sexual rehabilitation programme). Emphasis has been placed on the need for a structured programme to report, review and manage late side-effects through rehabilitation programmes. The working party considered that a low recurrence rate and low rate of late complications is indicative of high quality radiation treatment, through the optimisation of tumour dose and minimising dose to organs at risk. In the manuscript the importance of assessing the level of care by collecting QoL data is highlighted, with an acknowledgement that underestimation of treatment morbidity has been shown in EMBRACE I data (Kirchheiner *et al.*, 2012). However, this does not acknowledge the difference between a medical understanding of quality of care and *patient* care, which could be indicated through patient satisfaction data rather than QoL data. In the manuscript it was recommended that patient-reported outcomes should be integrated into routine clinical practice.

The ESTRO gynaecological brachytherapy specialist group may be an appropriate network to develop ESTRO patient care recommendations or guidelines for brachytherapy for LACC, potentially following a similar method to the cervical cancer QI development. If this method was used for the development of patient care recommendations, a limitation compared to the BGCS method (Reed *et al.*, 2021) would be the lack of involvement of patient groups. The flow diagram in the ESGO-ESTRO manuscript shows a step where the external panel of physicians and patients were to be invited to evaluate the relevance and feasibility of the QIs. However, the described method states that only international practicing clinicians were to be invited to comment. In practice, 99 clinicians provided feedback, mostly medical professionals. This may have been considered appropriate as the QIs were quite technical and there was little focus on patient care, with only three QIs relating to patient outcomes. However, patient and public involvement in development of patient care recommendations was suggested to be beneficial in the NGT workshops (study three), and would be desirable for consultation in future development stages.

UK charity development of CGPs for patient care in brachytherapy

In October 2022 the PRDA launched their Best Practice Guidelines for Pelvic Radiation, a 163-page toolkit for healthcare professionals. It is described as a "reference tool for clinical decision-making for health services in the UK". It was developed by the PRDA Patient Advisory Group, people with lived experience of pelvic radiation disease (PRD) and a panel of clinical experts including Cardio-Oncologists, Clinical Oncologists, Clinical Psychologists, Dieticians, Endocrinologists, Gastroenterologists, General Practitioners, Late Effects and Lymphoedema practitioners, Oncology Nurses, Pain Medicine specialists, Psychosexual Therapists, Therapeutic Radiographers, and Urologists. The guidelines include information about the side effects of radiotherapy, how to identify and help people with PRD and where to access professional information and guidance on management. In addition to providing a toolkit for healthcare professionals the guidance is useful for health service managers, commissioners, researchers, and patients and carers. There is little detail within the document about how it was developed, other than by a consensus of experts, consisting of healthcare professionals and people with lived experience, considering current evidence and guidance relating to PRD and living with and beyond cancer. The panel of approximately 30 experts were appointed members of a PRDA Professional Engagement team, a PRDA Medical Advisory Panel and a steering group. The development of the PRDA Best Practice Guidelines provides a recent example of how interested parties or experts have managed to produce a consensus document in a similar area of clinical practice, and may be worth exploring in greater detail to see how consensus was reached. Ascertaining the methodology used may enable the doctoral fellow to critique and compare with research methods from literature. This information may influence the formulation of a strategy for the future development and implementation of patient care recommendations for brachytherapy. The strength of this type of approach to development and implementation would be that it adheres closely to the principles of co-design. This includes shared decision making between patients and healthcare professionals, listening and valuing the voices and opinions of patients and where possible, acting together to improve services (Robert *et al.*, 2015; Donetto, Tsianakas and Robert, 2014; Slay and Stephens, 2013).

Possible process for implementation of CGPs for patient care in brachytherapy

To facilitate impact from the patient care recommendations, methods for implementation need to be considered. A pilot implementation project in the doctoral fellow's department will be considered initially, using a quality improvement approach. This could utilise popular improvement models and tools originating from the manufacturing industry, such as the Plan-Do-Study-Act Cycle or Fishbone or Ishikawa diagram (Nicolay *et al.*, 2012; Ishikawa, 1990). Initially, the areas requiring improvement will need to be identified, focusing on the findings of this research programme and proposed patient care recommendations. Consideration would be given to the barriers and facilitators for change and how change can be measured and evaluated. Taking each area of the recommendations, a plan for step-by-step change could then be developed. For example, considering pain management improvements, a Fishbone analysis could be used to identify the root causes of the problem. This may show that a pain protocol needs to be written to assist anesthetists, who are less familiar with brachytherapy techniques, to provide appropriate anaesthesia and analgesia during brachytherapy procedures. Key stakeholders should be involved in the development of the protocol, such as patients, oncologists, anaesthetists and theatre nurses. It may also be identified that healthcare professionals need more training in management of complex pain. This may already be available, such as a training package provided by the Acute Pain Service in the doctoral fellow's workplace, or in some centres bespoke training may need to be developed. Consideration will need to be given to project leadership and development of a mission or shared goals to ensure staff engagement in implementing change. This has been identified as a key component in NHS quality improvement success and provision of high quality care (Dixon-Woods *et al.*, 2014).

There may be many barriers to change by healthcare professionals, such as lack of motivation, time, ability or capability, and a lack of understanding of the problem needing improvement. The NGT workshops highlighted that healthcare professionals may not realise the divergence between their perceptions of patient experience of brachytherapy and the view of care from the patient's perspective. Therefore, raising awareness of the patient experience through dissemination of findings from this research will be critical to the future success of implementation.

Implementation projects could be supported in other UK centres. A write up of study two is being prepared for submission for publication. Following publication of study two, the doctoral fellow plans to contact key healthcare professionals at the four UK recruitment sites for study two, and invite them to take part in implementation projects in their centres, and potentially roll this out to other centres. Collaboration with other researchers in this field may provide further momentum for change.

6.4.2 Identification of individuals at highest risk of poor experiences

From this programme of research, it is clear that some patients have worse experiences of brachytherapy than others. When standard care is improved through implementing the developed recommendations, it is likely that there will still be some patients who have poor experiences of brachytherapy. However, it is hoped that the number of these patients will be smaller if care is optimal. Identification of patients at risk of a poor experience, may allow targeted additional support. For example, Kirchheiner *et al*. (2014b) concluded that those at risk of development of PTSD should be offered targeted psychosocial support. There is anecdotal evidence that some patients are unable to complete brachytherapy due to high anxiety levels or fear of the procedure, fear of re-triggering existing PTSD or poor prior experience of brachytherapy. However, the only study reporting compliance rates for brachytherapy, found non-compliance rates of 1.27% across all types of brachytherapy, with 100% of non-compliant cases occurring in patients having gynaecological brachytherapy (Khanna *et al.*, 2022). It is hoped that improving patient experiences, including targeted additional support would improve patient concordance and therefore completion of brachytherapy. Better management of pain, anxiety and distress may also impact on post treatment healthcare, such as number of visits to general practitioners or other healthcare services. However, further research and evaluation would be required to explore correlations.

Predictive factors for PTSD have previously been identified as a history of sexual violence; poor physical functioning; higher anxiety levels and lower emotional functioning (Kirchheiner *et al.*, 2014b). Kirchheiner recommended identifying patients at risk of PTSD so that they can be offered targeted psychosocial support (Kirchheiner, 2014). More recent research identified an association between use of opioids and age of patients, with younger

patients needing more opioids during brachytherapy (Wilson *et al.*, 2021; Mendez *et al.*, 2017a). This is also found in general surgery, with younger people requiring more analgesia in the post-operative period (Ip *et al.*, 2009). Another important consideration is previous healthcare experiences and health beliefs. Some patient participants (study two) had lost trust in healthcare professionals because of not being listened to, believed or understood, which in some cases had led to a delayed cancer diagnosis. The impact of loss of fertility was highlighted in the interview stage of this research, with added significance from the context of a life-threatening cancer diagnosis. This may need to be carefully explored with individuals, due to the obvious emotional or traumatic triggers that may arise during brachytherapy. This type of assessment may need the involvement of clinical psychology experts, either to carry out the assessment or to work with the research team to develop an appropriate assessment tool or questionnaire that could be used by other brachytherapy expert practitioners. The risk assessment might include previous pain experiences and past or current use of analgesia or recreational drugs, due to their impact on subsequent responses to anaesthesia and analgesia. Development of this assessment should involve clinical oncologists, anaesthetists, pain experts such as the acute pain team and palliative care team, and experienced brachytherapy radiographers. Overall, a multifactorial toolkit or risk assessment is needed to identify those more likely to experience anxiety and distress, uncontrolled pain, or PTSD as a result of brachytherapy.

6.4.3 Targeted additional support for individuals at highest risk of poor experiences

Individuals identified as being at high risk of having difficult brachytherapy experiences may benefit from individualised support. For example, those with a history of poor pain management, previous or current use of opioids or recreational drugs, may need the involvement of expert pain management healthcare professionals such as the Acute Pain team or Palliative Care team. A better understanding of their pain and medication history may help develop improved pain management strategies to avoid periods of severe or uncontrolled pain. Others may need additional support from a clinical psychologist to develop strategies to cope with anxiety and distress as well as raising awareness amongst brachytherapy healthcare professionals of potential triggers and how to minimise or avoid these. Although offering clinical psychology support before brachytherapy should ideally be part of standard care, the UK survey (study one) found only three of 38 participants said this

was routinely provided in their centre. It is anticipated that the publication of QIs for radiotherapy for cervical cancer will give rise to development of accredited centres of excellence. This accreditation will be awarded to those centres who are able to provide evidence that they meet the specified quality indicators, including aspects of brachytherapy for LACC (Chargari and ESGO and ESTRO International Development Group, 2023). In the future, there is potential for brachytherapy to be provided for those at greatest risk of poor experiences in a centre of excellence.

The principle of 'parity of esteem' described by the Royal College of Psychiatrists (2013) acknowledges the importance of addressing mental health issues and inequalities in services. They advocate for health and social care services to give equal status to mental and physical health provision (Royal College of Psychiatrists, 2013). However, Millard and Wessely (2014) report the difficulties with definitions and implementation of the 'parity of esteem' principle and the difficulties in overcoming the stigma of mental illness. They conclude that application of this principle is not only about finances, but more about attitudes to mental health and that we need to start by addressing the disparities through integration of mental and physical health services (Millard and Wessely, 2014). A model such as 'trauma-informed care' may provide a set of principles to help healthcare professionals recognise how a person's history will have a significant impact on how they experience their health and healthcare interventions. This model has derived from an understanding of the impact of Adverse Childhood Events on mental and physical health (Purkey, Patel and Phillips, 2018). In brachytherapy, viewing or assessing patients through a trauma-informed lens may help build relationships of understanding and trust, leading to more targeted and appropriate support.

6.4.4 Evaluation of the implementation of patient care recommendations

For centres that introduce some or all of the developed patient care recommendations, it will be important to assess the impact of the service development or QI. This would require a pre and post implementation evaluation. Examples of data to be captured could include patient's pain scores throughout the procedure, levels of anxiety and distress at different time points, satisfaction with information provision (accuracy and timeliness), and satisfaction with facilities and care on the wards. Consideration needs to be given to where,

when and how the impact of service improvements are evaluated. Poor timing or method of evaluation may lead to inaccurate results. For example, Bhannabai *et al.* (2013) reported that all patients commented on satisfaction with their pain control during the procedure. The study methods state that nurses asked patients in the recovery room after completion of brachytherapy if they were satisfied with the degree of pain control. A closed question, asked by a member of staff who had been providing the care immediately after the procedure would not be likely to capture an accurate or relevant evaluation of patient satisfaction. Patient satisfaction scores reported in some of the quantitative studies of analgesia and anaesthesia techniques do not fit well with the lived experiences described in the qualitative studies, where patients reported pain, anxiety and distress. It has been shown that healthcare professionals underestimated the anxiety experienced by patients during brachytherapy (Anderson *et al*., 1984). Kirchheiner *et al*. (2012) reports mismatches between patient reported symptoms after treatment compared with clinician reports, with clinicians underestimating the severity or impact of symptoms. Therefore it is important that patient-reported outcome measures (PROMs) that are completed by patients (not healthcare professionals) and not linked to individuals are used to evaluate patient experiences.

The development of patient-reported experience measures (PREMs) can provide a view of patient experiences, such as whether they were listened to or not, and is an important means of evaluating quality of care (Kingsley and Patel, 2017). The use of patient satisfaction surveys has been criticised for a lack of translation of data into real improvements for patients (Coulter *et al.*, 2014). Surveys such as the Friends and Family Test and the National Cancer Patient Experience Survey provide large quantities of data about NHS services and specifically cancer treatments but there is currently no co-ordination of the patient experience data collected and it is difficult to track what changes are made in light of patient feedback (Coulter *et al.*, 2014). It is possible that the optimal way to obtain accurate and detailed feedback after brachytherapy would be from a patient interview conducted by an independent party, not part of the clinical care team, carried out at a suitable time after completion of treatment. Patients may need reassurance of their anonymity if providing negative feedback, with reassurance that their ongoing care will not be affected. It was clear in the interview study and the study by Kirchheiner *et al*. (2014b)

that participants were very grateful for the care that they received and did not want to directly criticise their healthcare professionals, even when they had poor experiences. Alternatively, the deployment of a PREM questionnaire could be considered, perhaps to be conducted over the phone rather than online or posting out a paper questionnaire, so that appropriate support or signposting to participants after brachytherapy could be provided if poor experiences or trauma are being reported. This would also allow qualitative data to be collected in addition to quantitative data, and would therefore provide detail of reasons and explanations for the quantitative results. In this research programme, the patient interviews were carried out between 4 weeks and 18 months after brachytherapy and good recall of brachytherapy experiences was apparent by all except one of the participants. Reflection on events and the impact of their brachytherapy experiences on their lives was captured well in the interviews. Therefore, an evaluation framework could be explored and developed, with the involvement of patients with lived experience of brachytherapy. Centres would need a baseline assessment or feedback to evaluate current services and then re-evaluation after implementation of the patient care recommendations. Ideally, both quantitative and qualitative data could be used to evaluate patient experiences before and after service improvements.

Evaluation of the provision of bespoke brachytherapy training for ward staff should be included in future recommendations, to ensure that brachytherapy patients are being cared for by healthcare professionals with a good understanding of the additional complex needs of patients, to be best able to help them cope with the physical and psychological aspects of the treatment.

6.5 Strengths and limitations of thesis

Limitations

The overall focus of the research programme has been on service provision and experiences of UK patients. Therefore, the findings may be less applicable to patients having brachytherapy in developing countries, where there are higher numbers of cases but less resources, particularly anaesthetic resources. To be applicable or generalisable internationally, the patient care recommendations would need to be adapted to local

resources and logistics. However, it is hoped that the developed recommendations will provide some guidance to support centres to campaign for increased resources.

Qualitative research is considered to be less generalisable than quantitative, with greater emphasis often placed on large samples rather than rich, thick and messy qualitative data derived from a small sample. This could have implications on how the findings from this research are received and the significance or weight of the data when recommendations are being developed or evaluated. However, the doctoral fellow recognises the importance of giving a balanced and rich account of patient experiences. This has been achieved by staying close to the data and demonstrating the wide range of patient experiences across four UK centres. It is also important to acknowledge that every patient story is valuable and relevant and can and should be used to direct where changes and improvements are needed.

There were low numbers of participants in the NGT workshops, however this allowed time for more detailed discussions of the recommendations. Future work to develop the recommendations further will need to include wider consultation with key stakeholders, and the NGT workshops have provided a starting point in relation to verification and clarification at this early stage of development.

Overall, it was not appropriate to develop a single intervention to improve the patient experience. However, it was important to recognise that the range and complexity of patient experiences need to be used to develop comprehensive and holistic service improvements through development of patient care recommendations.

Strengths

The exploratory nature of the overall research programme has provided a comprehensive picture of the current service provision and a depth of understanding of women's experiences of these services. Having a high percentage of UK centres responding to the survey and so many patient voices being heard through the interviews gave a broad view of current service provision and what needed improving. Including four UK centres where brachytherapy is delivered differently for interview recruitment provided insight to the

impact of short and long duration brachytherapy on patient experiences. This has helped the findings to be potentially transferable to most UK centres delivering brachytherapy.

The importance of the patient voice has been shown in the strength and depth of data from the patient interview study, and added to by service user participants in the NGT workshops. The appointment early in the doctoral fellowship of two research partners with lived experience of brachytherapy for LACC added valuable insights from a patient perspective. As members of the research steering group, the research partners have taken part in discussions on direction of the research, methods to be considered, reviewing protocols and participant facing documents and finally in co-facilitation of the NGT workshops. Initially their role was mainly consultative, but over the course of the research programme this evolved into a fully collaborative partnership, fulfilling the title of 'patient research partner'. Their involvement has added strength and depth and reassurance to the doctoral fellow of the significance and relevance of the programme of research. The involvement of patient research partners has ensured that the research project was patient-centred from the planning stages through to the data analysis and dissemination.

The quantity and quality of data from the interview study has provided information about a wide range of experiences, showing a breadth and depth of understanding of the lived experiences of women having brachytherapy for LACC.

In the NGT workshops (study three) the use of co-production was a strength of the study. It was an advantage having both service users and service providers in the same workshops, as clinical staff were able to listen directly to service users and hear their experiences, what they thought of the recommendations and the importance they placed on some of the recommendations. From the service user's perspective, having the service providers in the same workshop made them mindful of what was feasible or possible, the realities and practicalities of the service.

The support from the supervisory team and research partners was a strength of the research programme. Input from academic supervisors with considerable experience in mixed methods research and qualitative research, including content analysis and thematic

analysis, has provided the doctoral fellow with the underpinning support required for a novice researcher. Having a clinical supervisor with an international view on gynaecological brachytherapy techniques leading the development of the more technical aspects of service improvement has provided a depth of understanding to the supervisory team of the relevance and context of this programme of research.

Findings from this research programme have been disseminated through conference abstracts, poster, video and oral presentations at national and international conferences (see Appendices 30, 31, 32, 33, 34, 35 and 36). Full write-up of study one has been published in Radiotherapy and Oncology, Humphrey *et al.*, 2021 (see Appendix 37).

6.6 Personal reflections on thesis journey

The four-year clinical doctoral research fellowship has been an amazing opportunity for me to learn and develop my research skills. I had previously felt this was an area I knew little about and a weakness in my ability to fulfil the four pillars of the consultant practitioner role. The programme of training and education, underpinned by academic and clinical supervision has enabled me to move from a novice researcher to a researcher with experience in specific areas of qualitative and mixed methods research. I have also benefited professionally from the support and advice of an Integrated Clinical Academic (ICA) mentor, external to the supervisory team, someone who had been on a similar journey a few years ahead of me, able to understand and sympathise with the difficulties of juggling between studying and a senior clinical role.

I was privileged to be able to complete an overseas trip as part of my doctoral fellowship. I chose to visit Sunnybrook Cancer Centre in Toronto for a three-day observership, to watch the delivery of complex gynaecological brachytherapy under GA for the whole duration of the procedure. In my clinical practice I have met many patients who have asked if they could be asleep for the whole treatment, and had to explain to them that this was not possible. The standard response from myself and colleagues was that they would have to be under GA for too long, transfers for imaging would not be possible and an anaesthetic team could not be allocated to stay with them all day. By chance I had discovered that Sunnybrook

completed brachytherapy with patients under GA throughout, and I was curious to see how the team managed the logistics and safety of this practice. I observed limitations to capacity as the number of patient numbers was limited to one per morning or afternoon list, a maximum of two patients per day. The patient had applicators placed in theatre under GA and was transferred to a MR imaging compatible trolley and wheeled into MR unit in the adjacent room. The anaesthetic team had a second set of anaesthetic equipment in the MR imaging room (MR imaging compatible) and were able to quickly switch from one anaesthetic unit to the other. I observed brachytherapy planning being carried out in a parallel method, something I had not seen in any UK departments. At times there were three healthcare professionals working simultaneously on the planning, using three separate computer workstations. This shortened the planning time to approximately one hour. The overall time from induction of anaesthesia to end of procedure was between three and four hours. For each patient this would be repeated three times over a two-week period. I observed a very smooth procedure delivered by an experienced team. The brachytherapy staff said that patients really appreciated being under GA throughout the brachytherapy and some chose to travel to the centre specifically for this. However, I am not aware that any formal review of toxicity from this duration of anaesthesia has been carried out to date. A full assessment of this technique and publication of findings, including a cost analysis would be needed before this could be considered in other centres. Further observations and reflections from the Toronto observership are included in Appendix 29.

Through my interviewing and analysis of interview data, I was surprised and shocked by the reports of inconsistent and poor care on the wards. This was strongly reinforced when I presented a summary of the first eight interviews to the research steering group, consisting of the PhD supervisory team and two research partners. As a clinician, in my head I had begun to make excuses for the poor care, such as ‘but brachy is complex’, ‘pain management can be problematic’, ‘everyone is so different’. However, presenting a report to the steering group, the shock and disappointment regarding nursing care was evident in their responses, and brought the reality home to me. This strengthened my view that brachytherapy for LACC is a difficult and complex treatment to deliver, however I concluded that basics of nursing care need to be in place before other service improvements can be considered.

The impact of the patients' stories on me has been quite challenging at times. To hear stories of poor experiences, poor nursing care, episodes of severe pain and the harmful effect this has had on brachytherapy patients has been quite disturbing. I found the narratives from some of the younger women quite upsetting to hear. It was distressing to witness and try to comprehend the impact of their loss of fertility. Also, the impact of a cancer diagnosis, a life-threatening diagnosis, for women of all ages was significant for me. As a clinician working in radiotherapy for over 30 years, I am very aware of the impact of a cancer diagnosis. However, to get through my working day, week, year, I think I may have become hardened to some of those feelings, possibly to protect myself from burnout. The impact of listening to those stories through the research process, listening again and again to unpick, analyse, consider what they were telling me and how to put that across in my synthesis of the data, has perhaps made it more impactful to me. I am aware that I wouldn't normally hear those stories in my day-to-day clinical work. In my clinical practice I don't usually meet patients after they finish treatment, so the depth and understanding of brachytherapy experiences on their lives really struck me. This has made me consider the question of the most effective way to evaluate patient experiences, to find out if we are improving them. How can we best capture real, in-depth, impactful and insightful reflections from the patients on what they experienced and the impact this has made on their future lives? Listening and engaging with patients through the patient interviews has truly opened my eyes to the importance of obtaining an in-depth understanding of their experiences and the power and significance of hearing the patient voice.

Patient-centred care is a phrase used so much in healthcare, but I wonder if we really spend sufficient time and energy to make this happen in clinical practice. Due to high numbers of patients and in recognition of our finite resources, I wonder if the NHS is often limited to work within protocols and guidelines, because adapting them to the needs of individual patients would become resource intensive. I was struck by a comment from one of our workshop participants, that despite having protocols and guidelines, we also need to react and respond to the individual patient in front of us. For example, if a patient is crying out in pain, we should not be waiting for the four-hourly review specified in the protocol, we need

to respond to the immediate needs of the patient. So individualised, patient centred care is vital, and perhaps the protocol should be introduced as only a minimum standard of care.

Through the doctoral fellowship I believe I have had a good introduction to qualitative research and developed a real passion for listening to patient experiences. I now have an understanding and appreciation of how powerful that is for me as a researcher, but also the importance of giving clinicians the opportunity to hear the patient voice. I have realised that in clinical practice we rarely get to hear the patient voice in any reflective way. We do not get to listen to patients when they've had a chance to think and reflect on their experiences, when they can offer their insights to us. I think we need to put more effort and resources into gathering patient experience information if we want to improve our services.

Through my doctoral journey I have become more confident in my understanding of research processes, firstly through focusing on identifying research aims and objectives. Questions such as 'What is the justification for the research?', 'What is the research question?', and working out the best method to answer that question. I now have a better understanding of research processes and the multiple steps required to carry out research correctly. I now have an appreciation that you are not able go back and do it again, so you must get it right first time. I have observed a different approach in research practices compared with clinical work. This may be due to having patients and carers in front of you in the clinical environment, therefore a greater need to act and react in the moment, to adapt to different situations, however much planning and preparation has taken place. Whereas in research you can take more time to explore the best way. I have learned that I need to take time to get it right first time, and that makes me feel guilty that we are not doing that in clinical practice. There seems to be a more pragmatic approach when you have a patient or several patients in front of you, with only a certain amount of time to get through the work that needs to be done. Patients do not want you to postpone or ask them to come back on another day, and in the field of oncology their treatment is usually urgent. In research, I have learned that I need to take the necessary time, to consider options and consult other people before making decisions.

In the field of oncology there is a great emphasis placed on providing the most effective treatment for cancers, to increase survival, improve local control or minimise potential side effects, and rightly so. However, I believe that this should not be to the detriment of patient care or ignoring patient experiences. There are many published studies about technical aspects of brachytherapy for LACC, optimal imaging, planning, dose reporting, but much fewer studies about patient experiences. Even the studies about pain management frequently omit patient reported outcomes, or any meaningful evaluation of patient satisfaction. Some of the cancer charities such as Macmillan, PRDA and Jo's Cervical Cancer Trust, have been striving to improve aspects of patient experience through providing information and support and funding development of support roles, such as services for late radiation effects. However, perhaps in time these support roles should be part of the NHS funded services, a key component rather than an add-on. If further development of the use of PREMs by NHS quality improvement services takes off, this may raise awareness of the importance and relevance of patient experiences in mainstream services.

6.7 Final conclusions

Brachytherapy for LACC has been reported to cause pain, anxiety and distress. At the outset, the aim of this programme of research was to develop an understanding of women's experiences of brachytherapy for LACC to inform interventions to improve the patient experience. A UK survey of practice showed there were eleven different scheduling regimes being used and a duration with applicators in place ranging from three to 52 hours. Interviews with patients showed widely variable experiences, ranging from poor care whilst on the ward and episodes of uncontrolled pain, to no pain and overall good experiences. From the interview data, survey data and literature, it was clear that standard care needed to be improved. The findings indicated that patient care recommendations are required for pain management, including pre, peri and post-operative anaesthesia and analgesia; provision of information and support; general medical management; ward nursing care, including bespoke training of healthcare professionals; communication, staffing and logistics and ward facilities. At NGT workshops the developed patient care recommendations were well supported by service users and service providers, verifying that most recommendations were useful, achievable and relevant. These patient care recommendations require further

refinement and consultation with a larger stakeholder group before implementation in clinical practice. It is anticipated that future implementation of patient care recommendations will raise standards and improve consistency of the patient experience of brachytherapy for LACC. Re-evaluation is advised when services are developed or changed, to explore the impact on patient experiences.

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Appendices

Appendix 1: Role description for Research Partners

People in Health West of England

Better involvement · Better research · Better health

Role Description

Public Contributor for *the Brachytherapy for cervical cancer research project*

1. Background

People in Health West of England (PHWE) aims to share good practice and resources encouraging the involvement and participation of patients and members of the public. It was set up by the WEAHSN, the Collaboration for Applied Health Research and Care (CLAHRC) West, the Clinical Research Network (CRN) and Bristol Health Partners (BHP). This joint approach is unique.

2. Main responsibilities

2.1. To act as a critical friend and offer advice and support to the Brachytherapy for cervical cancer research project

2.2. To prepare for and actively participate in the Steering Group. This will include reading meeting papers that may be lengthy and/or complex. It is anticipate that the Steering group will meet once a year, and can be either face to face or via skype or telephone conference.

2.3. To respond and comment on any promotional materials being produced, for example Patient Information Leaflet for semi-structured interviews.

2.4. To undertake activities between meetings as ***mutually agreed***. This may include some or all of the following:

- Attending events organised by the steering group (for example, a seminar or workshop).
- Attending or presenting at a conference if appropriate.

Promoting a strong public voice...

Bristol Health Partners · Clinical Research Network: West of England · Collaboration for Leadership in Applied Health Research and Care West · University of the West of England, Bristol · West of England Academic Health Science Network

- Involvement in other relevant activities as appropriate.

2.5. When appropriate, provide support to new public members.

3. Commitment

The role is anticipated to require a time commitment of less than *one hour per month for four years.* Arrangements for this role can be reviewed at any time, but will formally be reviewed after three months of your role commencing.

4. Payment and expenses

We endeavour to make sure you are recompensed for your time and travel. Payment for time spent on an advisory (or steering) group will be £20.79 per hour, which covers the time spent preparing for meetings such as reading minutes and associated papers. Other out of pocket expenses such as travel (45p per mile by car) or carer's allowances will be paid in addition.

http://www.invo.org.uk/wp-content/uploads/2016/12/INVOLVE_payment_document_v4-NOV16.pdf

http://www.phwe.org.uk/resources/phwe-resources-guides/

Members of the public who are in receipt of welfare benefits and are offered payment for involvement need to consider how the payment might affect their benefits. This is a complex topic on which INVOLVE has set up a Benefits Advice Service to offer their expert knowledge. The advice is free, confidential, informed by the latest regulations and personalised (the advice is specific to the individual's circumstances). Please ask anyone wishing to access the service to email benefits@invo.org.uk or to phone on: 02380 651088.

5. Induction and support

All new patient/public members will be encouraged to read INVOLVE guides to getting involved in NHS, public health and social care research prior to starting this role, to prepare new members for their role and provide practical information about getting involved (for example, style of meetings, format of papers, how to contribute effectively, expenses and payment). INVOLVE Public Information Packs 1-4 are available at http://www.invo.org.uk/posttypepublication/public-information-pack-pip-booklet-1-a-quick-guide/

http://www.invo.org.uk/posttypepublication/public-information-pack-pip-booklet-2-getting-started/

http://www.invo.org.uk/posttypepublication/pip-3-finding-out-more/

http://www.invo.org.uk/posttypepublication/pip-4-jargon-buster/

6. Public contributor role requirements

Skill/Experience	Essential
Experience of *cervical cancer and brachytherapy* as patient or carer	**Y**
Experience of working with others to address common issues of concern.	**Y**
Knowledge and experience of the NHS, social care and/or public health services as a service user or carer/ family member.	**Y**

Proven interpersonal skills and the ability to listen and to express own views about relevant issues in a way that respects the contributions of others and avoids jargon as far as possible.

Y

Ability to work as part of a group with people from a wide range of different backgrounds.

Y

Ability to focus on tasks and achieving outcomes.

Y

Ability to bring relevant knowledge from the perspective of members of the public.

Y

Ability to draw on personal experiences and work constructively with others towards service improvement.

Y

A commitment to promoting diversity and equality of opportunity.

Y

A commitment to prepare fully for meetings.

Y

Access to the internet and basic IT skills.

Y

To respect any requests for confidentiality, declare any conflicts of interest if these arise and abide by an agreed code of conduct.

Y

Appendix 2: SLR Pre-proof manuscript

SLR Pre-proof manuscript accepted for publication in *Radiography* (2018)

The experiences of women receiving brachytherapy for cervical cancer: a systematic literature review

Authors: P. Humphrey, C. Bennett, F. Cramp

Abstract

Objectives: To determine women's experiences of brachytherapy for cervical cancer.

Key findings: Nineteen studies were included for data extraction/synthesis. Twelve studies focussed on psychological issues, seven on pharmacological aspects of women's experiences. Themes of anxiety, distress, pain, informational needs and non-pharmacological interventions were found. Nine out of ten psychological studies described brachytherapy as a distressing experience causing anxiety and distress for most women. Non-pharmacological interventions were found to be effective and inexpensive adjuncts. Peri and post-operative pharmacological management was variable, but duration of procedure was an important factor.

Conclusion: Brachytherapy for gynaecological cancer causes varying levels of pain, anxiety and distress. To improve women's experiences there needs to be better pain management, patient information and the development of non-pharmacological interventions. Future recommendations are to develop clinical support guidelines, audit the quality of services and develop effective interventions to improve women's experiences of brachytherapy for locally advanced cervical cancer.

Keywords: Brachytherapy; Cervical cancer; high dose rate; anesthesia; analgesia; anxiety

Introduction

The worldwide incidence of cervical cancer has been estimated as 528,000 newly diagnosed cases annually and is the 4th most common cancer in women.[1] Global incidence is highest in less developed countries (85%) with higher mortality rates where there is less access to diagnostic and therapeutic health services.[1] Approximately 3,000 new cases of cervical cancer are diagnosed each year in the UK[2]. Despite a comprehensive national cervical screening programme, about a third of these women present with locally advanced disease, unsuitable for surgery. For about 1,000 women per year chemotherapy and radiotherapy including brachytherapy is standard treatment in the UK. Brachytherapy is a type of internal radiation therapy where a radioactive source is placed close to the tumour. To deliver the radiation dose to treat locally advanced cervix cancer, hollow applicators are placed in the

uterus and vagina and the radioactive source is passed into the hollow applicators. This technique is currently offered at 42 UK radiotherapy centres.[3]

In the past treatment machines used low dose rate (LDR) radioactive sources with treatment times typically 2-3 days. Treatment was delivered in a shielded radiation room on a ward. Patients were immobilised and in isolation to prevent irradiation of hospital staff. The radiation could be switched off for short periods to allow nursing care, medication delivery and food and drink supplies. However any break in treatment was minimised to keep overall time as short as possible. Visitors were kept to a minimum or prohibited. This was the most common type of brachytherapy in the UK until the early 2000s. Due to lack of availability of replacements for the LDR afterloader caesium sources most UK departments purchased a high dose rate (HDR) afterloader so the treatment could be delivered in minutes[3]. The newer HDR system requires multiple fractions (typically 3-5) to give the equivalent radiobiological effect as LDR treatment.

Recent technical developments include brachytherapy applicators compatible with Computerised Tomography (CT) and Magnetic Resonance Imaging (MRI) to enable acquisition of CT and MRI scans with applicators inside patients. Previously treatment planning was 2-dimensional and dose prescribed to a defined point. However with new treatment planning software 3-dimensional CT and MR images are used to prescribe dose to a volume. With improved imaging and planning it is possible to minimise dose to structures that are sensitive to radiation, known as organs at risk (OARs). Excessive radiation dose to OARs would cause acute and long term side effects. The introduction of extra needle applicators into the cervix tumour has allowed dose escalation which has been shown to increase local tumour control to 85-100%.[4, 5, 6, 7, 8] As the planning has become more complex, with the requirement to draw the tumour (target volume) and OARs onto the 3D images, so the time taken to plan treatments has increased. Anecdotally it is reported that planning time has increased from a matter of minutes to 2-5 hours.

Some centres give HDR brachytherapy as a day case procedure.[9, 10] Patients arrive early in the morning for anaesthetic and theatre procedure for applicator/needle insertion, then CT and/or MR imaging, planning, treatment delivery, applicator removal and discharged home later the same day. Some centres keep patients in hospital overnight with applicators/needles remaining in place and repeat treatments over 2-3 days.[11] Although the patient does not need to remain in isolation in a radiation treatment room like the old LDR treatments, it does mean they have to remain immobile in bed for a long time. However, their treatment may be completed in one hospital visit and only require one theatre and anaesthetic procedure. Some centres do two treatments for one theatre procedure with one overnight stay, then repeated a week later.[12] Some centres deliver the radiation in pulses, using a source typically 1/10th the activity of a HDR source which is pulsed hourly (Pulsed dose rate, PDR). This is usually given in an isolation room on a ward. The introduction of interstitial needles may have led to the potential for greater pain for women, and some centres have altered their anaesthesia and analgesia techniques to help women cope with this.[10]

There are some benefits and disadvantages for these different methods of dose delivery but the impact of these technical and scheduling changes on patients is unknown. A systematic literature review (SLR) was carried out with the aim to determine women's experiences of brachytherapy for cervical cancer so that consideration could be given to patient's needs.

Methods

The SLR was carried out following PRISMA guidelines (*Preferred Reporting Items for Systematic Reviews and Meta-Analyses),*[13] registered on PROSPERO International prospective register of systematic reviews, and completed in May 2017.[14]

A systematic literature search was carried out independently by two researchers. Five databases: MEDLINE; CINAHL; EMBASE; PsychINFO and AMED were selected to ensure journals would be included that were authored and read by oncologists, anaesthetists, psychologists, nurses and radiographers, i.e. all those involved in the care of women during brachytherapy. No restriction to publication date was applied as it was important to include older papers that referred to LDR brachytherapy as the longer duration of treatment may report experiences and coping strategies that are also relevant to newer techniques of HDR brachytherapy with multiple fractions per insertion and PDR brachytherapy. The search strategy was detailed on the PROSPERO entry.[14] Key terms used for the search are listed in Table 1.

Table 1- Key search terms

Key words and search extent	Search terms
Cancer, neoplasm or tumour in all text	cancer*, neoplasm*, tumo*
AND	
Cervix or gynaecological in all text	cervi*, gyn*
AND	
Brachytherapy or intracavitary in all text	brachytherapy*, intracavit*
AND	
Anaesthesia, sedation or analgesia in all text	anaesthesi*, anesthesi*, sedat*, analgesi*
OR	
Anxiety, stress, anxious, PTSD, psychology, coping, phenomenon, distress in all text	Anxiet*, stress*, anxious*, ptsd*, psychology*, coping*, phenomen*, distress*

Additional sources were searched, including grey literature (Open Grey, GreyNet International, UK Institutional Repository Search and The Healthcare Management Information Consortium), three clinical experts from different professions, snowballing of

reference lists of included studies and reverse snowballing to insure that no relevant studies had been missed out. Inclusion criteria were any study which focussed on women's experiences of brachytherapy rather than other factors such as local control, survival or radiation dose planning. Studies were included if their main focus was women's experiences of brachytherapy for gynaecological cancers. As there was no set definition of "patient experience" it was decided by the two researchers that studies where pain scores were reported by the patients would be included. There was no restriction on study design or setting. It was agreed that full text articles were required as abstracts would not contain enough detail for analysis, and English language only could be considered due to prohibitive costs of translation services.

Duplicate studies and those reporting the same cohort of patients were removed. The two researchers independently screened firstly by titles then abstracts to exclude articles that were obviously irrelevant. Full text articles were obtained and full texts in other languages were excluded at this point. Any disagreement between the two researchers was discussed at the full text stage and any remaining discrepancies discussed with a third party (academic supervisor- third author) to make a final decision. Assessment of the quality of papers was carried out independently by the two researchers using specific Critical Appraisal Skills Programme (CASP) tool for each type of study design.[15] The results were collated, to improve internal validity and reduce risk of subjective bias. Papers deemed as poor quality (more than 75% No or can't tell to CASP tool questions) were excluded before data extraction and synthesis. This step was a change from the method described in the original PROSPERO publication due to the larger than anticipated number of eligible studies and time limitation to complete data extraction and synthesis and to avoid degradation of findings with poor data. A bespoke data extraction tool was created *'a priori'* and data extraction was carried out by one researcher (first author) and checked by the second researcher (second author). Data synthesis was carried out by first researcher, then discussed with the second researcher and agreed upon.

Results

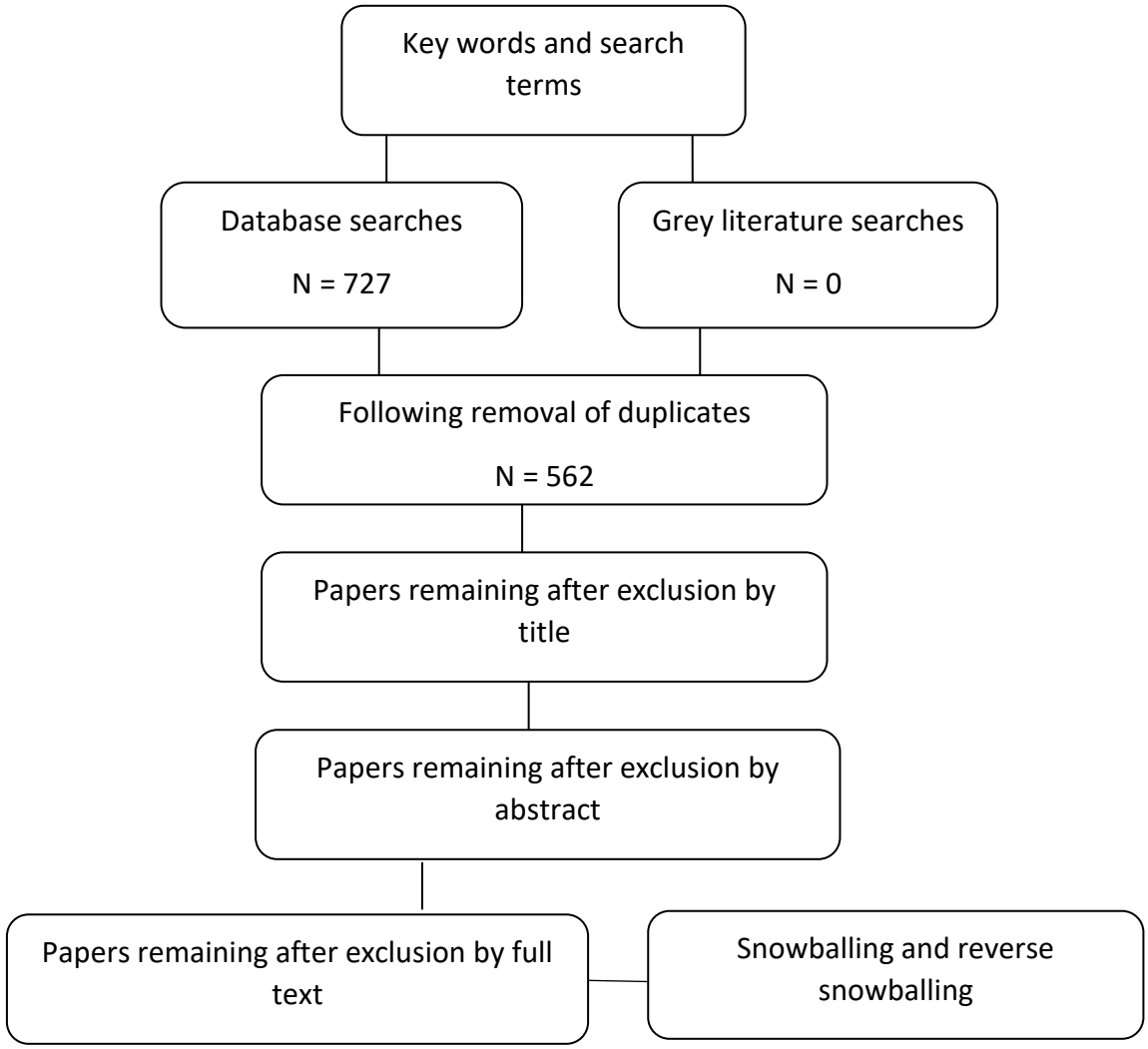
The search strategy produced 727 articles and removing duplicates reduced this to 562. Searching of grey literature produced no additional articles. Screening of titles excluded 438 articles leaving 124. Screening of abstracts excluded 78 articles to leave 44. Full text articles were obtained at this point and snowballing and reverse snowballing found 2 new articles. The 46 full text articles were examined and a further 24 were rejected for the reasons shown in table 2. There were 22 remaining articles. Five studies were RCTs,[16, 17, 18, 19, 20] two case control studies,[21, 22] nine cohort studies,[11, 12, 23, 24, 25, 26, 27, 28, 29] five qualitative studies[30, 31, 32, 33, 34] and 1 systematic literature review.[35]

Table 2 Reason for exclusion from full text

Reason for exclusion	Number of articles
No full text available- conference abstract/poster only	12

Full text not in English	4
Duplicate discovered (author name different spelling, same patient cohort)	2
Feature article, letter (opinions-not research)	2
Literature study to develop an intervention, no patient data	1
No patient experience found	3

Figure 1. Flow diagram of the literature search and screening process



Critical Appraisal

Critical appraisal with appropriate CASP tools led to exclusion of three studies due poor methodology or not enough information. [22, 29, 35] See Table 3 for summary of the critical appraisal. The three studies excluded at this stage had a large majority (>75%) of negative answers or "can't tell" when the CASP tools were applied. A cohort study by Watanabe

Nemoto appears to have recorded pain scores by sending a questionnaire to patients after the procedure had been completed, however sedation was given throughout the procedure.[29] Therefore an overall pain score would be potentially unreliable and likely to indicate whether a woman can remember experiencing pain.[29] Recruitment to this study is unclear as they report that 57 patients received 178 sessions of brachytherapy, however only 74 questionnaires were returned, and the number of women who responded is not reported. The two researchers were unable to understand the method or results of this study. A case control study by Rollison and Strang compared experiences of women undergoing cervical brachytherapy with women having palpation (examination) under anaesthesia for a gynaecological cancer.[22] The LDR brachytherapy meant that women had to lie flat with applicators in place for 15 to 20 hours. The two researchers agreed that the control group was inappropriate and gave no information that would not have been obvious at the outset. For example 8/20 women lying flat for brachytherapy would have preferred an alternative menu compared to 18/20 women in the control group who approved of the food. This study was considered by the two researchers to be unsuitable to include in data extraction and synthesis. A literature review by Barros and Labate only used 2 search terms and did not include any databases of nursing journals.[35] There was no reported quality assessment of the included studies. The results and discussion are combined and both researchers found the findings were unclear and therefore deemed this study not appropriate for data extraction or synthesis for this SLR.

The nineteen remaining studies included twelve studies focusing on psychological and seven on pharmacological aspects of experiences of brachytherapy. Ten of the twelve psychological studies explored the lived experiences of women undergoing brachytherapy for gynaecological cancer. Two studies investigated interventions to improve the experiences of women during treatment. Themes of anxiety, distress, pain, informational needs and non-pharmacological interventions were found. The characteristics of the 19 studies are shown in Table 4.

Table 3 Summary of the critical appraisal

3a. CASP tool for randomised controlled trials	Chen et al, 1998	Chi et al, 2015	Jain et al, 2007	Leon-Pizzarro et al, 2007	Thanthong et al, 2017
Clearly focussed issue addressed?	Yes	Yes	Yes	Yes	Yes
Assignment of patients randomised?	Yes	Yes	Can't tell	Yes	Yes
Blinded patients, health workers and study personnel?	Can't tell	Not possible	Not possible	Not possible	Yes
Groups similar at start?	Can't tell	Yes	Can't tell	Yes	Yes
Aside from intervention, groups treated equally?	Yes	Yes	Yes	Yes	Yes
All patients accounted for at conclusion?	Yes	Yes	Can't tell	Yes	Yes
How large was treatment effect?	Significant	Significant	Significant	Significant	No difference
How precise was estimate of treatment effect?	$p < 0.001$	Small p values	$p = 0.038$	Small p values	High p values
Results can be applied to the local population?	Partially	Yes	Partially	Yes	Partially
Were all clinically important outcomes considered?	No	Yes	Yes	Yes	Yes
Are benefits worth harms and costs?	Yes	Yes	Yes	Yes	N/A
Suitable quality for data extraction/synthesis	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*

3b. CASP tool for cohort studies	Amsbaugh et al, 2016	Anderson et al, 1984	Bhannabhai et al, 2013	Kamer et al, 2007	Kirchheiner et al, 2014	Kwekkeboom et al, 2009	Nail, 1994	Watanabe Nemoto et al, 2015	Wiebe et al, 2011
Clearly focussed issue?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Cohort recruitment acceptable?	Yes	Yes	Can't tell	Yes	Yes	Yes	Yes	No	Yes
Exposure accurately measured to minimise bias?	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes
Outcome accurately measured to minimise bias?	Can't tell	Yes	No	Yes	Yes	Yes	Yes	No	Yes
Important confounding factors identified?	Mostly	Mostly	No	Yes	Yes	N/A	Yes	No	Yes
Confounding factors in design/analysis?	No	No	No	Yes	Yes	N/A	Yes	No	Yes
Follow up complete enough?	N/A	Yes	No	Yes	Yes	Yes	Yes	Can't tell	Yes
Follow up long enough	N/A	No	No	No	No	No	Yes	Yes	Yes
Clear results?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Precise results?	Yes	Yes	Can't tell	Can't tell	Yes	Yes	Yes	No	Yes
Believable results?	Yes	Yes	Can't tell	Yes	Yes	Yes	Yes	No	Can't tell

Results can be applied to the local population?	Partially	Partially	Partially	Can't tell	Partially	Partially	Yes	No	Yes
Results fit with other evidence?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Can't tell	Yes
Value to practice?	Yes	Yes	Limited	Yes	Yes	Yes	Yes	No	Yes
Suitable quality for data extraction/synthesis	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*	*No*	*Yes*

3c. CASP tool for qualitative research	Velji & Fitch, 2001	Warnock, 2005	So & Chui, 2007	Dzaka et al, 2016	Long et al, 2016
Clear statement of aims?	Yes	Yes	Yes	Yes	Yes
Qualitative methodology appropriate?	Yes	Yes	Yes	Yes	Yes
Research design appropriate?	Yes	Yes	Yes	Yes	Yes
Recruitment strategy appropriate?	Unknown	Unknown	Yes	Unknown	Yes
Data collection clear/justified?	Yes	Yes	No	Yes	Yes
Relationship between researcher & participants considered?	Yes	No	Yes	Partial	Yes
Ethical issues considered?	Yes	Unknown	Yes	Yes	Yes
Data analysis sufficiently rigorous?	Yes	No detail	Yes	Yes	Yes
Clear statement of findings?	Yes	Yes	Yes	Yes	Yes
Research valuable to current practice/policy/literature?	Yes	Yes	Yes	Yes	Yes
Suitable quality for data extraction/synthesis	*Yes*	*Yes*	*Yes*	*Yes*	*Yes*

3d. CASP tool for case control studies	Isoyama-Shirakawa et al, 2015	Rollison & Strang, 1995
Clearly focussed issue?	Yes	Yes
Appropriate method?	Yes	No
Recruitment strategy appropriate?	No	No
Acceptable selection of controls?	Yes	No
Exposure accurately measured to minimise bias?	Yes	No
Important confounding factors identified?	Yes	No
Confounding factors in design/analysis?	Yes	No
Clear results?	Yes	Yes
Precise results?	Yes	Yes
Believable results?	Limited	Yes
Results can be applied to the local population?	Partially	No
Results fit with other evidence?	Yes	Can't tell
Suitable quality for data extraction/synthesis	*Yes*	*No*

3e. CASP tool for systematic review studies	Barros & Labate, 2008
Clearly focussed question?	Yes

Appropriate papers searched?	No
Were all relevant studies included?	No
Sufficient quality assessment?	No
Combined results appropriate?	N/A
Clear results?	No
Precise results?	No
Results can be applied to the local population?	Can't tell
Were all important outcomes considered?	No
Are benefits worth harms and costs?	Can't tell
Suitable quality for data extraction/synthesis	*No*

Table 4 Characteristics of studies for data extraction and synthesis

AUTHOR	PUBL DATE	COUNTRY	STUDY DESIGN	LDR/HDR/PDR
Anderson et al[24]	1984	USA	Cohort study, prospective	LDR
Nail et al[28]	1993	USA	Cohort study, prospective	LDR
Chen et al[16]	1998	China	Randomised controlled trial	HDR
Velji and Fitch[33]	2001	Canada	Qualitative, phenomenology	LDR/PDR
Warnock, C[34]	2005	UK	Qualitative study, prospective	HDR
Jain et al[18]	2007	India	Randomised controlled trial	HDR
Kamer et al[26]	2007	Turkey	Cohort study, prospective	HDR
Leon-Pizzarro et al[19]	2007	Spain	Randomised controlled study	LDR
So and Chui[32]	2007	Hong Kong	Qualitative study	LDR
Kwekkeboom et al[27]	2009	USA	Cohort study, longitudinal descriptive	HDR
Wiebe et al[11]	2011	Canada	Cohort study, prospective	HDR
Bhanabhai et al[25]	2013	Canada	Cohort study, retrospective observational	HDR
Kirchheiner et al[12]	2014	Austria	Cohort study, prospective observational pilot	HDR
Chi et al[17]	2015	USA	Randomised controlled trial	PDR
Isoyama-Shirakawa et al[21]	2015	Japan	Case control study- retrospective	HDR
Amsbaugh et al[23]	2016	USA	Cohort study, retrospective	HDR
Dzaka and Maree[30]	2016	South Africa	Qualitative study, descriptive	HDR
Long et al[31]	2016	South Africa	Qualitative, prospective, phenomenology	HDR
Thanthong et al[20]	2017	Thailand	Randomised controlled trial	HDR

Data extraction and synthesis

Anxiety and distress

Of ten studies regarding psychological issues, nine reported that brachytherapy caused anxiety and distress for most women.[12, 23, 26, 27, 30, 31, 32, 33, 34] However Nail found the procedure was well tolerated without high levels of distress, depression or anxiety in most women.[28] Anderson et al described anxiety levels taking a long time to reduce, following completion of treatment.[23] They found that patients' reports of anxiety were higher than assessed by nurses and doctors, which suggests that staff underestimated anxiety and/or that patient's disguised or under-reported anxiety .[23] It was also found that anxiety levels were not reduced prior to the second treatment, concluding that women did not adapt.[23] Kamer et al evaluated influencing factors and found anxiety significantly lower for married or widowed women and those with two or more children.[26] Warnock found incidence and severity of anxiety and distress was variable, presenting a challenge for nurses to provide appropriate care.[34] Kirchheiner et al found that brachytherapy was more stressful than other gynaecological cancer treatments with 30% having acute stress disorder one week after and 41% having post-traumatic stress disorder (PTSD) at three months. Predictive factors for PTSD were a history of sexual violence, poor performance status, higher anxiety levels and lower emotional functioning. Examples of direct quotes from women described the experience as "...like having no chance to defend myself against a rape" and "a debasing situation".[12]

Pain

Experiences of women receiving up to five outpatient HDR procedures described pain as mild to moderate for most but severe for 9%.[27] Significant recall of pain from previous brachytherapy was reported by 29-59% with the amnesic effect being less than anticipated. In contrast to this, distress decreased with each procedure.[27] The duration of the procedure was 2-3 hours with a mean of 127 minutes. A study from South Africa examined HDR brachytherapy with quick outpatient procedures.[30] The women reported negative experiences causing fear, pain and humiliation. They compared brachytherapy to childbirth with high levels of complex pain and described brachytherapy as their "worst experience". The authors recommended better pain management strategies and non-drug options to complement pharmacological management. They advised minimising observers and staff changes and providing individualised patient information. [30] Another study reported that all participants had varying degrees of pain, but that it was not as bad as expected and that discomfort was experienced as a totality, not limited to pain. [33] Kirchheiner et al reported that pain was the most frequently reported stressful experience during brachytherapy. [12]

Informational needs

Two studies reported women's experiences of lack of information before the procedure. [31, 33] Long et al focussed entirely on informational needs and concluded that women needed more information about their disease, preparation for treatment, the treatment itself, side effects and sexual intercourse. [31] They concluded that information should be delivered verbally and written in the patient's home language.[31]

Pharmacological studies

Seven studies reported investigations of pain medication during gynaecological brachytherapy and are summarised in Table 5. These were published from 1998 to 2017, but all reported on HDR techniques. All studies used a form of the 11 point Visual Analogue scale to record post-operative pain. There were five studies where patients received day case HDR brachytherapy with pain management only required for a few hours.[16, 18, 20, 21, 25] Overall there are a number of different approaches to peri and post-operative pain management, and it is inconclusive which method is superior, but duration of analgesia is a key factor in determining which method is chosen.

Table 5 shows the pharmacological studies data extraction summary and reviewer comments.

Non-pharmacological interventions

Two studies examined effects of non-pharmacological interventions. Leon-Pizzaro et al investigated the effect of relaxation and guided imagery during brachytherapy on anxiety and depression.[19] This RCT included 66 women receiving LDR brachytherapy for either breast or gynaecological cancer, with two thirds having brachytherapy for gynaecological cancer. Duration of treatment was typically two days. They reported significant reductions in anxiety, depression and body discomfort in the relaxation and guided imagery group compared to the control arm.[19] Chi et al explored the effects of a music relaxation video on pain and anxiety with a RCT of 60 women receiving PDR brachytherapy.[17] They delivered a music relaxation video four times during the first 44 hours of brachytherapy. Perceived pain and anxiety levels were significantly lower in the music relaxation group compared to the control group. They reported a significant reduction in pain after use of the music video indicating that relaxation can reduce pain. [17] Both studies showed significant benefits from their non-pharmacological experimental interventions.

Table 5 Pharmacological studies data extraction summary

Author	Study Aim	Study design	Population/context	Intervention	Results	Authors Recommendations	Reviewers comment
Chen et al, 1998	To investigate the effect of local vaginal anaesthesia on pain relief and safety by monitoring serum levels	RCT	40 patients with cervical cancer, 5 treatments each. Short duration-outpatient procedure	GA for 1st trt. Then randomised to trt-control-trt or control-trt-control-trt. Trt: lidocaine 10% sprayed onto cervix for 5 mins. Control- Placebo spray. Meperidine injection for all. No GA	10% lidocaine solution significantly decreased degree of painful sensation. Mean pain score 49.9 ± 24.1 SD; control mean 60.1 ± 24.8 SD. Sig difference P<0.001. No diff in physiological response or adverse effects. Serum levels didn't rise to unsafe levels.	Safe and effective method for analgesia.	Still had mean moderate pain scores compared with GA or spinal/epidural. Only suitable for short duration procedures.
Jain et al, 2007	To compare 3 different anaesthetic techniques, quality of analgesia and side effects.	RCT	35 women with cervical cancer, divided into 3 arms, Typically 1½ - 2 hours overall time, 3 treatments each, 1 per week.	Group A- subarachnoid block, Group B- GA with laryngeal mask airway, Group C - GA with face mask. Measured pain, motor block, sedation level, nausea and	Significantly less analgesia required by group A. P = 0.038. No sig difference in post op nausea and vomiting. No sig diff in sedation level. Overall 24.7% had mild pain, 18.1% moderate pain and	Regional anaesthesia provides better post op analgesia than GA.	Difficult to know if this could be applicable to longer duration schedules, PDR and multiple HDR trts per insertion.

				vomiting and post-operative analgesia requirements.	5.7% severe pain. Higher complication rates with GA.		
Wiebe et al, 2011	To assess adequacy of analgesia and symptom control with multiple fractions of HDR brachy during a single applicator insertion	Prospective cohort	18 patients with gynaecological cancers recruited. Data from 17. 14 intracavitary and 3 interstitial. Typical duration 25-36 hrs.	GA for insertion. Transferred to oral or subcut anaesthesia after GA. Interstitial had PCA pump after GA. Tolerability assessed by pain scores, anxiety and nausea, 5 time points: baseline, transfer to CT couch, after 1st trt, immediately after applicator removal, follow up (time point not specified).	Mean pain scores highest after CT transfer 3.3 ± 2.6 SD. Was 0.9 ± 1.7 SD at baseline. 5 pts reported no pain. Not sig higher pain with interstitial, 3.3 vs 2.3, P=0.42. Anxiety score highest before brachy 4.3 ± 3.4. During procedure resolved to 1.3 ± 1.6 SD. Slightly higher at FU appt 1.6 ± 1.5 SD. Nausea mode score = 0. Severe pain (7-10) in 4/17 pts, all at CT transfer + 1 after trt delivery, 1 at FU appt. Also 3 pts had severe anxiety, all at baseline.	Overall only mild pain and anxiety. Discussed anticipatory anxiety. Pre-emptive analgesia at specific points. Consider studies on management of emotional distress such as guided imagery or music relaxation.	Underestimate/ignoring severe pain-reported in 4/17 at specific time point. Small number of participants. Overall good pain management therefore applicable to longer duration procedures.

Bhanabhai et al, 2013	To assess the effectiveness of conscious sedation	Retrospective observational	20 patients with cervical cancer, 57 procedures. Weekly outpatient procedure. Median duration 1.4 hours.	Pain scores recorded every 10 mins and at key points during HDR brachy procedure. Qualitative notes by nursing staff. Satisfaction with pain control recorded in recovery room. Midazolam and opioid used.	Good pain control achieved with conscious sedation. Brief moments of moderate to severe pain mostly when ring and tandem applicator inserted. Maximal pain ranged from 0-10, mean 4.7. All pts satisfied with pain control.	Effective regime. Fentanyl now opioid of choice as fast onset and rapid clearance.	May only be suitable for short duration procedures. Patient satisfaction scoring not explained.
Isoyama-Shirakawa et al, 2015	To investigate the effects of caudal epidural anaesthesia	Retrospective case control	34 women with cervical cancer. Control group, earlier time period, 30 pts cervical cancer, same applicator. 4 trts in control group, 5 in anaesthesia group, no duration but likely to be short outpatient trt	Experimental group had caudal epidural with mepivicaine + other analgesia or sedation. Control group had analgesia and sedation only- no anaesthesia.	Caudal epidural success rate 97%. Patient reported pain scores sig less for anaesthesia group (P=0.038 and P=0.037). Outcomes from 30 pts only. Mean score 5.17 ± 2.97 SD vs 6.8 ± 2.59 SD (P=0.035). Lower use of sedation but higher use of opiates in anaesthesia group.	Caudal is an option for safe and effective regional anaesthesia.	High levels of pain in caudal epidural group compared to other studies. May not have blocked pain caused by applicators in uterus. May give better block for cervix, vagina and perineum, not uterus. Could be applicable to short brachy procedures, not PDR or HDR with

					No complications from caudal.		multiple trts per insertion.
Amsbaugh et al, 2016	To determine optimal epidural anaesthesia for interstitial brachy for gynaecological cancers	Retrospective cohort	71 patients with gynae cancers (35 cervix, 16 vagina, 13 uterus, 7 vulva), Interstitial brachytherapy	3 arms: 12 ropivocaine only; 59 opioid + ropivicaine. Subgroup: 14 fentanyl + ropivicaine; 45 hydromorphone + ropivicaine	More pain in ropivicaine only group, needed more additional opiates, suggests inadequate pain control.; no difference in nausea	Combined modality epidural improves pain control, opioid with local anaesthetic, compared with local anaesthetic alone	All Interstitial cases, but analgesic technique may still be applicable to Intracavitary or hybrid techniques.
Thanthong et al, 2017	To compare the effectiveness of two sedative regimens in relieving pain	RCT, double blind crossover	40 pts, 160 treatments, all cervical cancer 4 treatments each, typically 2-3 hours.	Benzodiazepine to all, then 2 x fentanyl and 2 x meperidine. Researchers, HCPs and patients blinded. Pain score before intervention and every 15 minutes. If pain score >4 then an additional opioid was given. QoL using EQ-5D.	Treatment effect- no sig difference in effectiveness of sedation types. Pain peaked at 45 minutes. Most experienced moderate pain during procedure, similar to other studies.	No significant difference therefore cheapest sedation is appropriate.	Applicable for day case HDR brachy, but not for multiple # as duration too long.

Abbreviations key: RCT Randomised controlled study; GA general anaesthetic; trt treatment; pts patients; gynae gynaecological; SD = Standard Deviation

Discussion

Overall the nineteen studies included in this SLR show that brachytherapy causes pain, anxiety and distress and identified a need for better information provision. It was also found that different pharmacological and non-pharmacological approaches can improve women's experiences of brachytherapy. Factors influencing decisions about how to implement dose escalation and reduce toxicity, by implementing new techniques and technological advances to improve local control, are often based around availability of staff and facilities, such as access to imaging, planning, anaesthetic resources and extra time needed for clinical oncologists, physicists and radiographers. However, the psychological impact for women undergoing the treatment has not been reported as an influencing factor within any reports of implementation of developments or clinical guidelines. The development of HDR brachytherapy from LDR techniques was originally welcomed as an improvement which would allow short day case procedures that would be more tolerable for women. Longer duration for increasingly complex planning requirements, such as extra dose points and constraints for EMBRACE II study[36] and longer treatments such as PDR or multiple HDR fractions per insertion over a number of days would seem likely to increase anxiety and distress. Some studies reported no decrease, or sometimes an increase in anxiety for subsequent insertions and concerns raised that women did not adapt and were not re-assured after their first treatment.[24, 27, 30] Therefore it is possible that multiple day case procedures may lead to a re-traumatisation for women if their first experience of brachytherapy caused distress.

An international survey of practice reported that 97% of 72 respondents used some form of anaesthesia with insertion of brachytherapy applicators[9] and the findings are referred to in the American Brachytherapy Society (ABS) Guidelines general principles.[10] However, only two of the seven pharmacological studies describe analgesia and anaesthesia techniques which would be applicable to centres which deliver HDR brachytherapy with a longer time period with applicators in place.[11, 23] Effective pain management for short procedures taking less than 2 hours in total is unlikely to be applicable for this longer duration technique, or when interstitial needles are added. Local anaesthetic spray onto the cervix or conscious sedation would not provide the required duration of analgesia, especially if interstitial needles are introduced. Wiebe et al suggested that this multi-fraction technique required greater vaginal packing to secure the applicators in place for the prolonged duration when compared with a single fraction technique, and may have contributed to higher levels of pain.[11] Interestingly this centre used PCA opioid pump for post-operative pain control for interstitial techniques and oral/intravenous analgesia for intracavitary techniques, acknowledging that interstitial needles required different analgesia. The use of oral transmucosal fentanyl citrate for brachytherapy procedures has been previously reported.[37] This may provide another option for procedure analgesia or for breakthrough pain at identified points in the procedure likely to cause higher pain, such as transfers for imaging or during applicator removal. Various techniques will be developed in centres with different resources or constraints, and following guidelines may be useful when new techniques are introduced. The Groupe Européen de Curiethérapie and European Society for Radiotherapy & Oncology (GEC-ESTRO), The Royal College of Radiologists (RCR) and ABS guidelines for

treatment of locally advanced cervical cancer have been developed. [10, 38, 39, 40, 41, 42] However their main focus is to standardise planning and dose reporting. There is little or no mention of the delivery of clinical aspects relating to patient experience, psychological repercussions and any impact on quality of life after treatment. The use of a standard method of measuring and recording patient's pain scores could assist in auditing and developing best practice for pain management.

The use of non-pharmacological interventions could potentially be introduced to supplement the essential pharmacological approaches and provide women with some control over their own wellbeing during brachytherapy. Relaxation and guided imagery and a music relaxation video showed significant benefits for women undergoing long duration brachytherapy procedures.[17, 19] They were found to be simple, effective, non-invasive and cheap. Overall it can be surmised that these supplementary interventions may be beneficial to some women during brachytherapy.

Conclusion

There are a multitude of studies reporting technical advances and clinical implications of implementing new developments, but a lack of studies examining patient experiences in this context. This SLR showed that brachytherapy for gynaecological cancer can cause varying levels of pain, anxiety and distress. There is a need for better pain management, patient information and support and the development of non-pharmacological interventions to improve experiences. Pharmacological approaches should be explored and developed to minimise pain and discomfort throughout the procedure, including applicator insertion, patient bed transfers for imaging, waiting between fractions of dose delivery (if multiple doses per insertion) and applicator removal. Alongside optimal management of pain, women's anxiety and distress maybe reduced by non-pharmacological interventions. The development of clinical support guidelines may provide standards to improve women's experiences of the treatment or to facilitate audit to evaluate the quality of service provision, especially when new techniques such as interstitial brachytherapy is introduced. Acquiring patient satisfaction feedback about brachytherapy could also give valuable information about which areas are most distressing or satisfactory and which pharmacological or non-pharmacological support was helpful. This may lead to development of effective interventions (both pharmacological and non-pharmacological) to improve women's experiences of brachytherapy for locally advanced cervical cancer.

Conflict of interest statement

No conflicts of interest

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Appendix 3: Faculty Research Ethics Committee approval letter

Faculty of Health & Applied Sciences

[redacted]

UWE REC REF No: HAS.18.08.008

14th September 2018

Pauline Humphrey

[redacted]

Dear Pauline

Application title: Development of an intervention to reduce distress caused by brachytherapy for locally advanced cervical cancer. Exploratory phase part 1: UK survey of practice

Your ethics application was considered by the Faculty Research Ethics Committee and, based on the information provided, has been given ethical approval to proceed.

You must notify the committee in advance if you wish to make any significant amendments to the original application using the amendment form at http://www1.uwe.ac.uk/research/researchethics/applyingforapproval.aspx

Please note that any information sheets and consent forms should have the UWE logo. Further guidance is available on the web: https://intranet.uwe.ac.uk/tasks-guides/Guide/writing-and-creating-documents-in-the-uwe-bristol-brand

The following standard conditions also apply to all research given ethical approval by a UWE Research Ethics Committee:

1. You must notify the relevant UWE Research Ethics Committee in advance if you wish to make significant amendments to the original application: these include any changes to the study protocol which have an ethical dimension. Please note that any changes approved by an external research ethics committee must also be communicated to the relevant UWE committee.

2. You must notify the University Research Ethics Committee if you terminate your research before completion;

3. You must notify the University Research Ethics Committee if there are any serious events or developments in the research that have an ethical dimension.

The Faculty and University Research Ethics Committees (FRECs and UREC) are here to advise researchers on the ethical conduct of research projects and to approve projects that meet UWE's ethical standards. Please note that we are unable to give advice in relation to legal issues, including health and safety, privacy or data protection (including GDPR) compliance. Whilst we will use our best endeavours to identify and notify you of any obvious legal issues that arise in an application, the lead researcher remains responsible for ensuring that the project complies with UWE's policies, and with relevant legislation. If you need help with legal issues please contact [redacted] (for Health and Safety advice), [redacted] (for data protection, GDPR and privacy advice).

Please note: The UREC is required to monitor and audit the ethical conduct of research involving human participants, data and tissue conducted by academic staff, students and researchers. Your project may be selected for audit from the research projects submitted to and approved by the UREC and its committees.

Please remember to populate the HAS Research Governance Record with your ethics outcome via the following link: https://teams.uwe.ac.uk/sites/HASgovernance.

We wish you well with your research.

Yours sincerely

[redacted]

[redacted]
Chair
Faculty Research Ethics Committee

c.c. Fiona Cramp

Appendix 4: Email invitation to participants (study one)

Research to improve women's experiences of brachytherapy for locally advanced cervical cancer

Dear …….

Women's experiences of brachytherapy is a subject that we have discussed many times at our Brachytherapy Radiographers Forum annual meetings. To inform my research I need your help and would really appreciate your time to complete this short survey in relation to treatment in your department including:

- How brachytherapy is scheduled
- Duration of treatment
- Anaesthesia and analgesia
- Any support offered before, during or after brachytherapy
- Your opinions about what works well and how women's experiences could be improved

After this survey I will invite four centres to be involved in the next stage of the research involving patient interviews.

I would very much appreciate your participation in this online survey which will take about 15 minutes to complete.

Yours sincerely,

Pauline Humphrey

Consultant Radiographer for Brachytherapy and NIHR Clinical Doctoral Fellow

Appendix 5: Qualtrics survey, including consent form (study one)

Introduction to survey

UK survey of brachytherapy practice for treatment of locally advanced cervical cancer

This survey aims to find out about current UK brachytherapy service provision for locally advanced cervical cancer. Questions relate to:

- Brachytherapy scheduling
- Anaesthesia and analgesia
- Any support offered before, during or after brachytherapy
- Your opinions about what works well and how women's experiences could be improved

Your participation in this survey is voluntary and your consent is implicit in your completion of the survey. Once your responses have been submitted you will not be able to withdraw your data from the survey. It will take 10-15 minutes to complete the survey.

If you need to take a break from the survey you can exit at any point and your responses will be automatically saved, so you can return to complete the questionnaire at a later time.

The aim is to obtain one completed survey from each UK brachytherapy department. If there are multiple responses from a department, these responses will be amalgamated.

It will not be possible to anonymise your submitted responses as I need to know which department you work in, to ensure I have just one response from each centre and to be able to invite four centres for the next phase of the study. I will however anonymise the data by removing all identifiable features prior to sharing with the full research team. Any further dissemination beyond the research team will be reported in aggregate with no individual or department being identified. These anonymised findings will be shared with the Brachytherapy Radiographers Forum at the next Annual General meeting and via the email group.

Ethics approval has been given by University of the West of England, Faculty of Health and Applied Sciences

Please note that all questions relate to the treatment of **locally advanced cervical cancer** only. I am not planning to include women who have received brachytherapy following a hysterectomy for cervical cancer, or brachytherapy for endometrial cancer.

Thank you for agreeing to take part in this online survey. Your responses are much appreciated and will be valuable for ongoing research to improve women's experiences of brachytherapy for locally advanced cervical cancer.

○ Take me to the start of the survey

Department location

Q1. Which UK radiotherapy department do you work in?

Demographics

Q2.
Does your department deliver brachytherapy for locally advanced cervical cancer?

- ○ Yes
- ○ No

Department demographics

Q3. Does your department carry out:
Please select all that apply

- ☐ Intracavitary brachytherapy
- ☐ Interstitial brachytherapy
- ☐ Intracavitary/interstitial (hybrid) brachytherapy

Q4. Does your department carry out:
Please select all that apply

- ☐ LDR brachytherapy
- ☐ HDR brachytherapy
- ☐ PDR brachytherapy

Fractionation/scheduling

Q5.
What fractionation schedules do you use in your department, as standard routine practice?
Please select all that apply

- ☐ 1 insertion per week x 3 fractions
- ☐ 2 insertions per week x 3 fractions
- ☐ 3 fractions (one insertion) over 2 days
- ☐ 1 insertion per week x 4 fractions
- ☐ 2 insertions per week x 4 fractions
- ☐ 4 fractions (one insertion) over 2-3 days
- ☐ 4 fractions (with 2 insertions) a week apart
- ☐ 1 fraction using PDR
- ☐ 2 fractions using PDR
- ☐ _____ Other (add detail in box)

Q6.
Please write any comments about your answer to question 5 (such as how the brachytherapy fits in with external beam treatments or if different regimes are used for different stage disease or due to comorbidities):

Q7.
Are treatments given as inpatient or day case?

Please select all that apply

- ☐ **Inpatient**
- ☐ **Day case**

Q8.
Please add any comments about your answer to question 7 (such as using a mixture of day case or inpatient for different fractionation schedules):

Q9.
What is the typical duration of brachytherapy from start of applicator insertion to applicator removal? Please indicate the number of hours per insertion (not per fraction) ie how long the applicators remain inside the patient for a typical insertion

0 4 8 12 16 20 24 28 32 36 40 44 48 52 56 60 64 68 72

Number of hours

Q10.
Please any comments about your answer to question 9:

Pharmacological support

Q11.
What anaesthetic regimes do you use as standard care?
Please select all that apply

- ☐ **General anaesthetic alone**
- ☐ **Spinal anaesthetic alone**
- ☐ **Epidural anaesthetic alone**
- ☐ **Sedation alone**
- ☐ **A combination of any of the above (please explain in box)**
- ☐ **Other (please explain in box)**

Q12.
Please write any comments or explanation of your answer to question 12:

Q13. What types of analgesia do you provide as standard care?
Please select all that apply

- ☐ **Spinal anaesthetic including analgesia (eg diamorphine)**
- ☐ **Epidural anaesthetic including analgesia (eg fentanyl)**
- ☐ **Patient controlled analgesia (PCA) pump**
- ☐ **IV opioids (eg fentanyl/morphine/oxycodone)**

- [ ] Oral opioids (eg oramorph/codeine/tramadol/oxycodone)
- [ ] Oral paracetamol or ibuprofen
- [ ] IV paracetamol
- [ ] Other (please give details in box)

Q14.
Please write any comments about your answer to question 13:

Non pharmacological support

Q15.
Do you routinely provide any of the following support ***before*** brachytherapy begins?

Definition:
before brachytherapy- the weeks and days leading up to the first brachytherapy procedure

Please select all that apply

- [ ] Information/support from a specialist nurse
- [ ] Information/support from a radiographer
- [ ] Counselling
- [ ] Clinical psychology
- [ ] Relaxation therapy
- [ ] Guided imagery
- [ ] Music therapy
- [ ] None
- [ ] Other (please specify in box)

Q16. Please write any comments about your answer to question 15:

Q17.
Do you routinely provide any of the following support ***during*** brachytherapy?

Definition:
during brachytherapy- from arrival in hospital for brachytherapy to leaving hospital after brachytherapy

Please select all that apply

- [ ] Information/support from a specialist nurse
- [ ] Information/support from a radiographer
- [ ] Counselling
- [ ] Clinical psychology

- [ ] Relaxation therapy
- [ ] Guided imagery
- [ ] Music therapy
- [ ] None
- [ ] Other (please specify in box)

Q18. Please write any comments about your answer to question 17:

Q19.
Do you routinely provide any of the following support ***after*** brachytherapy?

Definition:
after brachytherapy- the days and weeks after completion of all brachytherapy

Please select all that apply

- [ ] Information/support from a specialist nurse
- [ ] Information/support from a radiographer
- [ ] Counselling
- [ ] Clinical psychology
- [ ] Relaxation therapy
- [ ] Guided imagery
- [ ] Music therapy
- [ ] None
- [ ] Other (please specify in box)

Q20. Please write any comments about your answer to question 19:

Management of distress

Q21. Please click to select how well women are supported ***before, during and after*** brachytherapy.

Definitions:
before brachytherapy- the weeks and days leading up to the first brachytherapy procedure
during brachytherapy- from arrival in hospital for brachytherapy to leaving hospital after brachytherapy
after brachytherapy- the days and weeks after completion of all brachytherapy

	Extremely well	Very well	Moderately well	Slightly well	Not well at all
Before brachytherapy	○	○	○	○	○

	Extremely well	Very well	Moderately well	Slightly well	Not well at all
During brachytherapy	○	○	○	○	○
After brachytherapy	○	○	○	○	○

Q22.
Please write what you think works well in your department in relation to women's experiences of brachytherapy:

Q23. Please write what you think needs to be improved in your department in relation to women's experiences of brachytherapy:

General comments

Q24.
Please write any further comments you would like to make about brachytherapy for locally advanced cervical cancer:

Powered by Qualtrics

Appendix 6: Interview schedule (study two)

University Hospitals Bristol NHS
NHS Foundation Trust

UWE Bristol University of the West of England

Interview schedule

A study of women's experiences of brachytherapy for cervical cancer

1. **Introduction**

Thank you for agreeing to meet with me today and talk about your brachytherapy. My name is Pauline Humphrey and I am a researcher from University of the West of England, in Bristol.

2. **Recap Participant Information Sheet.** Any questions.
3. **Written consent**- copy for participant, copy for research site file, copy for hospital patient records.
4. **Explain procedure for interview**- duration, audio recording, offer to switch the audio recording off if participant needs a break at any point, show them the button to turn it off themselves if necessary, can ask any questions at any time.
5. **Reminder** that the interview is specifically about brachytherapy experiences, but obviously this is in the context of the whole cancer treatment pathway…
6. **Note taking**- I might take a few notes as we go along, just in case I need to come back to something later on…
7. **Format and context**- I have a few questions to start us off, but nothing too rigid as I really want to hear about how it all went for you and what you would like to tell me about your brachytherapy…
8. **Start audio recording**
9. **Interview:**

Topic	Questions and prompts
Warm-up questions (knowledge and expectations)	Can you tell me about how you felt before the brachytherapy? What had you heard or been told about it? Had you read up about it yourself or did the staff tell you about it, or other patients? So, what were your thoughts and feelings before going in for the brachytherapy?
Experience/ overall	Can you tell me about your experience of brachytherapy? What was it like for you? Prompts: How long ago was it? How many times did you have brachytherapy? Did you go home in-between?
Pain/discomfort	How did you feel when you woke up with the applicators inside you? Or How did you feel once the applicators had been put in position? What sort of anaesthetic or pain killers did you have? How much did this help? Notes: Reflect the words that the interviewee uses themselves. Use of probing questions to unpick and explore their words and their meanings eg anxious, discomfort

Interview schedule Version 1.0 Date 04.04.19

FUNDED BY
NIHR | National Institute for Health Research

This study is funded by the National Institute for Health Research (NIHR) [ICA-CDRF-2017-03-079]. The views expressed are those of the author and not necessarily those of the NIHR or the Department of Health and Social Care.

University Hospitals Bristol NHS
NHS Foundation Trust

UWE Bristol University of the West of England

	What do you mean by that? Can you explain that to me? Can you talk about that a bit more?
Time passing	How did you cope with the length of time for your brachytherapy? Did time pass quite quickly for you? How did you feel while you were waiting for treatment? Prompts: Was it a bit boring, were you quite sleepy, or restless, frustrated, uncomfortable, not really a problem, had things to help pass the time… Did you use anything to help pass the time? Eg music, books, prayer, meditation or mindfulness, people to talk to… But avoid leading questions here.
Feelings and emotions	Can you remember any of your thoughts and feelings while you were lying there with the applicators inside? Prompts: Can you explain that a bit more to me? Was it anything like what you had expected it to be?
Afterwards	After all the treatments were finished, how did you feel? Group two: How was the journey to recovery? or How was your recovery journey after the brachytherapy? Prompts: Physically? Mentally? Emotionally? Sexually?
Improvements or suggestions	Was there anything that worked particularly well for you? Or parts that went well? Or things that weren't as bad as you had expected or better than you expected? Were there things that were particularly difficult or hard for you? Can you think of anything that might have made it more comfortable or easier for you? Refer back to pervious replies and try to explore any ideas for positive changes. Was there anything that could have been done differently? Anything that may have made a difference to how you felt before, during or after the treatment? Was there anything that you would like to have been told before the brachytherapy? Is there any advice that you would give to another women who is about to have brachytherapy?
Closing comments	Really appreciate your time and your thoughts and really hope we can use all that you have told me to improve the treatment for other women in the future. Would you like me to keep you in touch with progress of this study and the outcomes from it?

Interview schedule Version 1.0 Date 04.04.19

FUNDED BY
NIHR | National Institute for Health Research

This study is funded by the National Institute for Health Research (NIHR) [ICA-CDRF-2017-03-079]. The views expressed are those of the author and not necessarily those of the NIHR or the Department of Health and Social Care.

Appendix 7: Study flyer (study two)

University Hospitals Bristol NHS
NHS Foundation Trust

Version 1.0 date 04.04.19

UWE Bristol

Can you help with our research?

A study of women's experiences of brachytherapy for cervical cancer

Brachytherapy can sometimes be a difficult treatment for women.

We want to find ways to make it easier.

Are you willing to tell us about your experience?

What went well? What could have been better?

What could we do to improve?

To find out more please read the Participant Information Sheet.
If you would like to know more, please fill in the tear off slip and post it to us in the envelope provided.
Our researcher, Pauline, will contact you and tell you more about the study.

If you have any questions about this research please phone [redacted] or email [redacted]

FUNDED BY NIHR National Institute for Health Research

This study is funded by the National Institute for Health Research (NIHR) [ICA-CDRF-2017-03-079].
The views expressed are those of the author and not necessarily those of the NIHR or the Department of Health and Social Care.

I agree to the researcher contacting me about this research.

My name:

My address:

My phone number: **My email address:**

I prefer to be contacted by phone ☐ email ☐ (please tick to show your preference)

Please return this slip in the envelope provided

Appendix 8: Participant information sheet (study two)

University Hospitals Bristol NHS
NHS Foundation Trust

UWE Bristol University of the West of England

A study of women's experiences of brachytherapy for cervical cancer

Participant Information Sheet

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information. Ask us if there is anything that you do not understand, or if you would like more information.

What is the purpose of the study?

Brachytherapy for cervical cancer can be a difficult treatment for women. There are reports showing that some women experienced discomfort, pain and anxiety before, during or after brachytherapy. To help us improve the experience for women receiving treatment we need to know more about what it is like at present, including what is difficult, what things help women to cope with the experience and what could be improved. In this study we are interviewing women who have had brachytherapy, to find out what brachytherapy was like for them. We will then use this information in future work to develop ways to improve women's experience of the treatment.

Why have I been invited to take part?

You have been invited because you have had brachytherapy treatment for cervix cancer and your experience may be able to help to improve other women's experiences of this treatment in the future.

Do I have to take part?

No, it is up to you to decide. If you decide not to take part, you do not have to give a reason, nobody will mind, and it will not change the standard of care that you receive. If you are happy to let us know why you don't want to take part, we would be interested to know why. If you do decide to take part, we will ask you to sign a consent form and give you a copy of this information sheet and the consent form to keep.

What will I be asked to do if I take part?

You will be asked to agree to the researcher contacting you by phone or email to make arrangements to interview you in person. If you are willing to be contacted, please complete the tear off slip and return it to the researcher using the stamped addressed envelope provided. The researcher will contact you to make an appointment to carry out the interview. You can arrange with the researcher where it would be best to do the interview. This may be at your treatment hospital, or somewhere close to your home, or at your home, whichever is best for you. It will need to be somewhere private and quiet and that you are comfortable with. If you consent to participating in the research, we will arrange to interview you. This will take between 30 and 45 minutes and will need to be audio recorded.

The researcher will later analyse the recording of what you have said along with the interviews from other women who have had brachytherapy. The researcher will look for common experiences, themes and understanding of the meaning of these experiences. They will then write a report which brings this understanding of the experiences and themes together, including examples of what women said.

University Hospitals Bristol NHS
NHS Foundation Trust

UWE Bristol University of the West of England

What are the possible disadvantages and risks of taking part?

There is a possibility that telling the researcher about your experience may be upsetting to you. It may bring back memories of a difficult experience. If you need further support to talk through any issues that this brings up, the researcher will contact your medical team at the centre that is looking after your ongoing care and support.

What are the possible benefits of taking part?

The study is not planned to benefit you, but it is possible that you may find it useful to talk through your experiences, like a debriefing session. We cannot promise that the study will help you, but the information we get from the study will help to increase the understanding of women's experience of brachytherapy for cervix cancer so that we can improve the treatment in the future.

Involvement of the General Practitioner/Family Doctor (GP)

With your permission we will inform your GP that you are taking part in this study, in case you wish to discuss this with them. If you agree, they will be sent a copy of this information leaflet, but no information from the interview itself.

Will my taking part in the study be kept confidential?

All information which is collected about you during the study will be kept strictly confidential, and any information which leaves the hospital or university will have your name and address removed so that you cannot be recognised. The audio recording will be loaded onto the University's password protected secure computer data storage. At this point the data will be anonymised and transcribed and the audio recording destroyed securely. The anonymised interview transcript will only be shared with members of the research team, for analysis and writing the report of the findings.

All data collection and management will adhere to General Data Protection Regulations 2018 and insure that only necessary research data will be retained and safely stored, password protected, with anonymity maintained.

Who is organising and funding the research?

The University of the West of England is the sponsor for this study. We will be using information from you to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of the West of England will keep information about you for 3 years after the study has finished. This research is solely for academic purposes and forms part of a doctoral research fellowship.

You can find out more about how we use your information by writing to the Data Protection Officer, UWE [redacted], or by email to [redacted].

This research is funded by the National Institute for Health Research. It has been approved by the NHS West of Scotland Research Ethics Committee 3 and the University of the West of England Research Ethics Committee.

What will happen if I don't carry on with the study?

You are free to withdraw at any time, and with no explanation needed. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about

University Hospitals Bristol NHS
NHS Foundation Trust

UWE Bristol | University of the West of England

you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.
Contact:
Pauline Humphrey (Chief Investigator, Clinical Doctoral Research Fellow)
University of the West of England, [redacted]
Tel: [redacted] or Email: [redacted]

If you remain unhappy and wish to complain formally you can do this through:
Professor Fiona Cramp (Director of Studies)
University of the West of England, [redacted] Blackberry Hill, Stapleton, Bristol BS16 1DD.
Tel: [redacted] or Email: [redacted]

Or by contacting the University of the West of England Complaints team.
Tel [redacted] or Email: [redacted]

What do I do now?

Thank you for considering taking part in this research. If you are happy to take part, or would like to know more, please complete the reply slip and return it in the stamped addressed envelope to **Pauline Humphrey**. She will contact you within a few days of receiving your reply. You can ask any questions you have and then let her know if you would like to take part.

Chief Investigator contact details:

Pauline Humphrey (Clinical Doctoral Research Fellow)
University of the West of England, [redacted]
Tel: [redacted] or Email: [redacted]

This study is funded by the National Institute for Health Research (NIHR) [ICA-CDRF-2017-03-079]. The views expressed are those of the author and not necessarily those of the NIHR or the Department of Health and Social Care.

FUNDED BY NIHR | National Institute for Health Research

Appendix 9: Research Ethics Committee approval letter (study two)

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Mrs Pauline Humphrey
[redacted]

West of Scotland REC 3
Research Ethics
Clinical Research and Development
[redacted]

Date 03 June 2019
Direct line [redacted]
E-mail

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

Dear Mrs Humphrey

Study title:	**Development of an intervention to reduce distress caused by brachytherapy for locally advanced cervical cancer. Exploratory phase part two: patient interviews**
REC reference:	**19/WS/0080**
Protocol number:	**HAS-AHP-18-005**
IRAS project ID:	**256311**

Thank you for resubmitting the PIS. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 29 May 2019

Documents received
The documents received were as follows:

Document	*Version*	*Date*
Participant information sheet (PIS) [Participant Information Sheet version 1.1 date 30.05.19]	1.1	30 May 2019

Approved documents
The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Study Flyer]	1.0	04 April 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UWE Professional Indemnity Letter 2018]	1	16 July 2018

GP/consultant information sheets or letters [Information letter for GP]	1.0	04 April 2019
Interview schedules or topic guides for participants [Interview Schedule]	1.0	04 April 2019
IRAS Application Form [IRAS_Form_07052019]		07 May 2019
Letter from funder [NIHR ICA CDRF Letter from funder]		15 March 2018
Participant consent form [Consent Form]	1.0	04 April 2019
Participant information sheet (PIS) [Participant Information Sheet version 1.1 date 30.05.19]	1.1	30 May 2019
Research protocol or project proposal [Protocol version 1.0 date 25.04.19]	1.0	25 April 2019
Summary CV for Chief Investigator (CI) [CV for P Humphrey CI v 1.0]	1	20 February 2019
Summary CV for supervisor (student research) [CV for F Cramp Director of studies and academic supervisor]		04 March 2019
Summary CV for supervisor (student research) [CV for E Dures Academic supervisor]		20 February 2019
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study Flow Chart]	1.0	04 April 2019

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

19/WS/0080 **Please quote this number on all correspondence**

Yours sincerely

[redacted]

Moyra Evans

Copy to: Mrs Pauline Humphrey
Ms Janet Forkes, Gloucestershire Hospitals NHS Foundation Trust
[redacted]

Appendix 10: Health Research Authority approval letter (study two)

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

24 June 2019

Mrs Pauline Humphrey
Consultant Radiographer and Clinical Doctoral Research Fellow
[redacted]

Dear Mrs Humphrey

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Development of an intervention to reduce distress caused by brachytherapy for locally advanced cervical cancer. Exploratory phase part two: patient interviews**
IRAS project ID:	**256311**
Protocol number:	**HAS-AHP-18-005**
REC reference:	**19/WS/0080**
Sponsor	**University of the West of England**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **256311**. Please quote this on all correspondence.

Yours sincerely,

Isobel Lyle
HRA Approvals Manager
Health Research Authority
[redacted]
T. [redacted]
E. [redacted]
W. [redacted]

Copy to: *Ms Leigh Taylor*

Appendix 11: Faculty Research Ethics Committee approval letter (study two)

Faculty of Health & Applied Sciences
Glenside Campus
Blackberry Hill
Stapleton
Bristol BS16 1DD
Tel: 0117 328 1170

Our ref: JW/lt

27th June 2019

Mrs Pauline Humphrey
[redacted]

Dear Pauline

Application Number: HAS.19.06.206
Application title: Development of an intervention to reduce distress caused by brachytherapy for locally advanced cervical cancer. Exploratory phase part two: patient interviews
REC reference: 19/WS/0080
IRAS project ID: 256311

Your NHS Ethics application and approval conditions have been considered by the Faculty Research Ethics Committee on behalf of the University. It has been given ethical approval to proceed with the following conditions:

- You comply with the conditions of the NHS Ethics approval.
- You notify the Faculty Research Ethics Committee of any further correspondence with the NHS Ethics Committee.
- You must notify the Faculty Research Ethics Committee in advance if you wish to make any significant amendments to the original application.
- If you have to terminate your research before completion, please inform the Faculty Research Ethics Committee within 14 days, indicating the reasons.
- Please notify the Faculty Research Ethics Committee if there are any serious events or developments in the research that have an ethical dimension.
- Any changes to the study protocol, which have an ethical dimension, will need to be approved by the Faculty Research Ethics Committee. You should send details of any such amendments to the committee with an explanation of the reason for the proposed changes. Any changes approved by an external research ethics committee must also be communicated to the relevant UWE committee.
- Please note that the University Research Ethics Committee (UREC) is required to monitor and audit the ethical conduct of research involving human participants, data and tissue conducted by academic staff, students and researchers. Your project may be selected

for audit from the research projects submitted to and approved by the UREC and its committees.

Please note that your study should not commence at any NHS site until you have obtained final management approval from the R&D department for the relevant NHS care organisation. A copy of the approval letter(s) must be forwarded to Leigh Taylor in line wit Research Governance requirements.

The Faculty and University Research Ethics Committees (FRECs and UREC) are here to advise researchers on the ethical conduct of research projects and to approve projects that meet UWE's ethical standards. Please note that we are unable to give advice in relation to legal issues, including health and safety, privacy or data protection (including GDPR) compliance Whilst we will use our best endeavours to identify and notify you of any obvious legal issues that arise in an application, the lead researcher remains responsible for ensuring that the project complies with UWE's policies, and with relevant legislation https://intranet.uwe.ac.uk/whats-happening/sites/gdpr/updates/pages/research-and-gdpr-compliance-update-08-may-2019.aspx. If you need help with legal issues please contact [redacted](for Health and Safety advice), [redacted](for data protection, GDPR and privacy advice).

Please remember to populate the HAS Research Governance Record with your ethics outcome via the following link: https://teams.uwe.ac.uk/sites/HASgovernance.

We wish you well with your research.

Yours sincerely

[redacted]

Dr Julie Woodley
Chair
Faculty Research Ethics Committee

c.c. Professor Fiona Cramp

Appendix 12: Consent form (study two)

University Hospitals Bristol NHS
NHS Foundation Trust

UWE Bristol | University of the West of England

CONSENT FORM

Title of Project: **A study of women's experiences of brachytherapy for cervical cancer**

IRAS ID: 256311

Participant Identification Centre:

Participant Number for this study:

Name of Researcher: Pauline Humphrey

Please initial box

1. I confirm that I have read the information sheet dated_____ (version_____) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. I agree to my General Practitioner being informed of my participation in the study (and will provide my GP name and address for this purpose). ☐
4. I agree to take part in the above study, to be interviewed with audio recording. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

This study is funded by the National Institute for Health Research (NIHR) [ICA-CDRF-2017-03-079]. The views expressed are those of the author and not necessarily those of the NIHR or the Department of Health and Social Care.

FUNDED BY NIHR | National Institute for Health Research

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

Consent Form Version 1.0 Date 04.04.19

Appendix 13: Letter to GP (study two)

University Hospitals Bristol NHS
NHS Foundation Trust

UWE Bristol University of the West of England

INFORMATION TO GENERAL PRACTITIONER

Title of Project: **A study of women's experiences of brachytherapy for cervical cancer**

IRAS ID: 256311

Researcher: Pauline Humphrey (Clinical Doctoral Research Fellow)

Patient's Name:

Address:

DOB: ____/____/___

Dear Dr

Your patient has kindly agreed to take part in the above study. This will involve a semi-structured interview with me, to find out about her experience of brachytherapy for locally advanced cervical cancer. The overall aim of the study is to develop supportive interventions to help women cope better with brachytherapy. The Participant Information Sheet is attached for your information. This research project has been funded by the NIHR as part of a Clinical Doctoral Research Fellowship.

Should you have any questions or require further information about this research, please do not hesitate to contact me on 0117 342 2482 or email me on pauline2.humphrey@uwe.ac.uk.

Yours sincerely,

Pauline Humphrey

Clinical Doctoral Research Fellow

University of the West of England,

Blue Lodge Post Graduate Research Centre.

Tel: 0117 342 2482 or Email: pauline2.humphrey@uwe.ac.uk

This study is funded by the National Institute for Health Research (NIHR) [ICA-CDRF-2017-03-079]. The views expressed are those of the author and not necessarily those of the NIHR or the Department of Health and Social Care.

FUNDED BY NIHR | National Institute for Health Research

Appendix 14: Non-substantial amendment (study two)

Partner Organisations:
Health Research Authority, England
NHS Research Scotland
HSC Research & Development, Public Health Agency, Northern Ireland
NIHR Clinical Research Network, England
NISCHR Permissions Co-ordinating Unit, Wales

Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

Instructions for using this template

- For guidance on amendments refer to http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/ . If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

1. Study Information

Full title of study:	Development of an intervention to reduce distress caused by brachytherapy for locally advanced cervical cancer. Exploratory phase part two: patient interviews
IRAS Project ID:	256311
Sponsor Amendment Notification number:	HAS.19.06.206
Sponsor Amendment Notification date:	13.5.2020
Details of Chief Investigator:	
Name [first name and surname]	Pauline Humphrey
Address:	Radiotherapy Department [redacted]
Postcode:	[redacted]
Contact telephone number:	[redacted]
Email address:	Email: [redacted]
Details of Lead Sponsor:	
Name:	Professor Olena Doran, Associate Dean (Research)
Contact email address:	Email: [redacted]
Details of Lead Nation:	
Name of lead nation *delete as appropriate*	England
If England led is the study going through CSP? *delete as appropriate*	Yes
Name of lead R&D office:	R&D Office, Leadon House Gloucestershire Royal Hospital, Gloucestershire Hospitals NHS Foundation Trust

Partner Organisations:
Health Research Authority, England — NIHR Clinical Research Network, England
NHS Research Scotland — NISCHR Permissions Co-ordinating Unit, Wales
HSC Research & Development, Public Health Agency, Northern Ireland

2. Summary of amendment(s)

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

No.	Brief description of amendment *(please enter each separate amendment in a new row)*	Amendment applies to *(delete/ list as appropriate)*		List relevant supporting document(s), including version numbers *(please ensure all referenced supporting documents are submitted with this form)*		R&D category of amendment *(category A, B, C) For office use only*
		Nation	Sites	Document	Version	
1	Due to COVID-19 pandemic, eligibility criteria for group one and two to be extended to include women up to six months post brachytherapy (group one) and up to 18 months post brachytherapy (group two).	England	All sites	Protocol	1.1	
2.	Due to COVID-19 pandemic it is possible that video conference or telephone interviews may be carried out if face to face interviews are not possible in the time frame allowed for this study.	England	All sites	Protocol	1.1	
3.	Due to COVID-19 pandemic, study period to be extended from 1 year to 2 years to allow sufficient time for recruitment and interviews for up to 40 participants.	England	All sites			
4.	Study paused during Covid-19 pandemic due to: • CI being required for clinical duties at NHS Trust. • One of four NHS recruitment sites temporarily closed to recruitment for studies unrelated to COVID-19 research • Unable to carry out face to face interviews during government enforced lockdown. Duration of pause currently unknown but anticipated to be in the region of 3-4 months.	England	All sites			

[Add further rows as required]

3. Declaration(s)

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment(s) to be implemented.

Signature of Chief Investigator: [redacted]

Print name: Pauline Humphrey

Date: 08.04.2020

Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules on delegated authority should be adhered to.

- I confirm the sponsor's support for the amendment(s) in this notification.

Signature of sponsor's representative: [redacted]

Print name Professor Olena Doran

Post: Associate Dean - Research

Organisation: Faculty of Health and Applied Sciences, University of the West of England

Date: 14th May 2020

Appendix 15: Newsletter to participants- summary of results (study two)

September 2021

Brachytherapy research project newsletter

UWE Bristol | University of the West of England

A really big

THANK YOU

to everyone who took part in the interview phase of this research. It was a privelege to meet you and listen to your stories

Key points

- *35 interviews were carried out*
- *6 face-to-face*
- *7 by telephone*
- *22 by videoconferencing*

Three themes:

1. **How I got through it**
   - *Coping strategies*
   - *Personal attitudes and resilience*
2. **The physical impact**
   - *Positioning/lying flat*
   - *Medical complications*
   - *Side effects*
3. **The psychological challenges**
   - *Trauma associated with a life threatening diagnosis*
   - *Trauma associated with the loss of fertility*
   - *Associations of applicator removal with childbirth*
   - *Feeling embarrassed, vulnerable, trapped*
   - *Not being listened or believed*

WHAT WOMEN SAY ABOUT THEIR EXPERIENCES OF BRACHYTHERAPY FOR LOCALLY ADVANCED CERVICAL CANCER: A QUALITATIVE INTERVIEW STUDY

Why did we do this research?

Brachytherapy for cervical cancer can cause pain, anxiety and distress. The reason for doing this study was to explore women's experiences of brachytherapy and ask their views on improvements needed.

How did we do it?

Between September 2019 and April 2021 interviews were carried out with women who had received brachytherapy for locally advanced cervical cancer at one of four UK hospitals. Some women had recently finished their brachytherapy and some were over a year after brachytherapy. The interviews were recorded and then analysed to look for important themes.

What did we do?

Thirty five interviews were completed. The women interviewed were aged between 28 and 87. The interviews took between 22 and 78 minutes. The first six interviews were face-to-face, before the Covid-19 pandemic began. The research had to be stopped for four months when the first Covid-19 lockdown began. The study restarted in August 2020 with permission to do telephone or video interviews.

What did you tell us?

Many women reported difficult and traumatic experiences with periods of severe pain and examples of poor nursing care on the wards.

Some women described more positive experiences, some had no pain and reported what had gone well.

Some women gave their ideas on how the treatment could be improved.

Three themes were developed from the data:

Theme 1 How I got through it

Sub theme: Coping strategies

Many women talked about the things that helped them cope with the anxiety and discomfort and long periods of time lying flat in bed. They did things like using their mobile phones to text or call friends and family, to look at the internet, play online games, using an iPad, watching TV, chatting to other women on the ward or people watching. Some women used relaxation techniques like breathing exercises, mindfulness or yoga and a few had access to complementary therapies like massage or reflexology. Some described just taking one step at a time and others talked about the benefits of having a good sense of humour.

Sub theme: Personal attitudes and resilience

Women talked about what it was in their attitudes or beliefs that helped them get through the treatment, their toughness or resilience, their past life experiences, having already been through a difficult treatment, really wanting to complete their treatment to have the best chance of cure, and a sheer determination to beat cancer and live!

Theme 2 The physical impact

Sub theme: Positioning/lying flat

Many women talked about the difficulties caused by lying flat in bed for so long, problems with back ache and stiffness which pain killers didn't seem to help, difficulty with eating and drinking, and food and drink not always within reach or not having the right utensils or help.

Sub theme: Medical complications

Some women developed complications like pressure sores from lying flat for long periods, blood clots or allergic reactions to the drugs they had been given, such as a rash or collapsing when tring to stand up after treatment was finished.

Sub theme: Side effects

Many women had side effects during brachytherapy, such as nausea and vomiting which was difficult to cope with when lying completely flat. Some had poorly controlled pain, especially when waiting on the ward for many hours through the night or during removal of applicators and packing. Some women described side effects in the days, weeks and months after treatment, such as bowel and bladder problems, tiredness and fatigue and taking a long time to regain their appetite and stamina.

Theme 3 The psychological challenges

Sub theme: Trauma associated with a life threatening diagnosis

For some women brachytherapy was described in the context of the trauma they experienced due to being diagnosed with a life threatening condition.

Sub theme: Trauma associated with loss of fertility

For some of the younger participants described their feelings of grief and loss coping which were particularly triggered by the brachytherapy procedure

Sub theme: Associations of applicator removal with childbirth

Some women reported feelings of loss or grief when the brachytherapy applicators were removed, relating this experience to childbirth, an experience they could never have or would not be able to have again. Some had vivid recollections and flashbacks of these powerful emotions.

Sub theme: Feeling embarrassed, vulnerable, trapped

Many wopmen talked about feeling embarrassed or vulnerable with applicators inside them, especially as they were not able to sit up or get out of bed, giving them a feeling of being trapped in bed, fearing that any movement could harm them or make the treatment inaccurate.

Sub theme: Not being listened or believed

Some women were upset by not being believed, made to feel like they were exaggerating or making it up when they had severe pain or reporting that the pain killers weren't working.

Examples of potential recommendations:

1. Develop and implement a protocol for pain management for applicator removal to meet the needs of individual patients.
2. Develop and implement a protocol regarding patient positioning and where possible avoid keeping patients in a totally flat position.
3. Implement a service evaluation programme for obtaining patient feedback about their brachytherapy services.
4. Ensure that patients do not experience delays to treatment or unnecessary transfers.
5. Train ward nurses about nutrition requirements and the need to monitor patients during brachytherapy to ensure they are supported to eat.

What are we doing with the interview information now?

The research team have been looking at the information gathered from their brachytherapy staff survey and your 35 interviews, focusing particularly on what you said could have been done better or what might help in the future. We have developed a list of possible recommendations for patient care, to aim to improve care standards and consistency of care throughout the brachytherapy pathway.

So what happens next?

We are planning to carry out some workshops (using videoconferencing) with a mix of brachytherapy healthcare professionals and service users, to be recruited via a link on Jo's Cervical Cancer Trust website. The selected partcipants will be allocated to a workshop where the possible recommendations will be discussed and voted on to find out which are the most relevant and important. We are hoping that these workshops will enable brachytherapy patients and healthcare professionals to learn from each others knowledge and experiences so that the recommendations will be relevant, useful and are able to be put into practice. After the workshops we will be working towards to take the recommendations to national bodies to get them accepted and implemented into hospitals in the UK.

FUNDED BY
NIHR | National Institute for Health Research

Thank you for taking part in this research study. Your time and support has been greatly appreciated.

If you have any comments or questions please contact the research team at The University of the West of England (UWE Bristol)

Contact:

Pauline Humphrey

Clinical Doctoral Research Fellow at UWE Bristol.

Email: [redacted]

Telephone: [redacted]

This study was funded by the National Institute for Health Research (NIHR) [ICA-CDRF-2017-03-079]. The views expressed are those of the author and not necessarily those of the NIHR or the Department of Health and Social Care.

Appendix 16: Table of interview findings (study three)

Study ID	Positive experiences/what helped	Negative experiences	Patient suggested improvements	Implied improvements- DF interpretation/suggestions
2-01	Said there was nothing good- but must have been good pain management when applicators in place. Slept a lot.	Conflicting information at the start. Lack of personal care on ward. Applicator removal like medieval torture. Discomfort, unable to sleep after it all finished. 2 days extra on ward. The aftermath- long recovery time, horrendous side effects.	More information about the after effects, more warning. Little suggestions for improvements- "it is what it is"	Better information before brachy. Better personal care on the wards. Support during applicator removal, or sedation? More support/help in ward after completion. Over opiated, age, more recovery time needed. Information about aftereffects at discharge home. More support when going home- living alone.
2-02	Was better the second time around. Counselling/support before 2nd time helped. Having parents on ward, helped feed her. Reading books helped.	Shocked by being on a cancer ward- all old people. Severe pain, crying out in pain, it wasn't right, had to have applicators removed after 2nd treatment. Not listened to/believed when in severe pain. Applicator removal- trauma, PTSD, association with childbirth. Loss.	Need warning about applicator removal, trigger for trauma. Need help with food choices. Need help to eat and drink.	Less pain. Better pain management. Being listened to/believed when in severe pain. More understanding from staff about loss of fertility and triggers for trauma/distress. Counselling/support after brachy.
3-01	Music and audio books. Large headphones to block out the ward.	Social isolation during and after treatment. Lack of control- being moved around by other people and immobility. Impact of loss of	To meet up with other young people after completing treatment/support group	Single room.

	PICC line really helped (needle phobia). Reflexology at one session.	fertility. Insensitive friends. Upset by seeing very ill/dying patients on the ward. Some pain, applicator removal worse second time, no epidural due to bleeding risk. Development of PE, anticoagulants started. Difficulty breathing (due to PE).		Prophylactic anticoagulants to avoid PE? But bleeding risk vs long time immobile. More understanding from staff about loss of fertility. More support after re social isolation? Reflexology on 2nd admission?
3-02	Books and radio helped. Reflexology- "It was Lovely" It cured me.	"Massive discomfort"/awful. Vomited after applicator removal, distressed lying flat and wrong shaped vomit bowls. Took 2 weeks to recover- just went to bed. Cannula painful- too large. Allergic reaction to plaster at epidural site, blistered skin. Changed plans for 2nd treatment.	Better vomit bowls.	Better management of nausea/vomiting.
2-03	Chatty nurse in theatre, surprised when that bit was finished. Not too uncomfortable. Applicator removal ok. Relief when all out. Excellent housekeeper on ward, very caring, extra cups of tea, popping in and out. Liked the single room and people watching beyond.	No hospital transport available for brachy. Had to drive herself home when not ready. Still a bit groggy. Bladder/catheter problems-severe pain on ward, cried out. Problems at home, loss of appetite, side effects bowel and bladder and fatigue- not warned.	Transport for brachytherapy. More warning about aftereffects.	More support to manage aftereffects. Better pain management for catheter/bladder pain.

	Local support group after brachy helped.			
1-01	Humour helped. Much better second time around.	Didn't like ward area, lack of privacy on 2nd admission. Low mood on ward. Trapped wind, very painful and embarrassing. Uncomfortable air mattress. Difficulty eating and swallowing tablets, lying so flat and mattress. Applicator removal, packing was cutting her, likened to childbirth.	Single room. More local anaesthetic on packing and at regular intervals to keep it moist.	Better support with eating and drinking/positioning Better pain management for applicator removal.
4-01	No pain at brachy, no problems. Couldn't feel applicators (spinal worked well)	Frightened before first brachy	Reassure other women not to worry.	
2-04	Applicator removal not too bad- had lots of morphine.	Anxiety before brachy re lying still/flat for 3 days. Poor ward experience- height of COVID-19. Not enough practical or correct information about the ward/facilities. Vomited every time she was moved. Took a while to get pain under control. Developed pressure sores after. Bored but hard to read lying flat and a bit dopey.	More information about the ward, more explanations. Access to TV.	More advice on activities to pass the time and positioning. Better pain management. Better management of nausea and vomiting.

1-02	Overall a good experience, not a problem. Felt well prepared. Single room 1st time. TV helped pass the time. Sweets helped.	2nd brachy not quite as good- more sore, catheter uncomfortable and pain at applicator removal. Vomited after each applicator removal. Didn't like ward on 2nd brachy. Too uncomfortable to read. Couldn't focus or concentrate on iPad. Difficulty eating and drinking- didn't go down, not the right foods. Unhelpful comments about pushing out a baby at applicator removal, not had children.	Encourage women to ask for painkillers and tell staff what you are feeling. Single room. Beaker with a lid and straw. Sweets!	Better pain management. Access to TV. Better positioning to eat and drink and appropriate food and utensils.
2-05	Not too bad experience overall. Good nursing care.	Poor communication between centres. Last minute referral to another centre, too many patients. Collapsed in shower, temperature, neutropaenic sepsis, prolonged admission by 3 days. No visits possible due to distance from home.		Better communication between hospitals. Earlier referral to different brachy centre. Brachy closer to home. Prophylactic antibiotics if neutropaenic/ sepsis prevention. Better supervision on ward post brachy.
1-03	Overall experience OK. Good information. Discomfort but not pain at applicator removal.	Lying in bed, felt trapped, wanted to move around, boredom.	Would have preferred day case procedures, not so long lying in bed, more "normal". Meeting other patients, a support group. More adaptive pharmacological management, not a "one size fits all".	More distractions/support when lying flat.

4-02	1st and 2nd brachy ok.	3rd brachy- more painful, longer waiting due to machine breakdown. Spinal had worn off. Painful applicator removal. PTSD, flashbacks during sex. Vomited after 1st brachy- too much analgesia?	Would not like overnight stays, home to own bed and family is best. Avoid delays.	Better pain management when delays happened. Better management of nausea and vomiting. Offer counselling/support after brachy including sexual counselling.
1-04	Had great care.	Was told it wouldn't be painful- but it was, especially applicator removal, painful both times. Nausea and vomiting throughout, ongoing since chemo. Didn't like shared ward on 2nd admission, embarrassed, lack of privacy, felt vulnerable. Loss of appetite before brachy, at a low point.	Advice to other women- trust the professionals. Single room.	Better pain management. Better management of nausea and vomiting. Better preparation- information and support?
2-06	Overall very positive experience of brachy. Prepared herself well, thought it all through. Really supportive staff, experienced nurse on ward sorted painkillers. Only one episode of pain. Analgesia by the clock. Applicator removal not painful.	Got panicky when spinal wore off, pain, but got more drugs and fell asleep.	Advice to other women- don't look for information on other websites, patient stories tend to be negative.	Better pain management, transition between spinal wearing off and PCA kicking in.

	Happy with shared ward, no one opposite her.			
1-05	No problems, had all in one go, due to COVID. Happy with 4 bedded ward and lying flat for 2 ½ days.	Moved to COVID ward due to cough. Distressed that other women had delayed discharge home. Developed pressure sores. District nurse for 3 weeks. Significant weight loss and muscle wastage during treatment.	Best to have it all in one go.	Better nursing care on ward to avoid development of pressure sores.
1-06		Went into cardiac failure, brachy abandoned after one treatment. Applicator removal- rough, done in a hurry on the ward due to complications. Urinary and faecal incontinence at home after brachy. Had been told this could happen but didn't think it would. Very upset by this.	Women should be warned more about potential aftereffects.	Risk assessment- obesity, cardiac risks with lying flat for so long. Better positioning for these risks? Should brachy be done differently if high risk?
3-03		Severe pain, not listened to or believed. Was told pain due to psychological trauma, grief, loss of baby. Pain till after removal. Never got on top of it. COVID-19 adaptation to protocol, 4 treatments from 1 insertion, not warned. Lonely on ward. Promised 1:1 nursing, false promises and reassurances. Insensitive staff at	Warning of change to schedule.	More sensitivity from staff re termination decision. To be listened to/believed when in pain. Better pain management. Better support from nursing staff on ward, especially when no visitors allowed.

		MRI re termination. Aftereffects- couldn't walk, ongoing pain. Lack of support after brachy. No complementary therapies- due to COVID-19?		Identification of high risk of trauma due to history, extra support? Better support after brachy. Debriefing? Access to complementary therapies.
4-03	Overall experience was ok. Personalised care- sedation in theatre. No pain, none at applicator removal, huge relief.	Petrified before brachy. Reassured by another patient. Some delays, waiting around, very busy. Lonely after finishing. Self-isolation for 3 months. Male rad at removal, embarrassed at first but then ok.		If hyper anxious- meet previous patients? Sensitivity re gender of staff. Support after brachy, waiting for results, debriefing?
3-04	Brachy experience ok, quite uncomplaining. Coped by sleeping a lot. Mostly good pain management. Liked TV on all night, liked single room. Support from parents on ward.	Anxiety before brachy. Worse experience due to young age, more embarrassed. Pain on 1st applicator removal, better on 2nd- used gas and air. Fertility loss, choices taken away, grief/loss. Felt vulnerable with applicators in, waiting in a staff room? Needed parents to support on ward, feed her. Complications- morphine allergy, collapsed, nausea. PTSD- diagnosis, shock, fear, can't move on.	Would have preferred sedation/GA in theatre. Would have preferred all treatments in one go (hard to go back in for 2nd time)	More support/counselling due to trauma of diagnosis (age 26) - high risk of distress at brachy? More support after? Debriefing.
3-05	Overall coped really well with brachy, very uncomplaining.	Frustrated by ward experience. Moved from single ward to general ward- noisy, lots of visitors, difficult	Would advise women not to worry.	Access to complementary therapies (given leaflets but not available).

	Shut curtains to block out the ward. Music and headphones helped. Liked people watching.	other patients, disturbed rest and sleep. Stayed in extra night, ward Dr too busy to discharge. Extra journeys for son to collect her. Complementary therapies not available (not due to COVID-19).	Would have preferred single room throughout.	
3-06	Good experience on ward, side room, had 1:1 care throughout first admission. Less on 2nd but didn't need it. Support from Macmillan nurses, always someone to talk to. Overall pain controlled well by spinal and PCA.	Was "quite unpleasant", painful but has high pain threshold. Unable to read a book, too sleepy, couldn't concentrate. Applicator removal- unpleasant but bearable, not as painful as childbirth. Aftereffects- bowels, insufficiency fractures/pain.	Liked the 2 admission with 5-6 day gap in between.	
3-07	Preferred general ward, people to talk to.	Main issue- lying flat, COPD, fear, anxiety, distress and panic. Same at 2nd admission. Shock of applicator removal, cried out with intense pain both times, but it was quick. Complications- reaction to morphine 1st admission. Out of it, head in plate, vomited. Delayed discharge home by 2 nights. Reaction 1 week after brachy, pain+++ ambulance, pressure sore/infection? IP 5 days.	Would have preferred day case brachy, not lying flat for so long, but not so keen on 4 spinals.	Positioning due to COPD- propping up a little may have made a huge difference to anxiety. Could staff have listened/understood and made adaptations?

4-04	Overall coped well. Mild pain only (had GA not spinal due to herpes lesion on back). Tried to avoid thinking about it till the day. Prayer helped. Excellent staff, trusted them.	Visions of medieval torture. Impact on sex life, PTS? Intrusive thoughts many months later. 3rd time had more pain, more sore, but liquid morphine helped. Felt vulnerable during dose delivery, trapped, alone.	Advice to others, go with it, don't overthink it, trust in the team.	Post brachy support, debriefing?
3-08	Single room.	Nausea since chemo, trade-off between pain and analgesia making nausea worse. Unable to sleep due to pain and nausea. Felt lonely on ward, especially at night, partner left, but happy with single room Applicator removal traumatic, distressing, thought about childbirth "the closest I'll get", sadness. Not able to use books, music, TV- too much nausea.	Diagram of applicators- tried to imagine what they would look like. Would have liked company on the ward, knowing someone was there. Sedation of GA for applicator removal.	Better support/sensitivity due to loss of fertility and age (32) especially at applicator removal. Anxiolytic may have helped, memory loss could be beneficial?
2-07	Overall a very good experience. Good explanations before brachy. Good pain management, drifting in and out of consciousness. Not painful, just discomfort.	Loss of appetite, weight down to 6 stone.	No improvements suggested, none needed	

	No delays going home, amazed that she just got up and walked out after lying flat for days.			
2-08	Choice of centres, oncologist advised all 4 in one go due to travelling, agreed this was best for her. Visualisation helped her, imagining beaches.	Poor experience on ward. No-one noticed that she wasn't eating or drinking. Lack of care, no compassion on ward. Some pain on applicator removal. No-one to talk to on ward, best to sleep, used visualisation. Unable to reach own iPad. After effects- collapsed at home, readmission, weight loss, weak.	Would have liked to see applicators or a diagram.	Access to distractions, iPad, TV, books. Ward staff to support patients better. Someone to talk to on ward, to help pass the time. Ward staff to show care, compassion and notice when patients are not eating or drinking. Discharge home- better support, food etc. Better preparation for care and support after discharge home?
2-09	Overall not as bad as expected, not as painful. Sleeping helped pass the time. Played games on phone, music with headphones helped. Brachy easier compared with previous experiences. Knew some of the ward staff from previous admissions- helped.	Scared, nervous beforehand, pain, lying flat. Pain first night, delay getting syringe driver up. Pain on movement. Felt isolated in single room. Nurses didn't chat (NB pre-COVID-19 time). Poor appetite, food not in reach. Didn't want to bother the nurses. Difficult to eat/drink due to position. No visitors- too far to travel.	Would advise women not to worry too much. Ask for painkillers and help with food. Would have preferred to be on main ward, more going on.	More company/someone to talk to on the ward. Ward staff to be more aware of difficulties with eating and drinking, provide help. Nurses to check in on patients more often, not wait to be called.
4-05	Overall very good experience. No pain, not even at applicator removal. Not as bad as EBRT,	Nervous about spinal injection, same each time.	Use of yoga breathing techniques to cope with anxiety/nerves.	

	delays, bladder fill, anxiety, frustrating. Complete confidence and trust in oncologist. Care and dedication.	After effects- pelvic insufficiency fractures or sciatica?		
4-06	Overall a good experience, caring and supportive staff in all areas. No pain at 1st brachy.	Pain especially at applicator removal on 2nd and 3rd time. Spinal wore off. Tensed up, something came apart. Complications- pain, temp, UTI	Shorten time between spinal and applicator removal. Shorter planning time. Spinal needs to last a bit longer.	Better pain management when spinal wearing off.
3-09	Says overall a good experience. Applicator removal- had extra pain killers, like taking off a plaster, very short, not a problem. iPad helped, message friends and family.	Significant back pain, but didn't complain, has high pain threshold. Morphine didn't work. Too much information before brachy, couldn't take it all in.	Could give women advice on some exercises to do in bed, yoga. Leaflet with instructions/advice. Need advice on how much you can move without risk of moving applicators.	
4-07	Overall ok experience. Not pleasant, but no other way to do it. Good care, and no pain, even applicator removal, 3rd time too bust chatting, didn't notice it. Hotel for 5 weeks was very helpful. Sedation before spinal on 3rd brachy helped.	Anxious pre brachy, especially about spinal. Didn't get any better on 2nd or 3rd time. Anticipation was the worst part. Fatigue, at lowest point at end of brachy. Sounded depressed, booked for counselling. The post brachy side effects, soreness and urinary pain	Can't see anything that would help. Sedation in theatre, before spinal. Virtual support groups might help.	Meeting ex patients before 1st brachy? More warning about post brachy soreness and urinary pain and what to do. More advice on analgesia post brachy- repeat information at discharge home.

4-08	Overall good experience of brachy. Applicator removal no pain. No pain overall. Hotel useful, mum stayed to support. Time passed easily, read a book, 3.5 hours each time.	Care transferred to another centre as brachy oncologist off sick. A bit confusing with different regimes. Worried about being awake during brachy as spinal instead of GA. Anxious++ going into theatre. Sedation only given on 3rd brachy. Confusion re post brachy support/follow up.	Would have preferred sedation every time.	Better information and support at end of brachy- clarity about which team.
4-09	Overall coped really well with brachy. Spinal worked well, history of back problem, u/s to check spinal would be OK. Spoke to another patient before brachy, she had no pain, reassured.	First brachy- uterine perforation, removed and went home, so extra procedure needed. Worst part- pain passing urine, a few hours after brachy. Every time. Not warned. Late effects- proctitis, lymphoedema, vaginal stenosis.	Need warning re urinary pain. Would be best if warned at time of discharge home.	Better post treatment support re late effects?
3-10	Reflexology before going home after first brachy. Very nice.	Not a nice experience, unpleasant. Lying flat and applicator removal- both bad, pain was unexpected. Shocked by this, no extra pain killers offered. Upset, still vivid recall at 4 months. Emotional. PTSD? 2nd time extra morphine helped a bit. Ward care- very little attention, booklet said 1:1 nursing care, very disappointed. No personal care. Noisy ward, disturbed sleep. Lack of	Needed a tray to put book/laptop on.	Ward care- more support, attention, help with positioning. Single room. Better pain management for applicator removal.

		information on ward, eg free TV in mornings. PE 2 months after brachy, but also had one month after.		
4-10	Overall had a very good experience. Easier than EBRT and chemo. Chatted to another patient throughout 3 brachys. No pain at all.	Pain passing urine, a few hours after getting home. Happened every time.	Can't think of any ideas for improvements as it was all done so well	Advice on discharge re possible urinary pain, how to manage it.

Appendix 17: Faculty Research Ethics Committee approval letter (study three)

Faculty of Health & Applied Sciences
Glenside Campus
[redacted]
Bristol [redacted]

Tel: [redacted]

UWE REC REF No: HAS.21.10.020

1st December 2021

Pauline Humphrey
Research Fellow

Dear Pauline

Application title: Development of patient care recommendations in brachytherapy for locally advanced cervical cancer using a nominal group technique

Your ethics application was considered by the Faculty Research Ethics Committee and, based on the information provided, has been given ethical approval to proceed.

Please note that despite the easing of lockdown in England and across the devolved nations, you must continue to follow guidance as set by the UK Government and the relevant devolved administrations. If you have any questions about how this may affect starting your research project or for further information, please contact [redacted]

In the UK, face-to-face research and fieldwork can be undertaken but there should still be consideration of whether the activities could be delivered in an alternative way. There must still be appropriate mitigations related to Covid-19 risks included within risk assessments, including account taken of requirements from stakeholders.

At the present time overseas travel on UWE business is not permitted. Please see the guidance at https://intranet.uwe.ac.uk/tasks-guides/guide/coronavirus-advice#part6. If you are planning any overseas activities involving personnel already located in the country concerned, then you must first contact [redacted] Please see COVID guidance: FAQs on conducting face-to-face activity and fieldwork (PDF).

The following standard conditions apply to all research given ethical approval by a UWE Research Ethics Committee:

1. You must notify the relevant UWE Research Ethics Committee in advance if you wish to make significant amendments to the original application: these include any changes to the study protocol which have an ethical dimension. Please note that any changes approved by an external research ethics committee must also be communicated to the relevant UWE committee.
2. You must notify the Faculty Research Ethics Committee if you terminate your research before completion.

3. You must notify the Faculty Research Ethics Committee if there are any serious events or developments in the research that have an ethical dimension.

Please ensure that before proceeding with your research:

- you have sought contractual advice from the UWE Contracts Team [redacted] if your research involves external funding and/or contracts with partner organisations;
- You have sought advice from the UWE Data Protection Team ([redacted] if, in relation to collecting and/or sharing personal data, a third party (i.e. any person or institution extraneous to UWE) is involved in the research project.

Please note: The RESC is required to monitor and audit the ethical conduct of research involving human participants, data and tissue conducted by academic staff, students and researchers. Your project may be selected for audit from the research projects submitted to and approved by the RESC and its committees.

We wish you well with your research.

Yours sincerely

[redacted]

Dr Julie Woodley
Chair
Faculty Research Ethics Committee

Appendix 18: Recruitment information for service providers (study three)

Brachytherapy research workshops: can you help?

If you are a healthcare professional who has experience of working in brachytherapy for locally advanced cervical cancer in a UK setting at any time during the last five years, you may be able to help with this research by joining an online (Zoom) workshop, with the aim of developing patient care recommendations.

I am a consultant therapeutic radiographer working at Bristol Cancer Institute and currently in my 4th year of a doctoral fellowship funded by the National Institute for Health Research.

My research began with a systematic literature review of women's experiences of brachytherapy[1]. This was followed with a UK survey of brachytherapy for cervical cancer, a staff survey to understand what services are currently available to support women during brachytherapy[2], then 35 patient interviews with women who had brachytherapy for cervical cancer at one of four UK centres where brachytherapy is given in different ways. I asked them about their experiences, what went well and what could be improved[3]. The women I interviewed reported a wide range of experiences, some traumatic with women experiencing periods of severe pain and examples of poor nursing care, and some were more positive with no pain and good experiences. From existing literature, survey and interview data I have compiled a list of potential patient care recommendations for brachytherapy. For the final stage of the research, I plan to hold four online (Zoom) workshops with a mix of service users and service providers, to discuss and rate the potential recommendations. The workshops are based on a co-design method, using Nominal Group Technique so that all participants have an equal voice. I hope to recruit four service users and four service providers for each workshop. Service users will be women who have had brachytherapy for locally advanced cervical cancer in a UK centre in the last 5 years. Service providers will be healthcare professionals working in brachytherapy in the UK in the last 5 years. Service users and service providers from the same centre will not be allocated to the same workshop. We hope to recruit healthcare professionals who are clinically involved in brachytherapy from across the professions, for example clinical oncologists, radiographers, nurses (theatre, ward, clinical nurse specialists), anaesthetists and psychologists.

Your knowledge and experience of this type of brachytherapy will help us to develop patient care recommendations and to improve women's experiences of this treatment in the future.

If you have any questions, need further information about this research or would like to take part, please email me, Pauline Humphrey, at [redacted]

References

1. Humphrey P, Bennett C, Cramp F. The experiences of women receiving brachytherapy for cervical cancer: A systematic literature review. Radiography. 2018;24(4):396–403.

2. Humphrey P, Dures E, Hoskin P, Cramp F. Brachytherapy for locally advanced cervical cancer : A survey of UK provision of care and support. Radiother Oncol. 2021;159:60–6. Available from: https://doi.org/10.1016/j.radonc.2021.03.007

3. Humphrey P, Dures E, Hoskin P, Cramp F. What do women say about their experience of brachytherapy for cervical cancer? A qualitative study. WCB 2021 Abstr B. 2021;S140(PO-0184):147–8.

Appendix 19: Recruitment information for service users (study three)

Brachytherapy research workshops: can you help?

If you have had brachytherapy for cervical cancer in the last five years, where the type of brachytherapy involved placing applicators into your womb, you may be able to help with this research by joining an online (Zoom) workshop, with the aim of improving women's experiences of this treatment in the future.

I am a consultant therapeutic radiographer working at Bristol Cancer Institute and currently in my 4th year of a doctoral fellowship funded by the National Institute for Health Research.

I have carried out a UK staff survey of brachytherapy for cervical cancer, to understand what services are currently available to support women during brachytherapy. I then carried out interviews with 35 women who had brachytherapy for cervical cancer at one of four UK centres where brachytherapy is given in different ways. I asked them about their experiences, what went well and what could be improved. The women I interviewed reported a wide range of experiences, some traumatic with women experiencing periods of severe pain and examples of poor nursing care, and some were more positive with no pain and good experiences. From the survey and interview data I have compiled a list of potential recommendations for patient care for brachytherapy. For the final stage of the research, I plan to hold four online (Zoom) workshops with a mix of service users and service providers, to discuss and rate the potential recommendations. The workshops are based on a co-design method, using Nominal Group Technique so that all participants have an equal voice. I hope to recruit four service users and four service providers for each workshop. Service users will be women who have had brachytherapy for locally advanced cervical cancer in a UK centre in the last 5 years, where the applicators were placed into the womb. Service providers will be healthcare professionals working in brachytherapy in the UK in the last 5 years. Service users and service providers from the same centre will not be allocated to the same workshop.

Please email me, Pauline Humphrey, at pauline2.humphrey@uwe.ac.uk if you have any questions, need further information about this research or would like to take part.

Appendix 20: Participant information sheet for service providers (study three)

Development of patient care recommendations in brachytherapy for cervical cancer using a Nominal Group Technique

Participant Information Sheet

(for Service Providers)

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information. Please ask if there is anything that is not clear, or if you would like more information.

What is the purpose of the study?

Brachytherapy for cervical cancer can be a difficult treatment for women. There are reports showing that some women experienced discomfort, pain and anxiety before, during or after brachytherapy and that there are some areas of patient care that need to be improved. To help us prioritise which areas of patient care need to be improved we are holding some online workshops with healthcare professionals and women who have had brachytherapy to explore what is most important and is potentially possible to change. We will use a method called Nominal Group Technique (NGT). In advance of the workshop participants will be given a list of possible recommendations for improving patient care and invited to score the importance of each one at the start of the workshop. The group will then have the opportunity to discuss the scores and if appropriate add to this list. The scoring of importance for remaining items will then be repeated individually. We will then use this information in future work to develop patient care recommendations and put them into practice, with the goal of improving women's experiences of brachytherapy.

This study is part of a PhD qualification at UWE Bristol.

Why have I been invited to take part?

You have been invited because you are a healthcare professional who has experience of working in brachytherapy for locally advanced cervical cancer in a UK setting at any time during the last five years. Your knowledge and experience of this type of brachytherapy may be able to help us to develop patient care recommendations and to improve women's experiences of this treatment in the future.

Do I have to take part?

No, it is up to you to decide. If you do decide to participate you will be invited to electronically sign a consent form. You are free to withdraw your consent before the recording of the workshop begins, without giving a reason. After the recording begins it will not be possible to remove your data from the workshop data.

What will I be asked to do if I take part?

If you would like to take part in the study we will ask you to complete a pre-study questionnaire and consent form. We will then send an email invitation for you to join one workshop using the online platform Zoom, at a time that is convenient to you. You will need to use either a smartphone, tablet , iPad or

computer to join the meeting and will need to have a microphone and camera available so that other people at the meeting can see and hear you. The email invitation will include some background information about the research project and a list of the possible recommendations so that you will have had a chance to read through them before the workshop takes place.

At the workshop you will be asked to do an online initial voting on which recommendations you think are important for patient care. Following the initial voting we will invite everyone in the group to share their views about the voting as well as any ideas for new recommendations to be added to the list, and then take part in a group discussion about the recommendations. You will then be asked to repeat the voting of all the remaining items.

The Zoom meeting will be audio and video recorded and stored securely at the UWE Bristol. More information about how your data will be stored is outlined below.

What are the possible disadvantages and risks of taking part?

We do not believe that there are any risks to taking part and the only disadvantage is the time needed to participate. We intend to limit the workshop to two hours and will ensure that there is a break scheduled within the meeting.

What are the possible benefits of taking part?

The study is not planned to benefit you but the information from the study will help to develop patient care recommendations with the aim to improve women's experience of brachytherapy for cervix cancer in the future.

What will happen to the results?

The results of this study will be used to develop patient care recommendations. A report of the study will be published in an academic journal and presented at conferences, which will help healthcare professionals to put patient care recommendations into practice. The findings will also form part of a doctoral thesis being undertaken at UWE Bristol. A lay summary of the study will be offered to participants and relevant charities.

Will my taking part in the study be kept confidential?

Yes, all information which is collected during the study will be kept strictly confidential and will have your name removed so that you cannot be recognised. In the pre-study questionnaire we will ask in which centre(s) your brachytherapy experience has been in during the last five years so we can avoid placing you in a workshop with service users where you may have been involved with their care. At the start of the online workshop participants will be reminded of the confidential nature of the workshop and asked not to share information outside of the meeting. At the online workshop, the other participants will be able to see and hear you, but you are welcome to choose another name or use your own name when you join the meeting, whichever you prefer. The audio and video recording of the meeting will be loaded onto the University's password protected secure computer data storage. Any information from the meeting will only be shared with members of the research team for the purpose of analysis and writing the report of the findings. Your name or chosen name for the meeting and any personal information will be anonymised with a code before the analysis and report writing. All names, places and identifying features mentioned in the meetings will also be anonymised. Nobody will be able to identify you from your responses.

All data collection and management will adhere to General Data Protection Regulations 2018 and ensure that only necessary research data will be retained and safely stored, password protected, with anonymity maintained.

Who is organising and funding the research?

UWE Bristol is the sponsor for this study. We will be using information from the group meeting you attend to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The UWE Bristol will keep information about you for 3 years after the study has finished.

You can find out more about how we use your information by writing to the Data Protection Officer, UWE Bristol, [redacted], or by email to [redacted].

This research is funded by the National Institute for Health Research as part of a Clinical Doctoral Research Fellowship being undertaken by the Chief Investigator, Pauline Humphrey. It has been approved by the UWE Bristol Research Ethics Committee. Academic staff at UWE Bristol will continuously monitor the study.

What will happen if I don't carry on with the study?

You are free to withdraw at any time and with no explanation needed. However, if you withdraw during or after the workshop has taken place it would not be possible for your data to be removed as it will be part of the data for the whole group. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.
Contact:
Pauline Humphrey (Chief Investigator, Clinical Doctoral Research Fellow)
UWE Bristol, [redacted]
Tel: [redacted] or Email: [redacted]

If you remain unhappy and wish to complain formally you can do this through:
Professor Fiona Cramp (Director of Studies)
UWE Bristol [redacted].
Tel: [redacted] or Email: [redacted]

Or by contacting the UWE Bristol team.
Tel [redacted] or Email: [redacted]

What do I do now?

If you are interested in taking part in the study, **please click on the survey link in the email to complete the online consent form and short questionnaire to check that you are eligible to take part in the study**. We will ask what type of brachytherapy you have been involved with (inpatient or day case) and when. We will ask which professional group you are in, for example oncologist, radiographer, clinical nurse specialist, ward or theatre nurse, psychologist or anaesthetist. We will ask whether you would prefer to

attend a daytime or evening workshop. You will be asked to provide your email address so that we can contact you about the workshop.

Thank you for considering taking part in this research. If you have any further questions then please contact Pauline Humphrey, contact details below.
Tel: [redacted] or Email: [redacted]

Chief Investigator contact details:

Pauline Humphrey (Clinical Doctoral Research Fellow)
UWE Bristol, [redacted]
Tel: [redacted] or Email: [redacted]

FUNDED BY
NIHR | National Institute for Health Research

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Appendix 21: Participant information sheet for service users (study three)

Development of patient care recommendations in brachytherapy for cervical cancer using Nominal Group Technique meetings

Participant Information Sheet

(for Service Users)

You are being invited to take part in a research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information. Please ask if there is anything that is not clear, or if you would like more information.

What is the purpose of the study?

Brachytherapy for cervical cancer can be a difficult treatment for women. There are reports showing that some women experienced discomfort, pain and anxiety before, during or after brachytherapy and that there are some areas of patient care that need to be improved. To help us prioritise which areas of patient care need to be improved we are holding some online workshops with healthcare professionals and women who have had brachytherapy to explore what is most important and is potentially possible to change. We will use a method called Nominal Group Technique (NGT). In advance of the workshop participants will be given a list of possible recommendations for improving patient care and invited to score the importance of each one at the start of the workshop. The group will then have the opportunity to discuss the scores and if appropriate add to this list. The scoring of importance for remaining items will then be repeated individually. We will then use this information in future work to develop patient care recommendations and put them into practice, with the goal of improving women's experiences of brachytherapy.

This study is part of a PhD qualification at UWE Bristol.

Why have I been invited to take part?

You have been invited because you have had brachytherapy for cervix cancer in the last five years, where the type of brachytherapy involved placing applicators into your womb. Your knowledge and experience of this type of brachytherapy may be able to help us to develop patient care recommendations and to improve women's experiences of this treatment in the future.

Do I have to take part?

No, it is up to you to decide. If you do decide to participate you will be invited to electronically sign a consent form. You are free to withdraw your consent before the recording of the workshop begins, without giving a reason. After the recording begins it will not be possible to remove your data from the workshop data. If you withdraw from the study your future healthcare will not be affected in any way.

What will I be asked to do if I take part?

If you would like to take part in the study we will ask you to complete a pre-study questionnaire and consent form. We will then send an email invitation for you to join one workshop using the online platform Zoom, at a time that is convenient to you. You will need to use either a smartphone, tablet , iPad or

computer to join the meeting and will need to have a microphone and camera available so that other people at the meeting can see and hear you. The email invitation will include some background information about the research project and a list of the possible recommendations so that you will have had a chance to read through them before the workshop takes place.

At the workshop you will be asked to do an online initial voting on which recommendations you think would be important to include in future recommendations for patient care. Following the initial voting we will invite everyone in the group to share their views about the voting as well as any ideas for new recommendations to be added to the list, and then take part in a group discussion about the recommendations. You will then be asked to repeat the voting of all the remaining items.

The Zoom meeting will be audio and video recorded and stored securely at UWE Bristol. More information about how your data will be stored is outlined below.

What are the possible disadvantages and risks of taking part?

A disadvantage to taking part in the study is the time needed to participate. We intend to limit the workshop to two hours and will ensure that there is a break scheduled within the meeting.

There is a possibility that talking to the group about brachytherapy may be upsetting to you. It could bring back memories if you had a difficult experience. If you need further support to talk through any issues that this brings up it may be useful for you to contact your medical team at the centre that is looking after your ongoing care and support, or one of the local or national charity helplines that offer support, or your GP.

Whether you decide to take part in this research or not, your future healthcare will not be affected in any way.

What are the possible benefits of taking part?

The study is not planned to benefit you but the information from the study will help to develop patient care recommendations with the aim to improve women's experience of brachytherapy for cervix cancer in the future.

What will happen to the results?

The results of this study will be used to develop patient care recommendations. A report of the study will be published in an academic journal and presented at conferences, which will help healthcare professionals to put patient care recommendations into practice. The findings will also form part of a doctoral thesis being undertaken at UWE Bristol. A lay summary of the study will be offered to participants and relevant charities.

Will my taking part in the study be kept confidential?

Yes, all information which is collected during the study will be kept strictly confidential and will have your name removed so that you cannot be recognised. In the pre-study questionnaire we will ask you which centre you had your brachytherapy so we can avoid placing you in a workshop with healthcare professionals from the same centre in case they had been involved in your care. At the start of the online workshop participants will be reminded of the confidential nature of the workshop and asked not to share information outside of the meeting. At the online workshop the other participants will be able to see and hear you, but you are welcome to choose another name or use your own name when you join the meeting,

whichever you prefer. The audio and video recording of the meeting will be loaded onto the University's password protected secure computer data storage. Any information from the meeting will only be shared with members of the research team for the purpose of analysis and writing the report of the findings. Your name or chosen name for the meeting and any personal information will be anonymised with a code before the analysis and report writing. All names, places and identifying features mentioned in the meetings will also be anonymised. Nobody will be able to identify you from your responses.

All data collection and management will adhere to General Data Protection Regulations 2018 and ensure that only necessary research data will be retained and safely stored, password protected, with anonymity maintained.

Who is organising and funding the research?

UWE Bristol is the sponsor for this study. We will be using information from the group meeting you attend to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. UWE Bristol will keep information about you for 3 years after the study has finished.

You can find out more about how we use your information by writing to the Data Protection Officer, UWE Bristol, [redacted], or by email to [redacted]

This research is funded by the National Institute for Health Research as part of a Clinical Doctoral Research Fellowship being undertaken by the Chief Investigator, Pauline Humphrey. It has been approved by the UWE Bristol Research Ethics Committee. Academic staff at UWE Bristol will continuously monitor the study.

What will happen if I don't carry on with the study?

You are free to withdraw at any time and with no explanation needed. However, if you withdraw during or after the workshop has taken place it would not be possible for your data to be removed as it will be part of the data for the whole group. To safeguard your rights, we will use the minimum personally-identifiable information possible.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.
Contact:
Pauline Humphrey (Chief Investigator, Clinical Doctoral Research Fellow)
UWE Bristol, [redacted] Blackberry Hill, Stapleton, Bristol BS16 1DD
Tel: [redacted] or Email: [redacted]

If you remain unhappy and wish to complain formally you can do this through:
Professor Fiona Cramp (Director of Studies)
UWE Bristol, [redacted] Blackberry Hill, Stapleton, Bristol BS16 1DD
Tel: [redacted] or Email: [redacted]

Or by contacting the UWE Bristol Complaints team.
Tel [redacted] or Email: [redacted]

What do I do now?

If you are interested in taking part in the study, **please click on the survey link in the email to complete the online consent form and short questionnaire to check that you are eligible to take part in the study.** We will ask what treatment you have had, inpatient or day case brachytherapy and when you had brachytherapy. We will also ask your age so that we can make sure there is a mixture of age groups of participants taking part in the study. We will ask whether you would prefer to attend a daytime or evening workshop. You will be asked to provide your email address so that we can contact you about the workshop.

Thank you for considering taking part in this research. If you have any further questions then please contact Pauline Humphrey (details below).
Tel: [redacted] or Email: [redacted]

Chief Investigator contact details:

Pauline Humphrey (Clinical Doctoral Research Fellow)
UWE Bristol, [redacted]
Tel: [redacted] or Email: [redacted]

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Appendix 22: Qualtrics survey (with consent form) for service providers (study three)

Consent form

ONLINE CONSENT FORM

Development of patient care recommendations in brachytherapy for locally advanced cervical cancer using a Nominal Group Technique

Please ensure that you have read and understood the information contained in the Participant Information Sheet and asked any questions before you sign this form. If you have any questions please contact a member of the research team, whose details are set out in the Participant Information Sheet.

- I confirm that I have read the information sheet (dated 05.08.21 version 1.0) for the above study and I have had the opportunity to ask/email questions and have received satisfactory answers.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.
- I understand that if I choose to withdraw from the study I can request that my personal data is destroyed. However, I understand that after the online workshop has taken place it will not be possible to withdraw my data.

- I consent to the use of my data for reporting and dissemination. Data will be anonymised with any personally identifiable data removed. Data will be securely stored under General Data Protection Legislation (GDPR) regulations.
- I agree to answer the survey questions to check my eligibility for the study
- I agree to take part in an online workshop for the above study.
- I consent to the audio and video recording of the online workshop for research purposes.

I agree to take part in this study.

◯ Yes
◯ No

Demographics and eligibility

Welcome!

Your answers to the following questions will be used to select participants to take part in an online workshop. We will use the results to select participants to include a mixture of different healthcare professions and roles in the workshops. The questions can be navigated using the 'Next' and 'Back' buttons and should take approximately 3 minutes to complete. Your participation, data and any information you give during the study will be kept confidential.

Have you worked in brachytherapy services for the treatment of locally advanced cervical cancer patients in the UK within the last 5 years?

- ○ Yes
- ○ No

What is your profession?

- ○ Clinical oncologist
- ○ Nurse
- ○ Radiographer
- ○ Psychologist
- ○ Anaesthetist
- ○ [ ] Other (please specify in the text box)

What is or was your role or involvement in brachytherapy for the treatment of locally advanced cervical cancer treatment ?

[ ]

In your centre is brachytherapy for locally advanced cervical cancer given predominantly as an inpatient or day case?

- ○ Inpatient
- ○ Day case
- ○ Equally split between inpatient and day case

In which centre(s) have you worked in brachytherapy during the last 5 years? Please list all in the box.

[ ]

If you are selected to join an online workshop, which day of the week and time of day would you prefer to attend?
Please select as many options as you like.

	Morning 9.00-11.00	Morning 10.00-12.00	Afternoon 14.00-16.00	Afternoon 15.00-17.00	Evening 17.00-1900	Evening 16.00-18.00	Evening 19.00-21.00
Monday	○	○	○	○	○	○	○

	Morning 9.00-11.00	Morning 10.00-12.00	Afternoon 14.00-16.00	Afternoon 15.00-17.00	Evening 17.00-1900	Evening 16.00-18.00	Evening 19.00-21.00
Tuesday	○	○	○	○	○	○	○
Wednesday	○	○	○	○	○	○	○
Thursday	○	○	○	○	○	○	○
Friday	○	○	○	○	○	○	○
Saturday	○	○	○	○	○	○	○
Sunday	○	○	○	○	○	○	○

Is there an alternative day of the week or time of day would you prefer to attend?

Please provide the email address that you would like us to use contact you about this study.

Please provide your name so that we can address the email to you correctly.

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Appendix 23: Qualtrics survey (with consent form) for service users (study three)

Consent form

ONLINE CONSENT FORM

Development of patient care recommendations in brachytherapy for cervical cancer using a Nominal Group Technique

Please ensure that you have read and understood the information contained in the Participant Information Sheet and asked any questions before you sign this form. If you have any questions please contact a member of the research team, whose details are set out in the Participant Information Sheet.

- I confirm that I have read the information sheet (dated 05.08.21 version 1.0) for the above study and I have had the opportunity to ask/email questions and have received satisfactory answers.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

- I understand that if I choose to withdraw from the study I can request that my personal data is destroyed. However, I understand that after the online workshop has taken place it will not be possible to withdraw my data.
- I consent to the use of my data for informing others of the results of the study. Data will be anonymised with any personally identifiable data removed. Data will be securely stored under General Data Protection Legislation (GDPR) regulations.
- I agree to answer the survey questions to check my eligibility for the study
- I agree to take part in an online workshop for the above study.
- I consent to the audio and video recording of the online workshop for research purposes.

I agree to take part in this study.

◯ Yes
◯ No

Demographics and eligibility

Welcome!

Your answers to the following questions will be used to select participants to take part in an online workshop. We will use the results to select participants of different ages and had brachytherapy at different hospitals.

The questions can be navigated using the 'Next' and 'Back' buttons and should take approximately 3 minutes to complete. Your participation, data and any information you give during the study will be kept confidential.

Have you had brachytherapy for cervical cancer in a UK hospital within the last 5 years?

- ○ Yes
- ○ No

Did you have a hysterectomy ***before*** your brachytherapy?

- ○ Yes
- ○ No
- ○ Don't know

Did the type of brachytherapy you had involve placing applicators inside your womb?

- ○ Yes
- ○ No
- ○ Don't know

Did you have brachytherapy as an inpatient or as a day case?

- ○ Inpatient
- ○ Day case
- ○ A combination of inpatient and day case

Which hospital did you have brachytherapy in?

Please tell us your age

Block 4

If you are selected to join an online workshop, which day of the week would you prefer to attend?
Please select as many options as you like.

	Morning 9.00-11.00	Morning 10.00-12.00	Afternoon 14.00-16.00	Afternoon 15.00-17.00	Evening 17.00-1900	Evening 16.00-18.00	Evening 19.00-21.00
Monday	☐	☐	☐	☐	☐	☐	☐
Tuesday	☐	☐	☐	☐	☐	☐	☐
Wednesday	☐	☐	☐	☐	☐	☐	☐
Thursday	☐	☐	☐	☐	☐	☐	☐
Friday	☐	☐	☐	☐	☐	☐	☐
Saturday	☐	☐	☐	☐	☐	☐	☐
Sunday	☐	☐	☐	☐	☐	☐	☐

Is there a different day of the week or time that you would prefer to attend?

Please provide the email address that you would like us to use contact you about this study.

Please provide your name so that we can address the email to you correctly. Please note- when you join the online workshop you may choose to use a made up name so that your real name is not seen by the other participants

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Appendix 24: Recommendations for short duration workshop (study three)

Points of recommendation for NGT study (short duration/day case brachy workshop)

Participants will be asked to rate the importance of each recommendation.

Single choice option for each point:

- **Not important/relevant**
- **Slightly important**
- **Important**
- **Very important**

Explanatory notes (shown here in italics) are included in the pre-meeting information email, so that participants can read through the recommendations with the explanatory notes in advance of the meeting. This should help to speed up the initial voting stage and allow participants some extra preparation time for the silent generation of ideas/amendments stage during the meeting. The explanatory notes will not be included in the Zoom polling questions as this would exceed the character count on the polling function.

The recommendations are aimed at the brachytherapy team, but also to the wider hospital teams that are involved in care of gynaecological cancer patients, for example, managers and healthcare professionals on wards and theatres where brachytherapy patients are cared for, the gynae-oncology multidisciplinary team including clinical nurse specialists and access to other healthcare professionals such as clinical psychologists. The use of the term 'centre' may mean radiotherapy or oncology centre or the broader hospital site, depending on the specific setting for brachytherapy services.

Poll 1: Pain management

1. Each centre should have a protocol for anaesthesia for applicator insertion, including options for anaesthesia for different types of applicators and adaptations to meet the needs of individual patients.
2. Each centre should have a protocol for pain management in theatre recovery, including options for pain and relaxant medication for different types of applicators and to meet the needs of individual patients.
3. Each centre should have a protocol for pain management for applicator removal to meet the needs of individual patients.
4. The protocol should include consideration of patient request or need for drugs to reduce anxiety and distress when coming into theatre.
5. The protocol should include consideration of patient request or need for drugs to reduce anxiety and distress during applicator removal.
6. The protocol should include consideration of patient choice or need for drugs to reduce their awareness of the theatre procedure.
7. The protocol should include consideration of patient choice or need for drugs to reduce their awareness of applicator removal.
8. Each centre should provide individualised advice on pain control before discharge from hospital.

Poll 2: General medical management

1. Each centre should have a protocol for prevention and treatment of nausea and vomiting, including additional options and adaptations when medication doesn't work.
2. Each centre should have a protocol for prevention of severe infection, including level of blood count where preventative antibiotics should be given and the level of infection risk with different applicator types.
3. Each centre should develop and implement a medical pre-brachytherapy assessment protocol, including when doctors should discuss individual cases to weigh up the risks and benefits of brachytherapy and any adaptations.
4. Senior brachytherapy clinicians should consider change of regime/technique or no brachytherapy if there are significant medical or psychological trauma risks.
   In cases of severe cardiac/respiratory risks or significant dementia, learning disabilities or significant history of sexual abuse a risk assessment may need to be carried out with relevant experts and oncologists.
5. Each centre should provide a late effects/long term side effects service, to help with bowel, bladder and sexual problems in the months and years after completion of treatment.
6. Each centre should have a protocol regarding patient positioning and where possible avoid keeping patients in a totally flat position.
   As part of this recommendation it will be important to consider what amount/angle of propping up is allowed and whether a standardised wedge could be used to obtain some consensus/consistency among healthcare professionals, rather than only using for high risk patients eg obesity or respiratory conditions .
7. Each centre should have a protocol for prevention of blood clots, including risk assessments, how often to re-assess risk and the use of preventative medication and mechanical devices (such as stockings or alternative devices).
8. Each centre should provide training for brachytherapy clinical staff on pain assessments and understanding individual pain experiences, including the impact of psychological trauma and mental health history, previous pain and analgesia history.
   This would help brachytherapy teams to respond appropriately when patients report severe or uncontrolled pain. This training may need to be developed with input from a clinical psychologist, pain specialist and anaesthetist.
9. Each centre should have a strategy for prevention of pressure sores.
   For example use of day case mattress, heel pads etc.

Poll 3: Information and support

1. Each centre should allocate appropriate time and resources to facilitate patient-centred pre-brachytherapy information and support.
   The information and support needs to be individualised as some patients will need or request more detailed information such as diagrams, access to talk to previous patients, to visit the ward, theatre or treatment areas and some will prefer not to know too much.
2. Each centre should provide training for the brachytherapy clinical team on potential trauma of cervical cancer diagnosis and triggers for trauma during treatment, especially for brachytherapy.
   For example the impact of loss of fertility and where in brachytherapy process this may trigger distress and trauma, previous pregnancy/delivery history, impact of staff gender, privacy and dignity and vulnerability.
3. Individual risk assessments to be carried out for potential trauma during brachytherapy, considering factors such as age, social history, previous pain/medication history, mental health, coping mechanisms, and adaptations/access to specialist support.

4. Each centre should provide written and verbal advice at the point of discharge from hospital on management of post treatment side effects and information on accessing help and support.
5. Each centre should provide support to patients after completion of brachytherapy, such as a telephone call a few days after discharge home, offering a debriefing session to talk through what happened and offering advice on management of aftereffects.
6. Each centre should provide information about patient support groups that the individual can access after completion of cancer treatment.
7. Each centre should provide assessment of the need for psychological support after brachytherapy.
   For example at follow up appointments clinicians could routinely ask about sexual health and offer psychosexual counselling when appropriate, not waiting for patients to ask for information or advice, and raise clinician's awareness of post-traumatic stress disorder and how to identify it and offer referral to clinical psychology services

Poll 4: Communication, logistics and staffing

1. Each centre should ensure that there is effective communication between referring centres and brachytherapy teams, especially where plans change including dates for treatment or centre for brachytherapy.
2. Each centre should offer transport for patients to attend brachytherapy and return home after brachytherapy, if there are no family/friends able to provide.
3. Each centre should carry out regular service evaluation to check that staffing levels are appropriate throughout the brachytherapy pathway.
   For example allocated time from information and support nurses or radiographers, access to interpreters for required duration.
4. Each centre should implement a service evaluation programme for obtaining patient feedback about their brachytherapy services, including patient reported pain and distress, especially after adaptations to service delivery are made or new services introduced.
5. Each centre should ensure that patients do not experience delays to treatment or unnecessary transfers.
   This may require service developments to speed up the time for treatment planning, such as purchasing extra planning software licences and streamlining imaging services and requirements.

Appendix 25: Recommendations for long duration workshop (study three)

Points of recommendation for NGT study (long duration brachy workshop)

Participants will be asked to rate the importance of each recommendation.
Single choice option for each point:

- **Not important/relevant**
- **Slightly important**
- **Important**
- **Very important**

Explanatory notes (shown here in italics) are included in the pre-meeting information email, so that participants can read through the recommendations with the explanatory notes in advance of the meeting. This should help to speed up the initial voting stage and allow participants some extra preparation time for the silent generation of ideas/amendments stage during the meeting. The explanatory notes will not be included in the Zoom polling questions as this would exceed the character count on the polling function.

The recommendations are aimed at the brachytherapy team, but also to the wider hospital teams that are involved in care of gynaecological cancer patients, for example, managers and healthcare professionals on wards and theatres where brachytherapy patients are cared for, the gynae-oncology multidisciplinary team including clinical nurse specialists and access to other healthcare professionals such as clinical psychologists. The use of the term 'centre' may mean radiotherapy or oncology centre or the broader hospital site, depending on the specific setting for brachytherapy services.

Poll 1: Pain management

1. Each centre should have a protocol for anaesthesia for applicator insertion, including options for anaesthesia for different types of applicators and adaptations to meet the needs of individual patients.
2. Each centre should have a protocol for pain management in theatre recovery, including options for pain and relaxant medication for different types of applicators and to meet the needs of individual patients.
3. Each centre should have a protocol for pain management on the ward for the duration with applicators in place, including options for continuous flow or patient-controlled pain medication and breakthrough pain to meet needs of individual patients.
4. Each centre should have a protocol for pain management for applicator removal to meet the needs of individual patients.
5. Each centre should provide individualised advice on short term pain management before discharge from hospital.

Poll 2. Management for anxiety and distress

1. The protocol should include consideration of medication to reduce anxiety while staying on the ward the night before brachytherapy.
2. The protocol should include consideration of patient request or need for drugs to reduce anxiety and distress when coming into theatre.
3. The protocol should include consideration of patient choice or need for drugs to reduce their awareness of the theatre procedure.
4. The protocol should include consideration of patient choice or need for drugs to help patients sleep when on the ward for long duration brachytherapy.

5. The protocol should state the frequency that pain, anxiety and distress will be reviewed by senior brachytherapy clinicians.
6. The protocol should include frequency of ward rounds with oncologist and nursing staff for regular review and management of pain, anxiety and distress.
7. The protocol should Include consideration of patient request or need for drugs to reduce anxiety and distress during applicator removal.
8. The protocol should Include consideration of patient choice or need for drugs to reduce their awareness of applicator removal.
9. Consider options for non-medical management of anxiety.

Poll 3: General medical management

1. Each centre should have a protocol for prevention and treatment of nausea and vomiting, including additional options and adaptations when medication doesn't work.
2. Each centre should have a protocol for prevention of severe infection, including the level of blood count where preventative antibiotics should be given and the level of infection risk with different applicator types.
3. Each centre should have a medical pre-brachytherapy assessment protocol, including when doctors should discuss individual cases to weigh up the risks and benefits of brachytherapy and any adaptations needed.
4. Senior brachytherapy clinicians should consider change of regime/technique or no brachytherapy if there are significant medical or psychological trauma risks.
   In cases of severe cardiac/respiratory risks or significant dementia, learning disabilities or significant history of sexual abuse a risk assessment may need to be carried out with relevant experts and oncologists.
5. Each centre should provide a late effects/long term side effects service, to help with bowel, bladder and sexual problems in the months and years after completion of treatment.
6. Each centre should have a protocol regarding patient positioning and where possible to avoid keeping patients in a totally flat position.
   As part of this recommendation it will be important to consider what amount/angle of propping up is allowed and whether a standardised wedge could be used to obtain some consensus/consistency among healthcare professionals, rather than only using for high risk patients eg obesity or respiratory conditions .
7. Each centre should have a protocol for prevention of blood clots, including risk assessments, how often to re-assess risk and the use of preventative medication and mechanical devices (such as stockings or alternative devices).
8. Each centre should provide training for brachytherapy clinical staff on pain assessments and understanding individual pain experiences, including the impact of psychological trauma and mental health history, previous pain and analgesia history.
   This would help brachytherapy teams to respond appropriately when patients report severe or uncontrolled pain. This training may need to be developed with input from a clinical psychologist, pain specialist and anaesthetist.
9. Each centre should have a strategy for prevention of pressure sores.
   For example special mattress, pads, gentle small turning/skin massage at regular intervals (if allowed).

Poll 4: Information and support

1. Each centre should allocate appropriate time and resources to facilitate patient-centred pre-brachytherapy information and support.
   The information and support needs to be individualised as some patients will need or request more detailed information such as diagrams, access to talk to previous patients, to visit the ward, theatre or treatment areas, pain management and potential side effects of medication and some will prefer not to know too much.
2. Each centre should provide training for the brachytherapy clinical team on potential psychological trauma of cervical cancer diagnosis and triggers for trauma during treatment, especially for brachytherapy.
   For example the impact of loss of fertility and where in brachytherapy process this may trigger distress and trauma, previous pregnancy/delivery history, impact of staff gender, privacy and dignity and vulnerability.
3. Individual risk assessments to be carried out for potential trauma during brachytherapy, considering factors such as age, social history, previous pain/medication history, mental health, coping mechanisms, and adaptations/access to specialist support.
4. Each centre should provide written and verbal advice at the point of discharge from hospital on management of post treatment side effects and information on accessing help and support.
5. Each centre should provide support to patients after completion of brachytherapy, such as a telephone call a few days after discharge home, offering a debriefing session to talk through what happened and offering advice on management of aftereffects.
6. Each centre should provide information about patient support groups that the individual can access after completion of cancer treatment.
7. Each centre should provide assessment of the need for psychological support after brachytherapy.
   For example at follow up appointments clinicians could routinely ask about sexual health and offer psychosexual counselling when appropriate, not waiting for patients to ask for information or advice, and raise clinician's awareness of post-traumatic stress disorder and how to identify it and offer referral to clinical psychology services

Poll 5: Patient care/ward nursing care

1. Ward nurses should offer advice and support in relation to eating and drinking while applicators are in place.
   For example checking that food is within reach, help to eat it if required, appropriate equipment such as beakers, advice on food selection, frequency and volume to minimise build-up of gas, general discomfort and nausea or vomiting.
2. Ward nurses should receive training about nutrition requirements and the need to monitor patients during brachytherapy to ensure they are supported to eat.
3. Wards should provide access to someone for the patient to communicate with when lying flat with applicators in place, especially if visiting is restricted.
4. Ward nurses should check in on patients at regular frequent intervals and provide support through the night if patients are unable to sleep due to pain/discomfort/distress.
5. Ward nurses should offer help and support with personal care.
   For example washing, cleaning teeth when unable to sit up or reach facilities.
6. Ward nurses should provide close supervision of patients after applicator removal to avoid risk of falls and monitor the effect of medication wearing off.
7. Ward nurses should help patients to prepare for discharge home, including washing, dressing and mobilising.

8. Ward staff should receive training on awareness and identification of drug reactions, especially for long duration brachytherapy or high levels of opiate use.
9. Ward staff should receive additional training in the care and compassion needed to support patients during brachytherapy.
10. Centres should provide intensified care standards for brachytherapy patients on ward, ie fewer patients that one nurse should be allocated to look after, therefore a greater allocation of nursing time to brachytherapy patients.
    For example one specialised brachy nurse per 2-3 patients could be advised, recognising the higher levels of care and support needed due to lack of mobility and vulnerability of patients on wards with brachytherapy applicators in place for a long duration. Standard ward ratios would typically be in the region of one registered nurse to eight patients, and less overnight.

Poll 6: Communication, logistics and staffing

1. Each centre should ensure that there is effective communication between referring centres and brachytherapy teams, especially where plans change including dates for treatment or centre for brachytherapy.
2. Each centre should offer transport for patients to attend brachytherapy and return home after brachytherapy, if there are no family/friends able to provide.
3. Each centre should carry out regular service evaluation to check that staffing levels are appropriate throughout the brachytherapy pathway.
   For example allocated time from information and support nurses or radiographers, access to interpreters for required duration.
4. Each centre should implement a service evaluation programme for obtaining patient feedback about their brachytherapy services, including patient reported pain and distress, especially after adaptations to service delivery are made or new services introduced.
5. Each centre should ensure that patients do not experience delays to treatment or unnecessary transfers.
   This may require service developments to speed up the time for treatment planning, such as purchasing extra planning software licences and streamlining imaging services and requirements.

Poll 7: Facilities on wards

1. Centres should offer patients a choice of single room or ward room, considering individual preferences for privacy or company/distractions.
2. Centres should provide clear information to patients about access to facilities such as TV, internet and music to help pass the time.
3. Centres should provide access to facilities such as an angled tray for reading and/or iPad to optimise patient comfort and enable access to facilities when lying flat for a long period of time.
4. Centres should offer complementary therapies during admission for brachytherapy.
   For example reflexology, massage and reiki.
5. Centres should provide information and support to help patient's use of relaxation techniques during admission for brachytherapy.
   For example mindfulness, yoga or gentle leg exercises (need to find out what is allowed with applicators in place).
6. Centres should provide pre-brachytherapy information to patients including detail of ward facilities, what to bring in, what to expect and to offer to show patients around in advance of brachytherapy.

7. Centres should offer patients a choice of brachytherapy regime, where possible and equally effective.
   For example all in one admission over two to three days or two insertions a week apart. There may be technical and logistical reasons why a centre would offer or prefer one regime over another, and there may be patient specific reasons such as complexity/size of tumour or individual health risk factors. But where both regimes are possible and assessed to be equally effective, could patient choice be considered?

Appendix 26: First and second poll results (study three)

		Workshop 1 (5 participants)				Workshop 2 (4 participants)				Workshop 3 (4 participants)				All WS	All WS		All WS
		Score poll 1 (points)	Score poll 1 (%)	Score poll 2 (points)	Score poll 2 (%)	Score poll 1 (points)	Score poll 1 (%)	Score poll 1 (%)	Score poll 2 (%)	Score poll 1 (points)	Score poll 1 (%)	Score poll 2 (points)	Score poll 2 (%)	Total score 2	Sorted by score		Sorted by % score
Poll 1	Rec 1.1	15	100	15	100	12	100	12	100	12	100	12	100	300	Rec 1.1	300	100
	Rec 1.2	15	100	15	100	10	83	11	92	9	75	10	82	274	Rec 1.3	300	100
	Rec 1.3	15	100	15	100	12	100	12	100	12	100	12	100	300	Rec 1.4	300	100
	Rec 1.4	15	100	15	100	12	100	12	100	12	100	12	100	300	Rec 1.5	300	100
	Rec 1.5	13	87	15	100	12	100	12	100	12	100	12	100	300	Rec 2.2	300	100
Poll 2	Rec 2.1	12	80	15	100	10	83	11	92	11	92	12	100	292	Rec 2.7	300	100
	Rec 2.2	14	93	15	100	11	92	12	100	9	75	12	100	300	Rec 3.1	300	100
	Rec 2.3	14	93	15	100	9	75	11	92	12	100	12	100	292	Rec 3.2	300	100
	Rec 2.4	13	87	15	100	9	75	8	67	10	83	12	100	267	Rec 3.3	300	100
	Rec 2.5	12	80	14	93	11	92	12	100	6	50	11	92	285	Rec 3.4	300	100
	Rec 2.6	11	73	14	93	10	83	11	92	7	58	12	100	285	Rec 3.5	300	100
	Rec 2.7	15	100	15	100	12	100	12	100	12	100	12	100	300	Rec 3.7	300	100
	Rec 2.8	15	100	15	100	9	75	11	92	11	92	12	100	292	Rec 3.8	300	100
Poll 3	Rec 3.1	15	100	15	100	11	92	12	100	11	92	12	100	300	Rec 4.1	300	100
	Rec 3.2	14	93	15	100	12	100	12	100	11	92	12	100	300	Rec 4.2	300	100
	Rec 3.3	13	87	15	100	11	92	12	100	12	100	12	100	300	Rec 4.3	300	100

		Workshop 1 (5 participants)				Workshop 2 (4 participants)				Workshop 3 (4 participants)				All WS	All WS		All WS
		Score poll 1 (points)	Score poll 1 (%)	Score poll 2 (points)	Score poll 2 (%)	Score poll 1 (points)	Score poll 1 (%)	Score poll 1 (%)	Score poll 2 (%)	Score poll 1 (points)	Score poll 1 (%)	Score poll 2 (points)	Score poll 2 (%)	Total score 2	Sorted by score		Sorted by % score
	Rec 3.4	14	93	15	100	12	100	12	100	12	100	12	100	300	Rec 4.4	300	100
	Rec 3.5	15	100	15	100	12	100	12	100	12	100	12	100	300	Rec 4.5	300	100
	Rec 3.6	11	73	15	100	11	92	10	83	11	92	11	92	275	Rec 4.7	300	100
	Rec 3.7	14	93	15	100	12	100	12	100	12	100	12	100	300	Rec 5.5	300	100
	Rec 3.8	14	93	15	100	11	92	12	100	12	100	12	100	300	Rec 5.6	300	100
	Rec 3.9	14	93	15	100	11	92	11	92	11	92	12	100	292	Rec 5.8	300	100
Poll 4	Rec 4.1	15	100	15	100	11	92	12	100	12	100	12	100	300	Rec 5.9	300	100
	Rec 4.2	15	100	15	100	11	92	12	100	12	100	12	100	300	Rec 6.3	300	100
	Rec 4.3	13	87	15	100	12	100	12	100	12	100	12	100	300	Rec 6.7*	300	100
	Rec 4.4	13	87	15	100	12	100	12	100	12	100	12	100	300	Rec 4.8*	293	98
	Rec 4.5	14	93	15	100	10	83	12	100	12	100	12	100	300	Rec 6.1	293	95
	Rec 4.6	14	93	14	100	10	83	10	83	12	100	12	100	283	Rec 7.6	293	98
	Rec 4.7	15	100	15	100	11	92	12	100	12	100	12	100	300	Rec 2.1	292	97
	Rec 4.8*	N/A	N/A	14	93	12	100	12	100	12	100	12	100	293	Rec 2.3	292	97
Poll 5	Rec 5.1	14	93	15	100	9	75	12	100	11	92	11	92	292	Rec 2.8	292	97
	Rec 5.2	12	80	15	100	10	83	11	92	10	83	9	75	267	Rec 3.9	292	97
	Rec 5.3	13	87	15	100	10	83	12	100	11	92	10	83	283	Rec 5.1	292	97

		Workshop 1 (5 participants)				Workshop 2 (4 participants)				Workshop 3 (4 participants)				All WS	All WS		All WS
		Score poll 1 (points)	Score poll 1 (%)	Score poll 2 (points)	Score poll 2 (%)	Score poll 1 (points)	Score poll 1 (%)	Score poll 1 (%)	Score poll 2 (%)	Score poll 1 (points)	Score poll 1 (%)	Score poll 2 (points)	Score poll 2 (%)	Total score 2	Sorted by score		Sorted by % score
	Rec 5.4	14	93	15	100	12	100	11	92	12	100	12	100	292	Rec 5.4	292	97
	Rec 5.5	14	93	15	100	12	100	12	100	12	100	12	100	300	Rec 2.5	285	95
	Rec 5.6	15	100	15	100	12	100	12	100	12	100	12	100	300	Rec 2.6	285	95
	Rec 5.7	11	73	14	93	11	92	11	92	12	100	12	100	285	Rec 5.7	285	95
	Rec 5.8	15	100	15	100	12	100	12	100	12	100	12	100	300	Rec 4.6	283	94
	Rec 5.9	15	100	15	100	12	100	12	100	12	100	12	100	300	Rec 5.3	283	94
	Rec 5.10	14	93	14	93	11	92	11	92	9	75	9	75	260	Rec 6.4	283	94
Poll 6	Rec 6.1	13	87	14	93	11	92	12	100	12	100	12	100	293	Rec 6.2	277	92
	Rec 6.2	15	100	14	93	10	83	11	92	11	92	11	92	277	Rec 6.5	277	92
	Rec 6.3	15	100	15	100	11	92	12	100	11	92	12	100	300	Rec 6.6*	276	92
	Rec 6.4	15	100	15	100	10	83	10	83	12	100	12	100	283	Rec 3.6	275	92
	Rec 6.5	14	93	14	93	12	100	11	92	11	92	11	92	277	Rec 1.2	274	91
	Rec 6.6*	N/A	N/A	14	93	11	92	10	83	11	92	12	100	276	Rec 7.7	270	90
	Rec 6.7*	N/A	N/A	15	100	11	92	12	100	12	100	12	100	300	Rec 2.4	267	89
Poll 7	Rec 7.1	10	67	12	80	7	58	7	58	11	75	10	83	238	Rec 5.2	267	89
	Rec 7.2	11	73	11	73	7	58	9	75	9	75	11	92	240	Rec 5.10	260	87
	Rec 7.3	13	87	12	80	6	50	9	75	10	83	11	92	247	Rec 7.8*	251	84

	Workshop 1 (5 participants)				Workshop 2 (4 participants)				Workshop 3 (4 participants)				All WS	All WS		All WS
	Score poll 1 (points)	Score poll 1 (%)	Score poll 2 (points)	Score poll 2 (%)	Score poll 1 (points)	Score poll 1 (%)	Score poll 1 (%)	Score poll 2 (%)	Score poll 1 (points)	Score poll 1 (%)	Score poll 2 (points)	Score poll 2 (%)	Total score 2	Sorted by score		Sorted by % score
Rec 7.4	10	67	11	73	7	58	10	82	9	75	8	67	222	Rec 7.3	247	82
Rec 7.5	13	87	12	80	7	58	8	67	11	92	11	92	239	Rec 7.2	240	80
Rec 7.6	14	93	15	100	11	92	11	93	12	100	12	100	293	Rec 7.5	239	80
Rec 7.7	13	87	13	87	11	92	12	100	9	75	10	83	270	Rec 7.1	238	79
Rec 7.8*	N/A	N/A	14	93	9	75	9	75	9	75	10	83	251	Rec 7.4	222	74

Abbreviations: Rec= Recommendation; WS= workshop; N/A= not applicable

Appendix 27: Poll results, service users versus service providers (study three)

	SU1	SU2	SU3	SU4	SU5	Total SU	Avge SU	SP1	SP2	SP3	SP4	SP5	SP6	SP7	SP8	Total SP	Avge SP
Rec 1.1	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 1.2	3	3	3	3	3	100	3	3	3	3	3	3	3	3	1	92	2.9
Rec 1.3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 1.4	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 1.5	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 2.1	3	3	3	2	3	93	2.8	3	3	3	3	3	3	3	3	100	3
Rec 2.2	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 2.3	3	3	3	3	3	100	3	3	3	3	3	2	3	3	3	96	2.9
Rec 2.4	3	3	3	2	3	93	2.8	3	3	2	2	1	3	3	2	83	2.5
Rec 2.5	3	3	3	3	3	100	3	3	2	3	3	3	3	3	3	96	2.9
Rec 2.6	3	3	3	3	3	100	3	2	3	3	2	2	3	3	3	92	2.8
Rec 2.7	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 2.8	3	3	3	3	3	100	3	3	3	3	2	3	3	3	3	96	2.9
Rec 3.1	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 3.2	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 3.3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 3.4	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 3.5	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 3.6	3	3	3	3	3	100	3	3	3	3	2	2	3	3	2	92	2.8
Rec 3.7	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 3.8	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 3.9	3	3	3	3	3	100	3	3	3	3	2	3	3	3	3	96	2.9
Rec 4.1	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 4.2	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 4.3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 4.4	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 4.5	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 4.6	3	3	3	1	3	87	2.6	2	3	3	3	3	3	3	3	100	3

	SU1	SU2	SU3	SU4	SU5	Total SU	Avge SU	SP1	SP2	SP3	SP4	SP5	SP6	SP7	SP8	Total SP	Avge SP
Rec 4.7	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 4.8*	3	3	3	3	3	100	3	2	3	3	3	3	3	3	3	96	2.9
Rec 5.1	3	3	3	3	3	100	3	3	3	3	3	3	3	3	2	96	2.9
Rec 5.2	3	3	3	3	3	100	3	3	3	3	2	2	2	3	1	83	2.5
Rec 5.3	3	3	3	3	2	93	2.8	3	3	3	3	2	2	3	3	96	2.9
Rec 5.4	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 5.5	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 5.6	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 5.7	3	3	3	2	3	93	2.8	3	3	3	3	3	3	3	3	96	2.9
Rec 5.8	3	3	3	3	3	100	3	2	3	3	3	3	3	3	3	100	3
Rec 5.9	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 5.10	3	3	3	2	2	87	2.6	3	3	2	3	1	1	3	3	88	2.6
Rec 6.1	2	3	3	3	3	93	2.8	3	3	3	3	3	3	3	3	100	3
Rec 6.2	3	3	3	2	2	93	2.8	3	3	2	3	3	3	3	2	92	2.8
Rec 6.3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 6.4	3	3	3	2	3	93	2.8	3	3	3	2	3	3	3	3	96	2.9
Rec 6.5	3	3	3	3	3	100	3	3	3	3	3	2	3	3	2	92	2.8
Rec 6.6*	3	3	3	3	3	100	3	2	3	3	2	2	3	3	3	88	2.6
Rec 6.7*	3	3	3	3	3	100	3	3	3	3	3	3	3	3	3	100	3
Rec 7.1	2	2	2	1	2	67	2	3	2	3	2	1	2	3	3	79	2.4
Rec 7.2	2	3	3	2	2	80	2.4	2	2	2	2	2	3	3	2	71	2.1
Rec 7.3	2	2	2	1	3	73	2.2	3	2	3	2	3	3	3	2	88	2.6
Rec 7.4	2	3	2	3	1	73	2.2	2	2	2	3	2	1	3	3	75	2.3
Rec 7.5	2	3	2	2	2	73	2.2	2	3	2	2	2	3	3	3	83	2.5
Rec 7.6	3	3	3	2	3	93	2.8	3	3	3	3	3	3	3	3	100	3
Rec 7.7	3	3	3	3	3	100	3	3	3	2	3	3	2	3	2	88	2.6
Rec 7.8*	2	3	3	2	3	93	2.8	2	3	3	1	3	1	3	3	79	2.4

Abbreviations: Rec= Recommendations; Avge= average; SU= service user; SP= service provider

*Denotes an additional recommendation

Appendix 28: Poll results, short versus long duration experience (study three)

	SD (SP)1	SD (SP)2	SD (SU)3	SD (SP)4	SD (SU)5	SD (SP)6	Total SD	Avge SD	LD (SU)1	LD (SP)2	LD (SU)3	LD (SP)4	LD (SP)5	LD (SP)6	LD (SU)7	Total LD	Avge LD
Rec 1.1	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 1.2	3	3	3	3	3	1	89	2.7	3	3	3	3	3	3	3	100	3
Rec 1.3	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 1.4	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 1.5	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 2.1	3	3	3	3	2	3	94	2.8	3	3	3	3	3	3	3	100	3
Rec 2.2	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 2.3	3	3	3	3	3	3	100	3	3	3	3	2	3	3	3	95	2.9
Rec 2.4	3	3	3	2	2	2	83	2.5	3	3	3	1	3	3	3	90	2.7
Rec 2.5	3	3	3	3	3	3	100	3	3	2	3	3	3	3	3	95	2.9
Rec 2.6	2	3	3	3	3	3	94	2.8	3	3	3	2	3	3	3	95	2.9
Rec 2.7	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 2.8	3	3	3	2	3	3	94	2.8	3	3	3	3	3	3	3	100	3
Rec 3.1	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 3.2	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 3.3	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 3.4	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 3.5	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 3.6	3	3	3	3	3	2	94	2.8	3	3	3	2	3	3	3	95	2.9
Rec 3.7	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 3.8	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 3.9	3	3	3	2	3	3	94	2.8	3	3	3	3	3	3	3	100	3
Rec 4.1	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 4.2	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 4.3	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 4.4	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 4.5	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 4.6	2	3	3	3	1	3	83	2.5	3	3	3	3	3	3	3	100	3

	SD (SP)1	SD (SP)2	SD (SU)3	SD (SP)4	SD (SU)5	SD (SP)6	Total SD	Avge SD	LD (SU)1	LD (SP)2	LD (SU)3	LD (SP)4	LD (SP)5	LD (SP)6	LD (SU)7	Total LD	Avge LD
Rec 4.7	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 4.8*	2	3	3	3	3	3	94	2.8	3	3	3	3	3	3	3	100	3
Rec 5.1	3	3	3	3	3	2	94	2.8	3	3	3	3	3	3	3	100	3
Rec 5.2	3	3	3	2	3	1	83	2.5	3	3	3	3	2	3	3	95	2.9
Rec 5.3	3	3	3	3	3	3	100	3	3	3	3	3	2	3	2	90	2.7
Rec 5.4	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 5.5	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 5.6	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 5.7	2	3	3	3	2	3	89	2.7	3	3	3	3	3	3	3	95	2.9
Rec 5.8	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 5.9	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 5.10	3	3	3	3	2	3	94	2.8	3	2	3	3	1	3	2	81	2.4
Rec 6.1	3	3	3	3	3	3	100	3	2	3	3	3	3	3	3	95	2.9
Rec 6.2	3	3	3	3	2	2	89	2.7	3	2	3	3	3	3	3	95	2.9
Rec 6.3	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	3
Rec 6.4	3	3	3	2	2	3	89	2.7	3	3	3	3	3	3	3	100	3
Rec 6.5	3	3	3	3	3	2	94	2.8	3	3	3	2	3	3	3	95	2.9
Rec 6.6*	2	3	3	2	3	3	89	2.7	3	3	3	2	3	3	3	95	2.9
Rec 6.7*	3	3	3	3	3	3	100	3	3	3	3	3	3	3	3	100	2
Rec 7.1	3	2	2	2	1	3	72	2.2	2	3	3	1	2	3	2	76	2.3
Rec 7.2	2	2	3	2	2	2	72	2.2	2	2	3	2	3	2	2	76	2.3
Rec 7.3	3	2	2	2	1	2	67	2	2	3	3	3	3	3	3	95	2.9
Rec 7.4	2	2	3	3	3	3	89	2.7	2	2	2	2	1	3	1	62	1.9
Rec 7.5	2	3	3	2	2	3	83	2.5	2	2	2	2	3	3	2	76	2.3
Rec 7.6	3	3	3	3	2	3	94	2.8	3	3	3	3	3	3	3	100	3
Rec 7.7	3	3	3	3	3	2	94	2.8	3	2	3	3	2	3	3	90	2.7
Rec 7.8*	2	3	3	1	2	3	78	2.3	3	3	3	3	1	3	3	90	2.7

Abbreviations: Rec= Recommendations; Avge= average; SD= short duration experience; LD= long duration experience; SU= service user; SP= service provider
*Denotes an additional recommendation

Appendix 29: Reflection on overseas observership

As part of the doctoral fellowship, I was encouraged to carry out an international visit, to improve my knowledge of my area of study. I chose to visit Sunnybrook Cancer Centre in Toronto, Canada. I found out from Dr Eric Leung that Sunnybrook had started delivering brachytherapy with their patients under anaesthetic for the whole duration. Although observation of this would not necessarily enhance my understanding of patient experiences, as patients would be asleep, I thought it would be useful to see the logistics behind this approach. In my clinical work, one of the most common questions from patients who are worried about brachytherapy is "why can't I be kept asleep for the whole process?" We explain to them that it would not be safe to put them to sleep and then move them around the hospital for imaging and treatment, and wait a few hours in between for planning, all while they are under anaesthetic. Potentially this would mean anaesthesia for four to six hours with multiple transfers. It would also mean the anaesthetic team looking after only one patient for four to six hours, so a morning and afternoon list for one patient. This would usually be cost and resource prohibitive.

How do they make this work in Sunnybrook?

Dr Eric Leung told me that they had previously received many patient complaints, especially when introducing interstitial needle techniques, related to pain and trauma from brachytherapy. At that time, they were developing a new treatment suite, including the introduction of a MRI scanner. They decided to build the MRI next to the brachytherapy theatre with a second entrance direct into the theatre. The theatre was built with extra shielding to provide sufficient radiation protection so the brachytherapy afterloader could be housed and treatment delivered within the operating theatre. On my three-day observership in Toronto I watched the delivery of complex gynaecological brachytherapy. The patient numbers were limited to one per morning or afternoon list, maximum of two patients per day. The patient had applicators place in theatre under general anaesthesia (GA) and were there transferred to a MRI compatible coach and into MRI in the next room. The anaesthetic team had a second set of anaesthetic equipment in the MRI room (MRI compatible) and were able to quickly switch from one anaesthetic unit to the other. I saw planning carried out in a parallel method, something I had not seen in any UK departments. At one point there were

three healthcare professionals working on the planning simultaneously, on three separate computer workstations. In parallel, an oncologist contoured the target volume, another oncologist or clinical fellow contoured the organs at risk and a radiation therapist marked the applicators. Total planning time was approximately one hour and included a peer review check of the plan from another oncologist and a check from a senior physicist. The overall time from induction of anaesthesia to end of procedure was between three and four hours. This would be repeated three times over a two-week period. I observed a very smooth procedure delivered by an experienced team. The brachytherapy staff said that patients really appreciated being under GA throughout the brachytherapy and some chose to travel to this centre for this.

Reflecting on what I had seen, I was interested to see if there is any data on toxicity or medical complications associated with long GA times for brachytherapy. I found two publications from the Sunnybrook team which were in abstract form only (Leung *et al.*, 2020; Smith *et al.*, 2020). They reported no anaesthetic complications using this technique, but stated that a prospective evaluation of patient toxicities, outcomes and experience was required. A recent publication briefly referred to this anaesthetic technique in the discussion section but provided no detail about complications (Locke *et al.*, 2022).

It became apparent during my visit to Sunnybrook, that the resource heavy technique was not possible when numbers of patient referrals were too high. There were some patients who chose to stay in the ward with applicators in place overnight to get three treatments completed in one admission. This was usually where patients lived too far from the centre to manage multiple journeys for brachytherapy. Therefore, it was good to see how the Sunnybrook team had adapted their resources to provide brachytherapy under total anaesthesia, but also the drawbacks where numbers of patients fluctuate and then having to manage patients on different pathways. This could be problematic if patients had been referred to the centre for brachy under total GA and then were unable to receive it due to their high caseload. Managing patient expectations could then be potentially problematic. Overall it was a wonderful opportunity to see brachytherapy delivered in a unique way, and may be something for other centres to strive for in the future.

Appendix 30: List of publications arising from the PhD research programme

Humphrey, P., Bennett, C. and Cramp, F. (2018) The experiences of women receiving brachytherapy for cervical cancer: A systematic literature review. *Radiography*. [online]. 24 (4), pp.396–403.

Humphrey, P., Dures, E., Hoskin, P. and Cramp, F. (2020) A UK survey of brachytherapy practice for locally advanced cervical cancer. *Radiography*. [online]. 26 (2020), p.S18.

Humphrey, P., Dures, E., Hoskin, P. and Cramp, F. (2021) Brachytherapy for locally advanced cervical cancer : A survey of UK provision of care and support. *Radiotherapy and Oncology*. [online]. 159, pp.60–66.

Humphrey, P., Dures, E., Hoskin, P. and Cramp, F. (2021) What do women say about their experience of brachytherapy for cervical cancer? A qualitative study. *WCB 2021 Abstract Book*. S140 (PO-0184), pp.147–148.

Humphrey, P., Dures, E., Hoskin, P., Reardon, L., Johnston, J. and Cramp, F. (2022) What women say about their experiences of brachytherapy for locally advanced cervical cancer: A qualitative interview study. *BGCS annual conference book of abstracts*. [online]. p.13. Available from: https://www.bgcs.org.uk/wp-content/uploads/2022/07/BGCS-2022-Book-of-Abstracts-.pdf.

Appendix 31: Abstract 1 Annual Radiotherapy Conference (ARC) January 2020

(Version accepted for publication)

Title: A UK survey of brachytherapy practice for locally advanced cervical cancer

Author(s): Pauline Humphrey; Emma Dures; Peter Hoskin; Fiona Cramp

Keywords: Brachytherapy; survey; cervical cancer

Introduction

Gynaecological brachytherapy can cause anxiety, distress and discomfort[1]. It is not known how variation in brachytherapy delivery impacts women's experiences. To inform future research an online survey was carried out to identify current UK service provision for women having brachytherapy for locally advanced cervical cancer.

Method and Materials

The online survey was sent to 44 UK brachytherapy centres using the Qualtrics® survey platform. It included questions about brachytherapy scheduling, inpatient/day case treatment, anaesthetic/analgesia protocols and non-pharmacological support. A mixture of closed questions with pre-specified options and open questions asking for opinions and comments about service provision, such as what worked well and what could be improved, were employed. Descriptive statistics were generated to identify variance in current UK practice. Free text responses were analysed using inductive content analysis.

Results

Responses were received from 39/43 eligible centres (91% response rate). Brachytherapy was predominantly given on an inpatient basis at 65% and day case at 35% of centres. Eleven different scheduling regimes were reported. The typical duration of brachytherapy at each centre (number of hours with applicators in place per insertion) *varied from 3 to 53 hours.*

Free text answers were given by 33 respondents to the question "What works well in your department?" The three main categories identified were: 'continuity of experienced staff'; 'good information and support' and 'trust and rapport'. The question "What could be improved?" was answered by 32 respondents. The three main categories identified were: 'follow up provision'; 'pain relief' and 'care on the wards'.

Conclusion and Discussion

Scheduling regimes and duration of applicators in place was found to be widely variable. Respondents were generally positive about the level of care and support currently offered and gave many examples of good practice and suggestions where improvements could be made to the patient pathway.

Reference

1. Humphrey P, Bennett C and Cramp F. The experiences of women receiving brachytherapy for cervical cancer: A systematic literature review. *Radiography*. 2018; 24(4):396-403 Available from doi: 10.1016/j.radi.2018.06.002.

Appendix 32: Abstract 2 World Congress of Brachytherapy (WCB) April 2020

(Version accepted for publication)

Not published. Abstract accepted but Conference cancelled at the start of the COVID-19 pandemic, no abstract book produced.

Title: Brachytherapy for locally advanced cervical cancer: UK service providers' views on improving care

Author(s): Pauline Humphrey; Emma Dures; Peter Hoskin; Fiona Cramp
Topic category: Gynaecology
Keyword: Cervix

Purpose/Objective
To identify service providers' opinions of current provision of care and support and ideas for improving women's experiences of brachytherapy for locally advanced cervical cancer.
Materials and Methods
An online survey was sent to 44 UK brachytherapy centres using the Qualtrics® survey platform. It included a mix of closed and open questions about brachytherapy scheduling, inpatient/day case treatment, anaesthetic/analgesia protocols and non-pharmacological support. Open questions asked respondents for opinions and comments about current service provision and what improvements were needed. Descriptive statistics were generated to identify variance in current UK practice. Free text responses were analysed using inductive content analysis.
Results
Responses were received from 39/43 eligible centres (91% response rate). Brachytherapy was predominantly given on an inpatient basis at 65% and day case at 35% of centres. Eleven different scheduling regimes were reported. The typical duration of brachytherapy at each centre (number of hours with applicators in place per insertion) *varied from 3 to 53 hours.*
Free text answers were given by 33 respondents to the question "What works well in your department?" Main themes identified were: 'continuity of care by experienced staff'; 'good provision of information'; 'good pharmacological and non-pharmacological support' and 'building a trusting relationship'. The question "What could be improved?" was answered by 32 respondents. The main themes identified were: 'follow up and support after brachytherapy'; 'pharmacological and non-pharmacological support during brachytherapy'; 'ward care/facilities'; 'staff training'; 'staff allocation/resources' and 'service improvements'. Suggestions for improvements included: provision of a telephone follow-up service; starting a late-effects clinic; better pain relief and use of complementary therapies; psychosexual counselling training for staff; better training about the procedure for ward staff and improving the patient pathway by shortening duration of the procedure or better access to MRI. Comments were given by 33 respondents about adaptations made for patients with special needs such as learning disabilities, dementia or victims of sexual abuse or female genital mutilation. The main finding was that extra time and support was given to assess individuals' needs and provide individualised care which included psychological support; involvement of carers and family or adapting the treatment technique.
Conclusions
Scheduling regimes and duration of applicators in place was found to be widely variable. While respondents were generally positive about their services, there were many suggestions for improvements including better follow up services, increased pharmacological and non-pharmacological support, greater allocation of resources and improving the patient pathway. These suggestions would be worthy of future consideration to improve women's experiences of brachytherapy.

Appendix 33: Abstract 3 World Congress of Brachytherapy (WCB) May 2021

(Version accepted for publication)

Title: What do women say about their experiences of brachytherapy for cervical cancer? A qualitative study.

Author(s): Pauline Humphrey; Emma Dures; Peter Hoskin; Fiona Cramp
Topic category: Gynaecology
Keyword: Cervix

Purpose/Objective

To explore women's experiences of brachytherapy in UK settings and to find out their ideas for improvements to reduce pain, anxiety and distress caused by brachytherapy.

Materials and Methods

Data were collected in semi-structured interviews with women who had received brachytherapy for locally advanced cervical cancer. Four UK recruitment sites were selected to include a cross section of brachytherapy treatment schedules with different numbers of applicator insertions and procedure duration. Two cohorts of women were recruited: cohort one had recently had brachytherapy and cohort two were a year post brachytherapy. Initial interviews were face to face but changed to remote interviews (video conference or phone) due to the COVID-19 pandemic. Consecutive brachytherapy patients were invited to interview to minimise risk of bias. Participants were invited to retell their brachytherapy story and explore views on their care and ideas for improvement. Interviews were audio-recorded and transcribed. Data were analysed following Braun and Clarke's method for reflexive thematic analysis (2006).

Results

Nineteen interviews were conducted by PH; six face to face, two by telephone and eleven by video. There were 12 participants that had brachytherapy 4 weeks to 6 months prior to interview, and seven were interviewed between 12 and 18 months after brachytherapy. Age ranged from 28 to 77 years. Interview duration ranged from 22 to 78 minutes (median 38 minutes). Women's reports of brachytherapy were variable, with stories of difficult experiences and suggestions for improvements. However, some women described positive experiences, reporting what had gone well. Three themes were developed, each with subthemes:

- *How I got through it*: Coping strategies (including passing time with music, reading, TV, phone, iPad and relaxation techniques; and personal attitudes and resilience (such as not overthinking it, taking one step at a time, and getting through the final hurdle).
- *The physical impact of brachytherapy*: positioning/lying flat (causing difficulty eating or drinking, build-up of gas and back ache); medical complications (such as pulmonary emboli, pressure sores and allergic reactions); and side-effects during and after treatment (including severe pain, nausea/vomiting and late effects on bowel and bladder).
- *The psychological impact of brachytherapy*: trauma associated with loss of fertility and associations with childbirth; privacy and dignity (including embarrassment, wanting a single room and feeling vulnerable); and not being listened to/believed (when experiencing severe pain).

Conclusions

Participants reported widely varying experiences of brachytherapy. The existing themes will be developed through further interviews. Women's ideas for improvements will be explored in further stages of this research to develop strategies for improving services.

This study was funded by the National Institute for Health Research (NIHR) [ICA-CDRF-2017-03-079].

Appendix 34: Abstract 4 MASCC Annual Meeting June 2021
(Multinational Association of Supportive Care in Cancer)

(Version accepted for publication)

Title: WHAT WOMEN SAY ABOUT THEIR EXPERIENCES OF BRACHYTHERAPY FOR LOCALLY ADVANCED CERVICAL CANCER: A QUALITATIVE INTERVIEW STUDY

Author(s): Pauline Humphrey; Emma Dures; Peter Hoskin; Jenny Johnston; Louise Reardon; Fiona Cramp
Topic: Models of supportive care
Keywords: Cervix; cancer; brachytherapy; qualitative; interview; patient experience

Introduction
Brachytherapy for gynaecological cancer can cause pain, anxiety and distress. The aim of this study was to explore women's experiences of brachytherapy and to seek their views on improvements needed.

Methods
Semi-structured interviews were undertaken with women who had received brachytherapy for locally advanced cervical cancer at one of four UK sites. Two cohorts were recruited: cohort one had recently had brachytherapy and cohort two were a year post brachytherapy. Consecutive patients were invited to interview to minimise risk of bias. Interviews were audio-recorded and transcribed. Data were analysed following Braun and Clarke's method for reflexive thematic analysis (2006).

Results
Thirty one interviews were conducted (17 cohort one and 14 cohort two). Age ranged from 28 to 87 years. Interview duration ranged from 22 to 78 minutes. Women's reports included difficult and traumatic experiences with periods of severe pain and poor nursing care on the wards. However, some women described positive experiences, reporting what had gone well. Three themes were developed, - see Table 1.

Table 1

Theme	Description of theme
How I got through it	Coping strategies (including passing time with music, reading, TV, phone, iPad and relaxation techniques; and personal attitudes and resilience (such as not overthinking it, taking one step at a time, and getting through the final hurdle).
The physical impact of brachytherapy	Positioning/lying flat (causing difficulty eating or drinking, build-up of gas and backache); medical complications (such as pulmonary emboli, pressure sores and allergic reactions); and side-effects during and after treatment (including severe pain, nausea/vomiting and aftereffects on bowel and bladder).
The psychological challenges of brachytherapy	Trauma associated with loss of fertility and associations of applicator removal with childbirth; privacy and dignity (including embarrassment, wanting a single room and feeling vulnerable); and not being listened to/believed (when experiencing severe pain).

Conclusions
Whilst some women had generally positive experiences of brachytherapy there are aspects of treatment that need to be improved to minimise difficult and traumatic experiences. Recommendations for improving holistic care of women receiving brachytherapy need to be developed.

This study was funded by the National Institute for Health Research (NIHR) [ICA-CDRF-2017-03-079].

Appendix 35: Abstract 5 BGCS Annual Scientific Meeting July 2022 (British Gynaecological Cancer Society) (Version accepted for publication)

Title: What do women say about their experiences of brachytherapy for locally advanced cervical cancer? A qualitative interview study

Author(s): Pauline Humphrey; Emma Dures; Peter Hoskin; Jenny Johnston; Louise Reardon; Fiona Cramp
Keywords: Cervix; cancer; brachytherapy; qualitative; interview; patient experience

Introduction
Brachytherapy for locally advanced cervical cancer can cause pain, anxiety and distress. The aim of this study was to explore women's experiences of brachytherapy and to seek their views on improvements.

Methods
Semi-structured interviews were undertaken with women who had received brachytherapy for locally advanced cervical cancer at one of four UK sites. Two cohorts were recruited: cohort one had recently had brachytherapy and cohort two were a year post brachytherapy. Consecutive patients were invited to interview. Participants were invited to retell their brachytherapy story and explore views on their care and ideas for improvement. Interviews were audio-recorded and transcribed. Data were analysed following Braun and Clarke's method for reflexive thematic analysis (2006).

Results
Thirty five interviews were conducted (20 cohort one and 15 cohort two). Age ranged from 28 to 87 years. Interview duration ranged from 22 to 78 minutes. Women's reports included difficult and traumatic experiences with periods of severe pain and poor nursing care on the wards. However, some women described positive experiences, reporting what had gone well. Three themes were developed, - see Table 1.

Table 1

Theme	Description of theme
How I got through it	The use of helpful coping strategies (including passing time with music, reading, TV, phone, iPad and relaxation techniques); and personal attitudes and resilience (such as not overthinking it, taking one step at a time, and getting through the final hurdle).
Unpleasantness, discomfort and the aftermath	Positioning/lying flat (causing difficulty eating or drinking, build-up of gas and backache); medical complications (such as pulmonary emboli, pressure sores and allergic reactions); and side-effects during and after treatment (including severe pain, nausea/vomiting and aftereffects on bowel and bladder).
Emotional consequences and trauma	Trauma associated with loss of fertility and associations of applicator removal with childbirth; privacy and dignity (including embarrassment, wanting a single room and feeling vulnerable); and not being listened to/believed (when experiencing severe pain).

Conclusions
Whilst some women had generally positive experiences of brachytherapy there are aspects of treatment that need to be improved to minimise difficult and traumatic experiences. Recommendations for improving holistic care of women receiving brachytherapy need to be developed.
This study was funded by the National Institute for Health Research (NIHR) [ICA-CDRF-2017-03-079].

Appendix 36: Abstract 6 CHCR Conference July 2022 (Centre for Health and Care Research Conference, UWE)

Pauline Humphrey; Emma Dures; Peter Hoskin; Louise Reardon; Jenny Johnston; Fiona Cramp

Title

What do women say about their experiences of brachytherapy for locally advanced cervical cancer? A qualitative interview study

Introduction

Brachytherapy for gynaecological cancer is reported to cause pain, anxiety and distress with no clear guidance for optimising women's experiences. The aim of this study was to explore women's experiences of brachytherapy and their views on improvements.

Methods

Semi-structured interviews were undertaken with women who had received brachytherapy for locally advanced cervical cancer at one of four UK sites. Two cohorts were recruited: cohort one had recently had brachytherapy, cohort two were a year post brachytherapy. Initial interviews were face to face but changed to remote interviews (video conference or phone) due to the COVID-19 pandemic. Consecutive patients were invited to interview. Participants were invited to retell their brachytherapy story, with views on their care and ideas for improvement also explored. Interviews were audio-recorded, transcribed and data analysed using Braun and Clarke's reflexive thematic analysis[1].

Results

Thirty five interviews were conducted (20 cohort one and 15 cohort two). Age ranged from 28 to 87 years. Interview duration ranged from 22 to 78 minutes. Difficult and traumatic experiences were reported, including periods of severe pain and perceptions of poor care. However, some participants described positive experiences and what went well. Three themes were developed, each with subthemes:

- *How I got through it:* Useful coping strategies; personal attitudes and resilience.
- *Unpleasantness, discomfort and the aftermath:* Problems caused by flat position; medical complications; early and late side-effects.
- *Emotional consequences and trauma:* Trauma associated with a life-threatening diagnosis: trauma associated with loss of fertility; associations of applicator removal with childbirth; feeling embarrassed, vulnerable, trapped; not being listened to or believed.

Conclusions

Whilst some women had generally positive experiences, some aspects of care could be improved to minimise difficult and traumatic experiences of brachytherapy. Study insights will inform future work to develop clinical care recommendations.

References

1. Braun, V. and Clarke, V. (2019) Reflecting on reflexive thematic analysis. *Qualitative Research in Sport, Exercise and Health*. 11 (4), pp. 589–597. doi:10.1080/2159676X.2019.1628806.

Appendix 37: Publication in Radiotherapy and Oncology (2021)

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Original Article

Brachytherapy for locally advanced cervical cancer: A survey of UK provision of care and support

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ABSTRACT

Background and purpose: Gynaecological brachytherapy can cause anxiety, distress and discomfort. It is not known how variation in delivery impacts women's experiences. To inform future research an online survey was carried out to identify variations in brachytherapy and support available to women receiving treatment for locally advanced cervical cancer (LACC).

Materials and methods: An online survey was sent to 44 UK brachytherapy centres using the Qualtrics® survey platform. It included questions about brachytherapy scheduling, inpatient/day case treatment, anaesthetic/analgesia, non-pharmacological support and health professionals' opinions regarding holistic care. A mixture of closed questions with pre-specified options and open questions were employed. Descriptive statistics were generated to identify variance in UK practice. Free text responses were analysed using inductive content analysis.

Results: Responses were received from 39/43 eligible centres (91% response rate). Brachytherapy was predominantly given on an inpatient basis at 65% and day case at 35% of centres. Eleven scheduling regimes were reported with typical duration of brachytherapy ranging from three to 52 h. The main categories identified in response to what worked well were: 'consistency of staff'; 'good information provision' and 'experienced/skilled/senior staff'. The main categories identified as needing improvement were: 'training of different staff groups' and 'follow up and support' with many suggestions for service improvements.

Conclusion: The survey provided a comprehensive overview of brachytherapy services for LACC demonstrating wide variability in scheduling regimes, duration of treatment and holistic care. The findings support the need to explore women's experiences with a range of treatment regimes and anaesthesia and analgesia techniques to inform improvements to future clinical care.

A systematic literature review has shown that brachytherapy for gynaecological cancer causes patients varying levels of pain, anxiety and distress and that there is a need for better pain management, patient information and support and the development of non-pharmacological interventions to improve experiences [1]. To date, previous research has not explored non-pharmacological support services (such as psychological support or use of complementary therapies) or the impact of treatment schedules on women's experiences of brachytherapy. To inform future research in this area it is first necessary to acquire knowledge of the ways that brachytherapy is currently provided and the range of existing support offered to women to help them cope with pain, anxiety and distress due to brachytherapy. The aim of this study was to identify current UK service provision for women having brachytherapy for locally advanced cervical cancer.

The objectives were to find out current brachytherapy treatment scheduling, and anaesthesia and analgesia provision for women receiving treatment for locally advanced cervix cancer to inform the development of an interview schedule; and to identify non-pharmacological support currently offered to women before, during and after brachytherapy.

Materials and methods

A cross-sectional survey was developed to gather information from UK centres carrying out gynaecological brachytherapy for locally advanced cervical cancer. Survey questions were informed by research literature [1–4] and discussion with the study team,

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0167-8140/

a brachytherapy anaesthetist, a clinical oncologist and two patient research partners.

The survey was piloted by four brachytherapy radiographers resulting in rewording of some questions, to minimise misinterpretation and improve consistency of responses. The final survey consisted of 30 questions covering brachytherapy techniques and scheduling, anaesthetic/analgesia protocols, inpatient/day case treatment and non-pharmacological support such as psychologist input. The survey is provided in supplementary data.

Ethical approval was given by the University Health and Applied Sciences Faculty Research Ethics Committee (UWE REC REF No: HAS.18.08.008).

The survey was distributed via the Qualtrics® survey platform to the 44 UK centres reported to be carrying out brachytherapy for locally advanced cervical cancer listed on the national cancer statistics database. Responses were requested from the lead brachytherapy radiographer as the person most likely to have an overview of the whole brachytherapy service. For three departments there was no lead radiographer identifiable. Email contact was made with these departments and an oncologist or physicist was invited to complete the survey with assistance from nurse or radiographer colleagues.

The on-line survey invitation was emailed out and responses collected over a three-month period from November 2018 to January 2019. For non-respondents a reminder was sent out after one month. The data obtained did not contain personal demographic information although professional opinions were requested. All identifiable features were removed from the data by the doctoral research fellow (PH) prior to sharing with the research team.

Descriptive statistics were used to analyse data from closed questions. Respondents free text comments to closed questions were grouped and summarised. The data from the three open-ended questions were analysed using content analysis. As survey data is uni-directional, without opportunities for co-creation between participant and the researcher, it can be used to provide "quasi- qualitative" data. The analytical process was informed by methods described by Kondracki et al [5], Hsieh and Shannon [6], and Elo and Kyngäs [7] using an inductive or "grounded" approach, with codes and categories arising from the data rather than applying a theory or preconceived ideas to the data. Frequency of codes was used to provide a sense of the significance of the results. The data were initially examined by PH by reading and rereading, to "achieve immersion and obtain a sense of the whole" [6]. Analysis began with open coding of responses. NVivo® software was used to provide a rigorous approach for counting code frequency. Codes that shared a similar meaning were grouped into categories.

Results

One of the 44 UK centres invited to take part in the survey was not eligible as their brachytherapy services had recently been transferred. Of the 43 remaining centres, 39 responses were received (91% response rate); including two from Scotland, one from Northern Ireland and 36 in England. The centre in Wales did not respond.

Most centres reported using high dose rate brachytherapy (36/39, 92%) and only four centres using pulsed dose rate (10%), with one using both HDR and PDR. Table 1 shows responses for type of brachytherapy, intracavitary, interstitial or hybrid (combination of intracavitary and interstitial in the same procedure), and predominant inpatient or day case service.

Eight respondents selected more than one fractionation regime from the nine options provided. Four responses were removed from the data as they did not correlate with responses to other questions, therefore likely to be errors of option selection. Fig. 1 shows the fractionation regimes selected by the respondents with "other" regimes described as "3 fractions (one insertion) over 3 days" and "3 fractions over 2–3 weeks".

Table 1
Type of brachytherapy and inpatient or day case service.

Type of brachytherapy (n = 39)	
Intracavitary	16 (41%)
Interstitial	1 (3%)
Hybrid	2 (5%)
Intracavitary + interstitial	4 (10%)
Intracavitary + hybrid	4 (10%)
Intracavitary + interstitial + hybrid	12 (31%)
Predominant inpatient or day case (n = 37)	
Inpatient	24 (62%)
Day case	13 (33%)

The average duration that applicators were in place for a typical insertion, measured from the start of the applicator insertion to applicator removal, ranged from 3 to 52 h with a median of 16 h. Interrogation of the data, including free text comments, showed the number of insertions predominantly used at each centre (Table 2).

The data indicates that there are 17 centres using long duration regimes involving overnight stays with applicators in place, and 17 centres using shorter duration regimes.

Respondents' comments showed that duration was influenced by factors such as scheduling choice, which is dependent on complexity of treatment (may choose multiple fractions for one insertion for a very complex case) and patient factors such as co-morbidities or contraindications (may choose shorter regime). Respondents provided examples of ways in which duration was shortened including using a Smit sleeve (indwelling intrauterine tube) for subsequent treatments; copy plans; and imaging/re-planning not used before subsequent fractions. Seven respondents commented on delays caused by increased planning time due to increased complexity; new addition of MRI imaging/planning; addition of interstitial needles; doctors in training requiring longer for planning (contouring) and limited access to MRI scanner. Other examples of causes of delays were limited clinician availability for applicator removal, medical complications needing clinician input; variable time needed in recovery room after general anaesthetic and number of cases that day, that is, more cases increases duration.

General anaesthetic (GA) was the most reported type of anaesthesia, by 82% (n = 31/38). Fig. 2 shows the responses for types of anaesthesia routinely used.

Eighteen respondents added free text comments on anaesthesia. Most comments referred to patient suitability, contraindications or medical reasons for anaesthesia selection. Four respondents mentioned patient choice or preference, for example:

"Patients are given a choice of GA or spinal. Most prefer a GA but occasionally we have a patient who would prefer a spinal"

One respondent indicated a different anaesthetic regime for initial and subsequent insertions:

"We only use general anaesthetic for the first fraction. Lorazepam is given 1 hour before subsequent fractions".

Most respondents indicated the use of four or five analgesia options. Fig. 2 shows type of analgesia used and number of respondents selecting each option.

The use of additional analgesia for applicator removal was reported by 68% of respondents (n = 26/38). Details of additional analgesia for applicator removal was provided in a free text comments box by 25 respondents (Fig. 2).

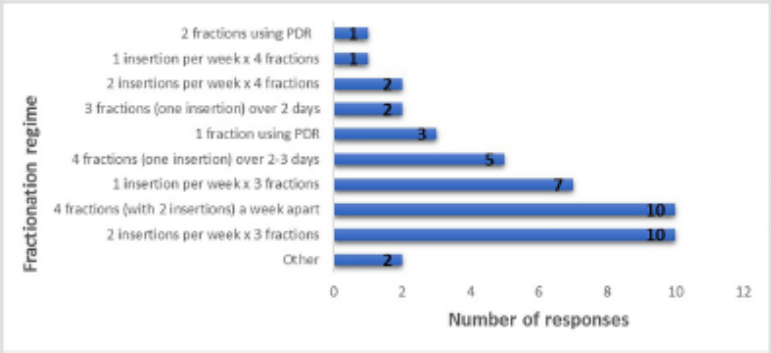

Fig. 1. Fractionation regimes routinely used ($n = 34$).

Respondents indicated that in most centres information/support was provided by radiographers before and during brachytherapy and by radiographers or specialist nurses after brachytherapy. In addition to the pre-defined categories, in free text comments some respondents reported that additional support was available from clinical psychology and counselling when required instead of routinely, and some patients had access to support facilities at on-site charitable organisations. Fig. 3 shows the type of support routinely provided before, during and after brachytherapy.

Participants were asked to rate how well they thought women were supported before, during and after brachytherapy in their department. Fig. 4 shows the 38 responses.

For the questions relating to what works well, what needs to be improved and adaptations for patients with special needs these data for each question were open-coded and grouped into categories and the number of responses in each category was counted. For each question an example from each category is shown in Table 3. Data from further comments at the end of the survey were managed in the same way and examples presented in Table 3.

Discussion

Survey responses indicated wide variation in insertion regimes with 17 respondents reporting a predominant use of a one or two applicator insertion regime which involved overnight stays with applicators in place, and 17 reporting three or four insertion regimes of shorter durations. This variation in regime choice has led to the large range of typical duration of applicators in place, from three to 52 h. The free text comments indicated that this wide disparity had arisen for complex operational reasons, such as access to operating theatres, availability of ward beds, numbers of oncologists and physicists and access to imaging facilities such as MRI. There was no evidence of patient input into individual treatment plans or service design, although this was not explicitly asked in the survey. Brachytherapy for cervical cancer causes patients varying levels of pain, anxiety and distress, and it has been proposed that the duration of the procedure and repetition of the procedure will impact on women's experiences [1]. Interstitial or hybrid techniques and use of MRI planning has been recommended and widely implemented, with the aim of improving local tumour control [2,4,8–12]. However, decisions on how to implement this development have been left to individual centres, as they have many different logistical factors to consider. Although service users cannot comment on lived experiences of different regimes, it would be useful to obtain their feedback on the brachytherapy insertion regime that they experienced so their views can be taken into consideration when deciding future fractionation regimes.

Table 2
Typical number of applicator insertions ($n = 34$).

Typical number of applicator insertions	1	2	3	4
Number of respondents ($n = 34$)	10	7	14	3

It is widely recognised that interstitial brachytherapy is likely to cause patients more pain than intracavitary brachytherapy [10,13,14]. Two studies which reported anaesthesia/analgesia regimes with long durations of interstitial brachytherapy had good outcomes using Patient Controlled Analgesia (PCA) after a general anesthetic [15] or a combined epidural medication [13]. In this survey six respondents reported no use of PCAs or epidural with long duration regimes. Further research is needed to assess women's experiences of pain with or without the use of continuous pain management (PCA or epidural) and for long duration procedures with interstitial needles.

Applicator removal has been reported to be the most problematic part of brachytherapy. One study reported that instrument removal was "the most physically uncomfortable aspect" and another that "maximal levels of pain coincided with applicator manipulation during insertion and removal" [16,17]. Smith et al. [18] reported a sudden increase in pain during applicator removal, at a time when other analgesia had worn off. They concluded that inhalation of nitrous oxide gas was appropriate to minimise this short term discomfort as it is short acting, easy to administer and has a rapid effect due to absorption into the blood stream through lung alveoli. A retrospective five year analysis in a single centre recommended that regional anaesthesia should continue until the end of the brachytherapy, including applicator removal [19]. In the current survey almost a third of respondents reported no additional analgesia being routinely offered at applicator removal. Where it was offered, the most popular additional drug at applicator removal was nitrous oxide and oxygen gas (Entonox®/gas and air). For some respondents the use of continuous pain management with PCA or epidural or spinal anaesthetic for short procedures may be considered sufficient for applicator removal. However, there were four centres that did not use continuous pain management techniques and did not routinely offer any additional analgesia at applicator removal. This was corroborated with some free text comments about analgesia needing to be improved. Therefore, inadequate pain management, especially for applicator removal is likely to still be a problem for some patients.

Some respondents indicated little experience of patients with special needs such as learning disabilities, dementia, victims of sexual abuse or female genital mutilation. This may reflect the

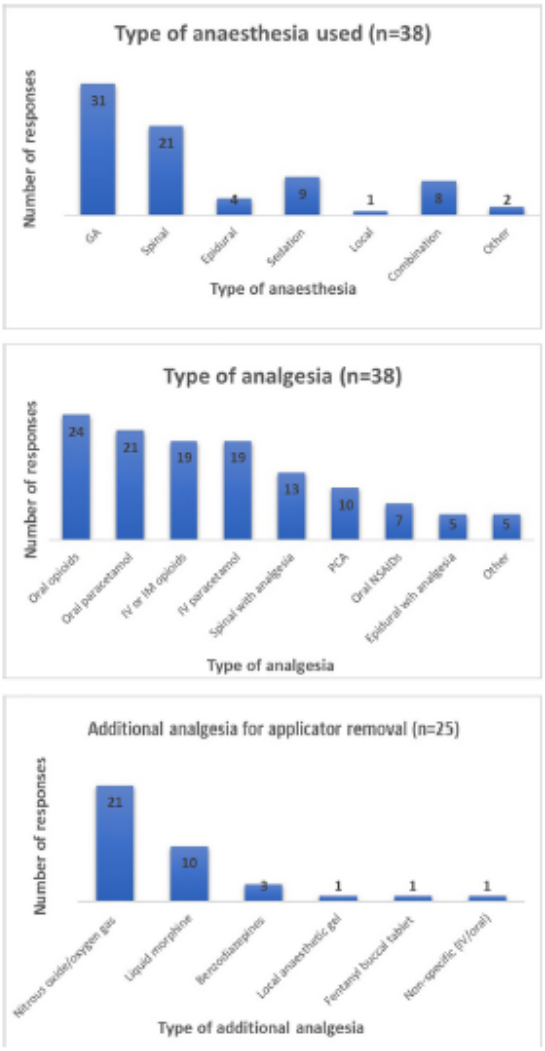

Fig. 2. Type of anaesthesia; Type of analgesia; Additional analgesia for applicator removal. Abbreviations: IV = Intravenous; IM = Intramuscular; PCA = Patient controlled analgesia; NSAIDS = Non-steroidal anti-inflammatory drugs.

low numbers of women having this type of brachytherapy, especially in smaller centres. However, it is important to consider that in the UK the incidence of women who experience domestic violence during their lifetime is one in four, and one in five for sexual assault [20]. Therefore, it may be assumed that clinicians will sometimes be unaware of patients' histories and access to additional support for brachytherapy would not have been sought. However, it is encouraging to see that many respondents in this survey reported that they have access to specialist support services and would assess and adapt their provision according to individual patient needs, assuming that those with special needs are identified.

Respondents rated highly the support given to patients at their centre before, during and after brachytherapy. In relation to what worked well, respondents referred to continuity of care, experienced staff, building trust and rapport and dedicated staff.

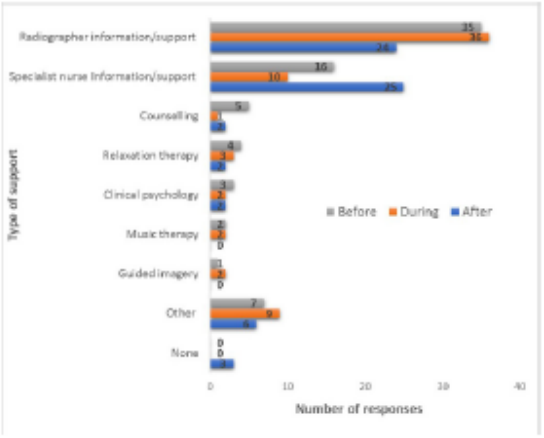

Fig. 3. Support routinely provided before, during and after brachytherapy ($n = 38$).

However, some responses regarding what needed to be improved identified care on the wards and education of ward and other staff. In a previous interview study, many women commented on their "Supportive treatment team (specialized staff members brachytherapy)" [21]. This contrasts with a report of the lived experiences of receiving LDR or PDR brachytherapy, where women reported some negative aspects of care, mostly relating to nursing care on the wards. Some women were distressed by nurses "lack of understanding of the technology associated with the treatment" and an uncaring attitude or awareness of the ordeal that they were going through. Participants reported inconsistent care in pain management, and a lack of help with basic hygiene and empathy and understanding [22]. Overall, the literature suggests mixed experiences that may be dependent on the level of knowledge, skill and experience of individual members of the brachytherapy or ward nursing teams and the supportive relationship they develop with patients. This is similar to contrasting and sometimes contradictory findings in this survey, that staff views on provision of support are highly positive but some state that provision of care and staff education needs improvement. Further research is therefore warranted to explore patients' views of care and support at each stage of treatment.

Survey respondents commented on the good provision of information and frequent opportunities for patients to ask questions.

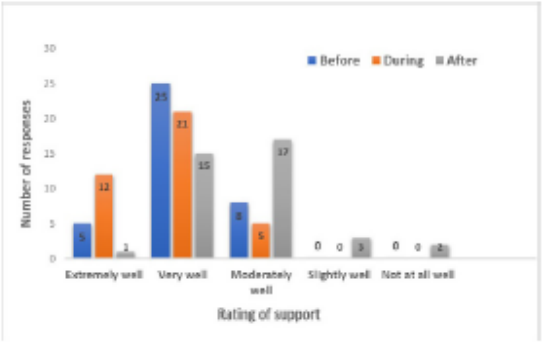

Fig. 4. How well do you think women are supported before, during and after brachytherapy in your department? ($n = 38$).

Table 3
Free text answers and comments.

SURVEY Question	Category	Example of response	n*
WHAT WORKS WELL IN YOUR DEPARTMENT? NUMBER OF RESPONSES TO QUESTION = 33 (85% OF TOTAL SAMPLE)	Consistency of staff	*…knowing the same radiographer from the start of EBRT to brachy support on day.*	19
	Good information from staff	*I feel that we give a lot of information at different times during the EBRT pathway so that patients are well informed about the brachytherapy treatment.*	18
	Experienced, skilled, senior staff	*We have a very focussed female oncologist, 2x CNS and specialist gynae surgical ward nurses plus brachytherapy/review radiographer.*	13
	Appropriate analgesia	*Pain relief is assessed from one week to the next to discuss which drug will best suit the patient in the PCA.*	6
	Service improvements and developments	*MDT team looking for ways to improve patient experience and service developments to reduce pathway length on the day for patients.*	6
	Relationships of trust, rapport and empathy from staff	*They are treated by a small team, all who have met the patient before, so there is already a relationship and a rapport with the patient.*	5
	Good follow up/aftercare	*We do radiographer led calls and follow ups at 3 and 6 weeks for support and to offer advice re dilators. Patients find it helpful to know they can contact us at any time. …*	4
	Provision of good facilities	*We have our own theatre which is on the day unit where the patients are cared for and this is a great bonus.*	4
	Patient care on wards	*…dedicated HDR sisters provide one to one care during inpatient stay.*	4
	Good teamwork	*Good relationships and communication between all staff members involved in patient care.*	2
	Access to psychological support	*…ongoing support during treatment and referrals for Psych Onc where appropriate.*	1
WHAT NEEDS TO BE IMPROVED IN YOUR DEPARTMENT? NUMBER OF RESPONSES TO QUESTION = 32 (82% OF TOTAL SAMPLE)	*Training for different staff group*	*Support for radiographers, ongoing training etc to deal with the emotional side of the treatment experience.*	12
	Follow up and support after brachytherapy	*Patients have a 10 day telephone F/U following completion of Brachy. They have a 3 month F/U in Gynae. I don't feel this is adequate for some women.*	10
	Pharmacological management	*It is being discussed whether to provide GA patients with a spinal block to aid with the control of the discomfort.*	6
	Appropriate allocation of staff	*We have no dedicated brachy radiographer- very physics and technician led. …*	6
	The patient pathway	*Access to the MRI facilities at the times required improved to save the waiting time*	6
	Obtain and use patient feedback	*Since introducing hybrid technique (interstitial/intracavitary) we have not got patient feedback.*	4
	Care on wards	*Improvements in the care and understanding of the procedure on the ward.*	3
	Ward facilities	*Although we try and allocate a side room to each patient, it isn't always possible.*	2
	Access to complementary therapies	*Need more therapists to provide relaxation while patients on ward.*	2
	Information and support	*I would like to ask some of our patients to consider writing a short paragraph about their experience to show to future patients to alleviate their concerns/provide support before treatment.*	2
	Technical developments	*Patients often report that they are transferred a great deal and the ward is at the opposite end of the hospital to the scanner. If we moved to MRI planning scan only this would reduce the moving.*	2
ADAPTATIONS FOR PATIENTS WITH SPECIAL NEEDS, FOR EXAMPLE LEARNING DISABILITIES, DEMENTIA, VICTIMS OF SEXUAL ABUSE OR FEMALE GENITAL MUTILATION NUMBER OF RESPONSES TO QUESTION = 33 (85% OF TOTAL SAMPLE)	Access to specialist support	*We have an 'additional needs team' that we can call on if we have patients that need extra help or support.*	14
	Identify and assess individual patients' needs	*Each patient is treated as an individual and everything is tailored to individual needs as far as possible.*	13
	Counselling or psychological support	*We have involved clinical psychologists early on to prep ahead for particularly anxious patients/ history of sexual abuse.*	8
	Extra CNS or radiographer support	*Unfortunately that support is limited to CNS and radiographers, we do not have routine counselling services.*	5
	Adaptations to treatment	*Altered fractionation and library plan available for patients unable to tolerate/cope with inpatient procedure.*	5
	Involvement of family/carers	*On occasion we have had family members present in theatre for patients with learning difficulties for example.*	4
	Appropriate information and support throughout	*Information and communication throughout.*	3
	Staff get to know the patient over time	*…we get to know the patient well from first consultation and support them throughout the entire course of treatment.*	2
	Consistency of staff/familiar face	*We also follow the patients through the dept from theatre to MRI then CT and back to the ward, so they have a familiar face with them throughout the procedure.*	2
	Extra time	*Allow extra time for information and support meetings with the patients.*	2
	Earlier involvement	*…we would arrange to meet with the patient earlier in their pathway to sensitively address any*	2

Table 3 (continued)

SURVEY Question	Category	Example of response	n*
		issues and individualise our approach accordingly.	
	Consider gender of staff	*Both male and female staff are available according to the patients … requests.*	2
	Accommodate patient's requests	*I am not sure we have needed it but will always work with requests from patients.*	2
FURTHER COMMENTS NUMBER OF RESPONSES TO QUESTION = 13 (33% OF TOTAL SAMPLE)	Follow up support and late effects	*…I suspect that this type of treatment could have significant mental effect and that survivorship support needs to address this as well as long term physical effects…*	4
	Treatment duration/number of treatments	*The possible option of moving to a 4 fraction technique will have implications- a longer stay or multiple implants (both will be harder for the patient).*	4
	Pain management at applicator removal	*…removal of the applicators using 'gas + air' has triggered thoughts about child-birth and has been described by one as the most horrendous part of her whole treatment.*	3
	Success/survival rates/ outcomes	*… it is heart breaking to realise how little there is in place to assist patients who don't have a good treatment outcome.*	3
	Resource heavy- time consuming and labour intensive	*It is a very labour intensive, time consuming process and relies very much on the co- operation of a huge team of people.*	2
	Interstitial needle introduction	*One of our consultants is keen to move towards interstitial needles for these patients, which is something we currently do not offer.*	2

*n = the number of open-ended responses in each category.

However, Velji and Fitch [22] reported that despite information provision, women did not feel fully prepared for their experience of brachytherapy. The effectiveness of information provision in reducing anxiety and distress is therefore questionable. A study of LDR brachytherapy reported women's satisfaction with information provision, but some negative views caused by a gap between theoretical knowledge and the actual experience of brachytherapy [23]. A study of the informational needs of women having brachytherapy for locally advanced cervical cancer reported significant unmet needs, such as information about side-effects, sexual intercourse, treatment preparation and appointments [24]. Their findings were used to develop patient-centred guidelines for use by multidiscplinary team members, to integrate patient experience into the development process [25]. The findings from this survey support the need to explore women's experiences of brachytherapy and suggestions for improvement in different UK settings. Recommendations from a recent study to improve well-being for women receiving vaginal brachytherapy (post hysterectomy) will be considered for comparison [26].

There are some limitations to this study as questionnaires do not provide an opportunity for the researcher to clarify ambiguities or check that questions have been interpreted correctly. It is also not possible to seek additional information via survey although the opportunity for respondents to provide free text comments did add valuable detail.

Conclusions

The excellent response rate to the survey provided a comprehensive overview of brachytherapy service provision for LACC which is highly likely to be representative of service provision in the UK. This survey has demonstrated a wide variability in scheduling regimes and duration of treatment. Anaesthesia (GA or spinal) was reported to be used in all centres but analgesia after applicator insertion and for applicator removal was more variable. Whilst these factors are highly likely to impact on women's experiences it is important not to make assumptions but to ask the service users directly. The findings therefore support the need to explore women's experiences with a range of different treatment regimes and anaesthesia and analgesia techniques to inform improvements to future clinical care.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.radonc.2021.03.007.

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