Quality of reporting on patient and public involvement within surgical research: a systematic review

Jones E.L, MSc[1] Williams-Yesson B.A, MSc[2] Hackett R.C[3] Staniszewska S.H DPhil[4] Evans D, DPhil [5] Francis N.K, PhD[2]

[1]University of Leicester, Department of Health Sciences, 22-28 Princes Road West, Leicester LE1 6TP, United Kingdom

[2]Yeovil District Hospital NHS Foundation Trust, Higher Kingston, Yeovil BA21 4AT, United Kingdom.

[3]Patient representative, colon aid PPI group, Yeovil District Hospital Foundation Trust

[3] RCN Research Institute, Division of Health Sciences, Warwick Medical School, University of Warwick, CV4 7AL

[5] University of the West of England, Glenside, Blackberry Hill, Bristol BS16 1DD

Correspondence and requests for re-prints to:

Mr Nader Francis, Consultant colo-rectal surgeon, Yeovil District Hospital NHS Foundation Trust, Higher Kingston, Yeovil, Somerset BA21 4AT, Tel: 01935 384244 Fax: 01935 384653 e-mail Nader.Francis@ydh.nhs.uk

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INTRODUCTION

Recruitment difficulties in randomised controlled trials (RCT) are well documented [1] with slow recruitment and inadequate patient numbers to achieve rigorous evaluation reported to be a concern in surgery.[2,3,4,5,6] Surgical research intends to benefit a large population with an estimated 234.2 million major surgical procedures undertaken world-wide each year[7] and there is a recognised need to address challenges in surgical trial design. This has resulted in a growing body of literature to explore reasons why surgical trials may encounter difficulties. Reported challenges to randomisation include equipoise; whereby the surgeon or the patient may hold a preference for one treatment arm, and language; where the technical complexity of the intervention is poorly presented during recruitment.[3]

Incorporating the knowledge, skills and experience of patients, carers and the public in clinical trials is one mechanism by which study design may be improved with a wider acceptability and relevance having the potential to impact on recruitment.[8] Patient involvement in systematic reviews has also been recommended by the Cochrane collaboration with the aim of ensuring accessibility and relevance of Cochrane reviews to patients and carers.[9] 'Patient and public involvement' (PPI) has therefore become a core component of good research practice and a topic under which peer reviewed health research applications are scrutinised. PPI within research has been defined as being conducted 'with' or 'by' patients or members of the public rather than being 'about' or 'for' them.[10] PPI methods vary but typical models of PPI include the use of PPI reference groups, patient research partners, patient co-authors, or joint grant holders. Patients' activities can involve identifying research priorities, commenting and developing information leaflets or other research materials and undertaking interviews with research participants.

Incorporating the views of recruited research participants are also linked to involvement but are more generally regarded as participation. Examples of participation are: i) being recruited to a clinical trial to take part in the research ii) completing a questionnaire as part of a research study. Sometimes this can lead to more active involvement, for example when participants comment on specific aspects of a trial that they feel should be amended.[8]

Previous reviews addressing PPI within health and social care research generally[11], and more specifically within cancer clinical trials[12,13] have identified that PPI can impact aspects of trial design in surgery including developing processes in relation to consenting, recruitment, patient information sheet design, and protocol amendments. PPI has also been linked to enhancing face validity and relevance of trials, which may then impact upon obtaining adequate study accrual. A recognised need to evaluate this impact[14] has resulted in the development of critical appraisal guidelines to assess the quality of user involvement[15] and how it is reported within research dissemination.[16]

However, despite a drive to improve surgical research and to utilise PPI, the extent to which this is reported in surgical research has not yet been systematically reviewed. It is also unclear how surgery conceptualises PPI, for example whether it is seen as active collaboration or different forms of 'participation' as research subjects which can lead to involvement contributions.

The aim of this paper is to systematically review the literature to identify how PPI has been reported in surgical research.

METHODS

Search strategy

All surgical literature published between 1996 (when significant numbers of papers on PPI in research first began to appear in the literature)[17] and September 2013 were searched. We undertook systematic searches of a number of sources, including the Ovid SP versions of EMBASE and MEDLINE using MeSH terms, search terms and Boolean operators with synonyms and plurals in addition to key words. The Cochrane Central Register of Controlled Trials and the related articles function of Pub Med were also searched electronically. The subject specific database PsychInfo was also used. We also contacted authors of relevant trials to ask if they could provide further summary data that had not been reported in the trial publication.

The search strategy was designed by two authors (DE and ELJ) and conducted by ELJ. Guidelines for the preferred reporting items for systematic reviews and meta-analysis (PRISMA) were followed.[18] The search strategy is summarised in table one and captured terms relating to (i) patients (ii) involvement iii) peri-operative care and (iv) impact (table 1). The category 'impact' included searching for PPI feed-back mechanisms to identify how information is exchanged between patients and researchers. Cancer was included as a key word because some papers addressing multi-disciplinary cancer care include a cross section of surgical resection patients. The most recent search was performed on the 23rd September 2013. The search results were supplemented with hand searching of the reference lists of identified papers (ELJ). Two recent systematic reviews[11,19,]and a structured literature review[20] of PPI in health and social care and their reference lists were also searched. We included randomised and non-randomised trials, and qualitative research. Systematic reviews and met-analysis were also included because reviews of high quality RCTs represents the highest level of evidence based medicine[21] which facilitate full use of existing health care research.

Two reviewers (ELJ and BWY) independently assessed titles and abstracts of all abstracts. **SS resolved discrepancies regarding inclusion criteria.** Full text articles were obtained and were reviewed by two authors. Discrepancies about the role of PPI, or over-lap between surgical and cancer research were discussed with the patient co-researcher (RH) and NKF. Data analysis was conducted by ELJ, BWY, NKF and **SS**. All authors contributed to manuscript drafts. The quality of PPI reporting was evaluated by ELJ and checked by NKF and **SS resolved discrepancies**.

A patient co-researcher (RH) was involved at all stages of the review which was overseen by DE and ELJ. He contributed to the development of the research question, search strategy and read drafts of the manuscripts to ensure the study retained salience to the public world. He also facilitated the formation of recommendations for the direction of future PPI strategy within surgical research.

Inclusion Criteria

The strategy included studies published between 1st January 1996 and 2nd September 2013 to include all literature since INVOLVE was established. INVOLVE is a National Institute for Health Research (NIHR) advisory group and co-ordinating centre supporting greater public involvement in research in the UK and this may have facilitated the development of PPI in surgical research. A key inclusion criterion was that papers reported upon the involvement or participation of patients within published surgical research studies. Definition of PPI in this study encompasses papers reporting on patient's involvement in: a) identification of research topics b) impacting recruitment c) impacting study protocol d) contributing to data collection, analysis, or dissemination. Surgical trials are defined as trials whose main aim is focussed upon surgical intervention.

Exclusion criteria

Papers exploring hypothetical and non-surgical trials were excluded. Papers involving patients or the public for service development or clinical guideline development were excluded. Case studies, articles not published in the English language and abstracts and conference proceedings were excluded because of the probability of incomplete data. Surveys or qualitative studies exploring problems in recruitment across surgical research were excluded because the aim of this study is to examine PPI reporting within individual published surgical studies.

Data extraction, methodological quality and data analysis

Data were extracted under categories including; publication, author, year, sample size, study design, surgical speciality, PPI methods, results, and mechanism of information exchange between patients and researchers. The Guidance for Reporting Involvement of Patients and Public (GRIPP) checklist[16] and the critical appraisal guidelines developed by Wright et al[15] were used to evaluate quality of PPI reporting within the literature. The GRIPP checklist describes 10 points encompassing the inclusion of PPI within the abstract, study aims, methodology, results, discussion, and conclusions. The critical appraisal guidelines developed by Wright et al[15] were designed to evaluate the quality of PPI methodology against nine criteria including; Is there clear rationale for involving service users? Is the level of user involvement appropriate? Is the recruitment strategy appropriate? Is the nature of training appropriate?

RESULTS

Identifying relevant papers

A total of 3031 titles and abstracts were reduced to 2335 after the removal of duplicates (fig 1). Of these, 20 were found to be on the topic of PPI in research in cancer, or surgery. Twelve papers were excluded because they did not specify the inclusion of surgical patients (9), because they reported on duplicated data (1) or because they did not conduct systematic review or an original clinical trial (2).

Eight full text articles were included describing a total of 489 patients (table 2). Surgical specialisms included: urology, (2) musculo-skeletal, (1) colorectal (1), ear nose and throat (ENT) (1) and gynaecology (1). One additional paper involving cancer patients from multiple surgical specialities and one systematic review paper were also included.

Five objectives for utilising PPI were reported: to improve the identification of research topics (1), study design (1), participant recruitment (6), participant retention (1), and to conduct to data collection (1).

Results are reported under three headings: 1) Original research using the recruited research participants to influence the research process 2) Original surgical research using non-participant patients and carers to influence the research process 3) PPI within surgical systematic review and meta-analysis. RH (patient representative) reviewed the results section of the manuscript and agreed headings under which analysis should be conducted placing particular emphasis on the importance of PPI for recruitment.

1) Original research using research participants to influence the research process

Five articles reported on qualitative data gained from participants enrolled in on-going research studies and clinicians on the process of recruitment. These studies were conducted across urology,[22,23] gynaecology,[24] musculo-skeletal[25,] and ENT[26] surgical specialities. A variety of methods enabled participants to become involved at strategic levels including

participant members of research steering committee,[27] and consultative levels including questionnaires[24] and interview.[22,25] Reasons given for using face to face interviews included the need to capture in-depth descriptions of the patients' views and experiences. Pragmatic reasons were given for the use of telephone interviews[25] and questionnaires[24,] including a requirement to obtain feedback quickly, patient convenience, and reducing burden on the research team.

These studies agreed that patients' views on treatment preference, study acceptability and feasibility, and the comprehensibility of written information may underpin barriers to the consenting and recruitment process. Qualitative data revealed that strong patient preferences were common in surgery with patients consenting to be randomised to bypass waiting lists[25] and being more aware of surgery as a curative treatment.[25,24,23] Qualitative data analysis identified understanding the type and strength of patients' treatment arm preferences and how this is explored by recruiters can result in patients being informed of treatment options in a more informative way.[23] One study identified that discussion of a preference arm did not reduce the number of patients who were willing to be randomised.[24] Two studies highlighted that patients preferences may change over time.[22,25] Thorstensson et al[25] identified that pre-randomisation three times as many patients were un-willing to be randomised because they did not wish to receive surgery than patients who did not wish to receive conservative care. However, in those who did take part in the RCT, patients crossed over to surgery on average 14 months after inclusion giving reasons including the belief that conservative care gave sub-optimal results. This finding was also shared by Mills et al[23] who found that participants expressing either no preference, a weak preference or uncertainty evolve their views after provision of further information by recruiters. **However, it cannot be determined whether**

multiple factors outside the scope of the extra information provided could have impacted the patients' choices.

Three studies explored the clinician's delivery of trial information and the patient's response to it using audio recordings.[26,22,23] The recruiters ability to 1) articulate technically complex information,[26] 2) ensure patients understand the concept of equipoise and explore preferences[23] and 3) articulate the concept of randomisation[23,] were all identified to impact upon participation within surgical clinical trials. Donovan et al[22] quantified the impact of incorporating the patients view into trial design by measuring recruitment rate before and after feeding back patient reported data to the recruiting staff. Training recruiting staff to use patient reported data to adapt their communication skills within the clinical encounter increased randomisation rate from 40% to 70%. However, it was not clear to what extent patients were involved in this training, and whether the information obtained from the audio recordings was used to facilitate it.

2) Original surgical research using non-participant patients and carers to influence the research process

Two studies described the involvement of patients in a manner which enabled their suggestions to become incorporated into the identification of research topics,[28] and the conduct and design of the intervention.[27] This demonstrates the use of 'real time PPI data' to achieve an immediate effect upon study aim, protocol, or outcome. PPI was directly linked to enhancing face validity, which could help to ensure good participation rates because the trial topic, delivery and purpose had salience to the public world. A variety of methods were used to implement PPI and integrate the patients' views including a research user partnership group, patient steering group members, interviews and focus groups. Reasons given for using

both interviews and focus groups included pragmatism (scheduling problems associated with focus groups) and to obtain data saturation.

Bartlett et al[27] described the involvement of 153 colorectal, gynaecology, prostate and upper gastro-intestinal surgical patients to design a web site as a new model of follow up care for cancer patients. This aimed to reduce the requirement for face to face appointments by providing remote monitoring for those with low risk of recurrence, and providing a mechanism for the exchange of information, encouraging self-management. Active collaboration with patients contributed towards the development of a user-friendly, feasible and acceptable web-site.

Feedback of real time PPI data was reported in detail by Bartlett et al[27] who describe a clear PPI feedback loop. Iterative group sessions facilitated by research and IT staff was followed by an audio-recorded discussion leading to an agreed consensus between researchers and patients on protocol amendments. Bartlett et al[27] also received feedback from patients as members of their research steering group, and via telephone interviews.

Welfare et al[28] used PPI to identify the research priorities of patients with ulcerative colitis. The views of patients were obtained using focus groups and interviews, which took place within the hospital. Saturation of topics was obtained with a sample size of 40. The sample included a diverse age range (19-71 years) with an equal number of males and females. Sessions were audio recorded and transcribed and the results subjected to thematic analysis. Research priorities included: identifying the cause of colitis, prevention and cure, improving communication with health care professionals, and service delivery. It is not clear how this framework of topics relevant to patients will be used in practice.

3) PPI within systematic review

One surgical systematic review was identified which reported upon the involvement of patients. Whistance et al (2013)[29] conducted a systematic review on outcome reporting in colorectal cancer where four patient representatives were involved as co-authors. These patients are reported to have provided contributions to the study conception and design, acquisition of data, analysis and interpretation of data; manuscript revision; and gave final approval of the version to be published. However, there is no detail within the content of the paper describing how the patients were involved, and what value this contribution gave to the overall publication.

Quality of PPI reporting and methodology

The quality of PPI reporting in this review was found to be sub-optimal. Of the five studies reporting on PPI within a specific surgical trial (anterior cruciate reconstruction, prostate cancer resection, and transcervical surgical resection of endometrium,) one 'parent' paper was identified, which did not report on the use of PPI within the context of the main RCT. [30] One of the studies (ProtecT), prostate cancer is still open to recruitment so the final RCT has not been written yet. Two reviewers independently assigned a judgement of 'yes', 'no', or 'un-clear' against each item within the Wright checklist and GRIPP framework to identify whether the criteria were met.

All seven papers utilising PPI within qualitative or randomised studies report upon the same points within the Wright checklist, each reporting on 4/9 aspects (table 3). They all describe in some detail the purpose and level of utilising patients' views, recruitment strategy, and the added value of the PPI to the research process. However, the training and support for patients, their involvement in dissemination, and a critique of the limitations of PPI were not reported. The papers touched upon methodological considerations of PPI within the context of the epistemological challenges associated with using patient reported data and the requirement

for triangulation. The systematic review paper addressed two points on the Wright checklist, reporting upon the contribution of the patients' view to the systematic review conduct and to dissemination via publication. Across all eight papers, PPI was also under reported against the criteria of the GRIPP checklist (table 4). None of them provided an adequate explanation of PPI within the abstract or a clear account of how PPI was conceptualised in relation to existing theoretical models. They all reported upon the methodology used to capture the patients view and they all attempted to define the concept of incorporating user's views or preferences.

DISCUSSION

Improved recruitment into clinical trials is one possible positive outcome of implementing PPI. Systematic review across different health care specialities have identified that barriers to recruitment can be prospectively identified through PPI to improve the design and conduct of health research.[11,13,31,32,33] Two reviews evaluating patients perception of cancer trials[13,12,] made specific recommendations to improve patient education and communication with the consenting clinician to encourage enrolment.

However, despite national and international drives to promote the utilisation of PPI within research, to our knowledge, this systematic review is the first to report on PPI in surgery and it has highlighted a paucity of surgical literature reporting the involvement of patients. There was also a sub-optimal quality of reporting of PPI according to the GRIPP guidelines[16] and Wright checklists.[15] **This is perhaps not surprising as this paper really identifies the initial green shoots of PPI in surgical research, and identifying potential for significant growth.**

Nevertheless, the limited number of papers selected within this review have shown that novel approaches to using PPI data have been explored such as integrating patients' views into the training of recruiters at site set up visits, and planning the design of the trial around the patients whole peri-operative journey. The importance of contemporaneous use of PPI data was highlighted because patients' views pre and post randomisation may change and understanding this may contribute towards a more optimal decision making process during recruitment. Trial infra-structure was also highlighted by patients to be important which included giving time to discuss and consider trial information with patients.[23] However, the majority of this data has been obtained from interviews, focus groups or audio-recordings, with patients as research subjects, contributing towards an understanding of their experiences of a study. While this is important, it does not fully reflect the intention of active collaborative involvement, with patients as partners in the research.

Active partnership was defined by Tritter within a conceptual model to consider the extent to which i) participants are delegated direct decision), participants act as sole agents or as part of a group, and iii) their participation is re-active to a pre-existing agenda or helps to shape it (proactive).[35] An active partnership with patient researchers has been recommended within the conduct of systematic review to ensure their responsiveness to both clinician's and patient's expectations.[36,37] This concept resonates with the intention of our systematic review, which has conceptualised PPI as an active partnership. Our patient representative (RH) was involved at all stages, commenting on the purpose, design and the categories within which analysis was undertaken via face to face meetings and electronic correspondence. He also highlighted the importance of reporting 'the story of PPI in surgery' as some papers reflect 'experience of participation' and others reflect active involvement.

Given that PPI is a priority within an international research governance framework it is perhaps surprising that this review identified a small number of surgical papers describing the measurement, impact and outcome of PPI activities, and in all of them PPI reporting has been sub-optimal. However, it was not clear whether this represents an under-utilisation of PPI or purely sub-optimal reporting within surgery more generally. **The GRIPP and Wright check lists were applied to provide a quality assurance of the level of PPI reporting. However, the GRIPP checklist was designed for active collaborative involvement and is less relevant for studies designed to report on participation or the 'patient experience' of the research process. Nevertheless, the concept of structured reporting of PPI in research has not been attempted before in surgery and by acknowledging the limitations of the application of existing checklists, this research could pave the way for further development of reporting tools.**

The identified sub-optimal reporting of PPI in surgical literature could highlight a need to raise the profile of PPI. Drawing upon areas such as mental health and maternity could facilitate PPI expansion within surgery. This is particularly important because most funders now require applicants to demonstrate active PPI. As such surgery stands at a pivotal point, with significant potential to enhance PPI in the future. This raises the issue of training, to grow the confidence and competency of surgical health care professionals and researchers to develop PPI. It is also possible that facilitating training for patients may help to overcome barriers in implementation and reporting, by encouraging the development of patient initiated and patient led research. Promoting awareness of surgical research within PPI organisations such as the Patient-Centred Outcomes Research Institute (PCORI (in the United States), INVOLVE (in the UK), and Ecancer patient (in Europe) may also be important to support researchers in

embedding PPI into their surgical work. Improving understanding is likely to contribute towards enhancing the quality of reporting and transparency of the evidence base.

There are limitations within this study. Firstly, the small number of studies identified may limit the ability to generalise conclusions. Also, the use of key words and MeSH terms is inconsistent in PPI, so **some papers may have been omitted. However, PPI reporting is encouraged to be explicit and direct, and surgical papers which may have been missed could confirm our conclusions on sub-optimal reporting. Also, our search strategy included telephone calls to authors to ensure that we did not miss potentially relevant data and we were successful in contacting authors where additional clarification was required.** This work may be susceptible to publication bias because sources of non-published studies were not searched, although no abstracts were excluded due to language.[30] Studies using surveys, to obtain the patients' view did not consider the validity of their tools. However, the qualitative studies included in this review utilised adequate sample sizes to obtain data saturation (table 2). Methods of recruiting participants for interview and cross-over or preference arm studies were clearly reported. Finally, it is also possible that sub-optimal reporting of PPI could reflect the real world constraints of word limits peer reviewed journals and the reality that reporting on PPI may not always be a priority.

In order to fully embrace the benefits which can be gained from utilising effective PPI it will be necessary to explore optimal feed-back mechanisms. Translating the patients' view into research practice may be dependent on overcoming organisational issues. Donovan et al touch on this by describing the use of PPI data within staff training to improve recruitment. However, the mechanisms by which PPI data can be communicated across the whole clinical research team and how patients might be involved in this process has not yet been reported.

Further work investigating the contemporaneous real time use of PPI data within different stages of the surgical trial process may also be helpful, building on the knowledge that patient preferences may change pre and post randomisation. This review has also found no reference within surgical research of the use of PPI to integrate the opinions of marginalised and minority groups. **While some studies have included feedback from individuals who are participants in studies, this is not the same as active collaborative involvement where patients become partners in the research process. More active forms of involvement could be developed in surgical research, or if the predominance of 'participatory' PPI continues further work to promote reporting which adequately reflects this could be undertaken.**

Conclusions

There are a limited number of studies that have reported upon active collaborative involvement in surgical research. Surgery is now poised to significantly expand its PPI activity through high quality involvement and reporting. This will ensure that surgical research is relevant, appropriate and acceptable to patients and have an optimum chance of creating the best health benefits.

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