THE USE OF KEY PERFORMANCE INDICATORS FOR EXTERNAL QUALITY CONTROL IN HISTOLOGICAL DISSECTION

Matthew Paul Griffiths

A thesis submitted in partial fulfilment of the requirements of the University of the West of England, Bristol for the degree of Professional Doctorate in Biomedical Science

FACULTY OF HEALTH AND APPLIED SCIENCES, UINVERSITY OF THE WEST OF ENGLAND
DEPARTMENT OF HISTOPATHOLOGY, DERBY ROYAL HOSPITAL

August 2015

Contents

List of Figures

List of Tables

Acknowledgements

I would like to thank Dr Rachel Gilibrand for her support and guidance throughout this research doctorate. Her wide ranging knowledge and sense of humour helped motivate my failing spirits on more than one occasion. She picked up an unfamiliar subject area and gave a wonderfully fresh perspective to the most frequently neglected aspect of laboratory medicine, the people in the laboratory.

Dr David Semeraro taught me many things, one of those things was "*Tout vient ß qui sait attendre*." It took me a while to learn that one, but it was a lesson worth learning. He possess an endless patience and a passion for teaching that I shamelessly exploited for my own ends when I prevailed up on him to be my clinical supervisor.

Abstract

The recent reports into standards in the NHS (Francis, 2013) and quality in pathology (Barnes, 2014) have focused scrutiny on the way in which we work in pathology and how we can provide assurance that this is of a sufficiently high standard. There are a number of external quality assurance schemes covering pathology generally and histopathology specifically (UKNEQAS), however, there is no scheme of any kind covering the process of histological surgical dissection. This is an area undergoing development currently, as it changes from an area which is the sole preserve of medically qualified pathologists, to an area utilising a number of highly trained biomedical scientists.

The concept of biomedical scientist led dissection has been around for some years, being codified into a document of best practice in 2005 (IBMS, 2005). This document placed the responsibility for the work of the BMS in the hands of the pathologist, without structured oversight or a quality assurance programme. Ten years on and specimen dissection, including the developing area of BMS led dissection, remains without any formal structured form of quality assurance.

This work builds on the points made by Barnes (2014), taking the guidance of the Royal College of Pathologists (RCPath) and Institute of Biomedical Science (IBMS) to form a series of key performance indicators (KPI) in relation to specimen dissection. These KPI can be used as an indicator of individual practice, highlighting areas of variation, weakness or strength. Once these are identified, a tailored feedback and training event provides an opportunity to address these errors & omissions, or to enable areas of strength to be shared. The results of this thesis show that introducing training events serves to drastically reduce variation by, and between, dissectors, driving up standards in the department.

Introduction

Few could fail to be aware of how badly Mid Staffordshire NHS Trust failed their patients. The Francis Report (Francis, 2013) examined in detail the practices of the Trust and found that the patient was not placed at the heart of the service, that targets were prioritised over good practice and that there were no effective sanctions to deal with poor performance. This was more than a decade after the Kennedy Report (2001), which looked into unnecessary deaths during paediatric heart surgery in Bristol. Kennedy noted that the mortality rate was double that in similar centres elsewhere. He also noted that the patients here were again not placed at the heart of the service. In his conclusions he stated that learning from errors is vital, and that openness and transparency are considered vital. Beyond this, he went on to consider the attitude of healthcare professionals to patients.

Kennedy speaks about the importance of a partnership between healthcare professionals and patients, one including respect and honesty. He is keen to move away from the traditional attitudes of "doctor in charge" and encourages an open collaborative approach. This is keenly echoed in the Francis Report, and, Secretary of State for Health, Jeremy Hunt's statement in response to the report clearly criticised the attitudes encountered. The Secretary of State went on to call for accountability and transparency (Hunt, 2013).

In this newly emerging culture of openness and transparent quality data, a report into possible misdiagnosis at Sherwood Forrest NHS Trust was commissioned (RCPath, 2013). Ultimately no misdiagnosis was found, however, a number of serious concerns were identified into the funding and organisation of the laboratory, attitude of the trust management to the pathology department, training and equipment; the most significant concern was in regard to the EQA scheme which gave rise to the original concern. The EQA scheme did not adequately consider the sample size and the statistical safety of extrapolating from the data, nor were the results sufficiently meaningful as to provide direction and specificity to their concerns. The report also detailed concerns regarding the methods used by an external agency appointed to investigate the issue; their apparent identification of “weak positivity” of oestrogen receptor (ER) staining, which they claimed had erroneously been reported as negative, were in fact false positives. The original report of ER negative was correct. This gave rise to another investigation, this time by Dr Barnes. The Barnes Report (2014) covered quality control in pathology and was quite exhaustive in nature. Barnes noted the reports from Francis and Sherwood Forrest, and echoed a number of their findings, particularly calling for open, transparent individual quality data and standardisation of practice in pathology. Currently there is some quality data available for pathology, however, it is obscure in nature and nonspecific. The national EQA scheme in histopathology is run by UKNEQAS (ukneqas.org.uk), the results generated by this scheme are fed back to the individual laboratory along with regional average rates. It is not possible to draw direct parallels between laboratories, nor is it possible for non-members of the scheme to view the data. Where a laboratory fails to meet the minimum standard, a letter is sent to the nominated “technical head” (UKNEQAS, 2015). This clearly does not fit within the framework of openness, accountability and transparency.

This work aims to go some way to addressing this failing. Barnes (2014) noted that quality procedures in pathology were no longer fit for purpose and called for individually identifiable, evidence based, key performance indicators. This work examines the evidence base for practices in surgical dissection in diagnostic histopathology, and establishes the premise of using key performance indicators to identify deviations in practice. It looks at how to feedback this data to the personnel involved, with methods of encouraging a collaborative team approach to determining best practice and optimising performance. Further, as Biomedical Scientist (BMS) led specimen dissection is an emerging field, this work looks to establish an objective standard of practice, by providing comparison with the current practice, performed by consultant Histopathologists.

Research Aims and Objectives

This research aims to investigate the feasibility of developing Key Performance Indicators that can be applied to the process of histopathological surgical dissection. The aim of this is to enable the use of KPI data to demonstrate variation in practice by and between individuals; demonstration of this variation then allows a form of remedial and preventative action to be introduced, to reduce variation and increase standards.

The objectives of the research are to:

- Create a set of histopathological dissection KPIs based on the best available professional and scientific guidance
- Collect performance data in relation to the KPIs from a number of dissectors
- Develop a mechanism for correcting errors or weak / poor practice
- Devise a team led system of training, education and feedback, based on the KPI data

Thesis Overview

Chapter One

Chapter one is a review of the current literature. Beginning with a consideration of histological dissection and its position within a framework of evidence based practice, the literature covering the emerging area of BMS led dissection and the devolution of responsibility this requires is reviewed. The evidence around the lack of current quality standards and why such are needed is examined. Along with this, the concept of, and evidence for, key performance indicators is considered. The literature review will then examine in detail the evidence regarding the need for standardisation of dissection practice, looking particularly at the literature published on lymph node sampling as its exemplar and will consider the findings with reference to current laboratory practices. The review continues and considers the evidence surrounding the use of checklists in practice, to reduce error; following the evidence from the aviation sector and its translation into a medical context. Finally, the literature review examines how best this performance data may be used to improve performance, considering change management and teaching & learning theories.

Chapter Two

Chapter two presents the findings of the first study which reviewed current practice in the laboratory. The reports were reviewed, examining a number of criteria, selected as KPIs. These criteria were selected as examples, exploring the concept of KPI reporting in surgical dissection, and the difference in practice between pathologists and BMS. The KPI were selected, based on the recommendations from the RCPath for macroscopic description and sampling. This is used to establish a picture of current practice for pathologists and BMS. The difference between the two groups are considered and the significance of the difference is investigated. Discovery of the variance in practice between individuals and groups allowed a consideration of how quality might be assured by monitoring key performance indicators. It goes on to provide an initial consideration of the results and how to develop the investigation further.

Chapter Three

Chapter three presents study two, the development and delivery of a training intervention employing a face-to-face training event, the use of a practice checklist and diagrammatic representations of dissection. Study two was an eight part trial which first created the checklists and collected baseline data then introduced the training event, checklists and guide diagrams in different combinations to assess the individual effectiveness of each. The results are presented for each stage in the appendices and then brought together and presented by different dissection types at the end of this chapter.

Chapter Four

Chapter four presents study three, where a series of interviews are performed. In these interviews a number of the dissectors who have been involved in study two, parts one to eight, are questioned regarding their experience of the study, what effect they thought the study had and their opinions were sought in regard to what further developments might be made. The transcripts of the interviews were reviewed and a thematic analysis performed

Chapter Five

Chapter five is a detailed discussion of the investigations in context. Here the variations are considered in their context and the significance of the variations in practice are discussed. The effect of the interventions is also discussed along with reflection upon individual practice and the methods that might be used to improved performance.

Chapter Six

Chapter six presents the conclusions of this work, where the new information gained in the study is presented in the context of a changing medical, social and political environment. The work is placed into the context of the changing NHS, with drives for identifiable, transparent quality performance data, with sanctions and rewards for poor or good performance.

The list of references is available on page 191 and the appendices start on page 203.

Chapter One - Literature Review

Histological Dissection

The specimens received by the histology laboratory range from a single fragment of tissue, such as an endoscopic biopsy, to a large multi organ resection, such as a pelvic exenteration; these specimens must then be handled in such a way as to enable microscopic analysis.

There are many terms employed in laboratories to cover the process of transforming specimens of all types into samples suitable for chemical treatment and subsequent sectioning. In the experience of the author, "Cut up", "Trimming" and "Dissection" are three of the more common. The term "dissection" will be used here, as this is the terminology used by the Royal College of Pathologists (RCPath) and the Institute of Biomedical Science (IBMS) in their co-authored documents (IBMS, 2009; IBMS, 2010a; IBMS, 2010b).

The process of dissection takes organs, or portions of organs, and selectively samples the specimen. This process is of paramount importance in providing an accurate diagnosis, staging of disease and prognosis for the patient. Histopathological dissection is a highly skilled procedure, performed in order to enable the microscopic analysis of the tissue. There is substantial guidance available for this process, the Royal College of Pathologists have issued a number of guidance documents on how to handle and report these specimens (Williams *et al.*, 2007; RCPath, 2009; Appendix One – Tissue Pathways and Minimum Datasets, on page 203). This process has traditionally been performed by medically qualified pathologists, according to their own preferred method. In recent years the process has been delegated to Biomedical Scientists and the RCPath best practice guidelines have been incorporated into standard operating procedures (SOPs), which BMS are expected to follow. The extent to which these SOPs are followed, by both the BMS and pathologist, is a debated topic; as are the relative standards of performance displayed by both groups (Sanders, 2009; Simmonds, 2011; Duthie, 2004).

Evidence Based Medicine

Standardisation in medical practice has been increasingly linked to improved patient outcomes (ACOG, 2012; Dhingra, 2010; Coombs, 2009; Ferran, 2008) and is an integral part of the current drive for Evidence Based Medicine (EBM). EBM may be thought to have originated with Dr Archie Cochrane with his book *Effectiveness and Efficiency: Random Reflections on Health Services* in 1972 (Shah, 2009). EBM seeks to base the practice of medicine on the best available evidence, rather than the individual preferences of the practitioner. As research indicates better methods, the guidance is updated. As such, the practice of medicine should follow the available guidance, based on the current evidence, and all practitioners should be working in very much the same way. The logical extension of this is that variation in practice, either within or between individuals, should be eliminated where possible.

EBM is not without its detractors. Croft (2011) provides a balanced review of EBM, covering both the positive and negative aspects. One of the criticisms levelled at EBM is that in some cases there is no evidence. Whilst this may be true, it does not preclude working to what evidence is available and being open to changing practice when research provides new evidence. Also, where no evidence is currently available, if practitioners note this lack and document their practice and outcomes, this forms the beginning of an evidence base for this area. Another criticism sometimes made is that EBM stifles innovation. Research is always ongoing in medicine, the newly emerging evidence is collated and evaluated by the appropriate professional body, who will issue best practice guidelines amended, or not, in light of the new findings. EBM does counsel a more rigorous approach to *adopting* new innovations; however, as EBM is by definition based on evidence gained from research, a culture of EBM encourages research and innovation. EBM only restricts the implementation of new practice, requiring that the change be evidence based (Glasziou *et al.*, 2011).

The concept of EBM, or rather evidence based practice (EPB), is not new to pathology. Within pathology the staging, diagnosis and reporting practices are based on evidence; even guidance on appropriate staffing is given, which is also evidence based (Lowe, 2014; Thorpe *et al.*, 2012; Ellis *et al*., 2005). The practice of histopathological dissection is based on variable amounts of evidence and in considered in detail within the "Standardisation of Dissection" section.

Devolution of Responsibility

Another emerging trend within pathology, and within the wider medical community, is the devolving of tasks and responsibilities traditionally undertaken by medically qualified doctors to appropriately qualified paramedical professionals. This has occurred extensively within nursing, with a great deal of traditional nursing roles being undertaken by Healthcare Assistants (Bosley, 2008; Daykin & Clark, 2000). This is also occurring in pathology, whereby the process of surgical dissection, which was traditionally the preserve of medically qualified pathologists, has been passed to suitably trained biomedical scientists. The concept of pathological dissection being performed by non-medically qualified staff (specifically, qualified Biomedical Scientists) has been present for some time. There has been considerable variation in range and scope of practice, which until recently has been uncoordinated and left to local agreement. In recent years there have been steps to formalise and standardise the range of specimens and personnel that are authorised to work with them (IBMS, 2009; IBMS, 2010a; IBMS, 2010b; RCPath, 2004). However, there are no protocols in place to ensure the standard of this work; the quality must be monitored locally, there are some suggestions made on how to perform this (IBMS, 2009, RCPath, 2007), but no structured or formal systems have yet been developed.

As might be expected, there is variation in attitudes to this change. Simmonds (2011) reported the results of a survey carried out on all the consultant pathologists registered with the RCPath, for whom they could obtain an email address, 463 individuals responded out of 1320 contacted (response rate of 35%). Those who responded showed a largely positive attitude towards BMS led dissection, with 98.9% of respondents being either fully in favour of BMS dissection or in favour with some reservations. There remains some controversy and arguments regarding exactly how BMS led dissection should progress and be monitored, but the prevailing attitudes expressed are positive.

The responsibility for histological dissection still, currently, remains with the consultant pathologist (IBMS, 2005). Consequently, it is easy to see where the hierarchical attitudes stem from, these are also noted in surgery (Bosk *et al.*, 2009). Medicine has traditionally been self-regulating, at least for the last 150 years since the 1858 Medical Act. This has changed, and continues to change; the General Medical Council, until very recently, took very little interest in the standard of work performed by their members, only censuring for occurrences of Serious Professional Misconduct (Dixon-Woods *et al.*, 2011). Dixon-Woods *et al.* (2011) relate a series of scandals that came to prominence through the 1990s, which had been occurring for decades, and where concerns had been raised previously, with no action taken. There is clearly a responsibility here, that of oversight and management. Dixon-Woods *et al.* claim that the scandals they discuss represent a failure of not only oversight, but also of the responsibilities of doctors towards their peers. However, the fundamental flaw was that the GMC set their threshold for involvement at the level of serious professional misconduct, with no lesser claims being entertained, also, their standard for conviction was akin to the criminal court standard of "beyond reasonable doubt". The institutional structure encouraged a lack of candour, something also seen in other professional arena, where "whistleblowing" can be at the cost of a career. Fortunately, things have changed. The GMC was restructured in 2009, after the Council for Healthcare Regulatory Excellence (now the Professional Standards Authority) was formed in 2003. The restructuring primarily ensured that the members of the GMC council would be equally registrant and laity.

The importance of noting these historical circumstances and their subsequent changes is to place the devolution of responsibility and attitudes to assessment in a proper context. Being a medical doctor has long held a social weight, a certain cachet; this came with certain responsibilities as a part of the social contract. The fabric of this social contract, the trust with which the public hold their doctors, has been successively damaged over the years, in no small part by these scandals. The consequence of this is a move to what Dixon-Woods *et al.* (2011) call a "confidence" system, whereby individuals (the patients) put their faith in the system of assurance and regulation around the individual, rather than in the individual themselves. This means that we must be able to demonstrate our quality within that system in order to promote this confidence in us. With the current political environment and the drive for ever increasing competition, any commissioning group will also be looking for evidence for putting their confidence in any particular hospital, department, or individual. Demonstrating appropriate team behaviours, attitudes and quality is going to be a necessity.

Quality in Pathology

Following the serious failings in standards of care, personal performance, oversight and leadership identified in the Frances Report (2013), the Secretary of State for Health published an initial response, committing the government to fully implementing 204 of the 290 recommendations (Hunt, 2013). In this response, Berwick (2013) was tasked with building on the work of Frances and finding a way forward. His prime recommendation was to place the quality and safety of patient care above all else. In this newly emerging environment of prioritising quality, concerns noted at Sherwood Forest Hospitals NHS Trust (RCPath, 2013) gave rise to an in depth review into quality control in pathology (Barnes, 2013). The Sherwood Forest Report makes a number of key findings, although the publication most relevant to pathology is the Barnes Report, which relates to quality in pathology. Both make a number of recommendations and are considered in some depth later in the literature review.

One of the methods used to ensure quality is External Quality Assurance (EQA). The value of EQA has been proven repeatedly (Hastings and Howell, 2010, Sciacovelli *et al.,* 2010), over many years (Barr & Williams, 1982). EQA is a method whereby an external agency provides independent feedback on performance, against an agreed standard. Within UK pathology the main sources of EQA are UKNEQAS and the Royal College of Pathologists, where substandard performance is identified, this is reported back to the laboratory. EQA has been used across all areas of histopathology, with the sole exception of pathological dissection. There are schemes covering the microscopic analysis of tissue sections (NHSBSP, 2003; RCPath, 2007), routine and special staining (UKNEQAS, 2011a), immunocytochemistry and *in situ* hybridisation (UKNEQAS, 2011b). Duthie *et al.* (2004) specifically highlight the lack of published literature regarding the quality of specimen handling. When considering how quality assurance of histopathological dissection might be performed, whether BMS or pathologist led, it is significant that dissection involves compromising and damaging the sample. The training process suggested by the IBMS (2009) suggests preview prior to dissection, moving on to review after dissection, progressing to dissection with regular audit. The concept of regular audit is, however, not further defined; nor are any recommendations made regarding EQA. Additionally, one of the drivers for BMS led dissection is the time saved by consultants, it is not practicable for each specimen to be viewed before, during and/or after dissection, beyond an initial training stage. This gap in knowledge and oversight is something we seek to address here. Whilst EQA clearly has much to offer, it lacks a robust framework in which poor performance of individuals can be identified, or whereby poor performance can be managed.

However, one of the recent outcomes of EQA has had far reaching consequences. An audit by East Midlands Breast Screening Programme Quality Assurance Reference Centre into aspects of the histopathology service at Sherwood Forest NHS Trust revealed concerns about the quality of the work performed. The Care Quality Commission, along with the Royal College of Pathologists, investigated the issue. Whilst they found that the concerns were unfounded, indeed criticisms were made of the external agency appointed to investigate the alleged discrepancies, they identified a number of further issues within the EQA system (RCPath, 2013).

The review undertaken was extensive, involving rescreening a great many slides and determining the Oestrogen Receptor (ER) status of breast tumours. This highlighted a number of areas of variation, both within this centre and between centres. However, the main problem noted was related to the EQA scheme. As Sherwood Forest Trust was handling a small number of cases, a small amount of variation was sufficient to create the appearance that this trust was an outlier. The subsequent investigation into the matter was further compounded the issue by the use of the antibody clone 6F11. 6F11 is now know to show false positive staining (Ibrahim, 2012; Rakha, 2012). This is something which was picked up by the EQA scheme, however, there is clearly a significant time lag in identifying and reporting these issues. The Sherwood Forest Report also highlighted a number of systematic faults with the statistical aspects of the EQA service. It also recommended that statistical monitoring of individual performance be introduced, using radiology or cervical screening methods as a starting point (RCPath, 2013).

As a consequence of this investigation, and the background of the Francis report, the NHS Medical Director, Sir Bruce Keogh, appointed the National Clinical Director for Pathology, Dr Ian Barnes, to review pathology quality assurance. Barnes (2014) states “the current systems of quality assurance in pathology are no longer able to meet the needs of modern healthcare” and “we cannot say the best interests of the patients are being served”. This could not be stated more clearly. He based this assertion on a number of factors, including the lack of key assurance indicators (KAIs) and the inability of the pathology service to provide evidence of quality to the Care Quality Commission (CQC).

This was published in January 2014 (Barnes, 2014). Barnes felt that pathology services must be visible to patients; accountable to boards and commissioners; reliable, robust, and responsive; rewarded when they make improvements in quality, patient safety, and in the contribution they make to patient experience; held to account when they fail to offer the level of service patients expect.

Barnes noted that there were a number of failings in pathology practices, particularly in relation to KAI and demonstrating quality data (Table 1 below).

Table 1 - Recommendations from Barnes, 2014

1.7.1	The broad assurance framework has a lack of KAIs to evidence quality and safety of pathology services, and to enable effective contract management both within organisations and by commissioners.
1.7.2	Pathology assurance and governance is not consistently embedded in provider governance and assurance frameworks.
1.7.3	Pathology is unable to provide evidence to the Care Quality Commission (CQC)/Hospital Inspectorate of the overall quality of pathology services.
1.7.4	Pathology needs to respond to changing and additional requirements from commissioners and the public for information and assurance around consistency of provision and reporting.
1.7.5	The impact of new technology and processes (genomics, point of care testing (POCT), digitalisation, molecular techniques, informatics) on delivering pathology services, and the impact on a rapidly changing workforce, require a strengthened quality assurance framework.
1.7.6	There is too much variation between pathology services, and a lack of harmonisation and standards, which is unacceptable to patients and users.
1.7.7	The current system was fit for the purpose for which it was designed, but it is not fit for the future, nor does it meet the emerging requirement for transparency and well-evidenced quality assurance. Therefore, the Review and the recommendations it makes will attempt to bring these features of the system into sharper focus, strengthening existing structures to ensure these gaps are filled.

One of the recommendations made by Barnes is:

"Further consideration must be given to the ways in which individual performance can be assessed, monitored and competence-assured. The National Medical Director will ask the

professional bodies, led by RCPath, to review these issues and report back within twelve months on their findings."

This clearly echoes the comments made in the Sherwood Forest investigation (RCPath, 2013), showing that these calls for individualised quality data are growing.

The RCPath, IBMS and Association of Clinical Biochemists (ACB) welcomed the publication of the report (Jayaram, 2014). They acknowledge that the report presents an opportunity for professionals in pathology to form a rationally based quality system. This work attempts to address some of the gaps identified by Barnes, by identifying KAIs / KPIs, demonstrating their evidence base, and investigating how poor performance or change in expectation can be addressed.

Foy *et al.* (2002) discuss how to best implement changes in professional practice. They performed an audit and regression analysis of the work done in the Gynaecology Audit Project in Scotland, and categorised the existing recommendations as having any of the following features:

- Addresses common issue
- Precisely described
- Compatible with values
- Key feature to a set of wider recommendations
- Based upon sound evidence
- Fits patient expectations
- Observable benefits
- Requires organizational change
- Requires changed routines
- High profile
- Complex
- Trialable

They assessed the degree to which each recommendation possessed each of these features, and the degree to which each recommendation was being followed. They then looked at the correlation between these and noted that there were four features that most correlated with change. Two showed a positive correlation and two showed a negative correlation. Those recommendations compatible with the views and values already held by practitioners relating to the performance of their duties and those recommendations that were termed “key features”, which is to say they formed part of a larger set of recommendations key to wider goals were seen to show a positive correlation to recommendation uptake. A negative correlation was seen to those recommendations that required organisational change or a change in routine. Foy also noted that although only 3% of recommendations could be classified as being trialable, that is, they could be adopted as a temporary measure and discarded if needed, these showed a higher level of uptake.

As a change in guidelines is likely to involve change in routine practice, and may well relate to practices where there is some disagreement over what is appropriate practice, this presents something of an obstacle to change. Since Foy noted measures that could be adopted on a temporary basis showed a greater and more sustained uptake, this is something that has been considered in the development of this study.

From this we can see that simply publishing new guidelines and expecting everyone to pick up on these and change practice is not an effective method, which may come as no surprise. As with other findings reported above, concordance was higher when the reasons behind the changes were explained, something which the paper by Pronovost (2006) (discussed extensively in the change management section) also commented on. Foy *et al.* (2002) found that disseminating new guidelines resulted in very little change in behaviour, the greatest change was reported after interactive implementation strategies, whereby steps were taken to engage practitioners in the guidelines, explaining the benefits to the changes. This tallies with the results reported by Ho *et al.* (2010) which are discussed in detail below, in the section on change management. Briefly, Ho *et al.* (2010) looked at episiotomy procedures, concluding that many unnecessary interventions were being made. They worked with a number of practitioners, explaining the research and the evidence for the recommendations, this enabled the practitioners to form their own opinion regarding the evidence and the recommendations, rather than simply responding to instruction, or ignoring the guidelines. This enabled the practitioners to preserve their autonomy and develop their knowledge and skills in light of new evidence. Ho *et al.* combined this with recommendations that could be adopted on a trial basis, as with the conclusions from Foy (2010), this showed the greatest change in practice. These papers have been considered in relation to the work currently being undertaken, whereby the training interventions are to involve as many people as possible, and are to be guided, interactive and initiated on a trial basis. This is considered in more depth later in the literature review, under the heading of "Change Management" on page 33.

Key Performance Indicators

The process of dissection is by its nature a destructive one, therefore, it is not possible to revisit the specimen and assess the adequacy of examination with complete certainty. Some review of cases after dissection is recommended as part of the training process. However, this is labour intensive, time consuming, and as the specimen has been dissected and partially sampled, such a review is of an altered state. The scenario has many parallels with surgery. It is clearly not feasible to re-open an apparently well patient to examine the quality of the surgery they have received, but some form of quality review is necessary. There is abundant evidence to show how standards slip in the absence of such monitoring, the Francis Report (Francis, 2013) being one of the more recent high profile examples; the Kennedy Report in 2001 shows that this is not a modern problem and the Barnes Report (2014) demonstrates clearly how such standards can be monitored. Francis and Kennedy both detail serious examples of substandard practice and care. In both cases, appropriate oversight and monitoring was missing. In the case of Francis, the Mid Staffordshire Trust had a great many targets to meet, but a lack of appropriate standards and monitoring led to the scandalous situation that arose. Barnes (2014) responded to the findings of the Francis and Sherwood Forrest reports, examining in great depth the quality assurance (QA) processes in pathology. He concludes that QA has worked well up to now, but in the expanded and more complex role pathology plays, QA in pathology needs to be fundamentally re-assessed as it is no longer fit for purpose. This is discussed in more depth later, however, one of the recommendations he makes is developing Key Performance Indicators (KPIs).

The use and importance of KPIs in a medical setting is well demonstrated by the reports of surgical site infections (SSIs). Public Health England (2014) reports on the number of SSIs in English NHS hospitals (2013/2014). This is one of the KPIs used by Care Commissioning Groups (CCGs) when determining which trust to award contracts to. NHS England have recently determined that mortality statistics for NHS surgery should be published on-line (nhs.uk/consultantdata), adding to the pool of performance data available. Bridgewater *et al.* (2007) looked at over 25,000 patients undergoing first time cardiac surgery, between 1997 and 2005. He reported how the recent introduction of the publication of surgical outcome reports has reduced both the observed and risk adjusted mortality rates. The ratio between the observed mortality and expected mortality before and after the public disclosure of outcome data was 0.71 and 0.53 respectively ($p<0.05$). Hannan *et al.* (2012) noted a drop in the risk adjusted mortality following cardiac surgery of 41% (from 4.17% in 1989 to 2.45%) in New York in 1992. The Hannan study examined over 57,000 patients undergoing surgery between 1989 and 1992, when New York State began to collate, compile and disseminate quality data relating to the risk factors, mortality, and complications of this type of surgery. There is much research into the use of KPIs within surgery, one area where this bridges into pathology is the use of a scoring system for total mesorectal excisions (TMEs). When a TME is submitted for histopathology the quality of the surgical specimen is assessed by the dissector and given a numerical score (Williams, 2007). This score reflects the quality of the surgery performed and is an important prognostic indicator (Quirke, 2009). Furthermore, Quirke discovered that giving feedback on these scores to the surgeons led to an improvement in the quality of the submitted specimen during the period of their study.

KPIs are not, of course, unique to healthcare, Gonzalez-Gil (2014) details the use of KPI in managing the energy use of a railway system, and Cai (2009) discussed their use in improving supply chain management. The unifying principle of KPIs and the inherent benefit of their incorporation into practice is that they are based on the best available evidence, and are amended in the light of new research. Here we identify KPIs relating to histological dissection and demonstrate how they can be used to demonstrate quality, how to improve quality and how to monitor quality.

Standardisation of Dissection

Duthie *et al.* (2004) introduced BMS led dissection in their lab in 1999, and wished to assess the quantitative and qualitative effects of this. They examined 672 specimens dissected by six consultants and 660 specimens dissected by two BMS. The specimens were limited to those in category B (Appendix Two – IBMS & RCPath Dissection Categories, page 204), they indicated that they found a higher concordance with Standard Operating Procedure (SOP) by BMS than pathologists. The authors noted that an increased number of blocks and levels was seen in BMS dissected specimens, but determined that the additional work of the increased number of blocks was more than offset by the time saved by pathologists. Whilst no investigation into the costs associated with this were performed, it is probable that a cost saving was made, as BMS time is substantially cheaper than pathologist time. Duthie *et al,* concluded that the quality of dissection performed by BMS was not reduced when compared with pathologists, suggesting this is potentially an area for further investigation, which would allow an evidence based approach to staff structuring and budgeting in this area. Additionally, the authors reported an increase in lymph node yield when dissection was performed by BMS when compared to the pathologists. This finding was supported by Shaw *et al.* (2008), showing BMS (median 15, range

12–20) identified more lymph nodes than consultant pathologists (median 10, range 7–13), confirming the findings of Thomas (2006).

When considering the differences between BMS led dissection and pathologist led dissection one must be aware of the different training backgrounds. Pathologists are medically trained, whilst BMSs have followed a scientific pathway, which clearly leads to a very different sphere of knowledge. Simmons (2011) investigated attitudes to BMS led dissection, they surveyed over 1300 consultant histopathologists, 25% of respondents expressed concern at the potential lack of knowledge and increased supervision required by the BMS. One of the concerns held by consultant pathologists, reported by Simmons was whether the BMS is aware of important and unusual clinical features, and when specimens might be best dealt with by a non-standard approach. This is a judicious concern, Chandra *et al.* (2010) published a review of best practice in bladder pathology specimens; they indicate the importance of being aware of the significant aspects of clinical information and the previous history. However, this is specifically addressed in the IBMS document (2005) relating to good practice in dissection – they explicitly recommend that BMS dissectors should seek advice on unusual or complex cases. The IBMS good practice document should be read in conjunction with the protocols recommended in the RCPath minimum datasets and tissue pathways (RCPath, 2014a; RCPath, 2009). These are evidence based, Flemming & Griffiths (2005) detail in their best practice article much of the reasoning behind the protocols and minimum dataset points. Whilst this is essential information, the knowledge, awareness and comprehension of these points is not monitored in either BMS or pathologists once they have passed their exams as currently there is no requirement for a periodic or on-going skills test or CPD in dissection.

When considering specimen dissection and the guidance available, Ludeman & Shepherd (2006) provide an excellent treatise on the macroscopic assessment of colorectal specimens. Perhaps unsurprisingly, they make no mention of competency assessment either as a gateway to practice or of an ongoing nature. The paper is an excellent reference indicating how various colorectal resection specimens should be handled according to current state, although they make no recommendations for further development or how to asses or ensure quality. However, they raise an interesting point regarding the RCPath minimum requirements. For example, the minimum dataset requires at least 12 lymph nodes to be sampled – they suggest that for some dissectors this minimum number becomes a target, this is something which has been echoed during personal communication with other pathologists. There is no incentive to obtain more than the baseline minimum number of lymph nodes, or indeed to do anything more than meet any minimum standard. The authors indicate that despite audits on lymph node numbers retrieved, the numbers of retrieved nodes remains low in some centres. Within Shepherd's laboratory there is an informal "leader board" with the number of nodes retrieved and the dissector noted, this, they state, has created a culture of ensuring high lymph node counts. Ludeman & Shepherd published their paper nine years ago, some eight years after the initial RCPath recommendation that a minimum of 12 nodes be obtained (Quirke and Williams, 1998) and with no on-going standardised framework to monitor this or to provide training / feedback, the authors consider this is unlikely to change. There is extensive evidence and evidence based guidance regarding lymph node retrieval, clearly though, the actual approach to lymph node retrieval is not meeting this guidance. Verrill (2004) highlighted the importance of sampling lymph nodes fully, detailing the prognostic relevance of tumour involvement in lymph nodes. Thus ensuring that minimum standards are consistently reached is critical.

Despite this clear evidence based guidance, Shia *et al.* (2012) reported that the number of hospitals meeting the 12 lymph node minimum standard increased from 15% in 1995/6 to only 38% in 2004/5. This was amongst hospitals in the USA; Bilimoria *et al.* (2008) reported that the increase was most notable among those hospitals which had been designated as "Comprehensive Cancer Centers" by the National Cancer Institute. The criteria for being designated a "Comprehensive Cancer Center" (CCC) include mandatory multidisciplinary team

(MDT) meetings, meeting specific designated care standards *etc.*, in such an environment it may come as no surprise that these hospitals showed more improvement. There was, however, little change reported amongst other hospitals. The CCC designation is made above and beyond the standard criteria required for status as a Cancer Centre. This is primarily made on the depth and extent of the research performed and the education provided by the institution (NIH, 2012). Those with CCC designation have demonstrated an integrated programme of research and education; it is perhaps therefore no surprise that they out-perform other centres. The UK designation of "Cancer Centre" requires many of the same criteria, *e.g.* MDT meetings, specific care standards, however, there is no requirement for research or any specific requirement for what form the on-going education should take. Linking education to continued practice is not new (Continuous Professional Development / Continuing Medical Education), and is a requirement for practice both as a BMS or pathologist (HPC, 2012; RCPath, 2010). Thus, developing and incorporating a structured method for determining how close to best practice an individual is working, and providing feedback, would fit within both EQA and CPD/CME. BMS are registered and governed by the Health and Care Professions Council (HCPC (previously the Health Professions Council, HPC)), who state that registrants must undertake CPD to maintain their registration. The IBMS provide a CPD scheme, enabling BMS to meet this requirement. The IBMS CPD guide encourages "professional activities with recognisable outcomes and benefits," (IBMS, 2014a) the use of KPIs to demonstrate and maintain quality clearly has recognisable outcomes and benefits. Pathologists are licensed and governed by the GMC, who stipulate that doctors registered with them must "keep [their] professional knowledge and skills up to date" and recommends that CPD is an appropriate way of doing this (GMC, 2012; GMC, 2013), the Royal College of Pathologists runs its own CPD scheme, enabling pathologists to meet this requirement. The RCPath CPD scheme makes specific note of the need for "maintenance of the reputation of the profession and assurance to the public", along with the recommendations from the Barnes report (detailed later), this clearly highlights a need for KPIs to be collated and actioned.

The literature supporting the notion of standardisation of dissection practise in this thesis is presented primarily from the perspective of lymph node sampling as the decision made on the number of lymph nodes required by the RCPath is possibly the most evidence based. The notion of stipulating a minimum number of lymph nodes began when Scott and Grace (1989) demonstrated a method of ensuring all the lymph nodes were recovered and examined. Scott and Grace collected data from 103 colorectal carcinoma specimens, traditional dissection methods yielded a mean 6.2 nodes whereas further sampling gained a further 12.4 nodes. These additional nodes showed tumour positivity in 5% of the cases which were initially reported as lymph node negative. Their data showed that when significantly more nodes, and more involved nodes, were found for each resection this resulted in upstaging of the tumours in 5% of the cases. The data analysis resulted in the recommendation that a minimum of 13 lymph nodes be sampled, forming a foundation for the later minimum number (12) given by the RCPath. Kim *et al.* (2007) determined that there was minimal added value to the extensive search for nodes, once 12 nodes had been found. Their conclusions suggested taking additional samples if no positive nodes were found, but if at least 12 nodes had already been found and at least one was positive, no further sampling was required. However, this recommendation of further sampling in the absence any positive nodes failed to make it into the RCPath guidelines (Quirke and Williams, 1998).

Therefore, we can see that the recommendations for sampling of lymph nodes is clearly evidence based, the standard of a minimum of 12 being based on a wide and rigorously tested set of published data. The other standards, relating to TME score, the size of the tumour, perforation of tumour, the distance of the tumour to the nearest surgical margin etc. are built on a similar foundation, although the RCPath do accept that evidence base is not as extensive

(RCPath, 2014a). The numerical data standards (number of lymph nodes) are easily assessed; other standards, such as adequacy of tumour sampling, are less easily judged. The distribution of tumour staging for different types of tumour is not available in any published format, an omission noted in the RCPath minimum dataset (RCPath, 2009). However, some data has been obtained in this area though freedom of information (FOI) requests and local data (Figure 1, below). This is currently unpublished, but does indicate that there is a broad concordance of stage at presentation.

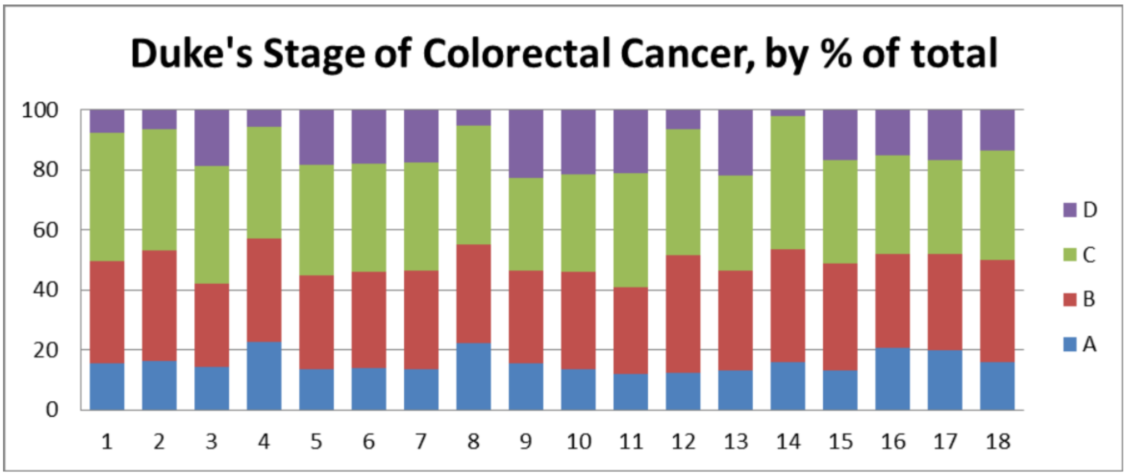


Figure 1 - Graph showing stage of colorectal tumour at presentation (Duke's staging). 2009 data, from 18 different cancer networks – data obtained via Freedom of Information Requests from the North Yorkshire Cancer Network.

Whilst some variation is apparent, it is evident from the data presented in Figure 1 (above) that there is a broad constancy across cancer networks. Some variation in staging would be expected nationally, as there is in the incidence of various cancers across England, Wales & Scotland (Cancer Research UK, 2012). Using the microscopic staging of the tumour allows another possible quality measure, as the accuracy of the diagnosis relies on the quality of the dissection (Ludeman & Shepherd, 2006). Comparison of staging between individual dissectors should show broadly similar proportions, as each is working with a similar pool of samples. If any individual within a group of dissectors, who are all working with the same pool of samples, shows a staging profile that differs from that of their peers, this would demonstrate a variation in practice worth investigating.

Using a rolling mean of tumour staging of resections begins to provide a dissection practice profile. Adding further evidence based data points to this would allow a clearer picture of individual practice to be seen. Another measure detailed in the RCPath minimum dataset is the frequency of extramural venous invasion; again, no published data is available in regard to this. A comparative analysis between individuals would allow some discussion as to quality of practice. There are a number of studies which indicate the importance of accurate assessment of vascular invasion, and its prognostic significance. Stefansson *et al.* (2004) examined 237 endometrial cancers and were able to report that vascular invasion is a strong prognostic factor, independent to the stage or grade of the tumour. Westenend *et al.* (2004) investigated 50 cases of breast cancer, they reported that tumour size and vascular invasion were the most important prognostic factors. Whilst there is a recommendation that pathologists audit the number of cases which they report as showing vascular invasion, there is no suggestion that dissectors should do similar. Personal experience and anecdotal evidence shows that poor practice can lead to the appearance of vascular invasion; therefore, this is another possible area for comparison.

Building on the clear and extensively published area of lymph node clearance, it should be possible to create similar clear guidelines regarding other quality standards for pathological dissection noted above. However, as Shia *et al.* (2012) reviewed the current state of practice and guidelines in relation to lymph nodes in colorectal cancer. They noted that whilst the lymph node yield showed little variation based on surgeon, there was notable variation based on the pathologist; this was echoed by Shaw *et al.* (2008) who correlated a higher standard of colorectal surgery with specialist colorectal surgeons than general surgeons and a higher lymph node yield with BMS than pathologists. They note that although the College of American Pathologists recommends resampling the resection if less than 12 lymph nodes are found, this seldom happens. Bilimoria *et al.* (2008) examined reports for 156789 colorectal cancer resections across the USA. They reported that 60% of hospitals failed to achieve a benchmark of 12 lymph nodes.

Shaw (2008) reports that less than 12 lymph nodes were found in 54% of the 1,194 cases they examined. Clearly, having guidelines in place does not mean that people will follow them or reach the standards detailed in them. There are a number of ways in which poor performance, or a change in expectations, can be managed. Mesmer-Magnus and Viswesvaran (2010) detail an extensive review of training methodologies, concluding that what they refer to as the "Why?" method is a particularly effective method. This methods causes the individual to move their attention from the details to the underlying process and back in a fluid manner. They detail a method of training primarily aimed at untrained individuals in which the trainee is encouraged to ask why certain things are done, or not done, in order to fully understand the process and their part in it. This is certainly something that is targeted to those in training; however, those who are already trained, but who take part in on-going training, CPD or reflective learning would also stand to benefit.

When considering the assessment of ongoing competency and performance it is worth considering the current state of initial training. The process currently in place for training BMS and pathologists in dissection is based entirely on local protocol. In a wider medical context one of the strongest assessment tools currently in place is the Objective Structured Clinical Examination (OSCE), this is used in several aspects of medical training. Newble (2004) goes in to some depth regarding the strengths of this method. The OSCE is becoming increasingly popular with time; however, it is used as an assessment during or at the end of training and has not been evaluated as an on-going tool. Whilst it could certainly be employed in such a role, the time involved in making such an examination would render it likely to be only done infrequently and a pronounced "observer effect" might be expected. Beard *et al.* (2005) indicate how such procedures may be used to identify when failings are due to a lack in technical knowledge, but note that poor performance on a routine basis would not be identified. Currently no suitable tool for on-going assessment / monitoring has been published, a lack that this work goes some way to address.

West (2005) and Syred (2005) provide an excellent breakdown of some of the problems faced by medical trainees in pathology. West published a mini symposium on training in histopathology where he discusses the demands placed on trainee histopathologists, and on the departments training them. The article by Syred should be read in concert as it is written across much the same topic, although from the point of view of the trainee. Many of the same problems are now being faced by BMS staff in their histology training; since much of the work has already been done, it would be foolish not to take advantage of this. The challenge we now face is in convincing an already pressured consultant pathologist workforce to take on a structured programme, rather than the *ad hoc* system currently employed in most places. Cross (2005) has written a good exposition on some of the more important qualities and character traits one may need as a histopathologist, as a BMS dissector many of the same will apply. His work may be very useful when considering how to structure training and feedback. He also considers the assessment methods used, some of which may be modified for the BMS role. He considers many possible methods of aptitude testing and draws comparisons with other professions, most of these comparisons have been made in surgical research literature. He considered skills such as manual dexterity, intelligence, visuospatial ability and personality traits, concluding that these specific traits, and combinations of traits, showed no specific association with performance or aptitude to surgical procedures. This data is gathered from a pool of skilled individuals, therefore their skills and aptitude may be considered to be greater than that in the general population; his work was considering aptitude testing and noted that there was no specific method that was able to accurately identity a particularly high aptitude for surgical skills, beyond the baseline demonstrated by the cohort. He determines there are currently no appropriate aptitude tests for histology and that the development of these would be of benefit to histology. The areas that Cross identifies as important for a practicing histologist are knowledge base, report generation, communication, clinical governance, audit, continuing professional development, laboratory management and macroscopy. He also states the objective assessment is the “holy grail” of assessment. Cross notes a number of areas where performance needs to be assessed (Table 2, below).

Table 2 - Performance assessment areas (from Cross, 2005)

Diagnosis by light microscopy	Not applicable to BMS, pathologists assessed by review, examination and EQA.
Diagnosis by other modalities	This would include macroscopy, specimen dissection, and has no form of assessment beyond gateway examinations.
Knowledge base	Assessed well by the appropriate pathological qualifications for both the BMS and pathologist.
Report generation and checking	These are reviewed by the reporting consultant, and by the requesting clinician. For the BMS the report is limited to a report of the macroscopic appearance, which may show characteristic features giving an indication of the diagnosis.
Communication with colleagues	Historically undervalued, but these are now being assessed as part of performance reviews in many centres.

Learning Theory

When considering performance, performance assessment, performance management and training interventions, it is useful to be aware of current learning theory. Torre *et al.* (2006) cover the main learning theories, in a context of medical education. They postulate that different goals require different theoretical approaches Within the area of surgical pathology dissection training we have three main goals; learning a new skill, developing critical thinking and clinical problem solving skills, initiating best practice in a clinical setting. Torre *et al.* suggest that these goals are best met by a behaviourist approach, a cognitive approach and a social learning approach, respectively.

Behaviourist learning focuses on the satisfactory performance of pre-requisite steps, prior to advancing on to subsequent tasks. This requires reinforcement from the teacher / trainer, who is central to this process. The learner models the behaviour demonstrated by the teacher, who is able to provide assessment of competency. The cognitivist approach uses the teacher to help the learner to develop the skills needed to develop their own learning. Enabling the learner to develop their knowledge and apply this to what they already know allows for meaningful applied learning. This integrates with the work of Mesmer-Magnus and Viswesvaran (2010), discussed above. Mesmer-Magnus and Viswesvaran detailed an approach whereby learners were encouraged to question why things were, or were not, done in certain ways. This questioning and investigation into theory and process clearly fits into a cognitivist model. This critical and reflective thinking is crucial to specimen dissection, moving beyond a simple stepwise process and applying critical judgement to a specimen is a necessary aspect of training in more complex work. The initial training in dissection can easily sit within the behaviourist approach, where training follows a pattern of "watch and repeat". However, moving away from simple specimens where the handling is very similar each time, to complex cases which much be closely assessed on its own merit, requires the application of clinical judgement, extensive knowledge of pathology and surgery. In order for this to be possible the learner must have a much greater depth of knowledge and skill base than would be possible with just a behaviourist approach. The social learning model seems largely to be an expansion of the behaviourist theory. The difference is that with social learning the observation is seen as the key learning feature, without a necessary step of repeating what has been observed. The learner is able to reproduce the learned behaviour / technique because they have evaluated and gained a cognitive insight into what they have observed, and is not merely copying what is highlighted as "good" behaviour. However, this does require a baseline of knowledge and practice in order to provide a framework in which this knowledge can sit.

A fourth area which Torre *et al*. (2006) discuss is constructivist learning. Constructivist learning is facilitated by the educator, who fosters critical reflection and helps to develop meaning from experience. The IBMS strongly promotes reflective learning in their dissection portfolios (IBMS, 2009; IBMS, 2010a; IBMS 2010b) and their CPD scheme (IBMS, 2014b). Colliver (2002) publishes what amounts to a wholesale dismissal of constructivism as anything other than a philosophic stand point. He concludes that constructivism "offer[s] little of value to medical education". However, Cobb (2002) rebuts all of Colliver's points, expanding on the meaning and application of constructivism and highlights Colliver's lack of questioning of assumptions. Cobb concludes that "constructivism might be of greatest relevance to educators", this appears to be a more widespread opinion.

Torre *et al.* (2006; 2007) provide an explanation of how reflective practice may be performed in a medical context, in a way which is easily applicable to specimen dissection, and details what may be gained from such an approach. They also note that their method of documenting their reflective learning leads well into group work. Bennett *et al.* (2002) provide a review of small group teaching, where they note that explaining material to another party is one of the most effective means of cognitive elaboration. Their review is comprehensive, covering aspects such as the composition of the group in terms of gender and ethnic mix (which appears to make little difference) ability (mixed ability shows most improvement for most people) and group size (6 learners and a facilitator appears to be the optimum number).

Bennett goes on to consider the practical considerations of group work, being in a circle, encouraging participation, supporting those that do not feel comfortable to speak up, ensuring a safe space, rewards and the perils of "social loafing", They note that well-functioning group work enable participants to "make overt their private speech". This enables those operating at a lower cognitive level to understand the thought process of those operating at a higher level and allow them to apply this model to their own thinking.

The research above clearly shows that there are many evidence based standards of practice, and that many people are failing to meet these standards. Having identified the veracity of the evidence base for and need for these standards, and having identified the failure to meet these standards, how do we then address this? The evidence in the area of learning theory provides us with an insight into how we might best approach the educational deficits in our practitioners. However, what is needed is not just education, there needs to be a change in practice. Creating and sustaining a change is a multifactorial process, which comes under the heading of change management.

Change Management

Change management is an extremely large area, one that forms its own subspecialty within project management (Crawford and Nahmias, 2010). We only need look at how much resistance there was to Semmelweis and his ideas about infection control (Scholl, 2013; Persson, 2009) to see how a badly handled attempt at change can backfire. Semmelweis noted a correlation; the knowledge of germ theory, infection and hygiene at that time was insufficient for Semmelweis to present a cogent argument behind why hand washing reduced infection. This, coupled with his somewhat dictatic style, led to a great deal of resistance. Very few were prepared to even try Semmelweis's idea of washing, this was a greatly wasted opportunity, and many more patients went on to die because of this lack of team approach to change. Organisational change and shifts in attitude/culture are needed to effect lasting change (Crawford and Nahmias, 2010). Ho *et al.* (2010) examined episiotomy procedures in 11,016 women, with the aim of decreasing unnecessary surgery. They described how after concluding their research they realised that a change in practice was needed. They go on to explain how they attempted to bring this change about and some of the difficulties they encountered. Most of the resistance was related to a reluctance to change from their current method, despite evidence to show this was not best practice. Being able to demonstrate the evidence to those who they wished to change was critical. Demonstrating how they came to their conclusions, discussing the reasons for the suggested change and listening to the concerns of those involved was critical. The most successful method of change reported by Ho *et al.* (2010) was in cases where the staff had been part of research projects that investigated the change proposed. Active engagement of staff, allowing them to evaluate the evidence were key aspects. This is echoed by the comments made around the research of Pronovost (2006) detailed later in the literature review. The training intervention which is to follow this literature review will be structured with these concerns in mind, drawing on research in medical practice, change management, and behaviour management.

Lim *et al.* (2012) discuss an interesting study based in the area of mental health workers and evidence based practice (EBP). They ran a series of workshops during which they examined a number of methods and practices, went through with participants (n=238) whether or not these were evidence based and explained the implications of these aspects. The participants were found to have a more positive attitude towards EBP at the end of the workshops. With this and the preceding paragraph in mind, the proposed method will be developed in conversation and negotiation with active staff members. Attempting to impose a quality system on reluctant subjects is unlikely to result in long term success.

Chisholm *et al.* (2012) investigate why some medical professionals (of varying experience levels) are less likely to engage in "behaviour change" discussions with patients. A similar attitude may be seen when it comes to behaviour change discussions with colleagues. The three primary reasons were listed as personal challenges, "someone else's responsibility" and prioritising the doctor – patient relationship. The first two clearly apply across a wide range of situations, the third is less relevant outside the clinical situation, although parallels may be drawn in prioritising professional relationships. Addressing these requires providing the right environment; if people feel valued for their work and contribution they are more likely to feel positively in regard to personal and professional development. If there are particular interpersonal difficulties regarding communication or addressing performance issues, these should be addressed regardless of any training or feedback event, however these issues are frequently pushed aside as it is often easier to work around these issues than to address them. Fostering this supportive and collaborative environment will go a long way towards addressing these issues.

There are key lessons to be learnt from Chisholm, if we are to engage in changing attitudes and behaviours. The most important thing she reports is that people are more likely to engage in such discussion if they have had some form of formal training in the theory behind behaviour change techniques. Drawing on this may help with the current work, finding key personnel and enabling them to undergo such training could help with engagement and dissemination of findings and recommendations. If we are able to demonstrate a robust quality monitoring and feedback system, we shall be reliant on others to deliver it elsewhere. As such, we must also provide some form of instruction on how to implement these changes.

One intervention making use of KPIs and dealing with behaviour change demonstrated startling effectiveness. Pronovost *et al.* (2006) set out to determine whether central line related blood stream infections in Intensive Care Units (ICU) could be reduced. They developed a Team Checklist, centred on five evidence based infection control procedures. This was a multicentre trial, where hospital participation was optional. When a hospital opted in, the use of the checklist within the ICU was mandatory for all staff involved in the placing of central lines. A number of training and educational interventions were planned, training staff in the science of the safety measures. If the individual placing the central line was not following the approved procedure, any team member was authorised to stop the procedure (in non-emergency situations).

The removal of lines was discussed at daily rounds, the number and rates of infections were regularly reported back to the team. The final version of which contained 20 items and is credited with a reduction in the rate of catheter-related bloodstream infection of up 66% sustained over the course of the 18 month study.

Checklists have been widely used in safety critical environments, notably aviation – the first published instance being in Life magazine (Anon, 1942). Since then there have been a number of attempts to bring checklists as a safety feature into the realm of healthcare. These continue to the current day, Ornato and Peberdy (2014) note the need for healthcare practitioners to respond in a consistent, high quality manner. Whilst they are talking in relation to emergency situations, this is clearly relatable to routine practice. They note the 2000 fold reduction in fatalities per million flight miles since 1929, and attribute this to the insistence on standardised procedures regardless of who is on the team. Kao and Thomas (2008) also strive to apply lessons from aviation into healthcare, specifically surgery. They note an intervention that reduced the incidence of wrong site surgery to 0, they also refer to a number of studies that state such interventions improve the safety climate and clinical outcomes. Pugel (2015) notes the number of errors in the operating room, and relates that communication errors are a common form of error. Dhingra (2010) backs this up, stating that 70% of serious events reported by the Joint Commission are due to communication errors. Pugel (2015) also discusses some of the drawbacks to checklists. Pugel notes that previous safety checks may be dropped and that the checklist can interrupt the performance of other safety tasks. She also states that without a firm commitment to the checklist it may become a routine activity of checking off boxes without actually driving behaviour change or improvement and that checklists may give staff a false sense of security that issues have truly been resolved when in fact they have not

However, they note that the checklist is in fact part of a much larger intervention. They characterise the checklist as the scaffolding on which teamwork and attitudes can be improved and managed. This is something that is often overlooked. One extremely powerful intervention was that mentioned above by Provonost *et al*. (2006). The ten-day line-infection rate went from

11% to zero. The reporting around this focused extensively on the checklist (Gawande, 2007; Lawrence, 2009; Seifert, 2009; Kingsbury, 2008). Whilst each of these reports makes some effort to explain the intervention around the checklist, it is clear that the checklist is given centre stage. This was noted by the authors, who published an update, giving greater emphasis on the surrounding parts of the intervention (Bosk *et al.,* 2009).

Whilst the checklist was not the only factor in the intervention detailed by Pronovost *et al.*, it is the central point around which the other factors revolve. Checklists have received considerable interest in medicine since their paper. After discussing the applications of aviation lessons to surgery, Kao and Thomas (2008) go on to discuss some of the differences. They note that when compared to pilots, surgeons tended to downplay the effect of stress and fatigue on decision making. Senior surgeons tended to prefer a rigid hierarchical structure, where junior members of the team do as instructed without question. Ornato and Peberdy (2013) support this conclusion, highlighting a difference in attitude between pilots and surgeons. They note that pilots recognise that permission to fly is a privilege, not a right and that this permission can be easily withdrawn. They also note that with pilots their own lives and safety are dependent upon the function of the team, whereas in surgery the only life at risk is likely to be that of the patient and the surgeon will take the majority of responsibility for the success, or not, of the surgery.

Sexton *et al.* (2000) reported that out of consultant surgeons, consultant anaesthetists and pilots there was a wide difference in who would acknowledge the effect of fatigue on performance (30%, 53% and 74%, respectively). Additionally, only 55% of consultant surgeons recommended a flat hierarchy in contrast to 94% of cockpit staff. Kao and Thomas (2008) suggest that approximately 25% of errors may not be admitted in morbidity and mortality.

Further investigating the attitude of surgeons, particularly in relation to checklists, Bosk *et al.* (2009) state that some feel that the checklists undermine their claims to expertise, are infantilising and impede their decision making. There is a clear difference here between the attitude of the pilots, who accept the need to satisfy requirements to prove their competence whereas many of the surgeons resent and resist attempts to introduce similar requirements. Within the Keystone intervention reported by Pronovost *et al.* (2006) and further expounded upon by Bosk *et al.* (2009), there was a large social aspect to the intervention, with the implementation phase lasting 9 months. Additionally, a member of the senior executive within each hospital had to agree to work with their ICU; a senior physician and senior nurse were also identified, along with team leaders who were tasked with explaining the principles of safety, the specifics of the investigation and the evidence base. The explanation of the evidence base is something that Ho *et al.* (2010) identified as a key factor in driving behaviour change.

Clearly this was an investigation far greater in scope than the introduction of a checklist, indeed it was not one single checklist. There were in fact over 100 different checklists. Each ICU was encouraged to take the template checklist and adapt it according to their own needs, but keeping within the needs of the investigation and the demands of the evidence (Bosk *et al.*, 2009).

There is an extensive body of evidence indicating the rationale behind the practices undertaken in diagnostic pathology, there is also a large body of evidence indicating the need for and importance of EQA. This review establishes both the need and the basis for a quality system, which would ideally integrate with the training programme for Biomedical Scientists and Pathologists involved in specimen dissection. It may be hoped that validation of such a scheme in one area might form the basis for further work within Histopathology and the wider Pathology field as is clearly needed.

Chapter Two – Study 1 – Review of Recent Practice

Study 1 – Archival Review

100 appendix, 100 gallbladder, 100 colon, 100 uterus reports reviewed

Unknown number of participants

Study 2 – The Training Intervention

Part One – The creation of the checklists and collecting baseline data

Part Two – Checklist Introduction (BMS N=5, Pathologist, N=7)

Part Three – Training Event and Checklists (BMS N=5, Pathologist, N=7)

Part Four – Training Event only (BMS N=5, Pathologist, N=7)

Part Five – Guide Diagrams (BMS N=5, Pathologist, N=7)

Part Six – Training Event and Guide Diagrams (BMS N=5, Pathologist, N=5)

Part Seven – Checklists only ((BMS N=5, Pathologist, N=0)

Part Eight – Training Event and Checklists (BMS N=6, Pathologist, N=8)

Study 3 – Participant Interviews

The dissectors were interviewed

BMS n=6, Pathologist n=4

Introduction

In order to investigate the level of variation in practice within the Royal Derby Hospital Histopathology Department, a retrospective review of practice was undertaken. A number of points were addressed, noted below in the procedure section, and these were completed against authorised reports from the preceding year.

This allowed a picture to form, regarding how frequently different features were noted or criteria met, at this stage only BMS or pathologist was noted, to investigate any differences between the two groups. The aim at this initial point was to explore the possibility of identifying data in the reports that could be mapped to good or bad practice. The Royal College of Pathologists minimum dataset and tissue pathway documents, along with the dissection SOPs in the department were reviewed, in order to identify the important points that ought to be mentioned in the description. Also, a number of macroscopic features of pathological conditions were considered. This was to enable some measurement of how frequently individuals were identifying these features, with the idea that this might enable some assessment of how accurate the description was.

Method

Design

An audit into the dissection processes performed in 2009 – 2010 was performed.

Participants

Individual participants were not personally identified at this stage, however, there were 18 practicing dissectors at this time (10 pathologists and 8 BMS). As the individual reports were examined, the dissector of that specimen was noted as either BMS or pathologist only.

Materials

Four data collection sheets were created (

Appendix Three – Baseline Data Collection Sheets, page 206), to capture data specific to the specimen type being considered. The specimens examined were appendix, gallbladder, uterus and colon. These were chosen as they represent an increasing level of complexity, whilst being within the scope of BMS dissection. Appendix and gallbladder are relatively straightforward specimens, with a limited range of presentations. The uterus and colon are of varying complexity and have a wide range of presentations, making dissection a more complex and multilevel activity.

Procedure

Ethical approval was granted by the University of the West of England Ethics Committee (UWEEC). The National Research Ethics Committee (NRES) determined that this investigation did not require ethical approval under their scheme. The Derby Teaching Hospitals NHS Foundation Trust (formerly the Derby Hospitals Foundation Trust) were satisfied with the ethical approval granted by UWEEC and the statement from NRES and gave their approval for this investigation to proceed, having registered the investigation with the trust R&D department. This covered study 1 and 2; study 3 required separate approval which is detailed in Chapter 4.

The pathology Laboratory Information Management System (LIMS) archive was searched, identifying 100 appendix, gallbladder, uterus and colon specimens from 2009 – 2010. The pathology report for each was checked against the data collection sheet and the sheets were structured as follows.

- All specimens
  - Time from receipt to dissection (working days)
  - Need for extra investigations (*e.g.* levels, Immunocytochemistry)
  - The status of dissector (*e.g.* Pathologist or BMS)
  - The number of blocks
  - Pathological staging under the TNM classification (for cancer cases)

- The need for and number of extra blocks
- A record of any errors in the macroscopic description
- Whether the manner of dissection and macroscopic description allows the minimum dataset to be completed.
- If there is agreement between the macroscopic description and the microscopic report.

Additionally, the macroscopic description was reviewed and more specific data was logged for each specimen type. These data points are all mandated by the Standard Operating Procedure (SOP), some are specifically required by the relevant minimum dataset. As such, if a feature is present it should be recorded; there is no requirement to record the absence of such features. The criteria marked in bold should return at 100% for all cases, as this mandatory information required by the SOP for that specimen. There is no expectation that the other criteria should return a specific value, simply that as all the dissectors are drawing their specimens from the same pool, theoretically working in the same manner, a similar value should be seen for each criteria for each group.

- Appendix
    - **Length**
    - **Diameter**
    - Serosa, exudate, perforation, mucin, fibrosis, faecolith, pus
    - Appearance suggestive of carcinoid / neuroendocrine tumour
    - Normal / unremarkable appendix
- Gall Bladder
    - **Length x width x breadth (or diameter)**
    - **Whether the specimen was received open or unopened**
    - Serosal surface, the contents of the lumen, the presence or absence of choleliths (gall stones) and their type, the presence of an exudate, the presence of a perforation
    - Fibrosis, mucin, the thickness of the gall bladder wall, mucosal polyps, mucosal cholesterolosis, empyema, Rokitansky-Aschoff sinuses, cystic duct lymph node, the mucosa
    - Any suspicion of a more serious underlying pathology

- Hysterectomies
    - The presence of fibroids, the appearance of the serosal surface
    - **The thickness of the endometrium**
    - **The appearance of the myometrium**
    - The presence of adenomyosis, the presence of endometriosis
- Colorectal
    - **Full measurements**
    - **Background mucosa described**
    - Polyps, diverticulae, ulceration, fissuring, loss of mucosal fold pattern
    - Thickening / thinning of wall, oedema, congestion, exudate, perforation

A sample of the data sheets were reviewed by an independent third party to check for accuracy. The data was transcribed on to an excel workbook, and the sheets shredded. Confidentially and data protection was maintained by following NHS Information Security Policy (NHS England, 2014a). All electronic records were kept within the NHS computer system within a password protected system, any paper copies were kept within a locked cabinet within a locked office, prior to shredding. No identifying characteristics for either staff or patients were carried over on to the data collection form, only a record of BMS or pathologist was made.

Results

The tables below show differences in practice between the two groups, whilst the true value for any category is not known, it is reasonable to suppose that both groups of dissectors are likely to encounter the same range of specimens, with the same pathological distribution, and therefore ought to return similar values for each category. Certainly each of the criteria marked in bold above ought to the noted at 100% for each group. For example, the RCPath tissue pathway for Gastrointestinal pathology (RCPath, 2009) indicates that the length and diameter of the appendix should be stated, also that the external surface, cut surface and luminal contents should be described. As the laboratory SOPs are based on the guidance from the college, and the dissection training is based on the SOPs, all of these things should be described, where present. Therefore the criteria in bold should be at 100% for both groups, and the other criteria should be at a similar level for both groups.

As was noted extensively in the literature review, variation in practice reflects poor patient outcomes (ACOG, 2012; Dhingra, 2010; Coombs, 2009; Ferran, 2008). As such, methods of identifying this variation, assessing the root cause, and providing an opportunity to reduce this variation, must be developed. This initial review provides an opportunity to assess practice and identify what, if any, variation is occurring.

t – test

The results were analysed with a t-test. As the data is in matched sets, each of the variables applying to both groups, the two columns were paired and a t-test run to consider the differences. As it is the differences in practice between each group, for each variable that is important, the standard deviation between the variables is calculated and this is used for the t-test. As these are small data pools, using the small areas of change are powerful, as such it would be unwise to make too many firm conclusions from the initial exploration, however, this basic statistical assessment allows for some initial impressions to be formed. Using a 95% confidence interval to assess significance, the results are then discussed below each table.

Table 3 - Recent practice in appendix dissection

	BMS (n=61)	Pathologist (N=39)	% difference
Time from receipt to dissection (working days, mean)	0	0	0
Need for extra investigations (*e.g.* levels, ICC)	0%	0%	0
The number of blocks (mean)	1	1	0
The need for and number of extra blocks	8.2%	5%	-3.2
A record of any errors in the macroscopic description	0	0	0
Whether the manner of dissection and macroscopic description allows the minimum dataset to be completed.	NA	NA	0
Whether the following are described in the macro:			
Length	100%	100%	0
Diameter	91.5%	69.0%	-22.5
Serosa	59.1%	51.7%	-7.4
Exudate	30.9%	13.8%	-17.1
Perforation	12.7%	6.9%	-5.8
Mucin	0%	0%	0
Fibrosis	1.4%	3.4%	+2
Appearance suggestive of malignancy	0%	0%	0
Faecolith	4.2%	10.3%	+6.1
Pus	1.4%	0%	-1.4
Diverticula	1.4%	3.4%	+2
Normal / unremarkable appendix	9.9%	34.5%	+24.6
If there is agreement between the macroscopic description and the microscopic report.	100%	100%	0
t = 0.579, df =17, p = 0.012			

Whilst it would be unwise to place too much significance on data from such a limited pool, the data above does demonstrate noticeable variation between BMS and pathologists. Several discrepancies are identified, most notable are the discrepancies regarding the description of the appendix as normal and the provision of the measurement of the diameter. These will be considered in the discussion section

As all data is pulled from the same pool, a paired two tailed t-test is most appropriate. Performing a paired two tailed t-test shows a statistically significant difference in the % differences between the two groups ($p=<0.05$) overall. There is a clear difference in some areas of practice, which indicates that this is an area requiring further investigation. Whilst the dissectors are human, and humans are individuals, these simple straightforward specimens ought to be handled in a near identical fashion. The fact that so much low level variation is noted is a cause for concern, and certainly makes the case for further work.

Table 4 - Recent practice in gallbladder dissection

	BMS (n=69)	Pathologist (N=31)	% difference
Time from receipt to dissection (working days, mean)	0	0	0
Need for extra investigations (*e.g.* levels, ICC)	1.4%	0%	1.4
The number of blocks (mean)	1	1	1
The need for and number of extra blocks	0%	3.2%	-3.2
A record of any errors in the macroscopic description	0	0	0
Whether the manner of dissection and macroscopic description allows the minimum dataset to be completed.	NA	NA	
Whether the following are described in the macro:			
Length	100%	100%	0
Width	98.5%	80.6%	17.9
Depth	56.5%	29.0%	27.5
Received open / unopened	29.4%	19.4%	10
Serosal surface	14.7%	3.2%	11.5
Luminal contents	94.1%	87.0%	7.1
Presence or absence of stones	97.1%	93.5%	3.6
Type of stones (if present)	5.1%	0%	5.1
Exudate	0%	0%	0
Perforation / incision	7.4%	3.2%	4.2
Fibrosis	4.4%	0%	4.4
Mucin	2.9%	0%	2.9
Wall thickness	100%	12.9%	87.1
Polyps	2.9%	0%	2.9
Appearance suggestive of cholesterolosis	13%	9.7%	3.3
Empyema	0%	0%	0
Rokitansky-Aschoff sinuses	0%	0%	0
Cystic duct lymph node	3.1%	0%	3.1
Suspicious of malignancy	0%	0%	0
Mucosa	97.1%	25.8%	71.3
If there is agreement between the macroscopic description and the microscopic report.	100%	100%	0
t = 0.026, df=25, p = 0.021			

As with the data from the appendix, this is a small pool. However, two large discrepancies are seen; the mucosal appearance and the wall thickness show a very large disparity. This will be further considered in the discussion section. A significant difference is noted in overall practice, as are several substantial individual differences, provision of a description of the mucosa being the more notable (97.1% vs 25.8%).

Table 5 - Recent practice in colon dissection

	BMS (n=46)	Pathologist (n=54)	% difference
Time from receipt to dissection (working days, mean)	1	2	-100
Need for extra investigations (*e.g.* levels, ICC)	1%	1.5%	-0.5
The number of blocks	18	18	0
Pathological T staging under the TNM classification	2.81	2.7	0.11
The number of lymph nodes recovered	16.1	9.5	170
The incidence of requests for extra blocks	3	1	300
A record of any errors in the macroscopic description	0	0	0
Whether the manner of dissection and macroscopic description allows the minimum dataset to be completed.	100%	100%	0
Whether the following are described in the macro:			
Full measurements	37.5%	27.0%	10.5
Background mucosa	46.3%	30.4%	-15.9
Polyps	8.7%	7.4%	1.3
Diverticula	15.2%	20.4%	-5.2
Ulceration	4.3%	22.2%	-17.9
Fissuring	4.3%	1.9%	2.4
Loss of fold pattern	4.3%	13.0%	-8.7
Thickening / thinning of wall	6.5%	11.1%	-4.6
Oedema	2.2%	13.0%	-10.8
Perforation	0%	7.4%	-7.4
Serosal puckering	0%	9.3%	-9.3
Exudate	2.2%	5.6%	-3.4
Agreement between the macroscopic description and the microscopic report	100%	100%	0
t = 0.327, df = 20, p = 0.116			

The review of the colorectal specimens shows conformity between BMS and pathologists in all areas, with the exception of lymph node yield. As previous studies have already demonstrated a higher lymph node yield with BMS dissection, this does not come as a surprise. The majority of the items in Table 5 on page 50) relates directly to the visual macroscopic features or numerical data (number of lymph nodes, number of blocks); however, one feature of the microscopic report is also correlated here – the T stage of the TMN classification. This has been done to assess distribution of mean staging. Acting on the premise that all dissectors are taking specimens from the same pool, they can be expected to encounter a similar distributions of tumours at different stages. Therefore, if sampling is being performed adequately and appropriately, the mean T stage for each group (BMS and pathologist) would be expected to be similar. A further development might be to plot out the individual TNM profile for each dissector, and compare the rolling plot for each dissector. A dissector with a persistently low N score may correlate with a low lymph node yield, or one with a high T score might correlate with poor dissection technique causing carryover or may be performing more through or more accurate sampling than others.

More interesting than the differences, however, are the similarities. A number of discrepancies are noted in the comparison of macroscopic description, however, no notable discrepancies are seen between the BMS cases and pathologist cases. Although the average BMS lymph node yield is 170% that of the pathologists.

Table 6 - Recent practice in uterus dissection

	BMS (n=86)	Pathologist (n=14)	% difference
Time from receipt to dissection (working days, mean)	1	2	-100
Need for extra investigations (*e.g.* levels, ICC)	1%	0	1
The number of blocks	9	9	0
The need for and number of extra blocks	2%	0	2
A record of any errors in the macroscopic description	0	0	0
Whether the manner of dissection and macroscopic description allows the minimum dataset to be completed.	100%	100%	0
Whether the following are described in the macro:			
The presence of fibroids	39.5%	33.3%	6.2
The appearance of the serosal surface	8.1%	7.7%	0.4
The thickness of the endometrium	85.1%	66.6%	18.5
The appearance of the myometrium	95.3%	93.3%	2
The presence of adenomyosis	22.1%	6.6%	15.5
The presence of endometriosis	0%	0%	0
If there is agreement between the macroscopic description and the microscopic report.	100%	100%	0
t = 0.310, df = 12, p = 0.034			

Review of the hysterectomy specimens does show a number of discrepancies. The need for extra investigations and extra blocks was minimally increased for cases dissected by BMS. This was an extremly small increase and has a minimal impact in terms of additional work performed. This correlates with the work published by Duthie, 2004; they performed an examination in to the quality of impact of BMS dissection. They noted that a larger proportion of cases required extra blocks and levels when the dissection was performed by BMS than by consultant pathologists. They highlighted other studies with lower rates of additional sampling, and suggested that their higher rates may be as they were comparing BMS early in dissection training with experienced consultant pathologists. They suggest that their resampling rates may fall with time, as their BMS become more experienced. This could well account for the lower rates seen in this study, as although there is a mix of experienced and more inexperienced BMS dissectors, it would appear that the BMS dissectors at Derby at the stage of this study were more experienced than those that Duthie assessed, at the time of publication. The larger discrepancies were in the area of endometrial thickness (18.5% lower) and the presence of adenomyosis (15.5% lower); in both cases the provision of data was far lower by pathologists than by BMS; supported by the t-test result.

Discussion

The review of the completed reports enabled an overview of dissection practice to be formed, and how quality measures might be introduced could be considered. As each of the dissectors is randomly drawing their work from the same sample pool, it is reasonable to suppose that they are each likely to encounter a similar range and distribution of pathologies. In this study a number of discrepancies have been identified. The pathologists described the appendix as "normal" or "unremarkable" in 34.5% of cases, in comparison to the BMS who stated this in 9.9% of cases. Whilst it is not particularly uncommon to encounter a macroscopically unremarkable appendix at dissection, it is unlikely that the BMS and pathologists would encounter them with such differing frequencies. Either the BMS are overcalling normal appendix, failing to recognise the normal appearance; or the pathologists are failing to recognise abnormal macroscopic appearances. Or both of these things may be happening, either way, identifying this variation allows the discrepancy to be investigated and for a more accurate description. Another area of variation for the appendix is in stating the diameter of the organ. Clearly there is a difference between an appendix which is 75 mm in length and 5 mm in diameter and one which is 75 mm in length and 25 mm in diameter. The diameter is a measurement called for by the RCPath tissue pathway, and there is no good reason for not including it. The data for study one indicates that the BMS recorded this measurement in 91.5% of cases, whilst the pathologists only in 69% of cases. Similarly, in the gallbladder data the mucosa of the gallbladder was described in 97.1% of cases by the BMS, but only in 25.8% of cases by the pathologist. It is possible that some cholecystectomy specimens may lack visible mucosa, although a statement to the effect ought to be made in the macroscopic description. There is, then, no accounting for those cases where there is no comment in relation to the mucosa. The gallbladder mucosa may show features of cholesterolosis, polyps (either cholesterol or adenomatous) or features indicating a more severe pathology such as dysplasia; or they may appear unremarkable. It is worth noting that whilst dysplasia is clearly a microscopic feature, there are macroscopic signs that ought to be recognised. This can be seen in other areas of the GI tract also, being aware of the features of a Dysplasia Associated Lesion or Mass (DALM) is important even when handling apparently benign material. DALM can show a number of features, including single or multiple polyps, bumps, plaques and velvety patches (Kitis and Maris, 2005). Given the possibility of abnormal appearance, it is customary to make a statement in relation to the mucosa, even if it only to state its apparent normalcy. This variation continues in the colon, although with a smaller gap between the BMS and pathologist groups. The background mucosa of the colon also ought to be described, as a number of pathologies, secondary to the main pathology, may be co-existent and recognisable macroscopically. The pathologists made a description in only 30% of cases and the BMS in only 46.3% of cases. Whilst there is not a significant difference between the two groups, there is no obvious reason why this is not at 100% for both groups, clearly both groups are varying from the recommend procedure. The uterus data also shows some variation between groups. The thickness of the endometrium should be recorded on the macroscopic description, yet the pathologist record this in only 66.6% of cases, and the BMS in only 85.1% of cases. Again, this should be at 100%. There is a normal range of thickness for pre- and post-menopausal women, measurements outside this range are an indication of possible benign or malignant conditions. The presence of adenomyosis in the myometrium should also be stated, this is not mandated by the RCPath, but is part of local protocol, this is noted in 6.6% of cases by the pathologists, and 22.1% of cases by the BMS. Whilst adenomyosis can be detected microscopically, a comment indicating macroscopic signs of adenomyosis would suggest a level of severity beyond that which can only be detected microscopically. Beyond this, the agreed protocol calls for the comment to be made, if the pathologists are not commenting because they feel it is unnecessary, then the same ought to hold for the BMS and the SOP should be amended. It may be that the pathologists are under calling adenomyosis, or that the BMS are over calling, or both; in any case, identifying this variation allows for the discrepancy to be investigated.

Many surgical KPIs are based on patient outcomes (surgical margins, re-operation rates, anastomotic dehiscence, 30 day mortality following surgical resection (Scottish Cancer Task Force, 2014)), these are clearly going to vary greatly depending upon the patients. However, the rates are translatable between surgeons operating within the same pool of patients. A similar principle is applied here, to histopathological surgical specimens – whilst it is not feasible to apply patient outcomes, it is feasible to use the frequency with which anatomical and pathological features are noted as a guide to performance. As there is no managed randomisation of specimens some variation, however, may be expected. In order to help standardise this, the NHS Consultant Outcome Data use Case Mix Adjustment (Radford *et al.*, 2015). As this is an initial work, there is no way to use existing data to model case mix correction into the current work, however, this is something that could become useful in the future.

Derby Hospitals Histopathology laboratory has been, and remains at, the forefront of BMS led dissection. The laboratory and its staff have an international reputation for their skills and knowledge, with some of the most advanced qualifications and practices in the country. Even so, the data above shows a great deal of variation in practice, which is a cause for concern as variation in practice leads to poorer patient outcomes and higher error rates (ACOG, 2012; Dhingra, 2010; Coombs, 2009; Ferran, 2008, Bridgewater *et al.*, 2007). A further study was devised, whereby selected KPIs could be used to monitor and feedback variations in practice.

Chapter Three – Study 2 – The Training Intervention

Study 1 – Archival Review

100 appendix, 100 gallbladder, 100 colon, 100 uterus reports reviewed

Unknown number of participants

↓

Study 2 – The Training Intervention

Part One – The creation of the checklists and collecting baseline data

Part Two – Checklist Introduction (BMS N=5, Pathologist, N=7)

Part Three – Training Event and Checklists (BMS N=5, Pathologist, N=7)

Part Four – Training Event only (BMS N=5, Pathologist, N=7)

Part Five – Guide Diagrams (BMS N=5, Pathologist, N=7)

Part Six – Training Event and Guide Diagrams (BMS N=5, Pathologist, N=5)

Part Seven – Checklists only ((BMS N=5, Pathologist, N=0)

Part Eight – Training Event and Checklists (BMS N=6, Pathologist, N=8)

↓

Study 3 – Participant Interviews

The dissectors were interviewed

BMS n=6, Pathologist n=4

Introduction

Chapter three begins study 2. After analysis of study 1, the results demonstrated that there was considerable variation in practice. As this investigation is predicated on the assertion that variation in practice is undesirable, and leads to worse patient outcomes, study 2 was designed to investigate and attempt to correct this variation.

Study 2 consists of eight parts. Study two, part one expands on the work done in study one by creating checklists to be used at the dissection bench (Appendix Four – Dissection Checklists on page 210). In part one, the checklists are used to analyse recent reports, similar to study 1, in order to establish the feasibility of using these for data collection.

In part two, the dissection checklists are introduced at the dissection bench for the first time. The dissectors, and their assistants, complete the checklists at the point of dissection. The checklists are returned and the data is analysed. From this analysis, there is clear variation in practice between individuals, as seen in the preceding investigation; this leads in to part three, where methods to correct this variation are considered.

Part three introduces a training intervention. This intervention is aimed at highlighting the variation to the dissectors and enabling a group conversation between the BMS dissectors and the pathologists. The checklists remain in place at this point, the training event highlighting their use and utility as a memory prompt and guide. The results from the checklists in this part demonstrated a reduction in variation, but some variation remained.

In part four, the training intervention remained, whilst the checklists were removed. The aim here was to demonstrate the effect of the training event in isolation. In order to identify the factors that were most effective, the training event was run without the checklists, and the checklists were used to analyse the reports of specimens dissected during this period, much as in study two, part one.

Part five marks the introduction of the guide diagrams. An alternative approach to the training event was taken, whereby indicative guide diagrams where introduced to the dissection rooms. The aim here was that the diagrams indicated the key features that they ought to be aware of, and what information was required in the macroscopic report, therefore, both the training event and checklists were removed. The checklists were used to perform a retrospective analysis of the completed reports of specimens dissected during this period.

In part six, the training events are reintroduced. The training events were much missed by the dissectors, whilst the diagrams were not well received by any of the dissectors. The diagrams remained in place for a further round of data collection, along with the re-introduced training event. Once again, the checklists were used to analyse the completed report from this period.

Part seven shows data gained with the checklists only. There have been many changes up to this point, and so a round of data collection using on the checklists was undertaken, to assess any changes since this was last done in study two, part 2.

In each of the preceding rounds, a reduction in variation had been seen, most notably with the use of the checklists and the training event. Therefore, a final round of data collection was undertaken using both of these interventions, to assess how this effected variance in contrast to the last time this combination was run in study two part three.

Study Two Part One – The creation of the checklists and collecting baseline data

Introduction

The checklists were created with reference to the RCPath minimum datasets and tissue pathways (Appendix One – Tissue Pathways and Minimum Datasets, page 203) and local SOPs. For example, as noted above, the tissue pathway for appendix states that the length and diameter of the appendix ought to be recorded, but there were a large percentage of cases where the diameter was not recorded, this was stated as a point on the checklist. Whilst there is no requirement in the RCPath guidelines for a measurement or description of the cervix, it is called for in the SOP based on a local requirement; also the RCPath tissue pathways call for a description of the endometrium, this can be in prose or a measurement of thickness, the local protocol calls for the thickness of the endometrium to be recorded. Both of these criteria were added to the checklists. The checklists were designed to act as a prompt to good practice, as well as a method of data recording.

The checklists were then used to assess current practice by completing the checklists against reports authorised in the previous month.

Method

Design

The analysis of the data sheets allowed a baseline of practice to be established for both groups for the variables stated in study 1. Building on the work of Pronovost (2006), this data collection was followed by the creation of a checklist, based on the discrepancies, minimum datasets, tissue pathways and best practice guidelines issued by the RCPath and IBMS (Appendix One – Tissue Pathways and Minimum Datasets, on page 203). Reports for the preceding month were analysed and checklists retrospectively completed against them.

The checklists comprised a number of criteria that might enable an assessment of performance to be made. The individual criteria is considered to be less important than the ability to identify variance. Whilst some of the specific criteria chosen may be questioned, as may the exclusion of some criteria, the use of these KPIs enables an ongoing review of practice. Subsequent iterations might use different criterion.

Participants

All staff practicing as dissectors with the pathology department participated. The retrospective completion of the checklists involved recording a numerical code for each participant, to maintain confidentiality. Twelve different individuals were identified as dissectors at this stage, five BMS and seven pathologists.

Materials

Dissection checklists (Appendix Four – Dissection Checklists on page 210)

Procedure

The dissection checklists were completed against authorised reports for appendix (n=50), gallbladder (n=50), colon (n=50) and uterus (n=50). Confidentially and data protection was maintained by following NHS Information Security Policy (NHS England, 2014a). All electronic records were kept within the NHS computer system within a password protected system, all paper copies were kept within a locked cabinet within a locked office. No identifying characteristics for either staff or patients were carried over on to the data collection form, a numerical code for the case and the dissector was recorded on the form. This was the case for each subsequent use of the checklists.

The checklists were completed by the Chief Investigator by reviewing the completed macroscopic report and determining whether a criterion had been met, not been met or was not applicable.

Study Two Part Two – The introduction of the checklist

Introduction

The checklists developed and used retrospectively in part one demonstrated the ability to obtain KPI data for individual dissectors. This showed the variation in practice occurring, on an individual basis, however, this showed what had already happened. In order to attempt to reduce the variation at the point of dissection, the checklists were introduced at the dissection bench. The aim of this intervention was to provide a prompt to the dissector, whilst the specimen was on the bench in front of them, whilst also allowing KPI data to be recorded. Affixing the checklists to the specimen request form placed the checklists directly in the sight of the dissector and their assistant, who needed to remove the checklist before dissection could commence.

Method

Design

The checklists developed in part one (Appendix Four – Dissection Checklists, on page 210) were affixed to the specimen request forms for 50 appendix, 50 gallbladder, 50 colon and 50 uterus specimens. The specimens were placed in the usual place for routine dissection.

Participants

All staff practicing as dissectors with the pathology department participated (n=5 BMS, 7 Pathologists). The dissection assistant completing the checklists involved recorded a numerical code for each participant, to maintain confidentiality.

Materials

50 Dissection checklists for each specimen type were attached to the relevant specimen request forms (Appendix Four – Dissection Checklists, on page 210)

Procedure

The dissection checklists were introduced to the staff in a departmental meeting. Their purpose was explained and all staff were asked for their help in completion of the checklists. Both the dissector and their assistant would need to be involved in completing the checklists, and from the literature discussed earlier, regarding checklists and teamwork, it is clear that the checklist facilitates, not drives, the team dynamic.

The dissection checklists were completed by the dissector and / or their assistant for appendix (n=48), gallbladder (n=50), colon (n=43) and uterus (n=48). The specific manner of completion was left to the discretion of the dissector and their assistant. The checklist mandated that the specimen number be recorded, a numerical code for the dissector and the initials of the assistant. In some cases the assistant would question the dissector and record their response, *e.g.* "Have you orientated the specimen?" in other cases the assistant was able to use their own judgement, *e.g.* if the dissector dictates a block key stating that one cassette contains the proximal margin and another contains the distal margin, the assistant knows that the dissector has orientated the specimen. This more informal manner of completion was favoured as the relationship between the dissector and their assistant was quite relaxed and informal, this collaborative approach to the checklist was felt to fit better into the team dynamic. At the end of a dissection sessions, completed checklists were placed in a designated place within the dissection area, for collection by the Chief Investigator.

Study Two Part Three – The training event plus checklist

Introduction

Part two showed a persistent level of variation from both the BMS and pathologists, although less variation was noted from the BMS group. In order to build on the advances found with the checklists, a training / feedback event was designed. The informal group discussions prompted by the use of the checklists up to this point had generated significant interest amongst the dissector group, notable the BMS dissectors. The pathologists were also interested in the output of the checklists and saw an opportunity to engage with the BMS dissectors as a group; efforts to encourage the pathologist to engage with the BMS and other pathologists and a whole group of dissectors were less positively received.

Method

Design

In order to enhance communication of expectations and needs between the BMS and the pathologists, and between the BMS, a group discussion format was envisaged, whereby a dissector would present a case, or a cohort of cases, exploring a theme or group of themes. A dialogue between all those present was envisaged, with challenge and response to points raised. Discussion of the rationale of points and a review of the SOP resulting in an agreed standardised approach was envisaged, which was expected to encourage buy in and uptake by all participants.

Participants

All BMS practicing as dissectors with the pathology department participated (n=7). Four of the pathologists were involved in the initial training events, this was later expanded to include all of the pathologists (n=13). The dissection assistant completing the checklists recorded a numerical code for each participant, to maintain confidentiality.

Materials

50 Dissection checklists for each specimen type were attached to the relevant specimen request form (Appendix Four – Dissection Checklists, on page 210)

Procedure

The dissection checklists were completed by the dissector and / or their assistant for appendix (n=50), gallbladder (n=50), colon (n=50) and uterus (n=50). The checklists were completed as detailed in study 3.

A training intervention was introduced, this was held each Friday at 12 o'clock – 10 minutes in length, in practice this was quite variable, lasting between 15 and 25 minutes. A request for a 10 minute commitment increased agreement to participate beyond the 30 minute event originally suggested. There are calls to integrate this event into our monthly CPD meeting, this will be trailed in future and the optimal structure determined.

Preparation

- Select case / cases sufficient for timespan
- Review SOP against macro and blocks provided, review blocks to determine accuracy of sections
- Note any deviations from SOP
- Return to specimen and examine remaining material
- Consider accuracy of description and sampling
- Take photos if desired

Feedback

- Give clinical and specimen details; highlight any important information
- Discuss the macro and blocks provided – indicate if poor embedding / sectioning / staining
- Compare the macro and sampling with findings on review of the specimen
- Indicate areas of discrepancy, good or poor practice
- Indicate areas for improvement

After four cycles of the training event, the dissection checklists were completed against the pathology reports, to assess the effect of the training event.

Study Two Part Four – The training event only

Introduction

Using the training event to engage the dissector group in a dialog, combined with the checklists has resulted in the elimination of most of the variation seen at the baseline. In order to try and isolate the effects of the training event, the checklists were removed from circulation.

The use of the checklists is not arduous or especially time consuming, however, if the effects were largely due to the training event and the checklists could be removed, this would be one less task to perform in a busy laboratory. Conversely, if the effects were due to the checklists and only showing now due to lag, removing them would remove the gains previously made.

Method

Design

The training event was continued and the checklists were removed. The BMS dissectors were reporting that the training event was very useful and something that they wished to continue. In order to assess the effectiveness of this alone, the checklists were withdrawn for a period of two months.

Participants

All staff practicing as dissectors with the pathology department participated (BMS=5, Pathologist=7). At this stage there were 6 of 12 pathologists taking part in the training event.

Materials

50 Dissection checklists for each specimen type completed (Appendix Four – Dissection Checklists, on page 210)

Procedure

After the two month withdrawal period the chief investigator performed a review of macroscopic reports on the laboratory computer system. The checklists were completed retrospectively by them based on these reports (n=50), gallbladder (n=50), colon (n=50) and uterus (n=50).

Study Two Part Five – The use of diagrams only

Introduction

In part 4, the data demonstrated that those taking an active part in the training events were benefiting most. Removing the checklists meant that those not taking part in the training events, *e.g.* most of the pathologists, were no longer receiving any input or prompt. In order to more fully engage with those dissectors that the training event was not reaching, a set of guide diagrams were created.

The idea behind the diagrams is that they indicate the key descriptive and sampling points in the SOP and RCPath guidance. This enables the dissector to concentrate on assessing the sample in front of them, without getting bogged down in protocol – looking at the diagram to prompt as needed, to ensure all the required information in recorded and all the necessary sampling is done.

Method

Design

The training event and checklists were discontinued. Indicative guide diagrams for each specimen type were introduced. These were intended to highlight the significant features of specimen dissection and provide a guide to dissection.

Participants

All staff practicing as dissectors with the pathology department participated. (BMS = 4, Pathologist = 7)

Materials

The diagrams were developed with reference to the Royal College of Pathologists tissue pathways and minimum datasets. Alongside these, the departmental SOPs were reviewed and the descriptive and sampling goals were considered. This allowed line diagrams to be drawn, and the diagrams were annotated with boxes to indicate sampling locations and key descriptive points. For dissection diagrams see Appendix Five – Dissection Guide Diagrams on page 214.

Procedure

The guide diagrams were introduced to the dissectors on a one to one basis. The intention and aim of the diagrams were explained to the individual dissector. Also, the diagrams were displayed and explained at the weekly departmental meeting. The diagrams were affixed to the wall, in direct sight of the dissector whilst working.

The dissection checklists were retrospectively completed against completed reports for appendix (n=50), gallbladder (n=50), colon (n=50) and uterus (n=50).

Study Two Part Six – The use of the training event with diagrams

Introduction

The previous section made use solely of guide diagrams, in an attempt to further engage those dissectors who had not yet shown much improvement. However, the diagrams were not well received, and the feedback event was missed by the BMS dissectors. Attempts were made to recruit more pathologists to deliver the training events, and for them to attend sessions run by other pathologists. Whilst enthusiastic response were given, only two further pathologists delivered training events, and none came to sessions delivered by another pathologist.

The diagrams were retained, and the training events were resumed. This was to assess the effect of the two interventions running concurrently.

Method

Design

The training event was re-introduced without the checklists. The indicative guide diagrams for each specimen type remained. Checklists were completed retrospectively against completed reports to assess the effect of the diagrams.

Participants

All staff practicing as dissectors with the pathology department participated (BMS = 4, pathologists = 5). At this stage there were 6 of 12 pathologists taking part in the training event.

Materials

Dissection checklists and diagrams (see appendices one and four)

Procedure

The dissection checklists were completed against completed reports for appendix (n=50), gallbladder (n=50), colon (n=50) and uterus (n=50).

Study Two Part Seven – The use of the checklists only

Introduction

In order to understand the current state of practice, and to assess the effect that the interventions have had, given that a number of changes in the individuals practice have been noted in the preceding studies, the checklists were used in isolation. This is the first time since their introduction that they have been used without either the training event or diagrams.

Method

Design

The training event and diagrams were discontinued. The checklists were reintroduced.

Participants

All staff practicing as dissectors with the pathology department participated (BMS = 5, pathologist = 2).

Materials

Dissection checklists (Appendix Four – Dissection Checklists, on page 210)

Procedure

The dissection checklists were completed by the dissector and / or their assistant for appendix (n=46), gallbladder (n=43), colon (n=39) and uterus (n=48).

Study Two Part Eight – Return to the use of the training event with checklists

Introduction

This repeat session aimed to assess the changes that have occurred in dissection over the preceding studies. A number of changes have been noted in each preceding study, some of which have been sustained, whilst others have not.

Method

Design

The training event was re-introduced alongside the checklists.

Participants

All staff practicing as dissectors with the pathology department participated (n=14). All pathologists (n=12) had agreed to take part in the training event.

Materials

Dissection checklists (Appendix Four – Dissection Checklists, on page 210)

Procedure

The dissection checklists were completed by the dissector and / or their assistant for appendix (n=46), gallbladder (n=43), colon (n=39) and uterus (n=48).

A pathologist facilitated a training session / discussion involving a case review. The case was examined on the bench to review the remaining material alongside the macroscopic description, the blocks taken and the slides produced. The SOP was reviewed and the manner in which the specimen had been described and handled was discussed. Any examples of good or poor practice were highlighted as learning opportunities. The dissectors were encouraged to challenge the pathologists requests and gain an evidence based justification for practices that were, or were not performed.

Results of Study Two

The results of study 2 highlighted substantial variation throughout histopathological dissection within the Royal Derby Hospital Histology laboratory. Study 2 generated a great deal of data, with each part informing the formation of the next part. The results for each part are presented and discussed briefly in sequence. After each round has been discussed, consideration is given to each specimen type and how practice relating to that specimen type has changed over time. Finally, the changes over time for all specimen types are considered as a whole. As clearly established in the literature review, variation in practice leads to worse patient outcomes (ACOG, 2012; Dhingra, 2010; Coombs, 2009; Ferran, 2008); as such, we seek to reduce unnecessary variation.

Study Two Part One – The creation of the checklists and collecting baseline data (BMS N=5, Pathologist, N=7)

The checklists clearly demonstrated the ability to capture variation in practice. The retrospective analysis of reports for appendix specimens showed a difference in sampling practice between the dissectors. One group was taking a longitudinal section from the tip of the appendix and two transverse sections from the body, whilst the rest were taking a longitudinal section from the tip and one transverse section from the body. The former approach is the one suggested by the RCPath and the one which all dissectors should have been following. The latter approach had previously been the standard practice in the department, but had been changed over a year previously. This had been communicated at the time to all dissectors, and the SOP had been updated. Upon discussion with both groups, those sampling correctly were able to clearly recall the change in practice, whilst those still performing the older style of sampling had no recollection of any notification of the change.

The gallbladder data also demonstrated variation in sampling protocols. The SOP calls for the fundus of the gallbladder to be sampled. This is based on the belief that the funds is the mostly frequent site of adenoma or dysplasia (Yamamoto, 1989; Levy, 2001), as such sampling of macroscopically unremarkable gallbladder wall should be from the fundus. Of course, any macroscopic abnormalities ought to be sampled, regardless of location. Again, a split was seen with two distinct groups of dissectors. One group was correctly sampling the gallbladder through the fundus, whilst the other group was sampling the body in transverse section. After discussion with the dissectors it transpired that one group, the fundus sampling group, had been trained by the departmental lead for GI pathology, whilst the other group had been trained a different pathologist.

The colon data showed a number of variations, the most widespread was the sampling of background mucosa. This is something which is mandated by the RCPath minimum dataset for colorectal cancers and the RCPath tissue pathway for GI pathology suggests that samples of macroscopically normal bowel may be informative (RCPath, 2009; RCPath, 2014a). This is a clear recommendation, one that involves minimal time or cost to satisfy and therefore ought to be met on all occasions. On discussion with the dissectors, some were unaware of this need, whilst some of the BMS stated that they had been asked not to sample background mucosa by pathologists, one of the pathologists stated that they simply did not wish to see “normal” tissue.

The checklists demonstrated a great deal of variation for the uterine dissection. The most common source of variation was in relation to the cervix. The tissue pathway for gynaecological pathology (RCPath, 2015) calls for the cervix to be described, the local SOP reiterates this, whilst also requiring a transverse measurement of the cervix. Clearly, this something which is not being performed with any degree of reliability or regularity. A discussion with the dissectors indicated that some were unaware of this requirement; others, on prompting, were able to recall that this something they were aware of, but had forgotten.

The various discrepancies were communicated to the dissectors in group discussion, this was a valuable exercise as it allowed for a two way dialogue. This discussion and feedback to the dissectors was greeted enthusiastically by the BMS dissectors, and formed the basis for the second intervention detailed in study 2, part 3.

The completion of a large number of checklists retrospectively was time consuming. For this reason, when planning part 2 (introducing the checklists to routine dissection) the checklists were introduced intermittently, the reason for this was so that no individual dissector encountered a glut of checklists at any one time. As there was likely to be some resistance to the checklists, minimising their impact on the dissector was a reasonable step to take during their introduction. Also, spreading the checklists out over a wider time frame enabled greater exposure to the checklists – rather than a single instance of encountering many checklists, the dissector was likely to encounter two or three in each dissection session, spread out over several weeks.

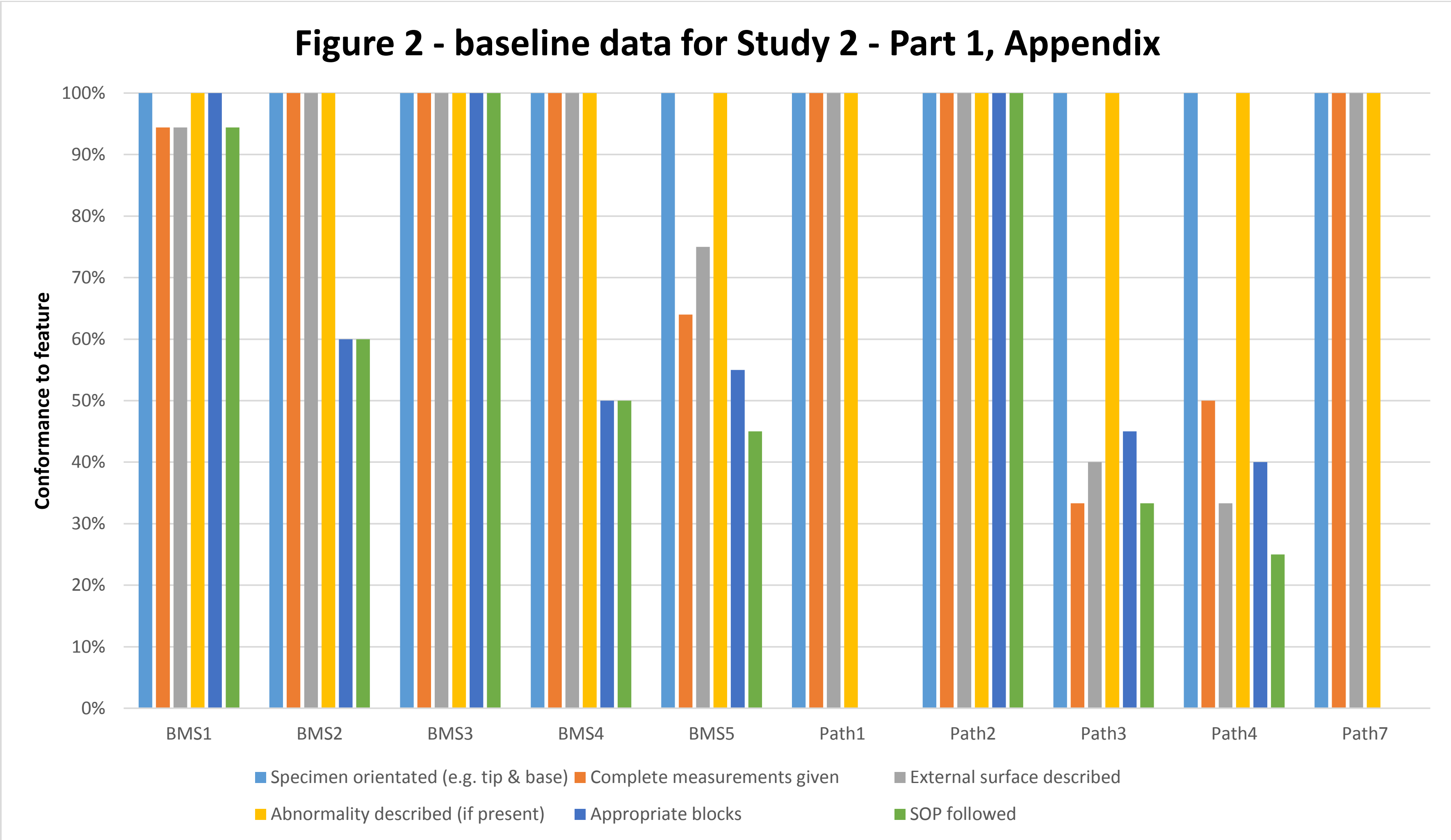


Figure 2- Baseline Data for Study 2 Part 1, Appendix. This figure shows the original baseline data collected by using the checklists to review the recent practice in appendix dissection.

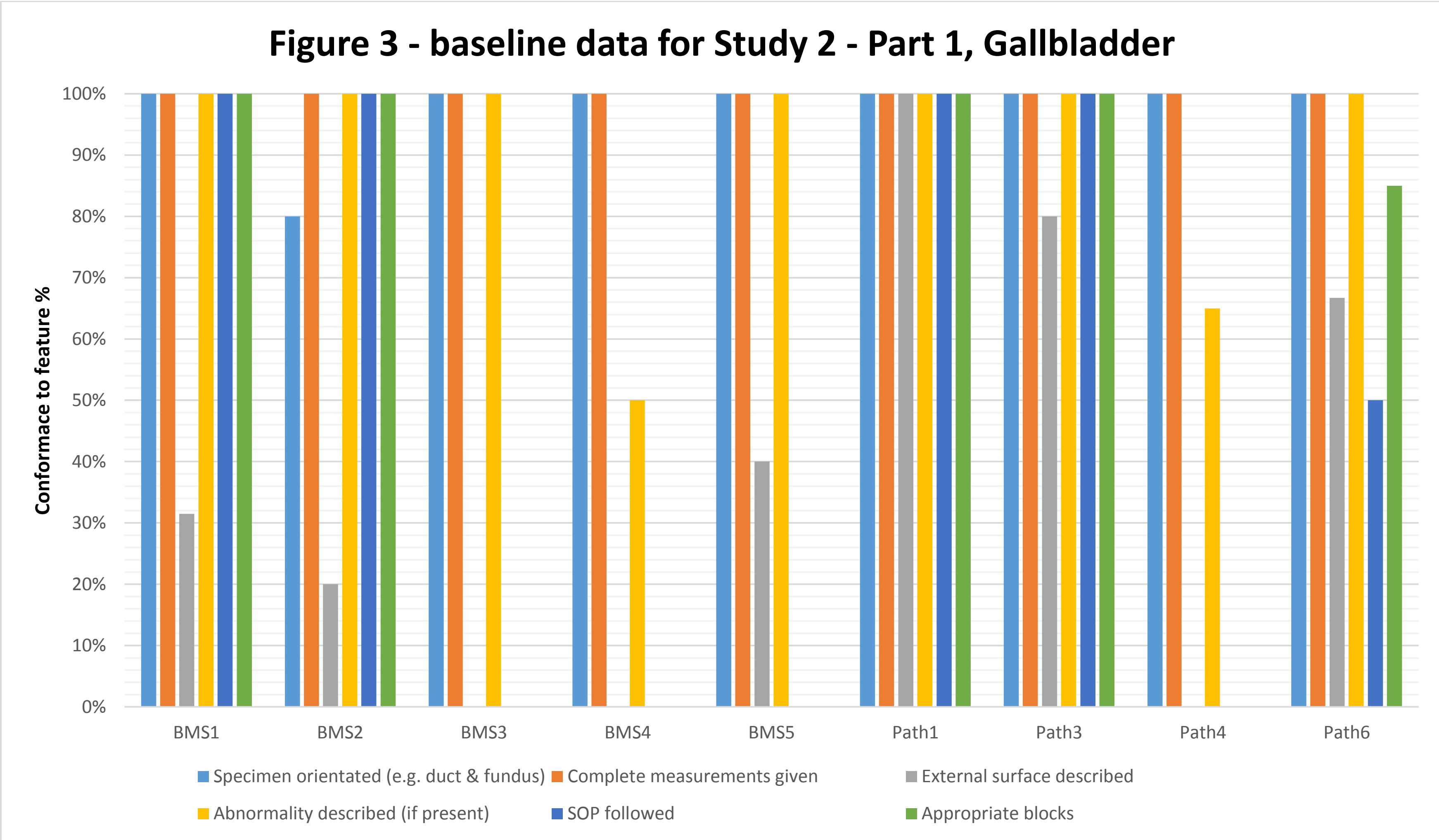


Figure 3 - Baseline Data for Study 2 Part 1, Gallbladder. Figure 3 shows the original baseline data collected by using the checklists to review the recent practice in gallbladder dissection

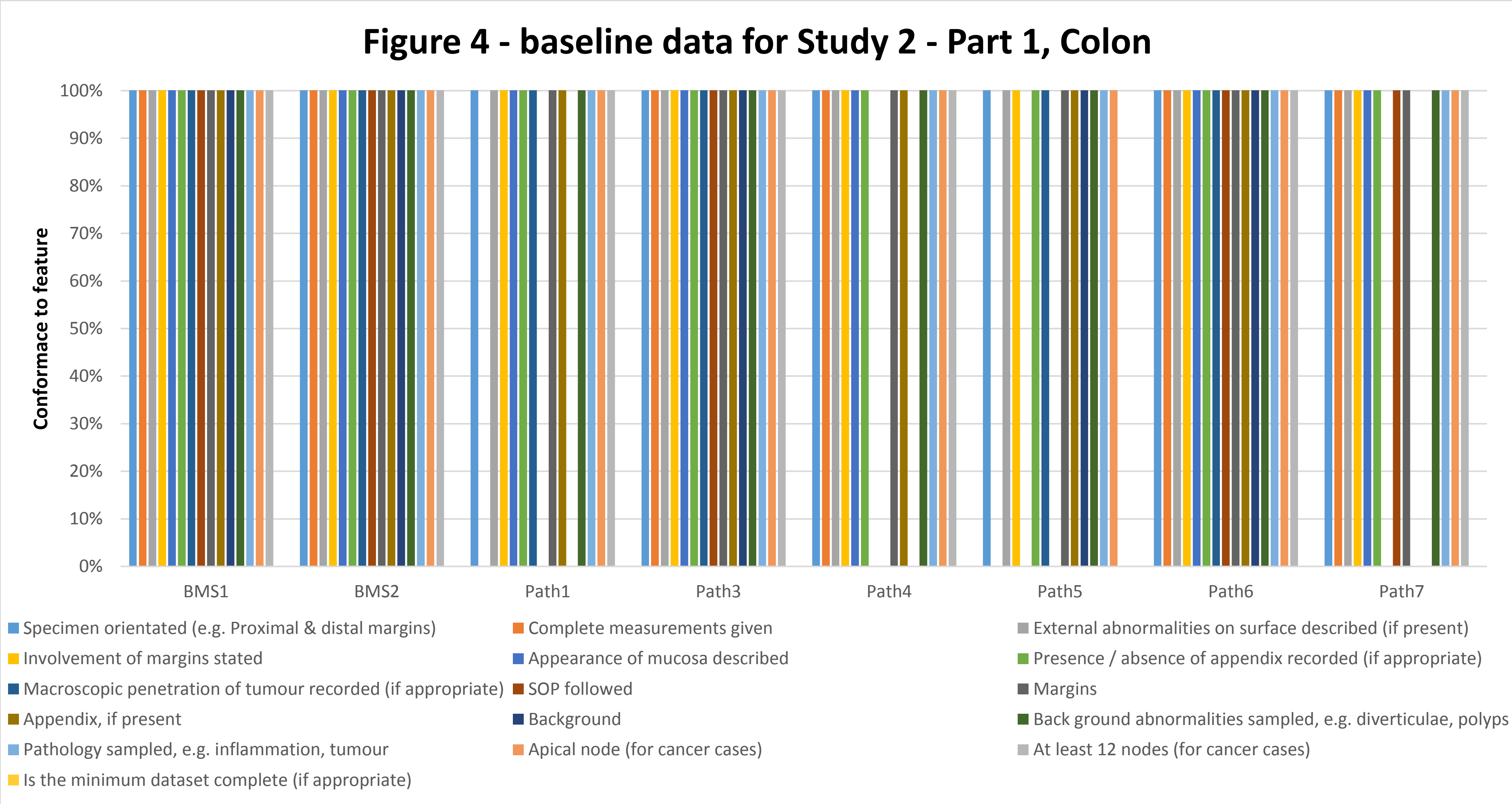


Figure 4 - Baseline Data for Study 2 Part 1, Colon. Figure 4 shows the original baseline data collected by using the checklists to review the recent practice in colon dissection

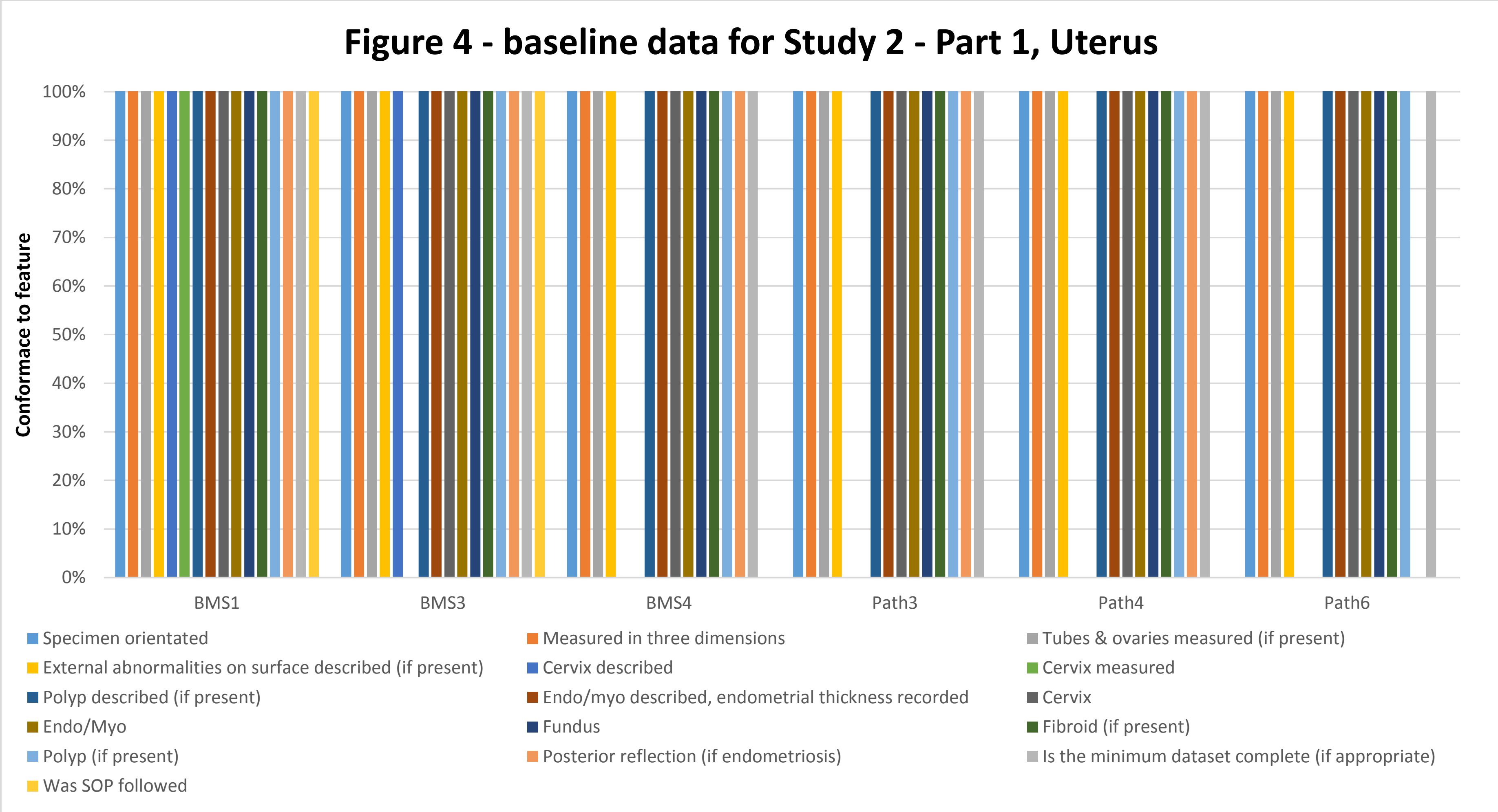


Figure 5 - Baseline Data for Study 2 Part 1, Uterus. . Figure 5 shows the original baseline data collected by using the checklists to review the recent practice in uterus dissection

Study Two Part Two – Checklist Introduction (BMS N=5, Pathologist, N=7)

The introduction of the checklists has clearly had an effect. There is a substantial change from the baseline data recorded before their introduction. There is a variable change across the range of personnel and specimens, as would be expected. Different dissectors will encounter the checklists with different frequencies and in different circumstances. Any change must be given time to take effect, and so several contacts with the checklists might be expected before a dissector begins to change their practice, if they change at all.

The appendix checklists show a noticeable improvement from the BMS dissector group, although some variation remains. The pathologists show lot of variation, but all show some improvement. Most of the variation is in the area of sampling and measurement. This is similar to what was seen in study one and two. Whilst the checklists have had an effect on the practices of the dissectors, there does still remain an unnecessary level of variance.

The gallbladder specimen checklists showed that most of the BMS were at 100%, with one BMS not taking appropriate blocks. The pathologists still show substantial variation, although it has reduced from the previous study. Pathologist one shows 100%, the variance of the other pathologists mostly centres on the description of the external surface and in the sampling, as seen in study two.

The colon dissection checklists show reduced variation among the pathologists, although some variation persists; the BMS show full 100% conformance. There is no clear area of deficit in practice, more a number a small variations. These small areas of variation are rather harder to manage. A complete failure to adhere to a KPI is most often due to a lack in knowledge, or a deliberate decision. In these cases, education and management can rectify this issue. However, when the dissector meets the KPI on some occasions, but not on others, it is more difficult to identify a cause and therefore a resolution.

The BMS and pathologists show a lot of reduction in variation for the uterine dissection. However, so variation does remain. The variation mostly relates to the description of the cervix and measurement of the endometrial thickness. The importance of this is discussed in study one. Whilst improvement is seen here, there is still room for improvement.

Overall, the change is more notable in the BMS group than the pathologist group, which may not be surprising. The BMS are all actively engaged in training and may be more amenable to changing their practice. Comparison between part 1 and part 2 shows a distinct reduction in variation. The introduction of the checklists resulted in standardisation in practice. Having the checklists available at the point of dissection appears to have focused attention on the process of dissection and allowed dissectors to think more specifically about the specimen without distraction. Discussion with several of the dissectors has indicated that reading the checklists highlighted requirements that they had not been aware of and that some used the checklist as a memory prompt. The introduction of the checklist allowed dissectors to become aware of what information was being collected, this prompted the dissectors to ask questions and check the requirements of the SOP. This dialog led to the development of training and feedback scheme, detailed in Chapter Four – Study 3 – Participant Interviews, on page 137.

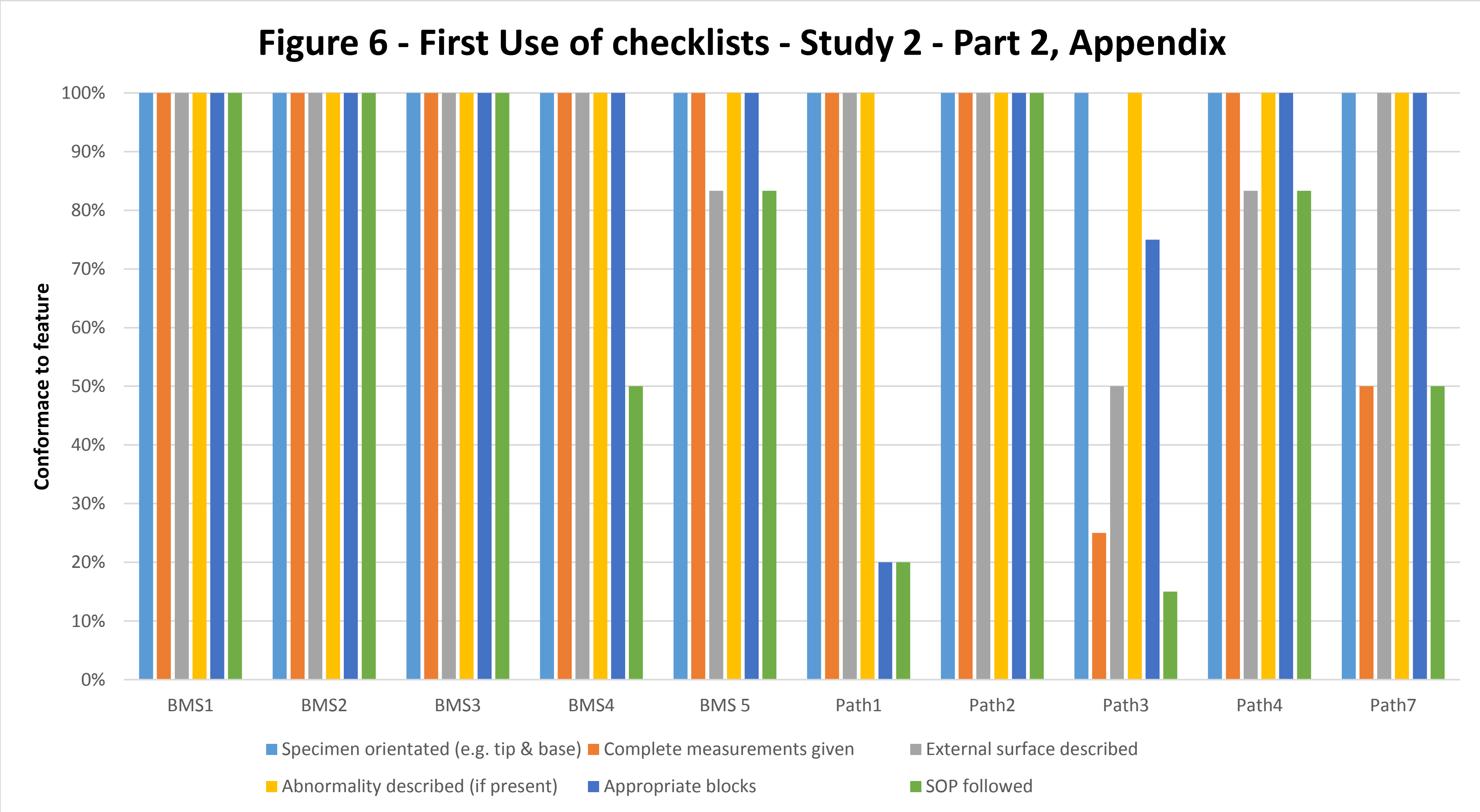


Figure 6 - First Use of Checklist, Study 2 Part 2 – Appendix. Figure 6 demonstrates the results gained when the checklists were first used on the dissection bench. A noticeable reduction in variation is seen when compared to Figure 2, page 75.

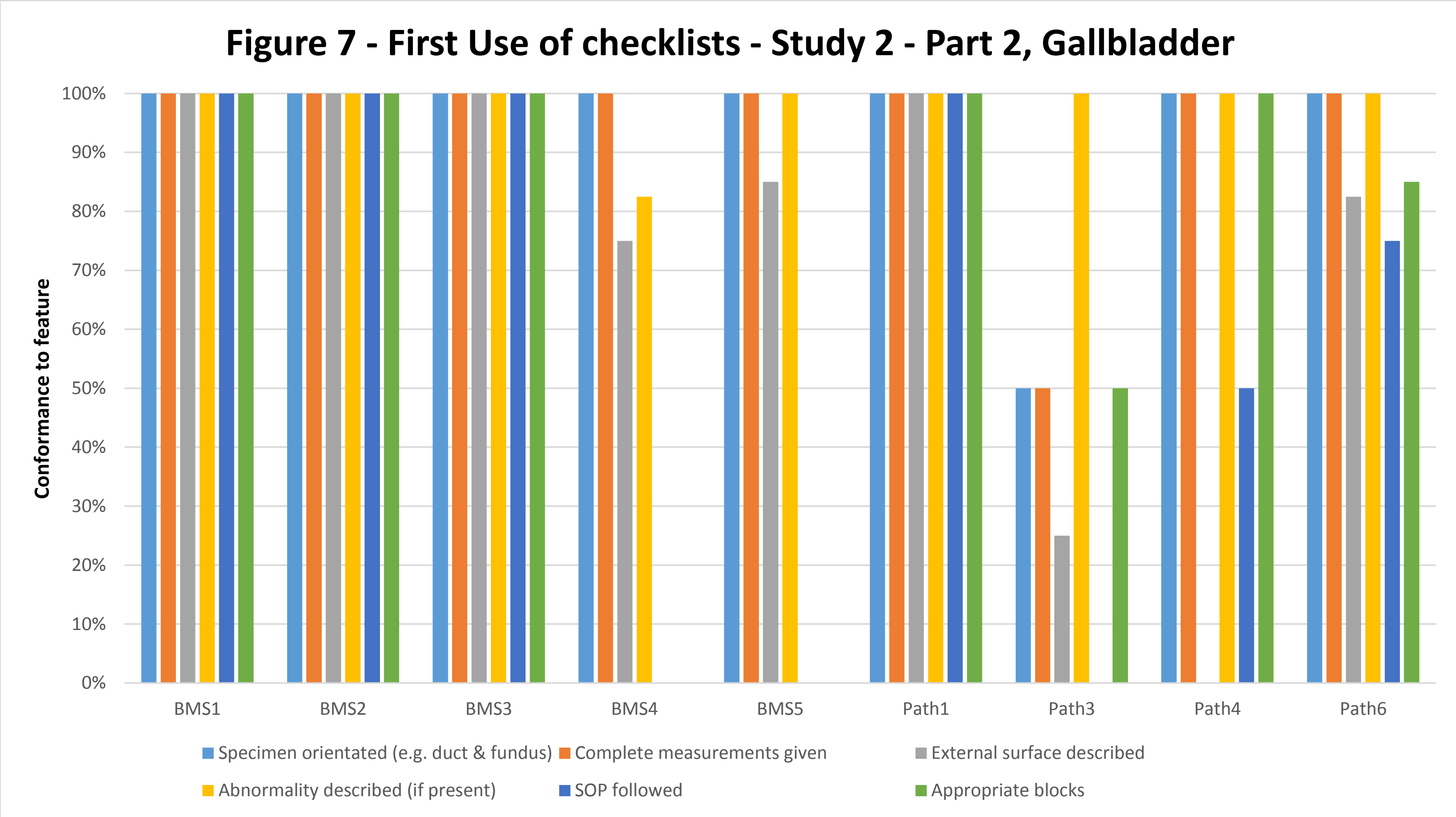


Figure 7 - First Use of Checklist, Study 2 Part 2 – Gallbladder. Figure 7 shows the data gained the first time the checklists were introduced to the dissection bench. Again, a notable reduction in variation is seen on the previous round, Figure 3, on page 76.

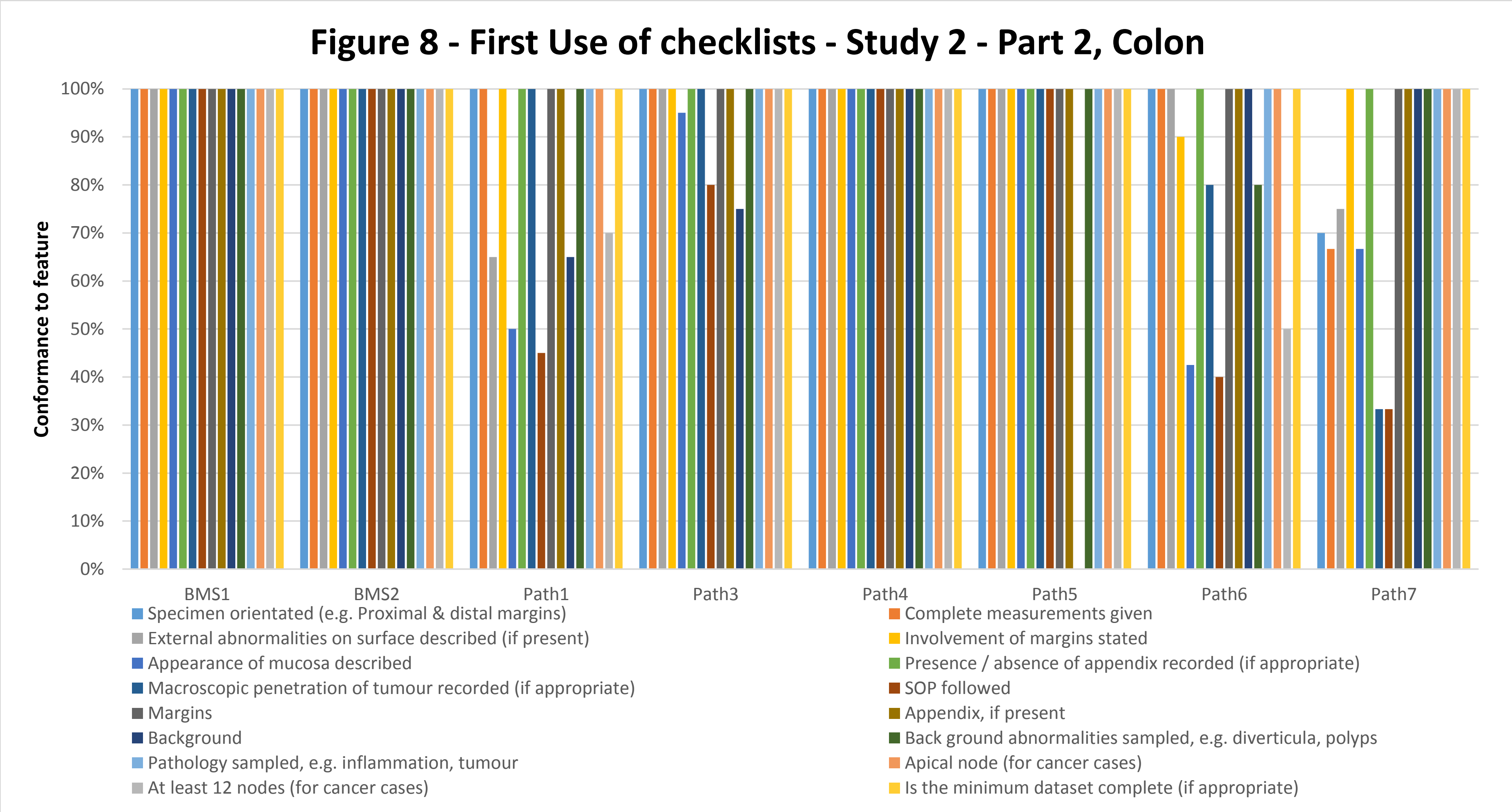


Figure 8 - First Use of Checklist, Study 2 Part 2 – Colon. Figure 8 also shows a reduction in variation, compared to the baseline, Figure 4 on page 77, although this is not quite as dramatic as that seen for the appendix and gallbladder.

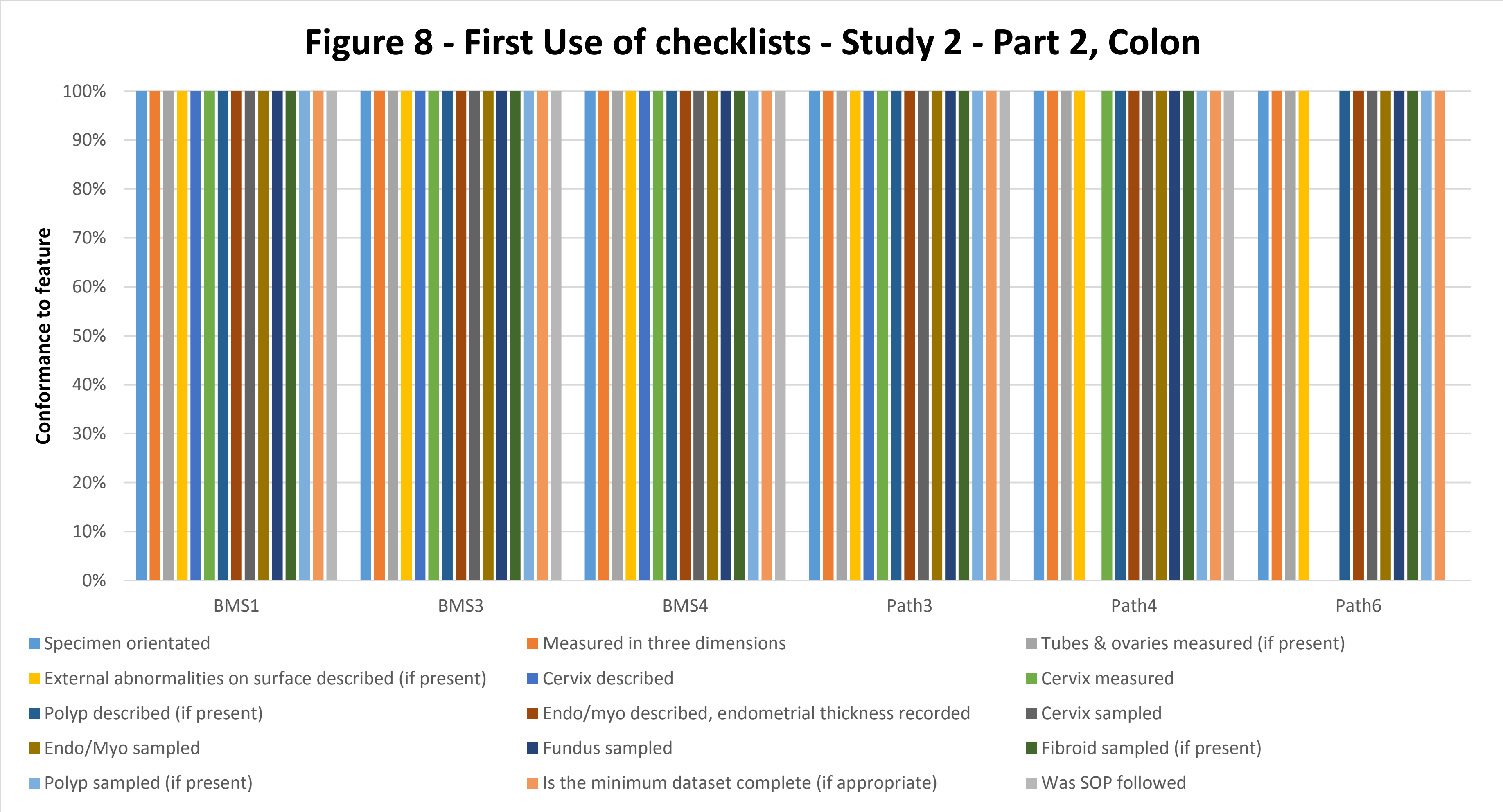


Figure 9 - First Use of Checklist, Study 2 Part 2 – Uterus. Here we can see the data gathered from the introduction of the checklist to the dissection bench. At baseline, Figure 5 on page 78, some variation in practice was seen – comparison of with this figure shows a reduction in variation.

Study Two Part Three – Training Event and Checklists (BMS N=5, Pathologist, N=7)

In part 3, with the introduction of the training event, the data for the appendix dissection shows only a slight variation from BMS 2, the other four BMS are showing full conformance to all KPI. Pathologist 3 continues to show substantial variation in practice, and pathologist 4 shows slight variation. Pathologist 1 and 7 show full conformance to KPI, continuing the improvements seen in the previous studies.

The gallbladder dissection data shows all the BMS, pathologists 1 and 3 meeting all of the KPI. Whilst pathologist 4 shows only slight variation and pathologist 6 shows a slightly worse performance than in previous round. The main discrepancies remain related to the external description and measurements.

The checklists for the colon both BMS meeting all KPI, as does pathologist 4. Pathologists 1, 3, 6 and 7 show moderate variation, whilst pathologist 5 once again shows full conformance for all KPI, except sampling background mucosa. As noted above, this was discovered to be a deliberate choice, in contrast to the RCPath guidelines.

The uterus checklists show a small amount of variation from BMS 1 and 2 and pathologist 6, whilst BMS 4 and pathologist 3 show full conformance to all KPI. Pathologist 4 continues to omit any data relating to the cervix. The other variations are without obvious pattern and appear to relate to simple omissions. This is something that the checklists may be able eliminate, given time.

In most areas the changes seen in the previous round, that of reduced variation and more concordance to SOP, was continued. Again, a variable response was seen from different individuals. It is noteworthy that all the BMS dissectors were attending the feedback events, however, only one pathologist attended a feedback event other than one that they were delivering. It is worth noting that the pathologists who have shown the greatest reduction in variation are those involved in delivering the feedback events (pathologists 1, 3 and 4).

As there were now two interventions running concurrently (the checklists and the training intervention), the checklists were removed in order to judge the effect of the training event in isolation.

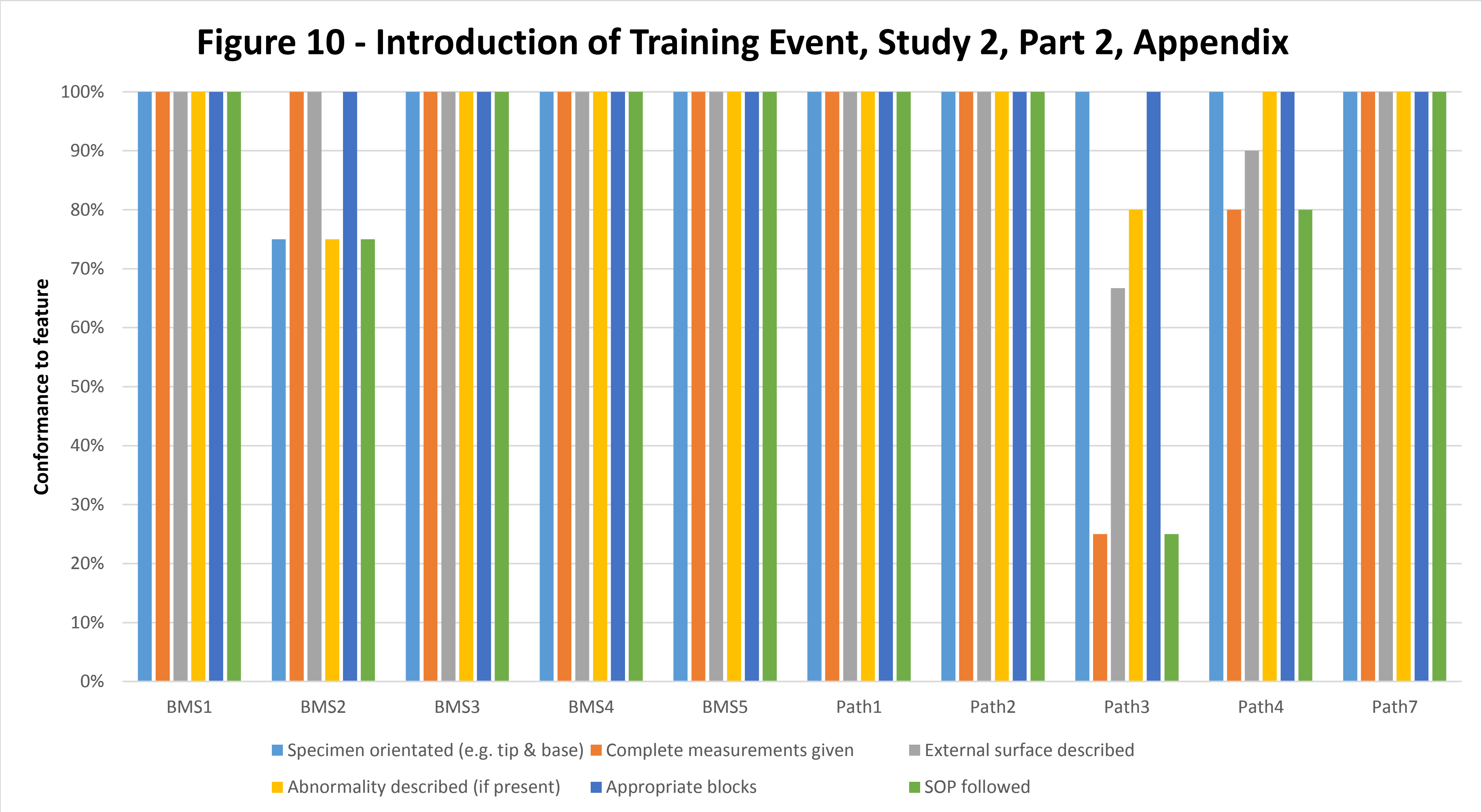


Figure 10 - Training Event - Study 2 Part 3, Appendix. Figure 10 presents the data gathered from the checklists at the introduction of the training event. Comparison with Figure 2 on page 75 and Figure 6 on page 81 shows a continued reduction in variation.

Figure 11 - Training Event - Study 2 Part 3, Gallbladder. This figure shows the data gathered using the checklists at the introduction of the training event. Comparison with Figure 3 on page 76 and Figure 7 on page 82 shows a continued reduction in variation.

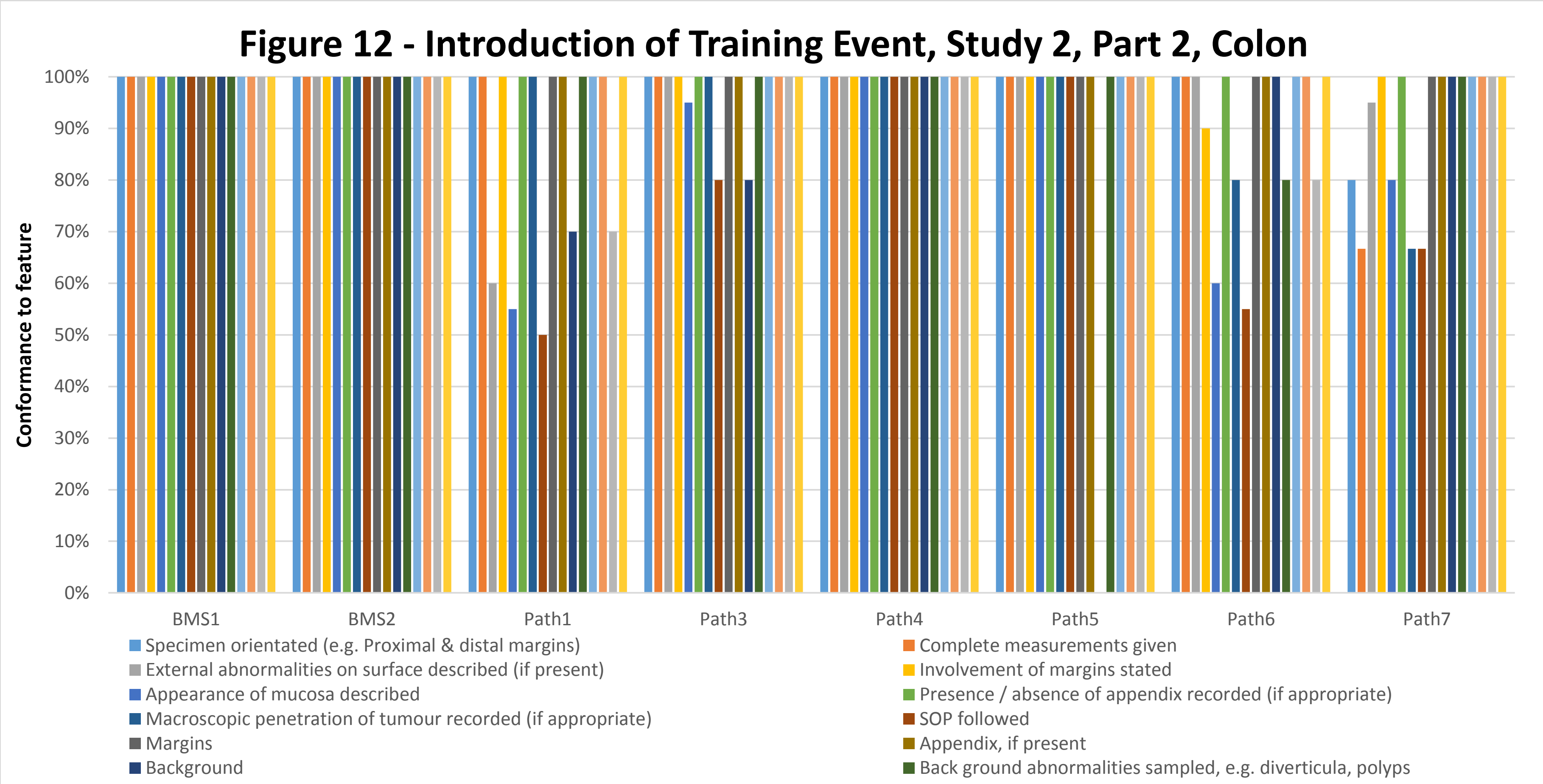


Figure 12 - Training Event - Study 2 Part 3, Colon. Figure 12 shows the same pattern noted with the other figures in this round. The data gathered using the checklists at the introduction of the training event presented here, continues to show a reduction in variation when compared to Figure 4 on page 77 and Figure 8 on page 83.

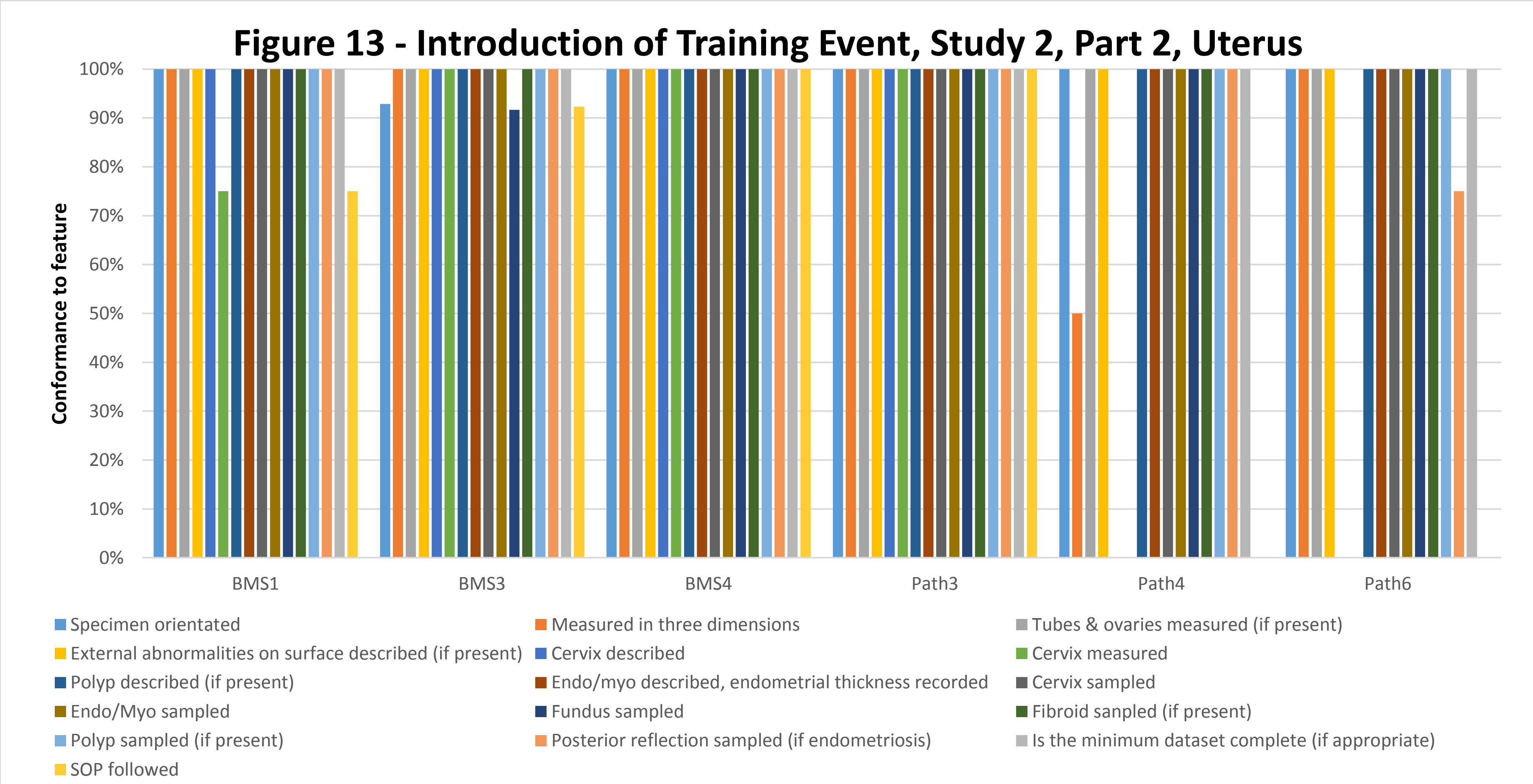


Figure 13 - Training Event - Study 2 Part 3, Uterus. The data collected with the checklists at the point the training event was introduced is shown here. Compared to the preceding rounds, shown in Figure 5 on page 78 and Figure 9 on page 84

Study Two Part Four – Training Event only (BMS N=5, Pathologist, N=7)

The review of macroscopic descriptions in this round revealed that in the dissection of the appendix all the BMS (1 – 5) were meeting all the KPI in call cases. Pathologists 1, 2 and 7 also showed full compliance to KPI. Pathologist 3 continued to show substantial variation, whilst pathologist 4 showed a small amount of variation. In both cases this again relates to the completeness of the measurements given and the external description.

The gallbladder data also shows all the BMS (1 – 5) and pathologist 1 showing full conformance, meeting all the KPI. Pathologist 3 shows minor variation, in relation to block selection, whilst pathologist 4 shows slight variation in relation to the description of the external surface. Pathologist 6, however, shows variation over several KPI, including the measurements, the description of the external surface, the description of abnormalities and the taking of appropriate blocks.

The dissection of the colon specimens shows the BMS (1 & 2), along with pathologists 3, 4 and 7 demonstrating full conformance on all KPI. Pathologist 5 continues their previous practice of omitting to sample the background mucosa, as described previously, Pathologist 6 shows a wide variation, over a number of KPI, as seen in their practice with the gallbladder and uterine dissection in study 5.

The uterus data continues to show variation from BMS 1 and 3, whilst BMS 3 and pathologist 3 maintain the full conformance to KPI noted previously. Pathologists 4 and 6 both show substantial variation, mostly in relation to the cervix and description of the endometrium, this also being where BMS 1 and 3 show variation.

After the initial large change reduction in variation seen with the checklists and training event, the improvements begin to plateau. Whilst the training event shows clear utility to the BMS, the pathologists are delivering their own feedback, but are choosing not to attend that delivered by others, meaning that they miss out on the opportunity to improve. However, attendance is voluntary – pressure of work has been often cited to explain or justify the pathologists choice not to attend.

In an attempt to widen exposure to the training material, beyond those that were able to attend the training events, and to provide more immediacy, *i.e.* placing the material at the point of dissection. A set of guide diagrams were created. These were drawn up with reference to the RCPath guidelines and the departmental SOPs.

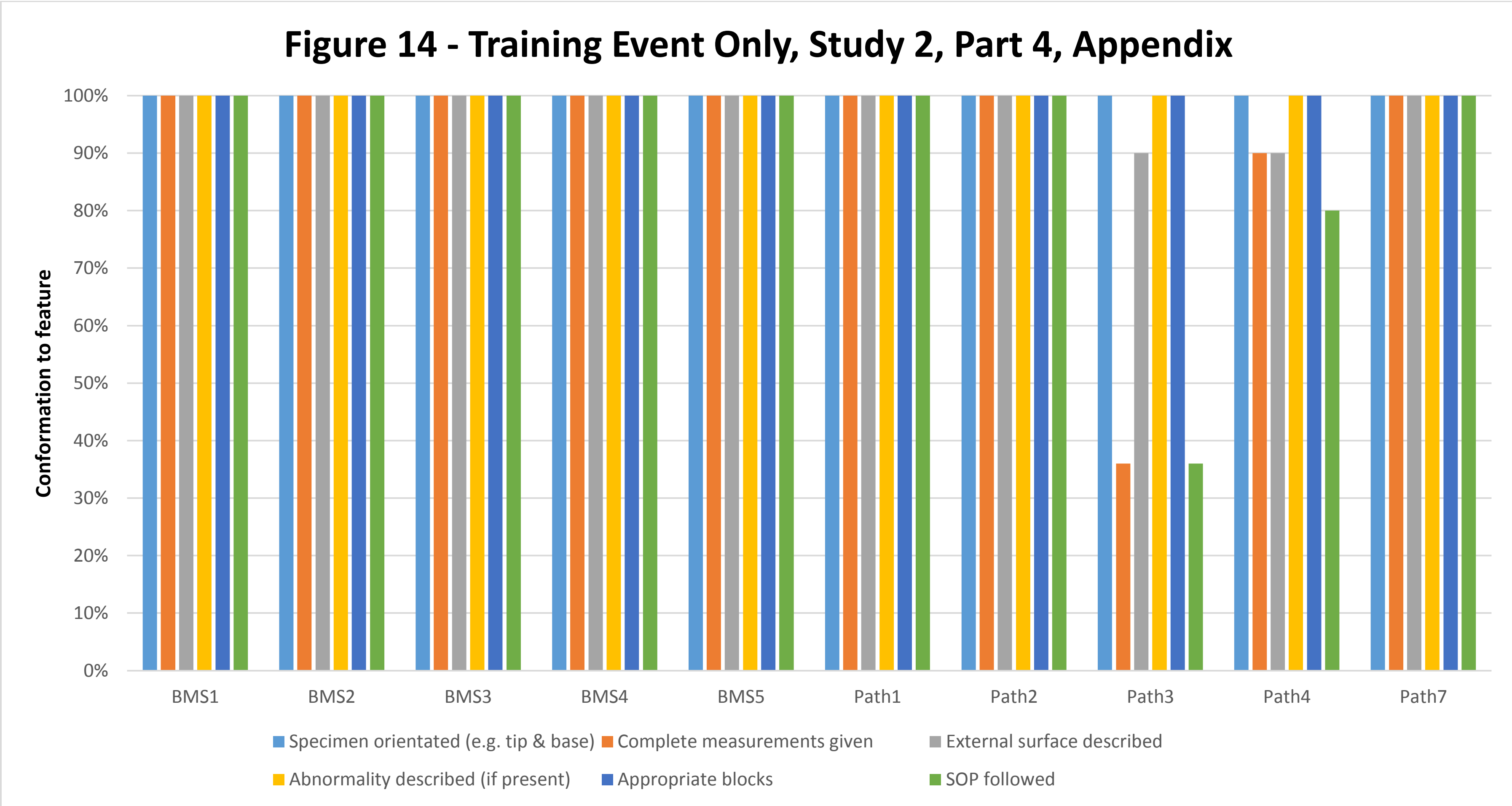


Figure 14 - Training Event Only - Study 2 Part 4, Appendix. In part 4 the training event was run without the checklists on the bench, the checklists were used retrospectively to gather the data. The patter noted in previous rounds is seen again here. Comparison with Figure 2 on page 75, Figure 6 on page 81 and Figure 10 on page 87 shows a continued reduction in variation.

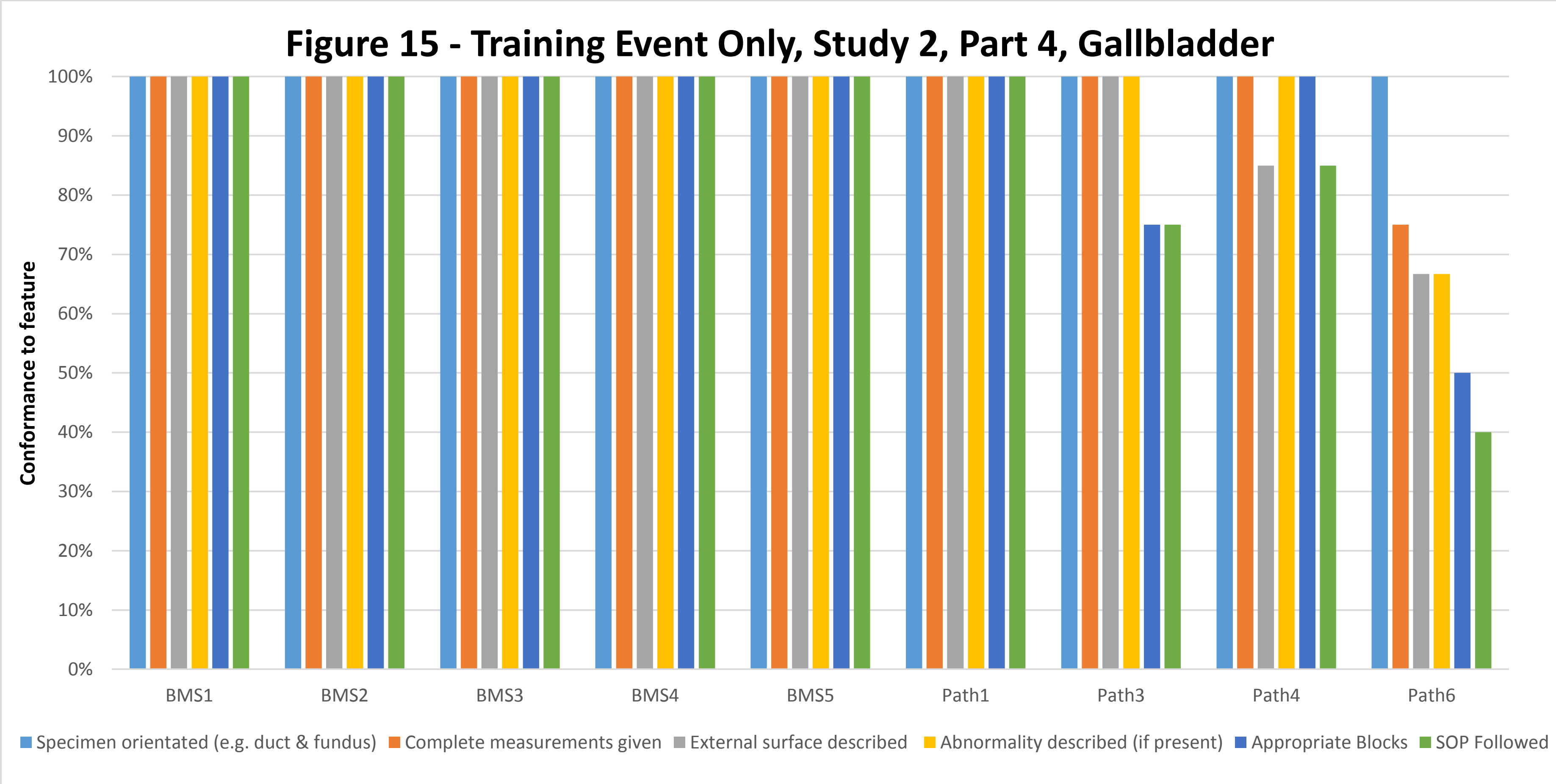


Figure 15 - Training Event Only - Study 2 Part 4, Gallbladder. This figure shows the data gained from running the training event in isolation. The checklists were used to retrospectively collate data from specimens dissected during this time. Here we see continuation of the reduction in variation noted in the previous rounds, seen in Figure 3 on page 76, Figure 7 on page 82 and Figure 11 on page 88

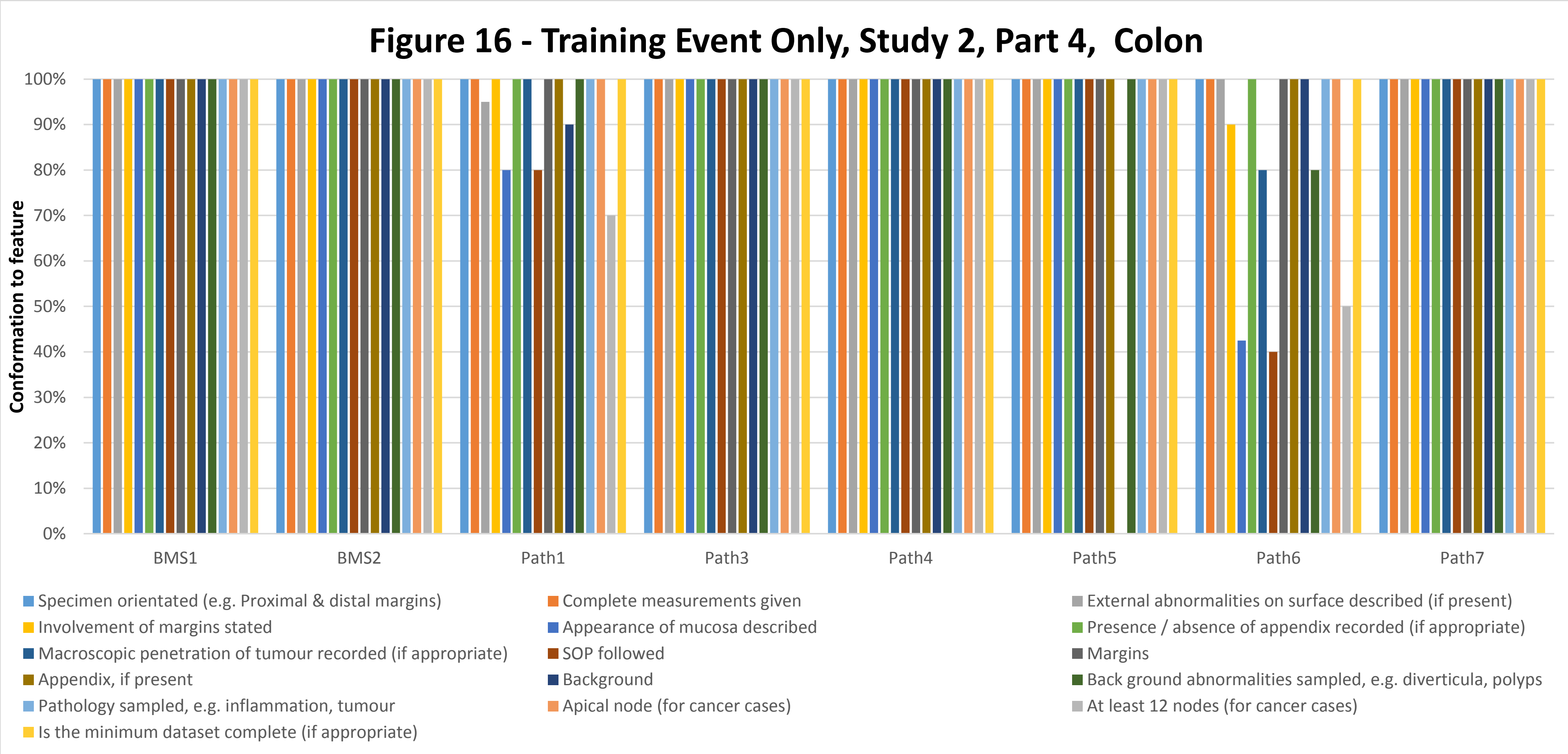


Figure 16 - Training Event Only - Study 2 Part 4, Colon. This figure demonstrates the data gathered during the period where the training event was running in isolation. The checklists were completed retrospectively, analysing the reports of specimens dissected during this time. The chart shows that the reduction in variation obtained in previous rounds is continued, and further reductions are noted from other dissectors when compared to Figure 4 on page 77, Figure 8 on page 83 and Figure 12 on page 89.

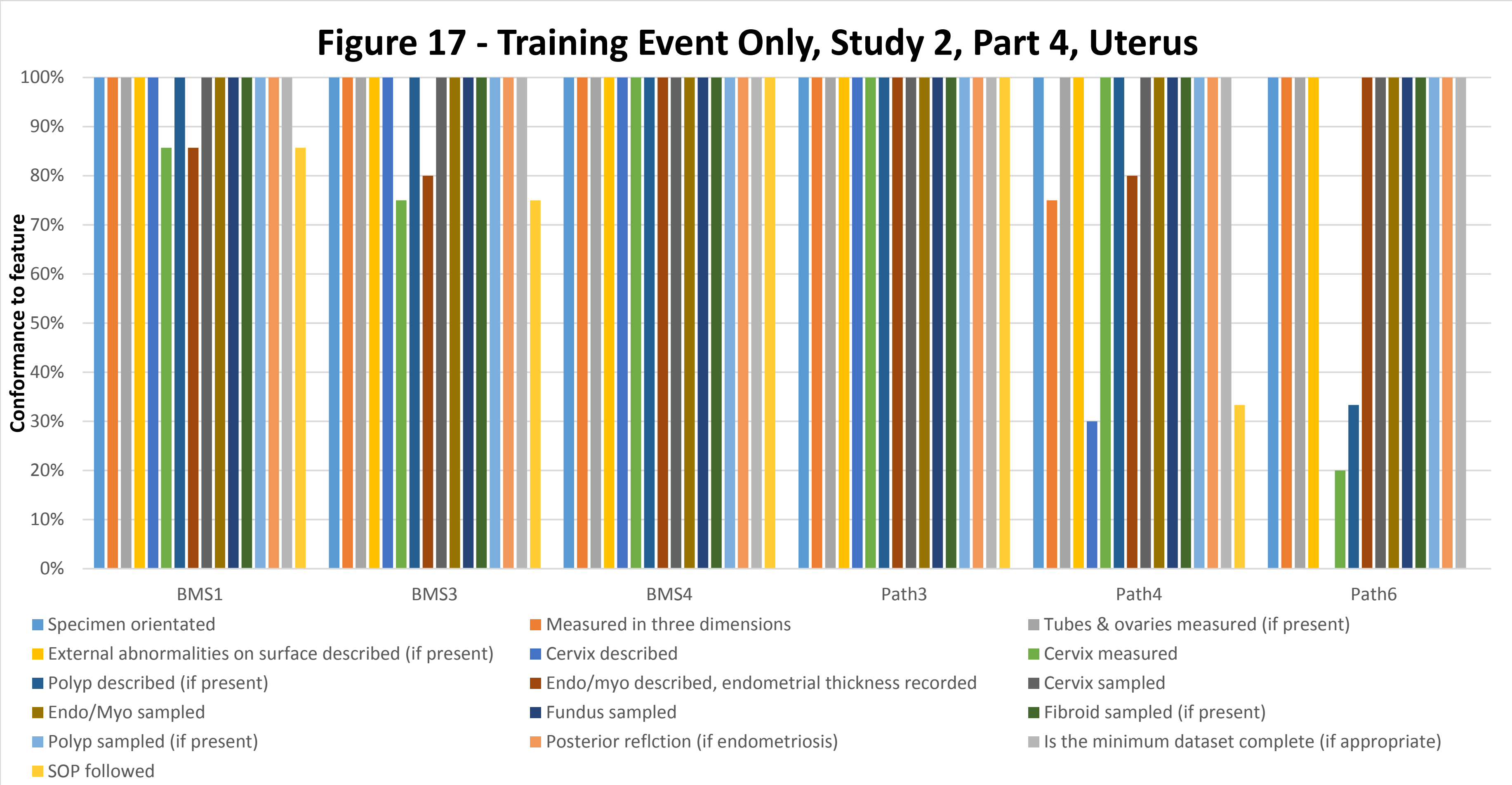


Figure 17 - Training Event Only - Study 2 Part 4, Uterus. In Study 2, Part 4 the reduction in variation seen in the preceding rounds, Figure 5 on page 78, Figure 9 on page 84 and Figure 13 on page 90, is continued; while a further reduction is seen by other dissectors. In this part of the investigation, the training event was run in isolation, and the checklists used to gather data retrospectively, for specimens dissected during this period.

Study Two Part Five – Guide Diagrams (BMS N=5, Pathologist, N=7)

The data for the appendix shows an almost unchanged picture from part 4. BMS 1, 3 – 5 show full conformance to KPI, although BMS 2 has shown a slight variation, with a reversion to the older sampling protocol on some cases. Pathologist 1 and 2 are also continuing to show full conformance to all KPI. Pathologist 3 and 4 continue to show the same variation noted previously, whilst pathologist 7 drops from their previous full conformance, showing minor variation in provision of full measurements.

Gallbladder dissection continues in much the same way, with the BMS (1 – 5) and pathologist 1 and 3 once again showing full conformance to all KPIs. Pathologists 4 and 6 continue to show variation on the same KPIs.

This is the same picture for the colon dissection, where minimal change is noted from study 5. The uterus data shows some change, in that the BMS 1, 3 & 4 now all show full conformance to KPI. Pathologist 3 continues to demonstrate full conformance seen previously, pathologist 4 now fully fails to describe or measure the cervix, whilst pathologist 6 now shows full conformance to all KPI.

Part 5 showed a continuation of the performance noted in the previous rounds, that is to say, continuation of practice at the newly reduced level of variation. However, some return back towards the previous variation was noted amongst some individuals. The diagrams were not well received by staff, and the discontinuation of the training event was lamented. As such, a further study was considered retaining the diagrams, allowing for further exposure to overcome the resistance to them, and reintroducing the training event.

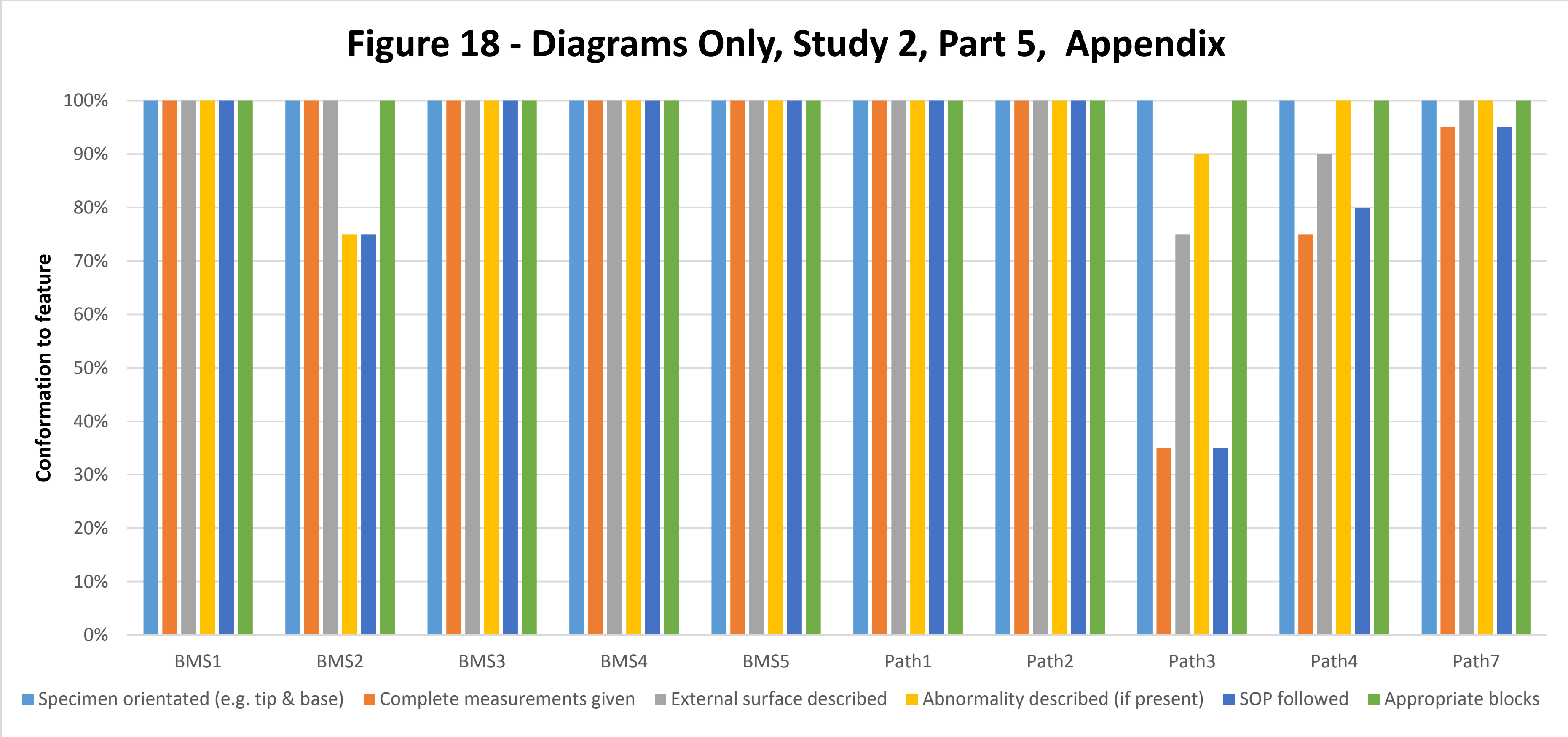


Figure 18 - Diagrams Only - Study 2 Part 5, Appendix. This figure represents the use of indicative guide diagrams for the first time. The diagrams were run in isolation, and the checklists were used retrospectively to obtain this data from specimens dissected during this period. A slight increase in variation is noted amongst some dissectors here, compared to previous rounds (Figure 2 on page 75, Figure 6 on page 81, Figure 10 on page 87 and Figure 14 on page 93).

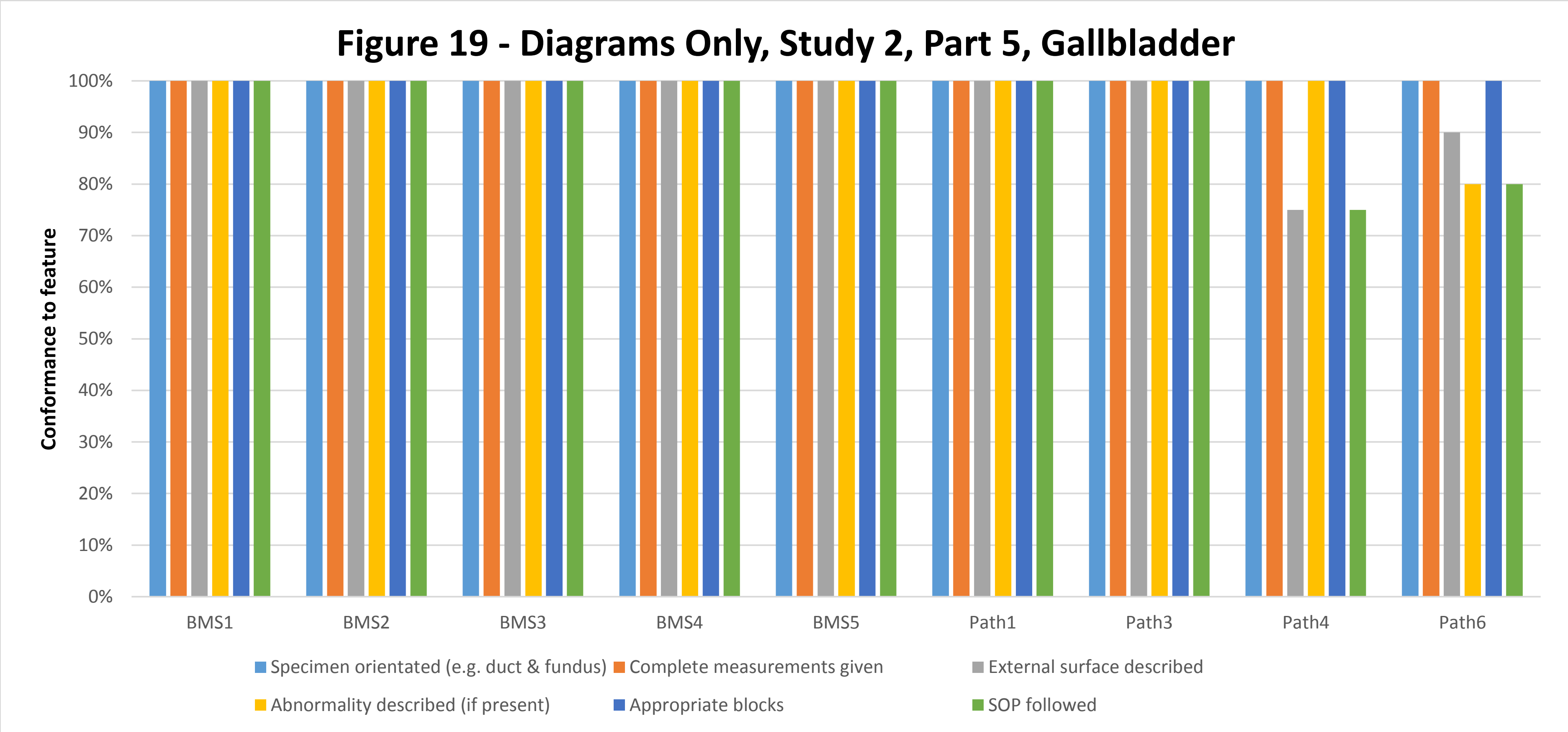


Figure 19 - Diagrams Only - Study 2 Part 5, Gallbladder. This figure represents the use of indicative guide diagrams for the first time. The diagrams were run in isolation, and the checklists were used retrospectively to obtain this data from specimens dissected during this period. A slight deduction in overall variation is noted amongst here, compared to previous rounds (Figure 3 on page 76, Figure 7 on page 82 and Figure 11 on page 88).

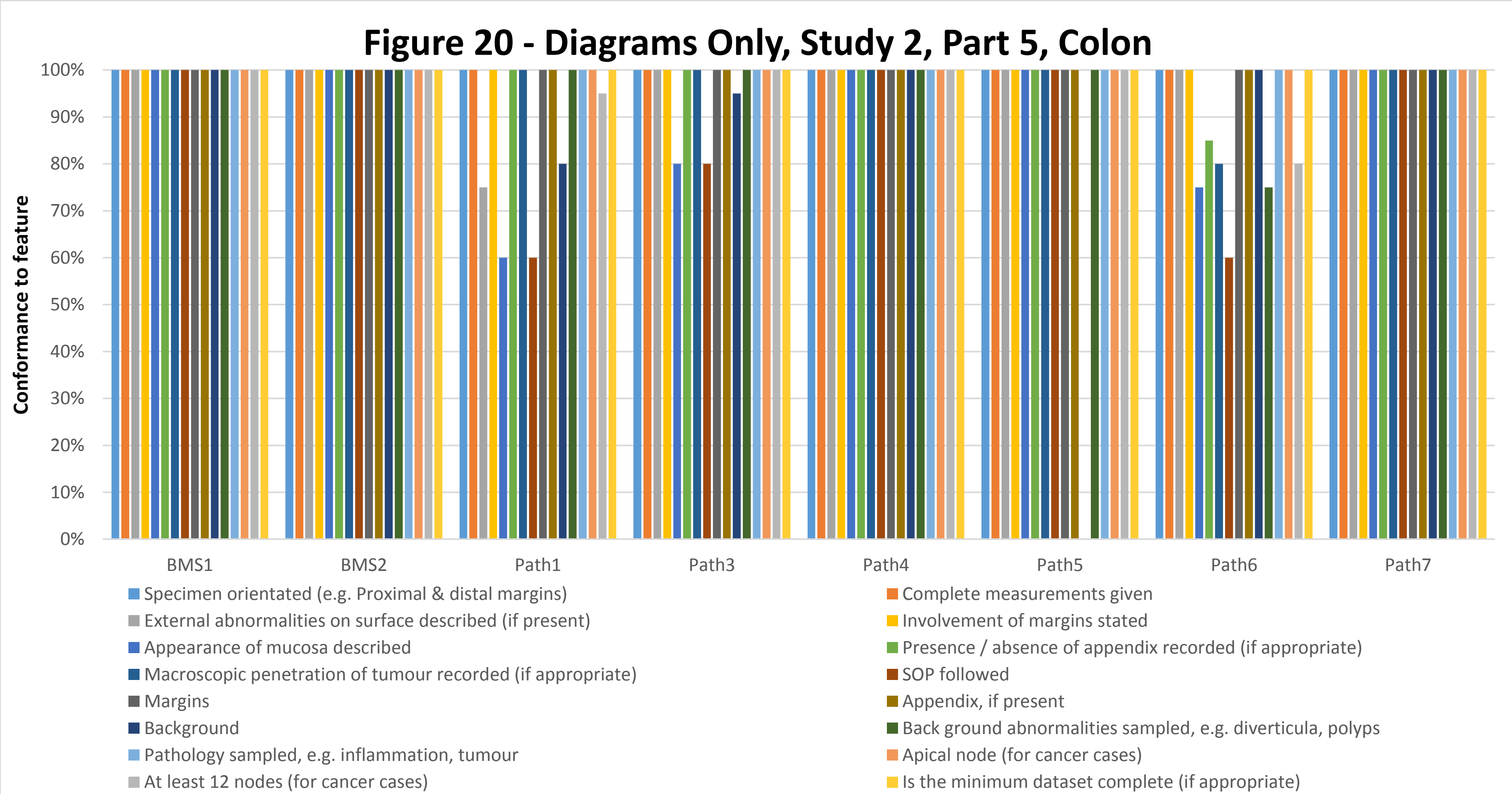


Figure 20 - Diagrams Only - Study 2 Part 5, Colon. This figure represents the use of indicative guide diagrams for the first time. The diagrams were run in isolation, and the checklists were used retrospectively to obtain this data from specimens dissected during this period. A slight increase in variation is noted amongst some dissectors here, compared to previous rounds (Figure 4 on page 77, Figure 8 on page 83, and Figure 12 on page 89).

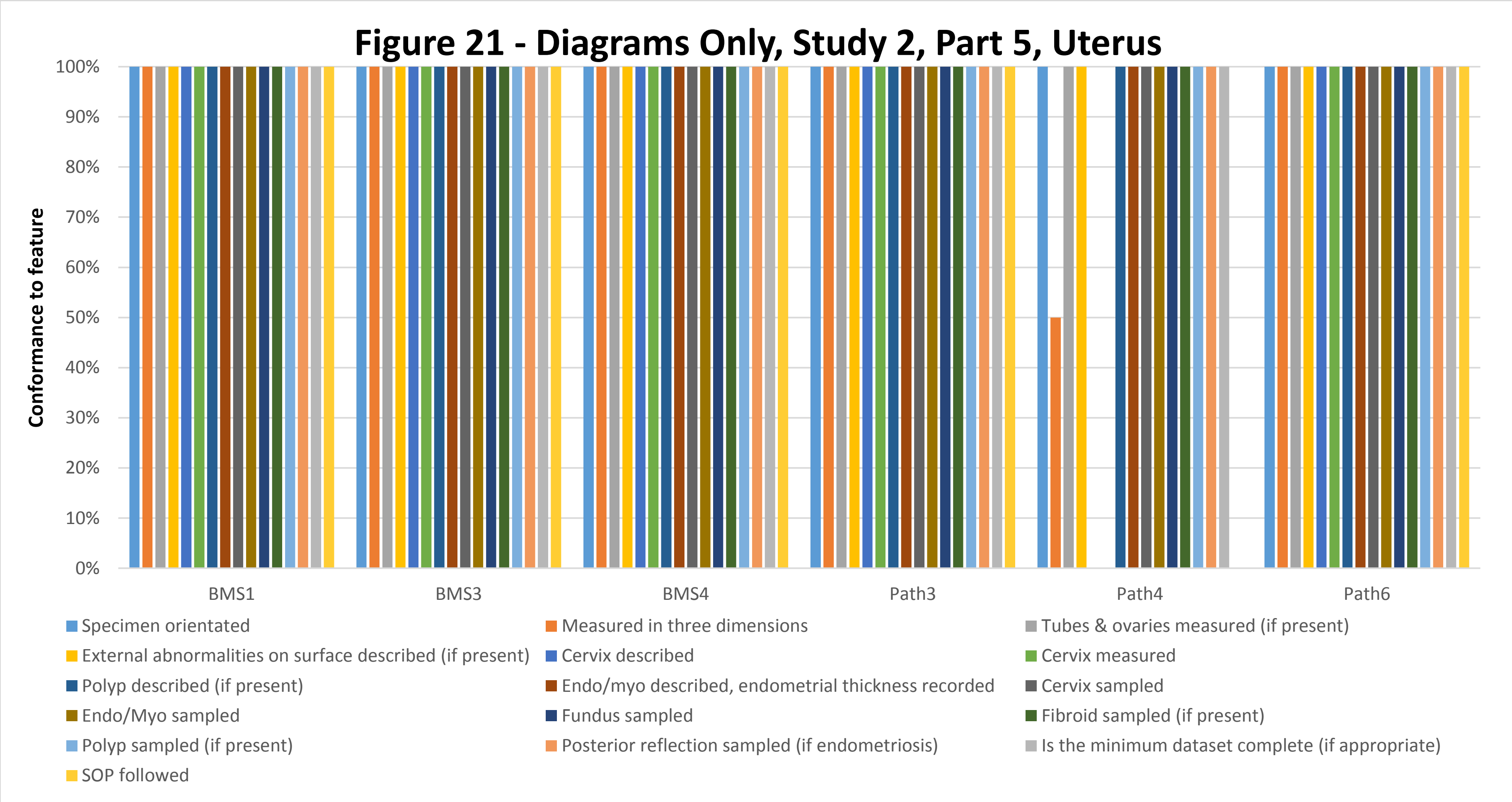


Figure 21 - Diagrams Only - Study 2 Part 5, Uterus. Comparison of figure 21 with the preceding rounds shows a reduction in variation from all dissectors, except pathologist4 - Figure 5 on page 78, Figure 9 on page 84, Figure 13 on page 90 and Figure 17 on page 96.

Study Two Part Six – Training Event and Guide Diagrams (BMS N=5, Pathologist, N=5)

Very little change is noted in study 6, in any of the specimen types. The only notable change is in relation to the uterus, where pathologist 4 now follows protocol and provides the mandated information in relation the cervix, in all cases.

Unfortunately, part 6 occurred at a time when several of the dissectors who were previously practicing either moved to new posts, or were simply unable to spend time in dissection, due to other pressures of work. As this was unlikely to change for the foreseeable future, part 6 was run with fewer participants. However, those that remained in dissection found themselves, by necessity, performing a higher volume of dissection.

Those dissectors showing variation in the preceding studies were largely pathologists who are not present in this study. The results show that the dissectors who had already reduced their variation were able to maintain their improved performance. Those dissectors who still demonstrated variation in the previous study (and were present in this study) demonstrated an incremental reduction in variation.

A number of changes have been introduced during the course of this and the preceding studies. In order to assess the effect of the interventions a further study was designed, using the checklists without the training event or diagrams.

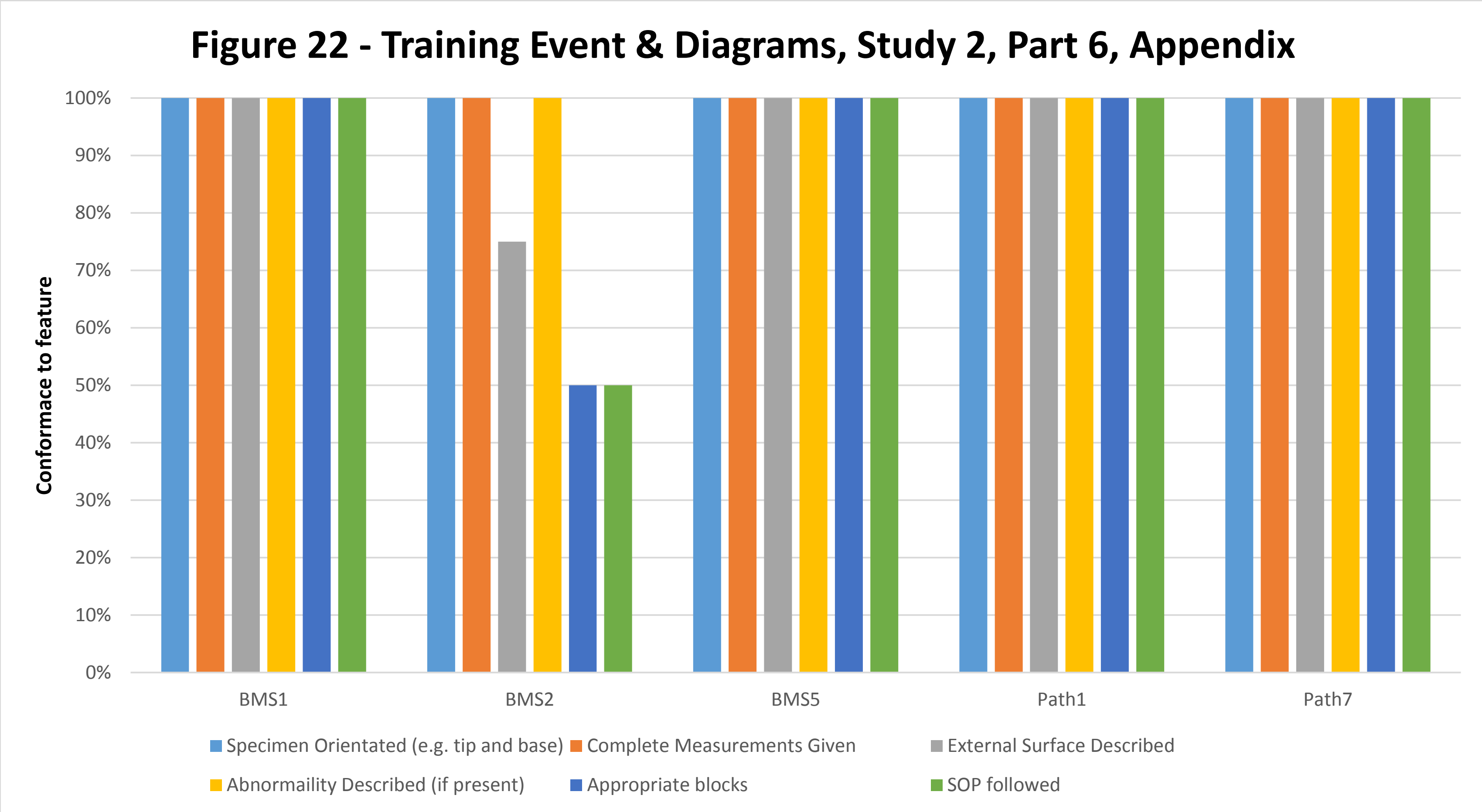


Figure 22- Training Event and Diagrams - Study 2 Part 6, Appendix. In this chart the variation noted in previous rounds by BMS2 persists, whilst the other dissectors sustain their newly found reduction in variation, compared to previous rounds (Figure 2 on page 75, Figure 6 on page 81, Figure 10 on page 87, Figure 14 on page 93 and Figure 18 on page 98)

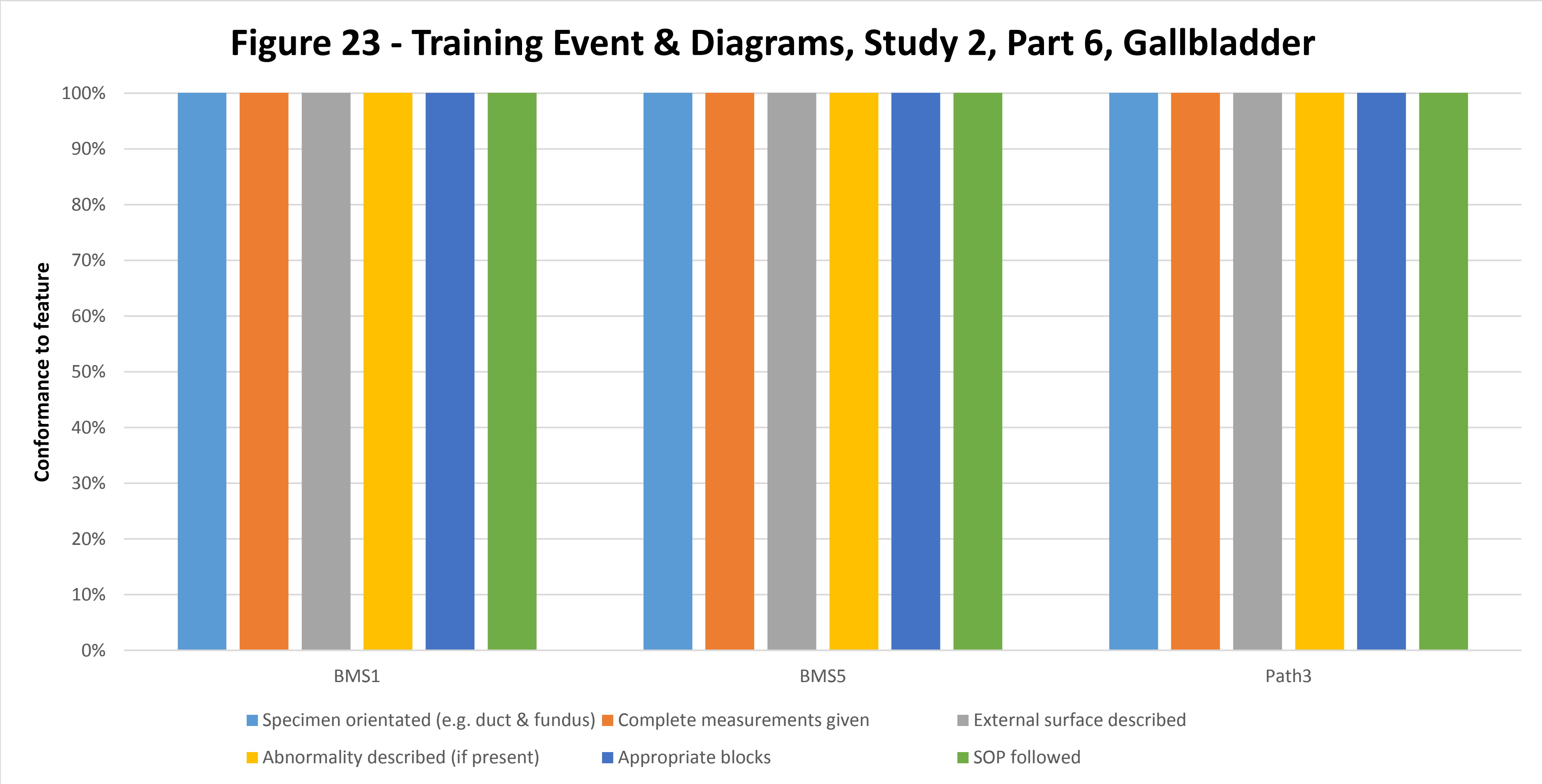


Figure 23 - Training Event and Diagrams - Study 2 Part 6, Gallbladder. The data here reflects that seen in the other rounds – the dissectors are maintaining the lack of variation gained in previous rounds (Figure 3 on page 76, Figure 7 on page 82, Figure 11 on page 88, Figure 15 on page 94 and Figure 19 on page 99)

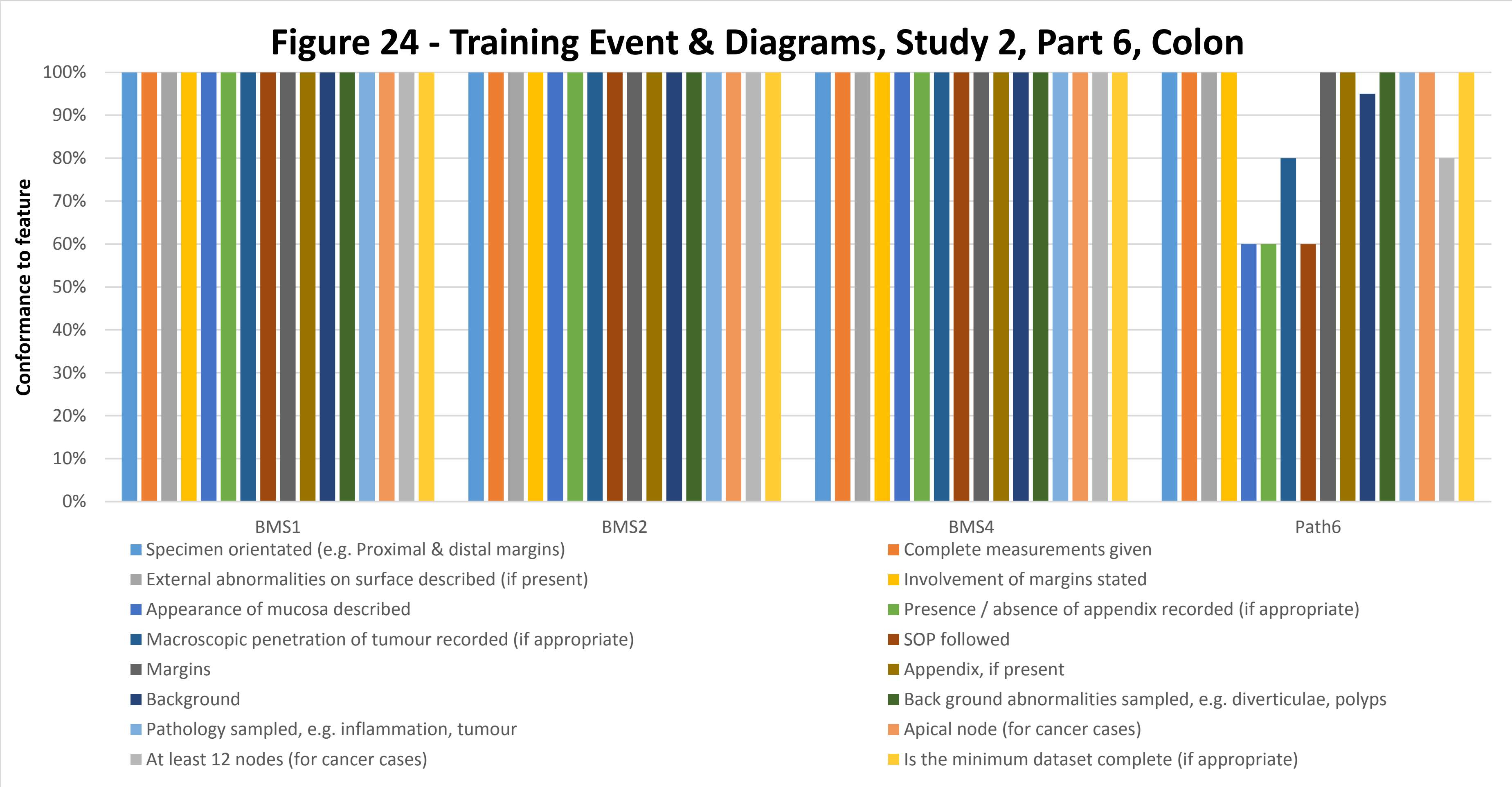


Figure 24 - Training Event and Diagrams - Study 2 Part 6, Colon. In part 6 only pathologist 6 is not reaching 100% for all data points, the other dissectors continue the 100% found in previous rounds (Figure 4 on page 77, Figure 8 on page 83, Figure 12 on page 89, Figure 16 on page 95 and Figure 20 on page 100)

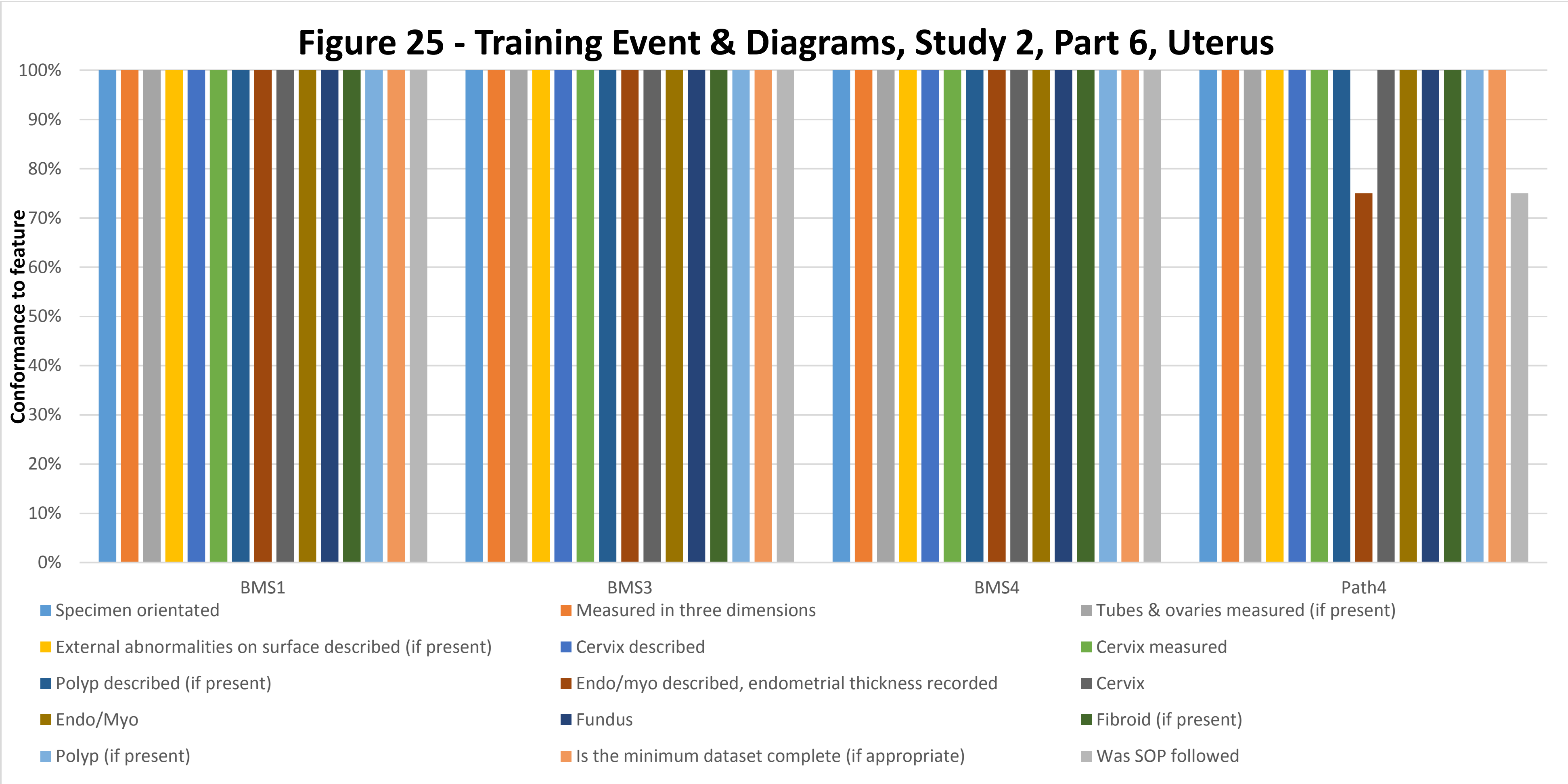


Figure 25 - Training Event and Diagrams - Study 2 Part 6, Uterus. In part 6, pathologist 4 still shows some variation, but it is reduced from previous rounds, whilst the other dissectors continue to demonstrate 100% conformance to all points as seen in previous rounds) (Figure 5 on page 78, Figure 9 on page 84, Figure 13 on page 90, Figure 17 on page 96 and Figure 21 on page 101).

Study Two Part Seven – Checklists only (BMS N=5, Pathologist, N=0)

The data for part 7 remains very similar to that in part 6. Those individuals remaining in dissection have increased the volume of work they are performing, in response to the lack of pathologist involvement. Some drift is noted in performance, with the removal or the training event, BMS 2 has reverted to their previous sampling method for appendix specimens, and BMS 4 is occasionally showing the same pattern. BMS 5 is beginning to omit an external description of the gallbladder, something which they had previously been doing for all cases. Also, BMS 3 is no longer describing the cervix or endometrium in call cases, something that they had previously been doing. Discussion with the dissectors attributed the most likely cause for this drift in performance to the withdrawal of the training event. The training event, it was felt, provided direction and the generalised feedback from the preceding studies enabled a discussion regarding appropriate practice.

The lack of pathologist data in part 7 is unfortunate, however, the BMS data clearly shows that dissectors are maintaining the reduction in variation that was seen with the introduction of the checklists. The training event was again missed by the dissectors, who were keen for its reintroduction. They made a number of suggestions as to how the training event might be developed. In order to draw the investigation to a close, a further study was designed

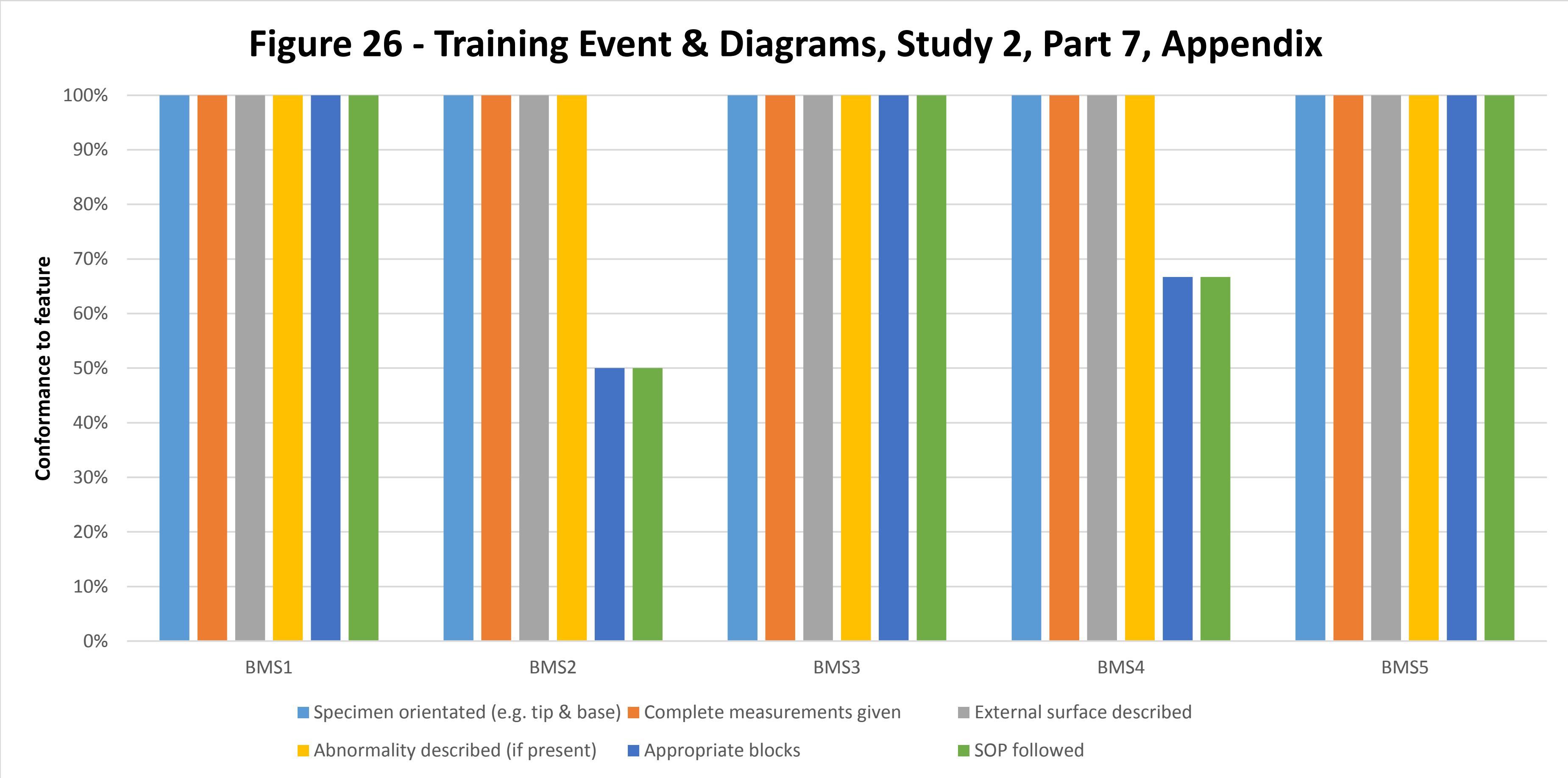


Figure 26 - Training Event and Diagrams - Study 2 Part 7, Appendix. In part 7 BMS 2 continues to show variation in their practice in regard to block taking, BMS drops from their previous 100% conformance in part 5, whilst the other dissectors maintain the 100% conformance seen in previous rounds (Figure 2 on page 75, Figure 6 on page 81, Figure 10 on page 87, Figure 14 on page 93, Figure 18 on page 98 and Figure 22 on page 103)

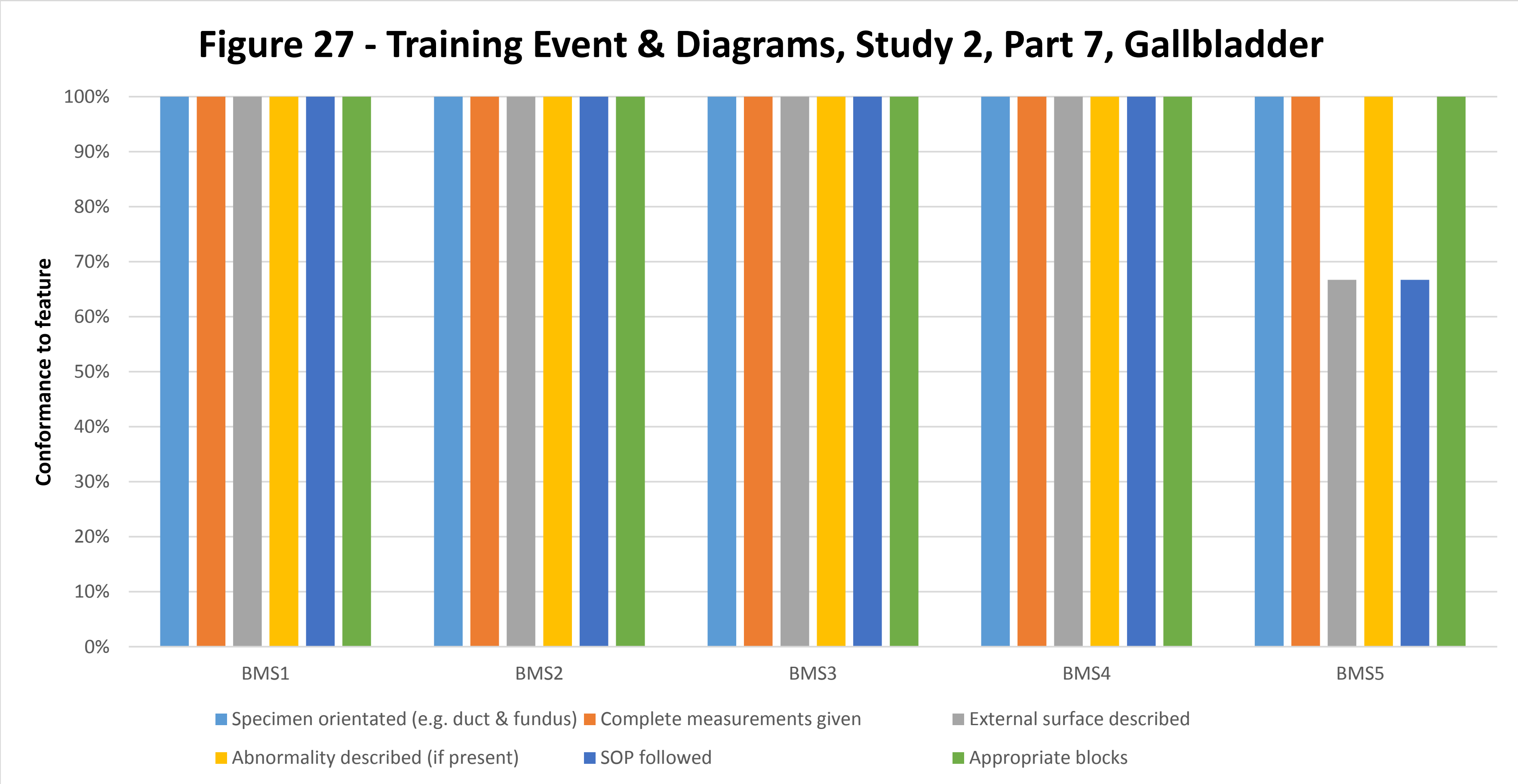


Figure 27 - Training Event and Diagrams - Study 2 Part 7, Gallbladder. The data gained in part 7 is much the same as that gained in part 6, although BMS 5 does show a slight decrease in their conformance compared to previous rounds (Figure 3 on page 76, Figure 7 on page 82, Figure 11 on page 88, Figure 15 on page 94, Figure 19 on page 99 and Figure 23 on page 104)

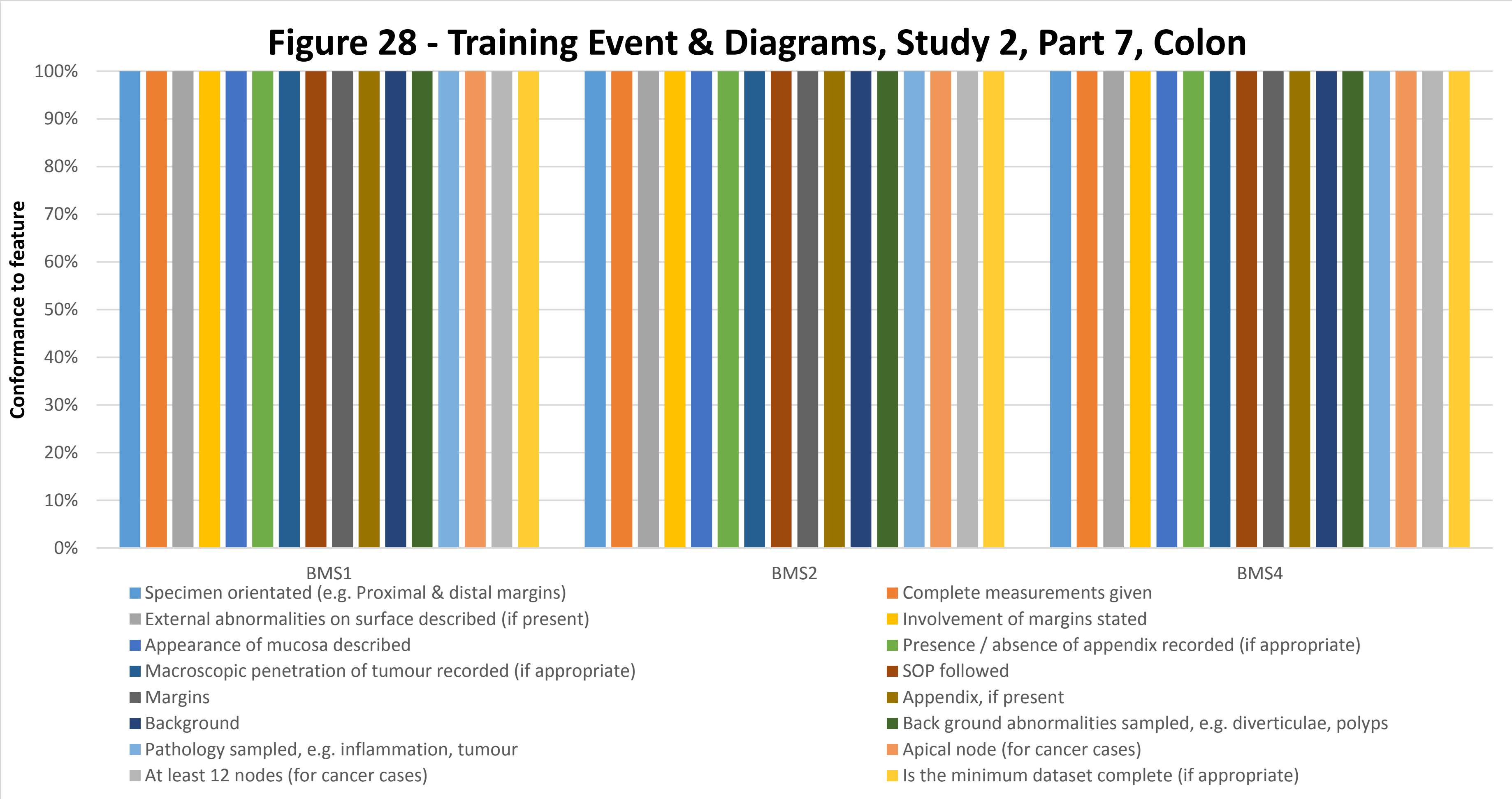


Figure 28 - Training Event and Diagrams - Study 2 Part 7, Colon. In part seven all dissectors reach full conformance to data points, although those dissectors showing most variation in previous rounds are missing from this part of the study (Figure 4 on page 77, Figure 8 on page 83, Figure 12 on page 89, Figure 16 on page 95, Figure 20 on page 100 and Figure 24 on page 105)

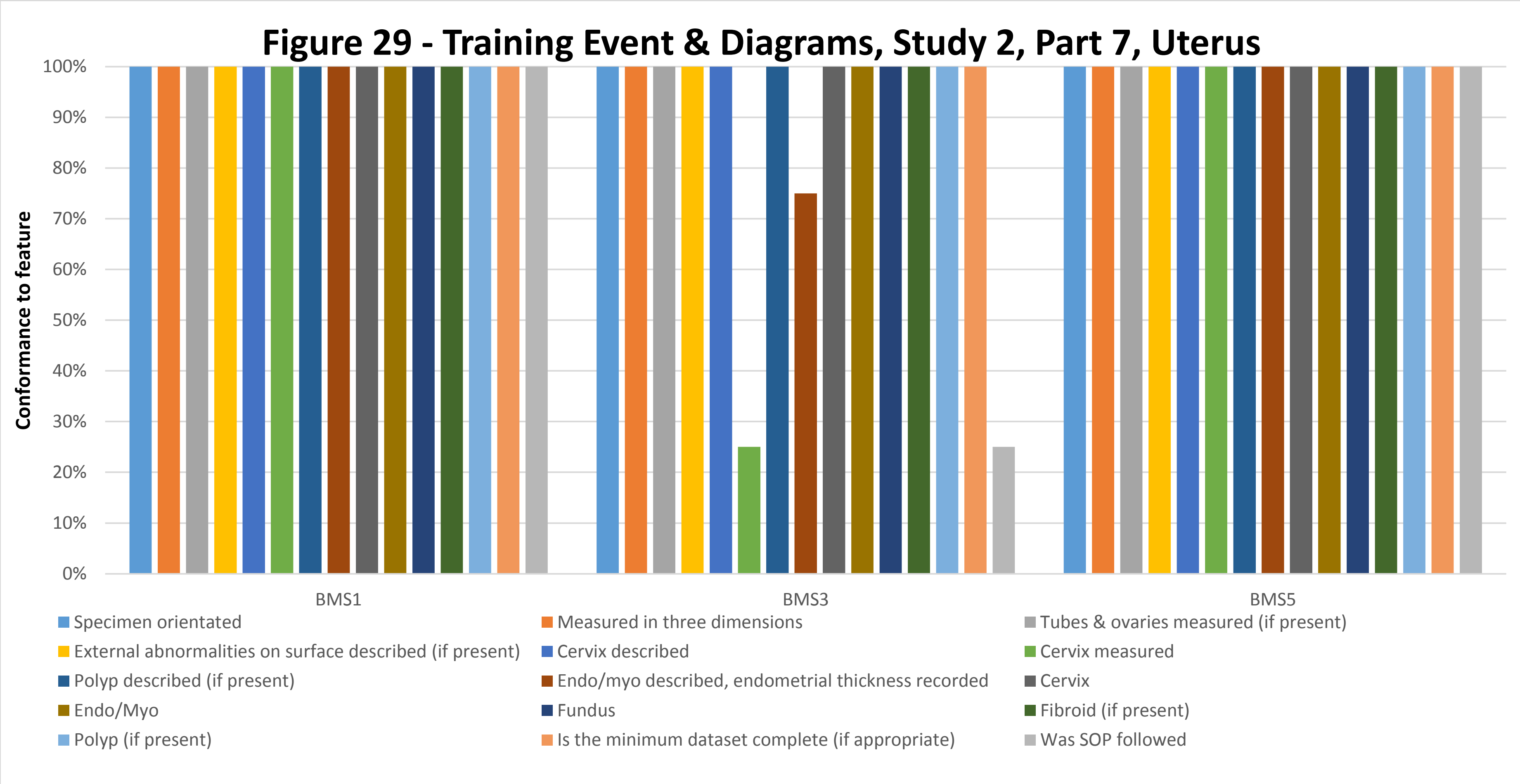


Figure 29 - Training Event and Diagrams - Study 2 Part 7, Uterus. In part 7 a reduction in conformance is seen from BMS 3, compared to their previous performance. BMS 5 appears in the uterus dissection data for the first time, and shows full conformance to SOP (Figure 5 on page 78, Figure 9 on page 84, Figure 13 on page 90, Figure 17 on page 96, Figure 21 on page 101 and Figure 25 on page 106)

Study Two Part Eight – Training Event and Checklists (BMS N=6, Pathologist, N=8)

Whilst a small amount of variation persists, the reintroduction of the training event appear to have reversed the drift in adherence to KPI noted in part 7. A number of dissectors are noted in part 7 who have not been seen previously. Some of these are established pathologists, who have not been practicing in dissection regularly, whilst other are new appointees.

Figure 30 on page 113 to Figure 33 - Training Event and Checklists - Study 2 Part 8, Uteru on page 116 show the lack of variation in practice gained over the course of this investigation. Those dissectors who have been a part of the investigation for several rounds all show a reduction in variation for all specimen types, those joining or intermittently participating show a higher level of variation. There are some dissectors who show full conformance at the outset, *e.g.* pathologists 8, 10 and 12, and these are considered in Chapter Three – Study 2 – The Training Intervention, Results of Study Two, on page 71.

A great deal of information has been gained in the preceding studies. In order to evaluate the impact of the studies in a longitudinal fashion, an overview of the results is presented in Chapter Three – Study 2 – The Training Intervention, Results of Study Two, on page 71.

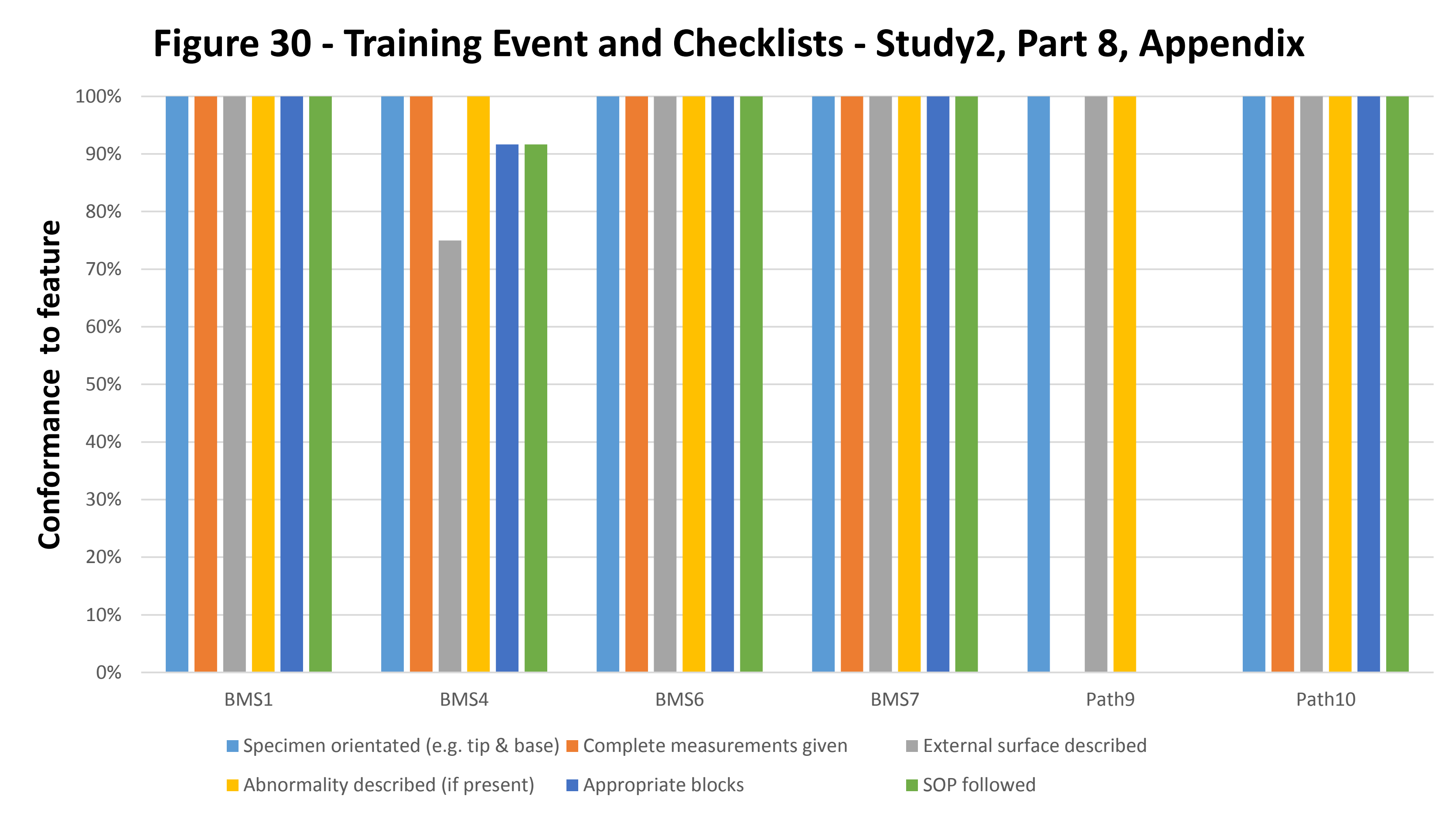


Figure 30 - Training Event and Checklists – Study2 Part 8, Appendix. Figure 30 demonstrates the frequency with which individual dissectors met each requirement of the checklists, whilst the training event was also running. A small amount of variation is noted from BMS4, whilst Pathologist 9 fails to meet half of the requirements, 100% of the time. Most dissectors present in previous rounds continue to show 100% conformance, whilst BMS 4 shows a small increase in variation compared to previous rounds (Figure 2 on page 75, Figure 6 on page 81, Figure 10 on page 87, Figure 14 on page 93, Figure 18 on page 98, Figure 22 on page 103 and Figure 26 on page 108)

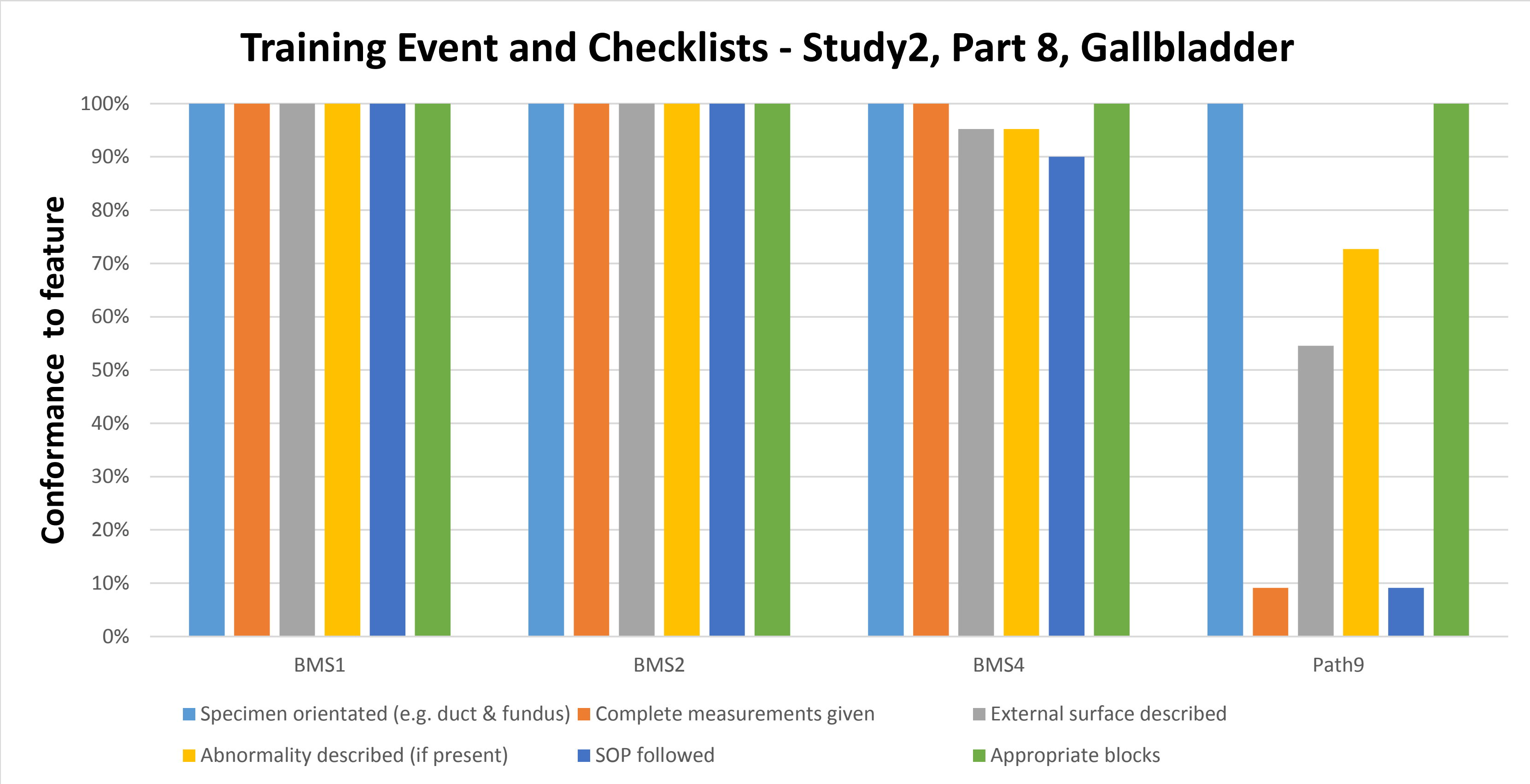


Figure 31 - Training Event and Checklists - Study 2 Part 8, Gallbladder. Figure 31 demonstrates the frequency with which individual dissectors met each requirement of the checklists, whilst the training event was also running. A small amount of variation is noted from BMS4, whilst Pathologist 9 fails to meet many of the requirements, much of the time. BMS 1 and 2 continue the 100% conformance seen in previous rounds, whilst BMS 4 shows an increase in variation from previous rounds (Figure 3 on page 76, Figure 7 on page 82, Figure 11 on page 88, Figure 15 on page 94, Figure 19 on page 99, Figure 23 on page 104 and Figure 27 on page 109)

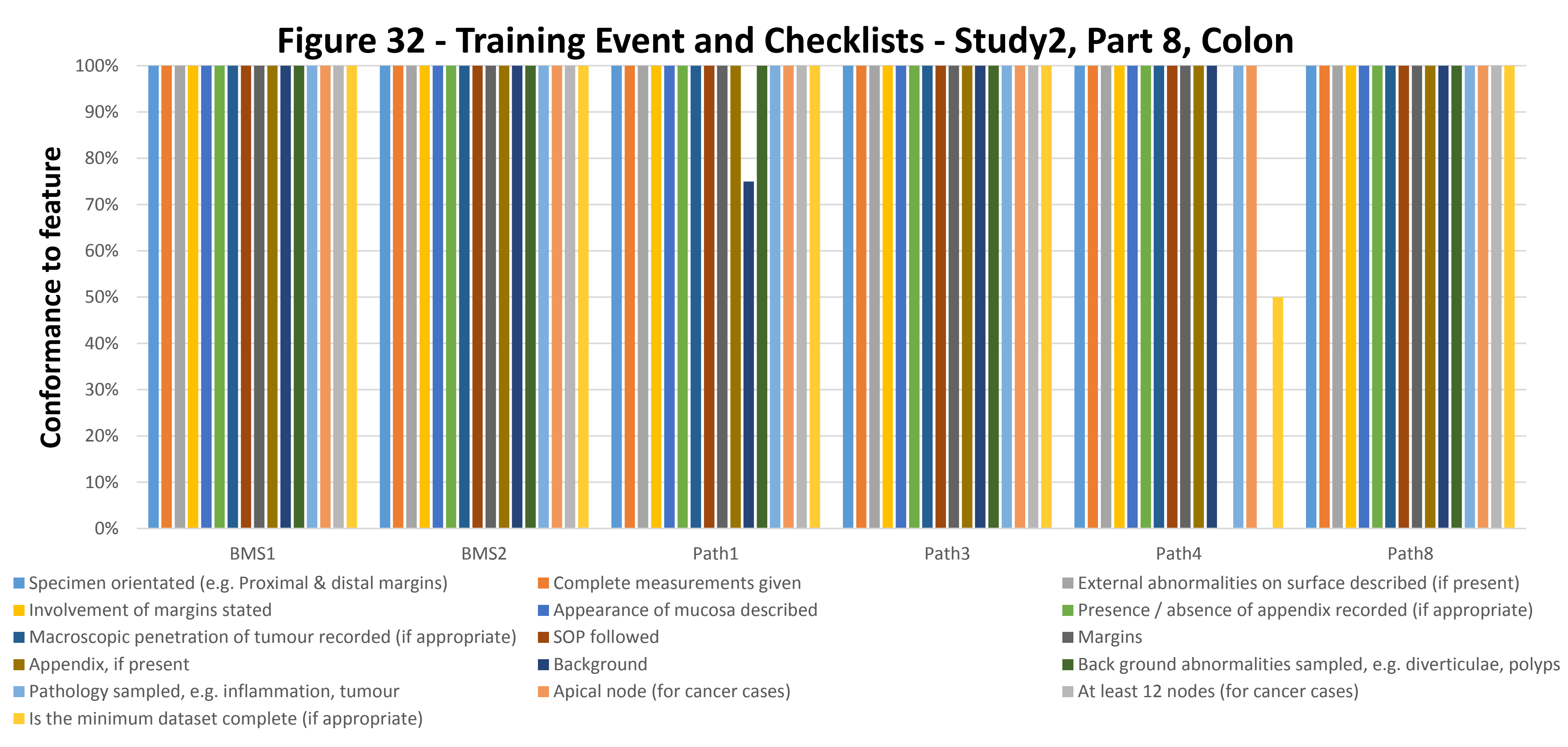


Figure 32 - Training Event and Checklists – Study 2 Part 8, Colon. Figure 32 demonstrates the frequency with which individual dissectors met each requirement of the checklists, whilst the training event was also running. A small amount of variation is noted from Pathologist 1, whilst Pathologist 4 fails to meet two of the requirements, 100% of the time and one of the requirements 50% of the time. Those present in previous rounds continue the reduction in variation previously noted (Figure 4 on page 77, Figure 8 on page 83, Figure 12 on page 89, Figure 16 on page 95, Figure 20 on page 100, Figure 24 on page 105 and Figure 28 on page 110)

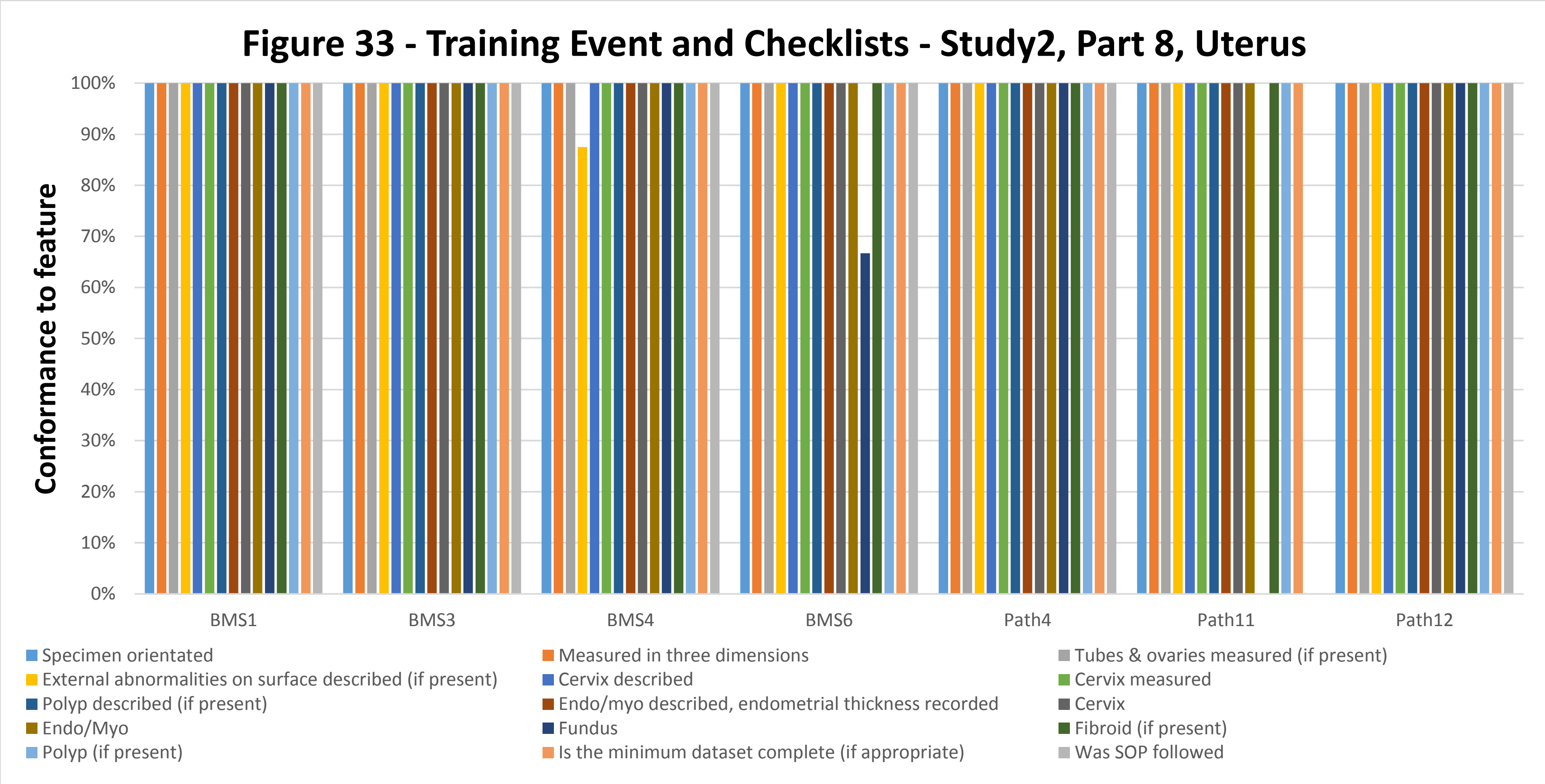


Figure 33 - Training Event and Checklists - Study 2 Part 8, Uterus. Figure 33 demonstrates the frequency with which individual dissectors met each requirement of the checklists, whilst the training event was also running. A small amount of variation is noted from BMS4 and 6, whilst Pathologist 11 fails to meet one of the requirements, 100% of the time. This shows a reduction of the variation noted in previous rounds (Figure 5 on page 78, Figure 9 on page 84, Figure 13 on page 90, Figure 17 on page 96, Figure 21 on page 101, Figure 25 on page 106 and Figure 29 on page 111)

Changes over time, by tissue type

The mean rate of adherence to SOP for each dissector is displayed in the following four graphs, one for each specimen type, covering all of the studies over time.

Appendix

Starting with study 2 part 1 (checklists completed against archive) and moving through each part in turn (P2 = checklists used at the dissection bench; P3 = training event and checklists; P4 = training event only; P5 = diagrams only; P6 = training event and checklists; P7 = checklists only) and ending with part 8 (training event and checklists), Figure 34 – presents the average conformance to SOP for each dissector handling appendix specimens in each study. The trends in individual conformance are then easily seen, allowing individuals to be compared against one another.

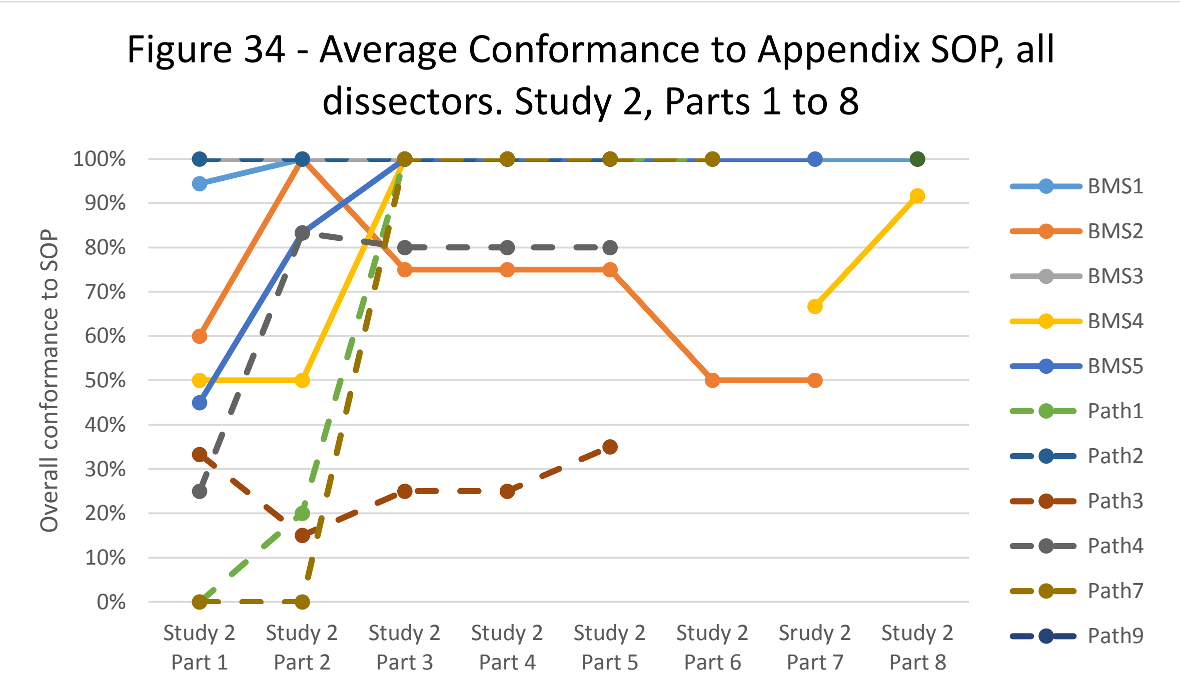


Figure 34 – This graph demonstrates the changes over time from each dissector when dealing with appendix specimens. This is a representation of their average conformance to the SOP, as measured by the checklists and report review. It is apparent that at S2P1 (baseline) there is much variation. A rapid, and sustained, convergence to agreed practice is seen from the majority of practitioners. However, some variation remains. This is discussed in detail later.

The graph for the baseline (S2 P1) data seen here (Figure 2, on page 75) clearly demonstrates a great deal of variation in practice. BMS 3 and Pathologist 2 are both demonstrating full concordance with all of the KPIs. BMS 1 is showing almost full compliance across the range, whereas BMS 2 and 4 are showing full compliance on some KPIs, and variable performance on the others. Pathologists 1 and 7 are fully compliant on the first few KPIs, but show zero conformance on the majority of the others. Pathologists 3 and 4 show a great deal of variation in their practice.

The difference between the baseline (S2 P1 - Figure 2, page 75) and the first round of checklists (S2 P2) (Figure 6, on page 81) is clear and obvious. BMS 1-3 show 100% conformance to all KPI, BMS 4 showed 50% on one KPI, also meaning that the SOP was followed 50% of the time; this being the same as was seen at baseline. BMS 5 also failed on one KPI, having described the external surface 83.3% of the time, this was the only failing, meaning that they followed the SOP 83.3% of the time; this was an improvement on the baseline where six KPIs were noted to fall short of the 100% mark. The pathologists also showed a marked improvement, although not as striking as that seen by the BMS. Pathologist 1 previously showed at 0% conformance on three KPI, one of those now returns at 100% and the other two are at 20%. Pathologist 2 continues to return 100% across the full range. Pathologist 3 shows a negative change, with them following the SOP 33.3% of the time at baseline compared to only 15% of the time with the checklists. Pathologist 4 showed a striking improvement, where only a single KPI fell short of 100%, this being reflected in the SOP being followed 83.3% of the time. Pathologist 7 showed minimal, if any, change. They failed to take appropriate blocks for all of their cases, both at baseline and with the checklists.

Data collated after the introduction of the training event (S2P3) (Figure 10 on page 87) continues the theme noted with the introduction of the checklists. A small amount of variation is noted from BMS 2, with half their KPIs returned at 75%. The remaining BMS all show full 100% conformance for all KPIs. Pathologists 1 and 2 also show 100% conformance for all KPIs, whilst pathologist 3 again shows a great deal of variation. Pathologist 4 shows a small amount of variation, similar to that seen in the previous round. Pathologist 7 shows a substantial improvement, with 100% conformance to all KPIs.

Assessing the current state of practice was achieved by a suspension of the training event. Data gathered in study 2 part 4 (Figure 14 on page 93) showed 100% conformance across all KPIs for BMS 1, 3, 4 and 5; however, BMS 2 showed a substantial drop in their performance. BMS 2 failed to orientate the specimen 25% of the time and failed to describe abnormal features for 25% of the cases. Pathologist 1 sustained their previous improvement and again returned 100% across all KPIs, as did Pathologist 2. Pathologist 3 failed to measure the specimen appropriately in 70% of cases and did not adequately describe the specimen in many cases. Pathologist 4 showed similar performance to BMS 2 with a few KPIs returning in the region of 80%. Pathologist 7 showed 100% conformance for all KPIs.

In study 2 part 5 (Figure 22, on page 103) the picture is almost unchanged from that seen in the previous round (S5). BMS 1, 3, 4 & 5 along with Pathologists 1, 2 & 7, show 100% conformance for all KPIs. The other dissectors (BMS 2, Pathologists 3 & 4) show virtually identical performance to the last round with only slight variation in their non-conformances.

All of the dissectors in study 2 part 6 (Figure 22 on page 103), except one (BMS 2), showed 100% conformance across all KPI. BMS 2 showed a similar level of non-conformance as in previous rounds.

In study 2 part 7 (Figure 26 on page 108) there is a similar picture to that seen in the last round. BMS 1, 3 and 5 continue their full compliance across all KPIs. BMS 2 continues to demonstrate variation across a similar range of KPIs. BMS 4, who was last seen in part 3 showing 100% of all KPIs, shows some variability in this round. They only follow the SOP in 66.7% of cases, all of the variation relates to one KPI, that of taking appropriate blocks.

Study 2 part 8 (Figure 30 on page 113) sees the introduction of new pathologists to the group of dissectors, this will be discussed in more detail in chapter 5. These dissectors show a distinct split in their behaviour, pathologist 9 does not follow the SOP in any of their cases, whilst pathologist 10 shows full conformance to SOP. This is seen across other specimen types.

The overall picture for appendix dissection shows a general trend towards the KPIs and hence compliance with SOP. Some individuals show less standardisation than others, and the change is more sustained in some than others.

Gallbladder

Starting with study 2 part 1 (checklists completed against archive) and moving through each study in turn (S2 P2 = checklists used at the dissection bench; S2 P3 = training event and checklists; S2 P4 = training event only; S2 P5 = diagrams only; S2 P6 = training event and checklists; S2 P7 = checklists only) and ending with study 2 part 8 (training event and checklists), Figure 35 - below, presents the average conformance to SOP for each dissector handling gallbladder specimens in each study. The trends in individual conformance are then easily seen, allowing individuals to be compared against one another.

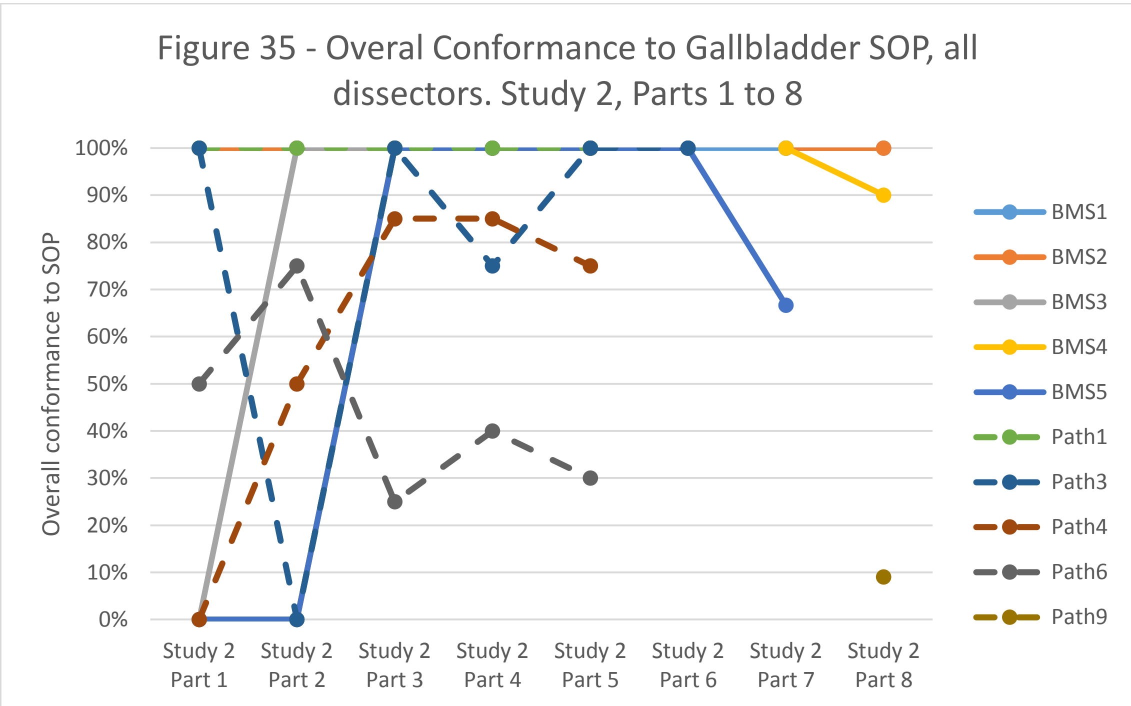


Figure 35 - This graph demonstrates the changes over time from each dissector when dealing with gallbladder specimens. This is a representation of their average conformance to the SOP, as measured by the checklists and report review. It is apparent that at Study 2 Part 1 (S2P1 (baseline)) there is much variation. A rapid, and sustained,

convergence to agreed practice is seen from the majority of practitioners. However, some variation remains. This is discussed in detail later.

The graph for the baseline data (S2P1) (Figure 3, page 76) for gallbladder shows a similar picture to that for the appendix. A great deal of variation is again seen. BMS 1 and 2 show similar variation, with 100% on a few KPI, then variation on the others. BMS 3, 4 and 5 all show substantial failings, with only a few KPIs reaching 100% and many being at 0%. Pathologist 1 is fully compliant across all KPIs, Pathologist 3 describes the external surface only 80% of the time but is otherwise fully compliant. Pathologist 4 fails to describe the external surface and take appropriate blocks every time. Pathologist 6 shows 100% for the initial KPIs, but then mirrors the variation seen with the other pathologists.

With the introduction of the checklists (S2P2) (Figure 7 on page 82) the results for the gallbladder demonstrated some interesting data. BMS 1, 2 and 3 showed a 100% conformance across all KPIs, BMS 4 showed 100% two KPIs, around 80% for two and 0% for the remaining two KPI. BMS 5 showed near 100% conformance for all except the same two KPI, where they returned also returned 0%. The reason for this spilt is discussed later. Pathologist 1 continued to return 100% conformance across all KPI. Pathologist 3 again showed a reduced performance when compared to their baseline, they failed to reach 100% on 5 KPIs in comparison to failing to reach 100% on 2 KPIs at baseline. Pathologist 4 showed a partial improvement, whilst still failing to describe the external surface on a single case, they were able to take appropriate blocks 75% of the time, in contrast to the 0% seen at baseline. Pathologist 6 showed a slight change with one KPI increased and one decreased.

In study 2 part 3 (Figure 11, on page 88), introduction of the training event, there is 100% standardisation from all of the BMS dissectors. The pathologists performance is also much improved. Pathologist 1 shows 100% conformance to all KPIs, as in the previous round. Pathologist 3 has much improved, with 100% conformance. Pathologist 4 shows a small amount of variation. Pathologist 6 shows a largely unchanged picture from the previous round.

A very similar picture is seen in this study 2 part 4 (Figure 15 on page 94), with all the BMS showing full conformance. Here the training event was suspended to obtain a view of current practice after the pervious changes. Pathologist 3 failed to sustain their improvement, with a drop in appropriate block taking to 75%. Pathologist 4 showed a slight improvement, whilst pathologist 6 showed improvement in block taking, but a decrease in the overall percentage of cases where they followed the SOP.

As with the data for the appendix, not much change is seen in study 2 part 5 (Figure 19 on page 99). However, there are some features of note. Whilst all the BMS (1 – 5) and pathologist 1 remain at 100%, pathologist 3 has improved from the previous round and now also reports 100% for all KPI. Pathologist 4 identically, whilst pathologist 6 shows some improvement on all KPI.

The three dissectors practicing in study 2 part 6 (Figure 23 on page 104**Error! Reference source not found.**) (BMS 1, 5, pathologist 3) all showed 100% conformance for all KPI. This was sustained from the previous round where they all previously returned 100%.

A slightly diminished picture is seen in study 2 part 7 (Figure 27 on page 109), compared to the previous round. BMS 1, 2, 3 and 4 continue to show the full conformance they demonstrated in the previous round. However, BMS 5 has not followed the SOP in 33.3% of cases. In each case, the variation relates to describing the external surface.

With study 2 part 8 (Figure 31 on page 114) performance remains much the same as in the preceding rounds. Pathologist 9 only has managed to perform appropriate dissection in only 10% of cases. Pathologist 9 declined to make use of the checklists. The remaining dissectors continue to show high conformance to SOP.

Colorectal

Starting with study 2 part 1 (checklists completed against archive) and moving through each study in turn (S2 P2 = checklists used at the dissection bench; S2 P3 = training event and checklists; S2 P4 = training event only; S2 P5 = diagrams only; S2 P6 = training event and checklists; S2 P7 = checklists only) and ending with study 2 part 8 (training event and checklists), Figure 36 - , below, presents the average conformance to SOP for each dissector handling appendix specimens in each study. The trends in individual conformance are then easily seen, allowing individuals to be compared against one another.

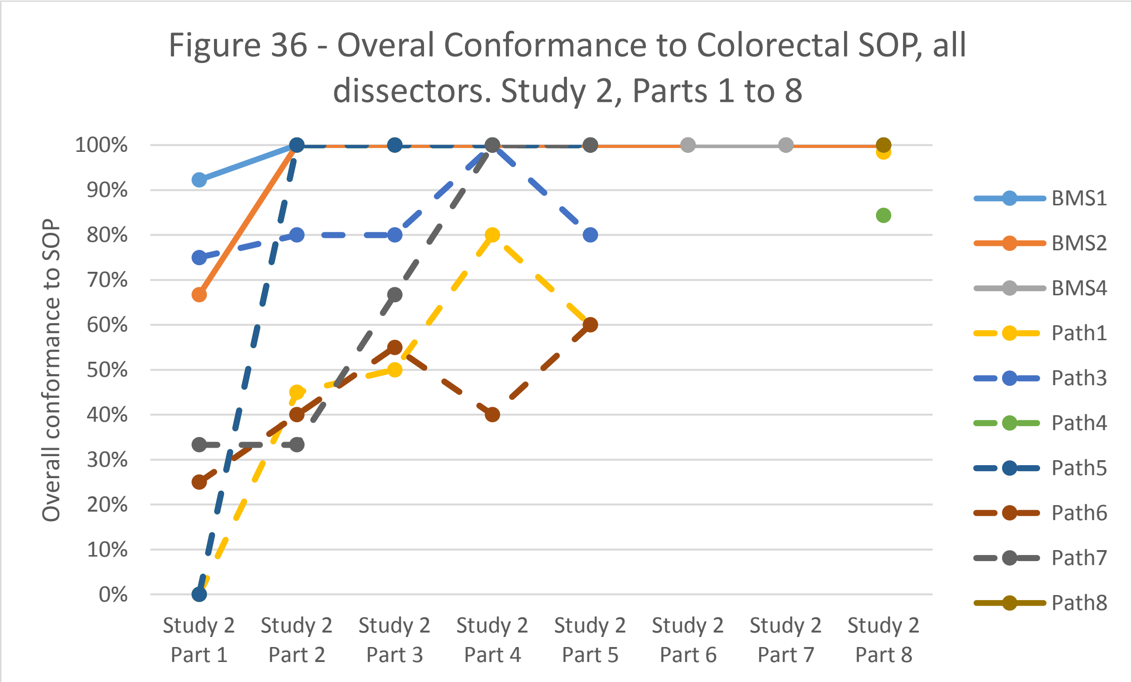


Figure 36 - This graph demonstrates the changes over time from each dissector when dealing with colorectal specimens. This is a representation of their average conformance to the SOP, as measured by the checklists and report review. It is apparent that at Study 2 Part 1 (S2P1 (baseline)) there is much variation. A rapid, and sustained, convergence to agreed practice is seen from the majority of practitioners. However, some variation remains. This is discussed in detail later.

At baseline (Study 2 part 1) (Figure 4 on page 77) across the range of BMS and Pathologists for the colorectal specimens, not a single individual shows 100% conformance. The BMS (1 and 2) both show greater concordance than the pathologists, although notable gaps are seen. Pathologist 1 shows an interesting picture with 100% on many items and 0% on several others, with three KPIs between 50 and 75%. The remaining pathologists show a similar pattern, with some things that they always do, some things they never do, and some things that they do some of the time. Pathologist 3 is perhaps closest to ideal of the pathologists, but even they only reach 75% average conformance to SOP.

As with the other specimen types, the introduction of the checklists (S2P2) (Figure 8 on page 83) gives clear results. BMS 1 and 2 show a full conformance to SOP across all KPI. Pathologist 1 showed a notable improvement, however, they were still fully following the SOP in only 45% of cases, with 4 KPIs returned at under 100%. Pathologist 3 showed a small overall increase in conformance to SOP, although no great change was seen. Pathologist 4, who had been demonstrating a very patchy conformance at baseline, demonstrated a 100% conformance to all KPIs with the introduction of the checklist. Pathologist 5 showed a similar improvement, with only one KPI below 100%, that of sampling the background mucosa, this was at 0%. Pathologists 6 and 7 both showed a similar limited improvement.

The improvements noted in the previous round have been sustained in study 2 part 3 (Figure 12 on page 89), with all but two dissectors showing full adherence to SOP with 100% conformance to all KPIs. Pathologist 1 has shown further improvement, although not yet reaching full 100% conformance. Pathologist 6 has shown no change in their practice in this round, although they did show an initial improvement in the first round.

The graph for study 2 part 4 (

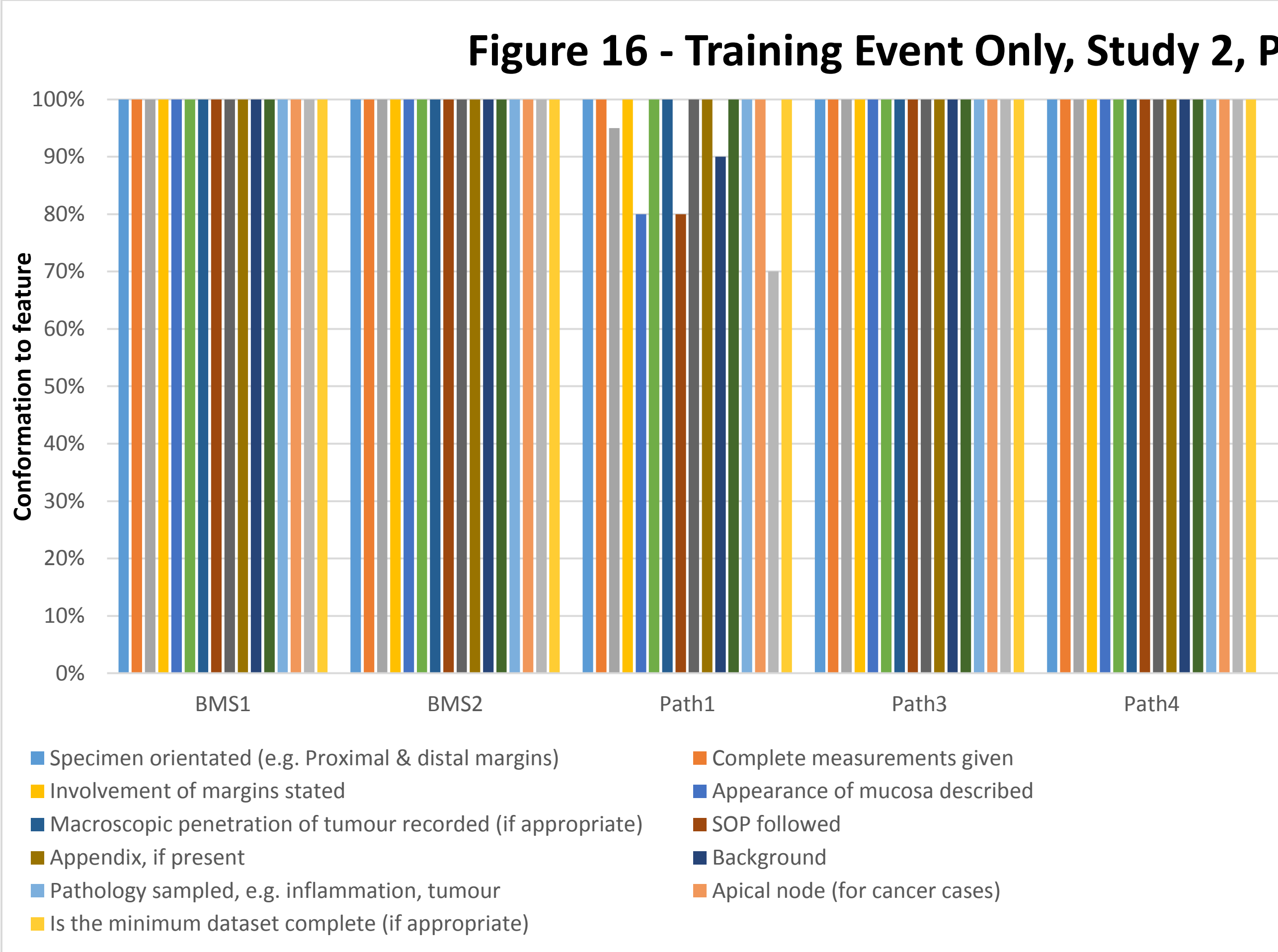


Figure 16 on page 95) shows only two dissectors (Pathologists 1 and 6) that fail to meet all of the targets. In the preceding round there were five dissectors failing to meet all targets; clearly, this is a notable improvement. Pathologist 1 shows 5 KPI around the 80% mark, whilst pathologist 6 shows three KPI around 40% and three around 75%; the rest are at 100%.

There is little change in study 2 part 5 (Figure 20 on page 100). Whilst BMS 1, BMS 2 pathologist 4 and pathologist 7 maintain their 100% score, pathologist 1 remains non-compliant on the same KPI as seen before. Pathologist 3 does show a small negative change, with the macroscopic penetration of the tumour only being recorded in 80% of cases. Pathologist 5 shows no change at all, with all except the sampling of background mucosa being at 100%.

The reduction in variation gained in the previous rounds are sustained in study 2 part 6 (Figure 24 on page 105) by BMS 1, 2 and 4, with 100% concordance with all KPIs. However, pathologist 6 continues to show a variation across a number of KPI.

Study 2 part 7 (Figure 28 on page 110) shows a slightly diminished picture, when compared to the previous round. BMS 1, 2, 3 and 4 continue to show the full conformance they demonstrated in the previous round. However, BMS 5 has not followed the SOP in 33.3% of cases. In each case, the variation relates to describing the external surface.

Study 2 part 8 (Figure 32 on page 115) shows a continuation of the high level of conformance to SOP reached previously. Pathologist 4, who was absent from studies 7 and 8, shows a drop in conformance from 100% to 84.4%. Pathologist 8 joins the dissection team here, and demonstrates 100% conformance at the outset. The BMS dissectors demonstrated a change to high or full conformance for all KPIs, whilst the pathologists showed a much more variable response. However, an overall trend towards conformance is noted in studies 2 to 5, with some drop in part 5. Unfortunately, this is where most pathologist input ends, making a longer assessment impossible.

Uterus

Starting with study 2 part 1 (checklists completed against archive) and moving through each study in turn (S2 P2 = checklists used at the dissection bench; S2 P3 = training event and checklists; S2 P4 = training event only; S2 P5 = diagrams only; S2 P6 = training event and checklists; S2 P7 = checklists only) and ending with study 2 part 8 (training event and checklists), Figure 37 - on page 127 presents the average conformance to SOP for each dissector handling appendix specimens in each study. The trends in individual conformance are then easily seen, allowing individuals to be compared against one another.

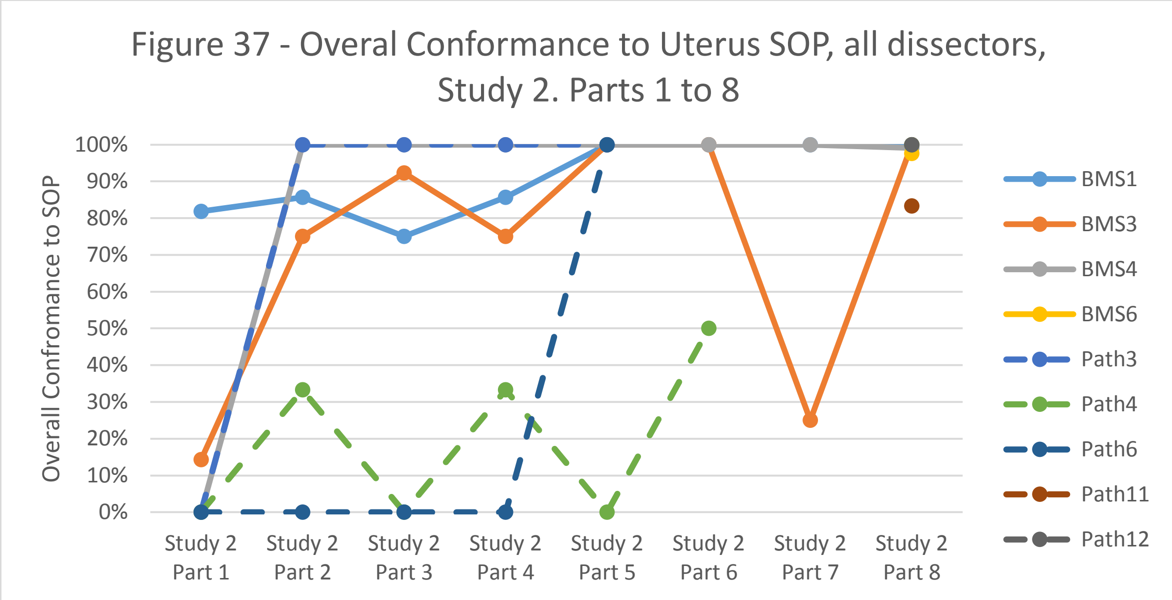


Figure 37 - This graph demonstrates the changes over time from each dissector when dealing with uterus specimens. This is a representation of their average conformance to the SOP, as measured by the checklists and report review. It is apparent that at S2P1 (baseline) there is much variation. A rapid, and sustained, convergence to agreed practice is seen from the majority of practitioners. However, some variation remains. This is discussed in detail later.

Once again we see extensive variation across all individuals at baseline (S2P1) (Figure 5 on page 78). BMS 1 is returning 100% for most KPIs although two of them are noted to be 75 & 80%. BMS 3 and 5 both show 100% on many KPI, however they both return at least one 0% and several ranging between 15 and 85%. Pathologist 3 returns three 0% and a number of variable conformances. Pathologist 4 shows 100% conformance across all KPIs. Pathologist 6 shows 100% across most KPIs with two 0% returns and one at 85%.

Again, the reduction in variation is noticeable with the introduction of the checklists (S2P2) (Figure 9 on page 84). The variation in performance between BMS 1, 3 & 4 all relate to the cervix. With the checklists in place, this variation is substantially reduced for BMS 1 & 3, for BMS4 the variation disappears entirely, with 100% conformance for all KPIs. Again, pathologist 3 shows a great deal of variation, across a number of KPIs, this disappears entirely with the checklist, with 100% conformance for all KPIs. Pathologist 4 and 6 also showed variation in regard to the cervix, although each showed variation in one other KPI. Pathologist 4 showed some improvement from the previous round, but there was no change from pathologist 6.

In next round (S2P3) (Figure 13 on page 90) BMS 1 and 3 show near 100% conformance, with slight improvements over the previous round. BMS 5 and pathologist 3 continue their improved performance of 100% returns for all KPIs. Pathologist 4 has again demonstrated a small improvement in some areas, whilst pathologist 6 has shown no change.

With the removal of the checklist and continuation of the training event (S2P4) (Figure 17 on page 96) BMS 1 continues to show variation in relation to the cervix and the endometrium/myometrium, although less than in the previous round. BMS 3 shows more variation in this round than in the previous round, in the same areas as BMS 1. BMS 4 and pathologist 1 continue to demonstrate the 100% conformance they showed in the last round. Pathologist 4 shows an improvement across a number of KPI, they improve their performance on measuring in three dimensions, now reporting 75%, they begin to measure the cervix in all cases, and describe it in 30% of cases. Pathologist 6 shows a reduction in conformance, no longer describing or measuring the cervix, and only describing a polyp in 25% of cases where one was found.

In the next dataset (S2P5) (Figure 21 on page 101) BMS 1, 3, 4, pathologist 3 and pathologist 6 all return 100% concordance across all KPI. Pathologist 4 measures the specimen in 50% of cases, and omits to measure or describe the cervix for every specimen. This is a clear improvement from the previous round, where two out of the three BMS and two out of the three pathologist showed variation. Interestingly, the positive change seen in the previous round from pathologist 4, in relation to the cervix KPI, has been entirely lost; with them returning to their previous practice of neither describing nor measuring the cervix.

In Study 2 part 6 (Figure 25 on page 106) BMS 1, 3 and 5 continue their 100% conformation with SOP across all KPIs, as seen in previous rounds. Pathologist 4 shows some improvement from the last round; here we see that there is variation only on the specimen measurement and in the description of the endometrium/myometrium, the previous variability in relation to the cervix has disappeared.

Study 2 part 7 (Figure 29 on page 111) shows BMS 1 and 5 maintaining the 100% adherence to SOP seen in the preceding two rounds. However, BMS 3 showed variation on two KPIs. Most notably the measurement of the cervix, the reason for this is discussed later.

Study 2 part 8 (Figure 33, on page 116) draws the dissectors to, or close to, 100% for all KPIs. This continues the pattern seen in previous rounds and with other specimen types. Again, more variation is noted from the pathologists than the BMS, but the overall trend for all dissectors is towards conformity and lack of variation.

Changes over time for all specimen types

The mean for all SOP conformance across all specimen types is plotted below (Figure 38 on page 131) for each dissector. The high level of variation seen in the individual graphs (Figure 34 on page 117 to Figure 37 on page 127) is evident. The overall trends that can be discerned show that the checklists have the most effect to the most people. When the checklists are withdrawn and other interventions run in their place, the average conformance drops. The use of diagrams alone saw the average conformance drop for one of the BMS and two of the pathologists. Reintroducing the checklists stabilises the drop, and the reintroduction of the training event brings most dissectors to an average of 100% for all KPIs. Participating in this investigation for the first time in study 2, part 8 are pathologists 8, 9, 10, 11 and 12. Pathologists 8, 10 and 12 show 100% conformance, pathologist 11 shows an average of 83% conformance to SOP, with only the presence of the checklist. Pathologist 11, however, did not wish to engage with the checklists, and demonstrated less than 10% conformance to SOP.

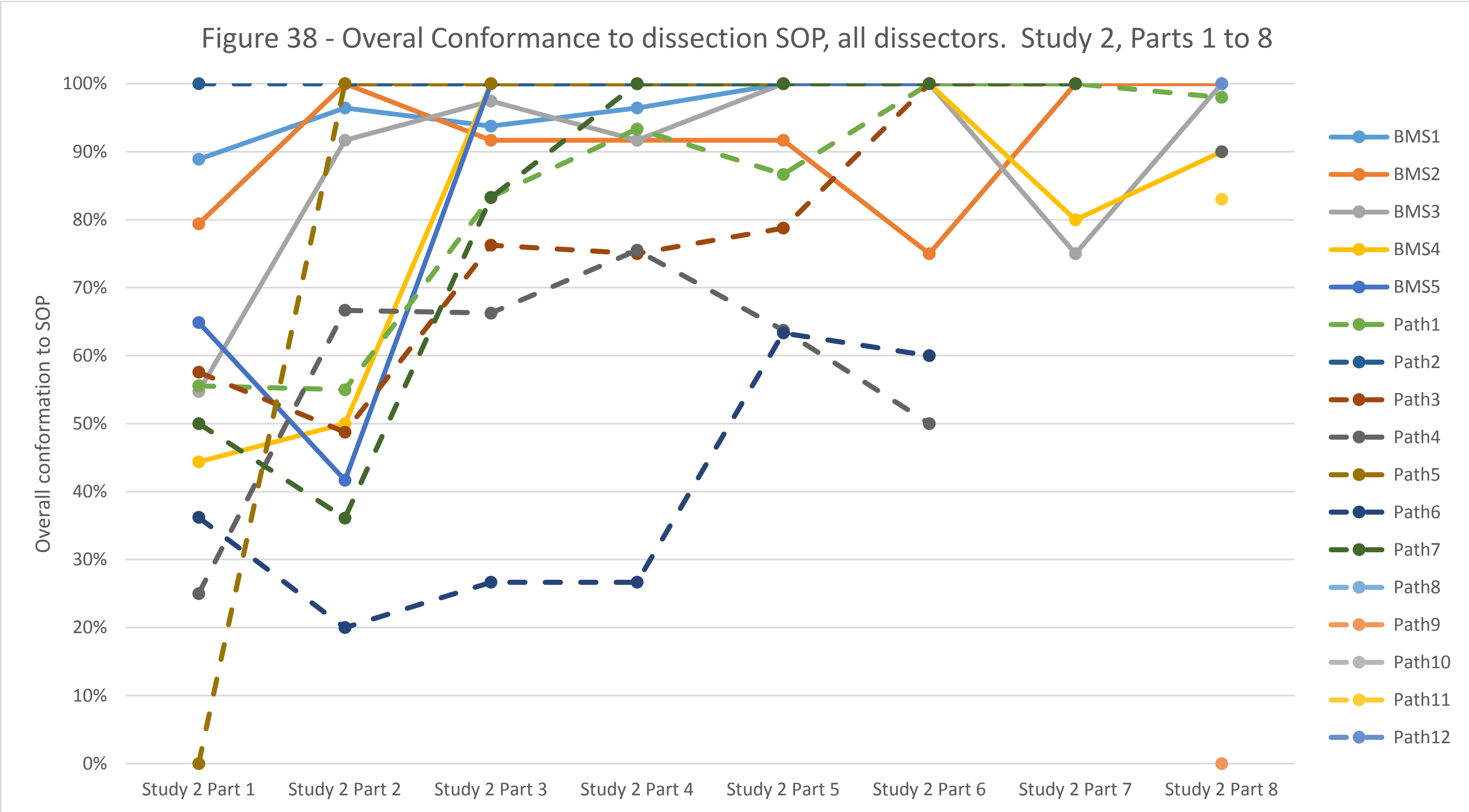


Figure 38 – This graph plots the overall conformance to SOP for each dissector (as assessed by the checklists and report review), for each stage of study 2. Whilst a great deal of variance is seen, a clear trend towards 100% conformance is seen over time for the majority of practitioners over each round. Some variation returns, and for some dissectors the amount of variation is in itself quite variable. This is discussed in detail in chapter 5

This is a complex picture, with a 17 total participants. What is immediately clear is that the BMS (solid lines) show a rapid response to the interventions, which is sustained. The BMS average conformance does not drop below 75% from study 3 onwards. The pathologist picture does show an overall reduction in variation, although it is somewhat less immediate and sustained. Each dissector finished the series of investigations with less variation than they demonstrated at the start. Of the five pathologists who first appear in part 8, one is showing 83% conformance to SOP, three are at 100%, whilst the fifth is showing a 0% conformance to SOP. This has already been discussed in part 8 and will be further considered in the discussion.

When attempting to unpick the effect of each individual intervention, this is a more complex issue than one might initially think. As the participants change throughout it is not possible to fully isolate the effects of each intervention – as each builds on the last, the effects of the programme also become apparent to the dissectors, increasing their investment and buy in to the system. Therefore the effect of each intervention is not so easy to isolate. However, Figure 39 on page 133 gives some indication of this. The chart shows the mean conformation to SOP for each round, by specimen type – the error bars indicating the standard deviation, illustrating the range in values obtained. Over each round, the variance and the standard deviation decrease, resulting in much greater conformation to SOP.

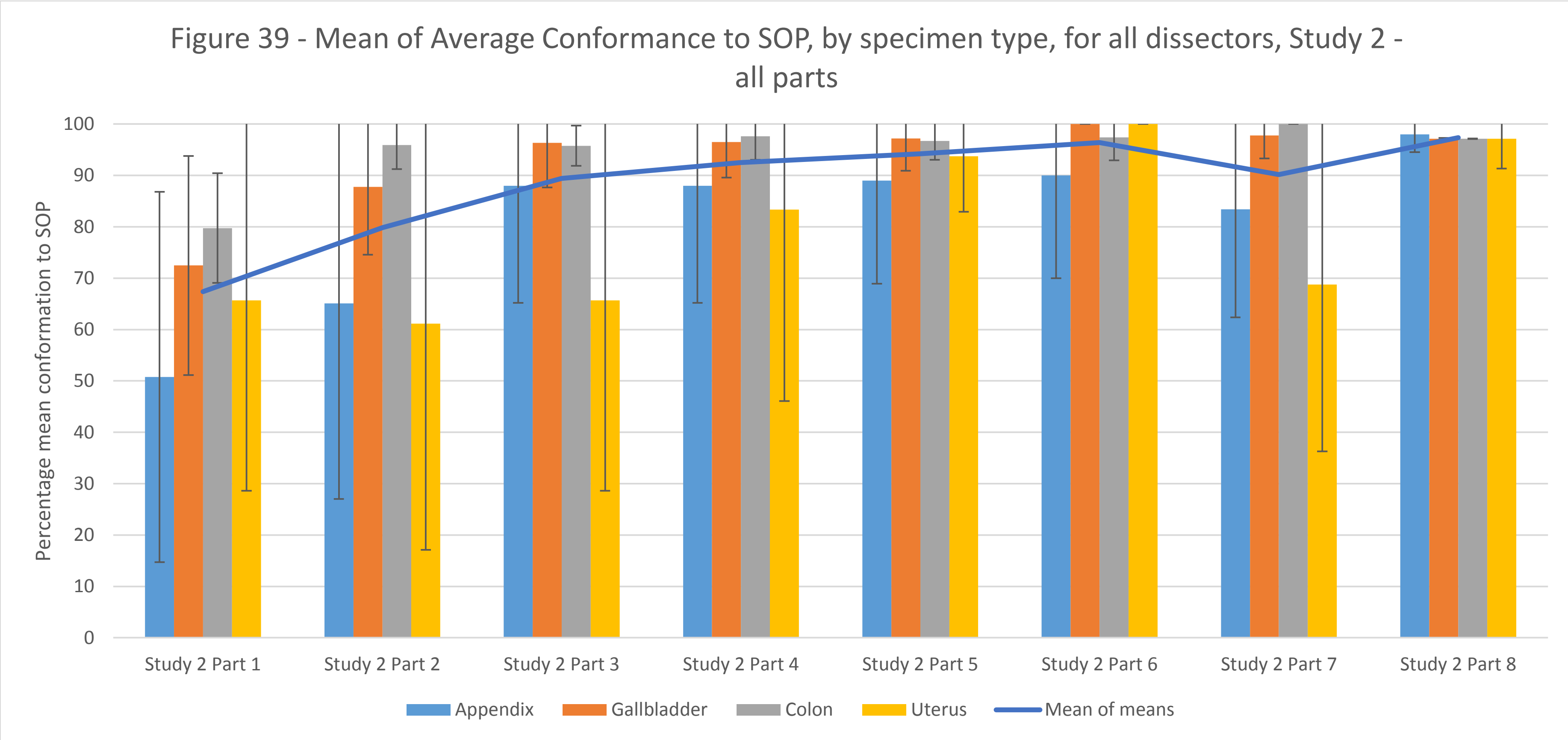


Figure 39 – Mean of Average Conformance to SOP, by specimen type, for all dissectors, Study 2 - all parts. This figure demonstrates the change in means for adherence to SOP for all dissectors in each round, broken down by specimen type. The error bars indicate one standard deviation, demonstrating the range of values. The chart clearly shows that conformance to SOP overall increases throughout each round, and a reduction in variance between dissectors is seen, by the reduction in size of the error bars.

Whilst this does track changes over time, it still does not isolate the individual effects of each intervention. As noted above, it is not possible to definitively identify exactly what changes are related to which interventions, as our experimental subjects are people, and the people involved are themselves changing; as are the particular individuals involved. However, we can make some statistical representation of the changes. Figure 39, above, shows the mean of the means shown in Figure 38. This figure demonstrates the change in means for adherence to SOP for all dissectors in each round, broken down by specimen type. The error bars indicate one standard deviation, demonstrating the range of values. The chart clearly shows that conformance to SOP overall increases throughout each round, and a reduction in variance between dissectors is seen, by the reduction in size of the error bars on page 133, adding the standard deviation of the means, and the mean of the standard deviations. In this table we can compare the changes in mean for each round against the baseline, and consider the standard deviation. Also included is a column demonstrating the t-test statistic, comparing each round against the baseline data.

Table 7- Mean of mean conformance to SOP, Mean of SD within this data and SD of the means – all dissectors, all specimen types, all rounds. The table demonstrates the increase in conformance to SOP over time, and a reduction in SD over time.

Stage	Mean of means %	Mean of SD	SD of means	T - test
Study 2 Part 1	67.38	26.27	10.695	
Study 2 Part 2	79.83	25.02	14.71489	0.36674
Study 2 Part 3	89.42	18.11	12.44693	0.089034
Study 2 Part 4	92.52	17.91	5.95346	0.020678
Study 2 Part 5	94.23	10.23	3.26793	0.017718
Study 2 Part 6	96.41	6.12	4.095559	0.011818
Study 2 Part 7	90.16	14.49	12.55288	0.07795
Study 2 Part 8	97.38	2.38	0.373436	0.016303

Table 7, above, neatly demonstrates the trends seen in the data. A consistently smaller t value is seen with each round (study 2 part 7 is an outlier, discussed below), compared against the baseline, this could be taken to indicate that study 2 part 8 was the most effective and most powerful. However, as noted above, this study has been cumulative with each round building on that which went before. In Table 7 the data for study 2 part 7 does not follow the trend seen in the other rounds, in that mean drops and the SD raises to near that seen in study 2 round 3. However, one must only note the mean of the standard deviations for the data here, to see how much individual variance there was in conformity. This is explained by the change in the people involved in these rounds. Had the specific individuals remained constant throughout the study, the data analysis would be much simpler and the trends clearer to see. However, even with this additional layer of complexity, the changes are clearly visible.

At the end of study 2 a substantial number of changes and investigations had been introduced. Consequently, all of the dissectors practicing at this time (n=10) were invited to take part in a series of semi-structured interviews. The goal was to review the investigation so far, from the point of view of the dissectors involved, to determine what they had gained from the process and how it might be improved.

Chapter Four – Study 3 – Participant Interviews

Study 1 – Archival Review

100 appendix, 100 gallbladder, 100 colon, 100 uterus reports reviewed

Unknown number of participants

Study 2 – The Training Intervention

Part One – The creation of the checklists and collecting baseline data

Part Two – Checklist Introduction (BMS N=5, Pathologist, N=7)

Part Three – Training Event and Checklists (BMS N=5, Pathologist, N=7)

Part Four – Training Event only (BMS N=5, Pathologist, N=7)

Part Five – Guide Diagrams (BMS N=5, Pathologist, N=7)

Part Six – Training Event and Guide Diagrams (BMS N=5, Pathologist, N=5)

Part Seven – Checklists only ((BMS N=5, Pathologist, N=0)

Part Eight – Training Event and Checklists (BMS N=6, Pathologist, N=8)

Study 3 – Participant Interviews

The dissectors were interviewed

BMS n=6, Pathologist n=4

Introduction

In order to evaluate the investigation, and understand its impact from the point of view of the dissectors, each dissector was invited to an interview. The interviews were semi-structured and designed to explore the dissectors view of the dissection process in the laboratory, their own abilities and how the investigation did, or did not, help them.

The investigation so far has concentrated on the output from the dissectors, and how to monitor and improve upon that. In this part, consideration is given to the subjects themselves. As this is a process that affects people, it is important to ensure enough attention is given to the individuals and their reactions to the work.

In order to investigate and explore the feelings and experiences of the participants an interview with each dissector was planned. A series of questions were devised prior to the interviews (see Appendix Six – Participant Information Pack and Question Sheet on page 218), and the interviews were recorded.

Design

After the interventions (checklist, feedback event and guide diagrams) had been introduced, several rounds of data collection were performed. Following this, the participants were interviewed. The information pack (comprising an information sheet, debriefing sheet and consent form) along with the question sheet (which was not disclosed in advance), can be found in Appendix Six – Participant Information Pack and Question Sheet on page 218.

This study was designed to explore the attitudes of the participants to the work undertaken. As such, quite open ended questions were devised. A foundational work by Schuman and Presser (1979) sets out very well the advantages and disadvantages of open and closed questions, including the obvious advantages when it comes to coding and numerical data analysis. However, they also detail how closed questions can enhance any bias on the part of the questioner or question setter. They note how open questions, whilst taking longer to ask and answer, and longer to process and code, result in a greater variety of answers – providing more insight into why people think or feel the way they do. One of the advantages of closed questions is that there is a higher response rate to questionnaires distributed with closed questions than those with open questions. As this study had a small number of participants, and the questions were to be asked face to face, most of the advantages of closed questions were lost. The advantage of easier coding and data analysis was considered to be offset by the additional insight that could be offered by open questions.

Bearing in mind the lessons from Schuman and Presser (1979), the work of Braun and Clarke (2006) was used here. Their work details how transcripts from interviews can be analysed and coded for analysis (see Thematic Analysis on page 141 for more details) allows for open ended, exploratory questions to be used. As the questions related to perceptions of experience and opinion, parallels may be drawn with the techniques used in sensory science. Kleji and Musters (2003) noted that open questions allow full use of expressive language, which is intrinsic to the self-expression of the individual. They note that an analysis of the data gained from open questions allow the clear generation of further questions, the questions used here (see page 223 for the questions) have been chosen to explore the thoughts, feelings and experiences of the participants. The goal in these interviews is to gain an insight into the participants' experiences, to further refine and improve this scheme.

Participants

All staff members (n=10) currently involved in histopathological dissection (at the time of interview) at the Royal Derby Hospital (RDH) were divided into two groups:

1) Pathologist (medically qualified, consultant or SPR grade) (n=4)

2) Biomedical Scientist (BMS)

i) Expert BMS (have gained the Institute of Biomedical Science (IBMS) Diploma of Extended Practice in Histological Dissection) (n=3)

ii) Advanced BMS (have gained Fellowship of the IBMS, without specific dissection qualification) (n=3)

Each person was approached informally by the chief investigator, to determine their initial opinion regarding being interviewed. The response was positive from all individuals. A consent form and information sheet were given to the participants, who were asked to return the consent form to the chief investigator within a week. The participants were assured that the interviews would be confidential, and that only anonymous excerpts would be quoted. They were told that they would be free to withdraw at any time.

Materials

Interview room with digital recorder. Recorded interviews and transcripts of the interviews. See Appendix Six – Participant Information Pack and Question Sheet on page 218 for interview pack.

Ethics

As this investigation involved human participants, the necessity for ethical approval was investigated. The Integrated Research Application System (IRAS) was contacted, as was the Research and Development department at the Derby Royal Hospitals NHS Foundation Trust. Both confirmed in writing that they considered that ethical approval was not required for the interviews. The Trust Service Evaluation and Audit lead delegated authority for approval to the Histopathology department manager. The Histopathology manager gave their authorisation for the interviews.

Method

A time was arranged with each individual at their convenience, and a private location agreed upon. For the pathologists, this was in their own office; for the BMS interviews a private office space was booked. The process was explained to the interviewees and they were encouraged to ask questions, should they have any. The recorder was started and the interview began with an introduction of the interviewer and interviewee. The questions in Appendix Six – Participant Information Pack and Question Sheet, on page 218, were worked through and the interviewees were encouraged to digress as they wished and to discuss any other areas they felt relevant. At the end of the interview the interviewee was thanked and the recording saved to a secure location.

The recordings were then transcribed on to the computer system and saved within a secure location on the hospitals NHS IT system.

The interview transcripts were examined with the aim of understanding the perspective of the interviewees in regard to the interventions undertaken in this investigation. The interviews were designed to explore the opinions of the interviewees in relation to their own practice, the quality of dissection in the laboratory as a whole, and how they felt the interventions had, or had not, helped them. The interviewees were also questioned to discover their thoughts on how the process could be improved upon.

Thematic Analysis of Participant Interviews

Each of the individuals who had been practicing in dissection during the period of data collection, (and were still working within the department) were approached to participate in these interviews. Everyone gave their consent to participate. Four of these were consultant pathologists, three were expert BMS dissectors and three were advanced BMS dissectors. Due to the small number of participants, the quotes discussed below are not attributed to individuals, to preserve anonymity.

Pathologist A is a highly experienced consultant pathologist, with international experience. They are involved with strategic governance of the Trust and setting the direction for the pathology laboratory within the Trust. They are enthusiastically involved with various pathology societies and have been recently involved in reviewing the tissue pathways for one of the histopathology specialities.

Pathologist B is a consultant pathologist of several years standing, they are involved with the management of the department at a senior level. Whilst they have fewer years of experience than pathologists A and C, they do have experience working across the country. They are correspondingly more recently trained, with more of a multidisciplinary, collaborative, forward-looking approach.

Pathologist C is the most experienced, with in the region of 40 years post qualification experience. They have a wealth of practical hands on knowledge, which they are often able to put to use in training.

BMS A to C are Advanced BMS. Their post registration experience ranges from ten to approximately forty years. None have specific qualifications in dissection and none are based fully in dissection. They all practice a general dissection role, handling specimens in the RCPath categories A – C (IBMS, 2005), and each has a specific area of more specialist dissection interest.

BMS D to F are Expert BMS. They have post registration experience ranging from ten to twenty five years. They all hold the IBMS Diploma of Expert Practice in Histological Dissection, and hold (or are working towards) the Advanced Specialist Diploma in Histological Dissection.

The interview transcripts were examined with the aim of understanding the perspective of the interviewees in regard to the interventions undertaken in this investigation. The interviews were designed to explore the opinions of the interviewees in relation to their own practice, the quality of dissection in the laboratory as a whole, and how they felt the interventions had, or had not, helped them. The interviewees were also questioned to discover their thoughts on how the process could be improved upon.

The interviews were recorded and transcribed. Braun & Clarke (2006) provides an excellent stepwise guide to performing a thematic analysis, their method was followed in this case:

1. Familiarising yourself with your data
2. Generating initial codes
3. Searching for themes
4. Reviewing themes
5. Defining and naming themes
6. Producing the report

The recordings were played and the transcripts read in detail, several times, and those points that recurred within an interview, or across different interviews, were highlighted on the transcripts. These coding points were then grouped into what appeared to be the most relevant categories, enabling themes to be identified. The interviews were replayed and transcripts read again, targeting each theme in turn; during this phase what was said was examined, along with the way in which it was said, and each remark was considered in context.

The interviews identified four main themes, which interlink and are supported by several sub-themes. The research supervisor reviewed the data and themes, also a Clinical Psychologist unconnected to the investigation was invited to review the data. Both were in broad agreement with the themes detailed below.

Knowledge – "it's not part of our culture"

There was much discussion of knowledge levels amongst all groups. The pathologists felt that their level of knowledge was a strength that they could bring to dissection, whilst the BMS commented on a perceived lack of knowledge. The consultants were all happy with the level of knowledge demonstrated by the BMS and with the training. Despite the consultants being happy with the levels of knowledge and performance demonstrated by the BMS, they were clear that their knowledge was greater. This is undoubtedly true, within this group the most experienced of the BMS dissectors have been performing dissection for approximately 10 years, whilst the least experienced pathologist has been performing dissection for approximately 20 years. However, the data gathered here shows that this knowledge and experience does not necessarily translate into higher standards. Attitudes to staff groups taking on tasks delegated to them by more senior groups are known to vary. One attitude often seen is a degree of distancing and protectionism, the delegation and control in these situations often remains with the more senior profession, as in this case. Scotland for Health (2011) note that providing the opportunity to undertake these complex activities and develop the new skills needed is sometimes resisted by the senior group. They note that there are number of reasons for this, one of the most frequently given is unrelated to perceptions of ability on the part of the delegate, and relates to decreased job satisfaction.

The comments regarding knowledge were also linked into experience and standardisation. One consultant considered the value of knowledge and experience:

"I think my strengths probably are experience" … "And you need to also understand the reasons why you are dissecting, what information you are actually trying to get out of the specimen"… "if it's not a straightforward case, with a specific clinical question you might want to modify your approach"

Another pathologist noted that their experience allowed a more targeted approach to dissection:

"…the recognition of a pathology macroscopically, then guides you how to take appropriate blocks. So, macroscopic recognition of pathology is my strength"

Whilst all the pathologists were very keen that BMS dissectors followed a standard protocol, they were very much aware that they did not always do this themselves. This was largely considered to be of little consequence, however, as seen earlier, variation in practice leads to higher error rates (ACOG, 2012; Haynes *et al.*, 2009). As there is no form of quality checking for this procedure, also discussed earlier, unnecessary variation should be avoided wherever possible. The latter quote certainly indicates an intention to make an individual judgement and sampling based on that judgment. That pathologist went on to indicate that one of their weaknesses was sometimes not taking enough blocks, indicating a deviation from normal practice. This is despite being well aware of the SOP and the tissue pathways. This is also seen in the attitudes of the other pathologists, in that there is an undercurrent indicating that they are sufficiently trained / educated that they can address a specimen on its individual merit, whereas they would expect the BMS to follow the SOP. This seems to be an example of "do as I say, not as I do", the consultants feel that they are happy to introduce variation based on their experience, which they would not expect in practice by the BMS. This contradiction is not new, nor confined to doctors or medicine (Kantele *et al.*, 2010). This option to make their own choices was worn almost as a badge of honour, and clearly became an aspiration of the expert BMS.

"there's always that stipulation that it's guidance, and not mandatory" was a comment made by one, another adding *"I know that we do do things a little differently…"*

One pathologist felt that one of their strengths was their ability to demonstrate and teach dissection principles. This, they felt, was due to their level of knowledge and experience.

"I'd like to think that because I was trained to do dissection very much as part of my job, I would very much be able to sort of apply the principles of good dissection to any specimen and what I also hope is a strength, is that I'm always very keen on passing on those skills in terms of explaining those skills to others."

This enthusiasm for teaching has been beneficial to both the Advanced and Expert BMS during their training, as this pathologist delivered a great deal of the training. However, as they themselves gain experience and competence, the importance of consultant led training is diminished as the BMS becomes a more independent practitioner, who themselves begin to train others. Naeger *et al.* (2014) demonstrate that no significant advantage is found when teaching is performed by a resident (registrar or Expert BMS equivalent) or an attending (consultant equivalent) in radiology. This is backed up by several other studies, including Donnelley *et al.* (1989) Whittaker *et al.* (2006). Further, performing teaching serves as an important learning opportunity for the more junior member of staff (Wamsley *et al.*, 2004; Hill *et al.*, 2009; Zabar *et al.*, 2004). Wamsley *et al.* describe a literature review covering Residents and teaching. They noted that residents' self-reported skills in teaching were increased over time, and in concert with teaching training programs. They also suggested that teaching skills may decline over time. Hill *et al.* make a number of good points in regard to near-peer training. The authors note that the resident may well be better placed to teach ancillary skills of time management, role constraint and appropriate practice. The competent BMS is perhaps better placed to train in BMS dissection, than a consultant pathologist. Zabar *et al.* report in detail on objective structured teaching exams (OSTEs), noting that the teachers reported these to have been an educational experience. OSTEs serve as an opportunity to observe teaching skills in a modelled clinical scenario and are representative of normal practice.

There appear to be two main benefits to using Expert BMS to deliver training to more junior BMS; they are near-peers and they are consciously competent (Snell, 2011). As individuals much closer in career standing to the trainee than the consultant, it is easier for the trainee to relate to the trainer. Being consciously competent means that the trainer is actively aware of the how, what, where and why of what they are doing; as such they are better placed to pass this on to the trainer. Snell (2011) goes on to note that those residents who are rated as better teachers tend to have higher levels of knowledge, enthusiasm and job satisfaction.

Whilst the level of experience might be expected to correlate to higher performance, the data in the results section demonstrates clearly that this is not necessarily the case. However, knowledge is shown to correlate well with performance (Nakhelh, 2013). Nakhleh notes that knowledge, and knowledge of ones' limitations, is of paramount importance when considering error rates and systems.

Some of the expert BMS commented on their level of knowledge, reflecting that performing slide review had given them a significant insight into the application of that knowledge in dissection.

"good knowledge of the microscopy aspect of the specimens I'm dissecting, … which I think helps when you're looking at the whole picture, the clinical picture"

Another was able to reflect on their own practice, and contrast their knowledge against their perception of the consultant level of knowledge. They felt that they had good experience of macroscopic pathology, but they lacked knowledge of how well that correlated to the diagnostic features being seen on the microscope slides:

"I do feel that there's a big gap and that needs to be improved. Slide review sessions, I think they need to be more often and more structured. So [that] we're doing them weekly" … "And I think the only way to get them stronger now is by having more slide review and looking at my macro and discussing it"

This sentiment, that the microscopic knowledge was integral to the dissection process, was also echoed by consultants.

"I think one of the main ways you know how to cut up, is by reporting the specimens you cut up. There are obviously very good guidelines and now the tissue pathways from the college are all useful, but I still think that the only way to know how to cut up is to report a reasonable number of specimens that you've cut up."

"I think it's vitally important that we do go back to slide review, so dissectors who have dissected specimens, they need to have adequate time in the week for slide review. I think that is lacking in the department, that will enhance the way the person will approach the specimen"

This desire for the BMS to have a greater knowledge of the microscopy aspect is explored in more depth later in the thesis the final theme of "Microscopy", the final theme in this chapter on page 157.

Knowledge of the wider pathological picture and of the evidence base behind the RCPath guidelines was lacking in the BMS when compared to the pathologists. Although this knowledge was not uniform across the pathologists. One pathologist was deeply involved in drafting the guidelines for the British Association for Gynaecological Pathology, and very well aware of the current literature for their specialist areas. Whilst another admitted that they were not as up to date as they felt they ought to be.

"Well, I don't know how much I've kept up to date, not as much as I ought to have done."

Overall, however, there was a reasonable awareness of, and engagement with, the literature.

"….I'll read through articles that are relevant to my practice, so I might not read all the articles, sometimes I will venture into one or two skin articles and so on, depending on the nature of the topic, but on the whole I tend to read through areas that are relevant to my areas of practice, but again, focusing on diagnostic applications rather than the raw science."

The BMS showed much lower level of engagement with the literature. The expert BMS showed some awareness of and a small amount of engagement with the literature.

“I haven’t looked, not really. Unless there’s something, unless it’s got some relevance to the specimen…”

“I’ve read some of the gynae references “

The advanced BMS showed even less awareness and engagement.

“I’m vaguely aware of it.”

“Not really …… I haven’t looked at the evidence behind that”

“I haven’t read any of the literature.”

Whilst this is not necessarily a problem, obtaining knowledge from multiple sources is an integral part of being a practitioner, rather than a technician (Crawford *et al.*, 2006). In the initial stages of training, observation is a key learning tool, however, this needs to be consolidated with an engagement with the appropriate literature. In the early stages of practice, the appropriate literature will be text books, RCPath tissue pathways and similar documents. When operating as a practitioner, the engagement needs to be with a deeper level of literature, that being the primary scientific documentation. Despite the Expert BMS previously expressing dissatisfaction with their level of knowledge, there is a definite lack of desire to invest time in the primary literature. Part of this clearly comes down to time, repeated mentions were made of time pressures, and the inability of the individual to complete the required tasks, even regularly working beyond their contracted hours.

“that it’s in your own time and if you want to learn any of these extra things, which I don’t mind doing to a certain degree, but I do feel that if it’s necessary for my job, it should be part of my everyday as well.”

"when that does happen, it usually has to be in our own time"

"I think we have definite lack of time…"

The conflicting demands placed upon the BMS were mentioned repeatedly, with the result that there was insufficient time to complete the routine workload. This had the effect that many, if not all, of the BMS were putting their training and development on hold. The lack of progression in their knowledge, and lack of engagement with the wider clinical team, can be largely explained by a lack of suitable staffing.

Standardisation – "there was a little bit of not everyone not doing the same thing"

This was a topic that was mentioned by all interviewees, to some degree. The advanced BMSs commented that there was good theoretical standardisation, with comprehensive SOPs giving good guidance on dissection. However, how well the SOPs were adhered to was questioned and whether or not the SOP had even been read:

"…but whether everybody follows the SOP to the letter, I don't think they do. I think there's probably a great deal of variation between staff members"

"…have people actually read the SOP?"

The data seen in the baseline round would indicate that these individuals were quite correct in thinking there was a great deal of variation. The Expert BMS commented on variation, in terms of the requirements of the pathologists. Despite all working to the same guidelines and minimum datasets, there is variation in how the pathologists interpret them, resulting in variation in how they wish dissection performed.

"…at one point some of us weren't doing it, because one pathologist told me that I didn't need to do that, then I got told otherwise, so there was a little bit of everyone not doing the same thing."

"….with Dr X I always take a background block with a cancer case, but recently Dr Y said 'I don't need to see that, you've just given me normal background, if you've said it's unremarkable, I don't expect you to take it.'"

The second quote was in relation to colorectal cancer resection, where the RCPath guidelines do specifically state that representative block of the background mucosa should be taken. The guidelines are not obligatory, and individual pathologists / laboratories are able to determine their own local practice; in this case the recommendation is met, albeit incidentally, in that the resection margins are sampled. This provides a piece of mucosa that is, given adequate surgical clearance, free of the tumour and therefore constitutes background mucosa. The dataset document (RCPath, 2014a) gives clear guidance that this is part of the recommended minimum sampling, and gives the reason for sampling (for microsatellite instability or germline testing).

This variation is reflected in many other areas of dissection, where one practice is required for one pathologist and another practice is required for another pathologist. The more complex the individual resection is, the more variety there is from individual consultants. Simple specimens, e.g. appendix and gallbladder, are easier to reach a consensus on how they should be approached. Despite all specimen types showing a similarly high level of variation in the initial baseline data, a collective decision on how to handle these specimens had already been reached, and introducing the checklists clearly brought everyone back on target. However, the checklists are not able to cover every eventuality and attempting to do so would remove their effectiveness (Bosk, 2009; Frakes, 2007). With the colorectal cancer specimens there is great scope for variation in practice. The checklists were based on the minimum dataset from the RCPath and on their tissue pathways; as the graphs show there was clearly great variation and the checklists reduced that variation. However, that only measures the variables that were checked, there are a great many other areas of potential variance. Attempting to standardise the requirements of the pathologists is one step in reducing this variance, although this must be combined with allowing the dissector and pathologist the freedom to act according to their judgment in non-standard cases.

It is ironic, then, that after being identified as a substantial source of variation, the pathologists themselves identified a lack of standardisation as an issue. The consultants highlighted variation in practice as a weakness and a possible area of difficulty; they were also aware of their own variance and how that might have a negative effect on the training of other dissectors.

"{weaknesses] *I'd say for me, it's the variance. There is a degree of variability," ….. "if we have a standard approach to specimens, in terms of assessment, description as well as blocks taken I think that will help to improve a lot of the areas"*

"…consultants have a degree of variance in terms of how we approach specimens ….. that sometimes has a negative impact on the BMS, because they will then see different practices and then that introduces a degree of doubt or uncertainty …. if the consultants have a more agreed standard approach, that would help overall."

Knowledge and experience came in to consideration in this area also. Variance in and of itself is not a negative factor; the skills of the dissector must be such that when presented with a non-standard case, they are able to employ non-standard methods in order to answer the clinical question fully. However, variation is something that should be employed towards a specific end, not due to drift in practice.

"I think you need a degree of experience to allow you to know when you should adhere to certain protocols, or when you can be at slight variance to it"

"…crucially, it's also being aware of the impact in terms of when you're taking blocks and so on, that has on the microscopy"

One pathologist also noted that reducing variation engendered more confidence in the dissectors, enabling them to practice with self-assurance and know where their limits are.

"I think we've got a good training structure which gives dissectors confidence in the way they are operating, so they can seek advice as and when needed."

A comment was made from a pathologist regarding another consequence of reducing variation. They noted that as there was a standardisation of practice, this lead to less revisiting of specimens, reducing interruptions to practice and removing delays from the pathway.

Another pathologist, when considering how we could build on this work, and how to improve dissection standards, felt that diagrammatic SOPs were the way forward. They had seen this used to great effect in other laboratories; having seen how the reference diagrams reduced variance in this work, they felt that there was scope to expand the range of these diagrams.

"…practical SOPs that are easier to access, and in a picture format, I think that will enhance standardisation."

Feedback – "You're working blindly"

This is a topic which was discussed universally. Feedback has many times been called the "heart of medical education" (Branch and Pranajape, 2002; Kaul *et al.*, 2014). Communication is rightly considered to be of paramount importance in teaching and training; failures in these areas are associated with the Joint Commission reporting that 70% of Sentinel Events are due to communication failures (Dhingra, 2010). This communication must be multidirectional. The process of dissection may be considered a method of communicating information regarding that specimen to the pathologist, there must be communication back to the dissector to enable them to have confidence in their practice. The training in the department follows the general pattern in medical education, with a variety of lectures, self-directed learning, directly supervised practice and indirect supervision leading to practicing independently, but within a hierarchical framework. The theory and science behind the practice is delivered both during formal learning and informal conversations when viewing cases – either macroscopically or microscopically. Once a practitioner (either a trainee pathologist or a BMS) is working without direct supervision, providing adequate feedback becomes very important. Feedback must be of sufficient depth to enable learning, but not so detailed that the practitioner becomes lost in the minutiae; it must be targeted to a specific case or specific cases, not general non-specific feedback and it must be timely enough to enable the practitioner to still be able to reflect on the case and apply the feedback to the case(s) (Branch and Paranajape, 2002; Archer, 2010).

Advanced BMSs commented in relation to the feedback events that:

"I thought they were very good. I learnt a lot from them. Because you've got the pathologist telling you these things and telling you why you need to do them. I did find them very helpful, yes."

"I think that any input that the pathologists can give is always good. And can also highlight, not exactly mistakes, just kind of maybe, assumptions."

Another, on being asked their opinion of the feedback event, exclaimed:

"Bloody great! Yeah, really good." …. "It's a bit of recognition, it's them saying, yes you've done this right and a few cases where they've said, this could have been done better. So, presumably better standardisation. It's just nice to get a bit of interaction and get a bit of the history of the case."

Commenting on feedback from the pathologists generally, they went on to say:

"the pathologists, if they don't think you've given then enough information on the macro they should be bringing it back to you, but whether they do, or if they don't bother…."

One of the expert BMSs also commented on the feedback events:

"I thought they were very good. Overall I think that they might have been more beneficial to the band 6s and below. From my point of view some of the specimens they dealt with were a bit basic"

These thoughts were echoed by another expert BMS:

"I thought, to start with, as an individual I didn't think they were good, because I thought they were of limited value for me. Then [thinking of training others] I had a different perspective. So think they could have been described a bit better to get people engaged. To say 'look, this is one of the audit processes we're going to put in place' but we didn't think of that until after. 'This is its value, it's not to pick fault with anyone, it's to look at the process.' So I think we could have shared it better, obviously we've got value in it, and we'll try and share it that way from now on."

Whilst the Advanced BMS enthusiastically welcomed the training events, not all of the Expert BMS were as open. There was some hostility towards the event; when exploring the results and reduction in variation the results were questioned quite aggressively:

"Was this with slide review?" … "So what difference did it make?" … "Are you aware of any SOP changes in that time though?"

However, another expert BMS found them very useful personally, and contrasted how little feedback they otherwise get from the pathologists:

[Prior to the feedback events] *"…you have a few weeks or months where you don't get any sort of feedback. You're working blindly" … "I feel like I have no idea how I'm doing" … "And you wait to hear feedback…"*

[With the feedback events] *"Brilliant. It's been a bit infrequent. But, yes. Definitely invaluable, because that's the feedback that you want constantly." … "everything that I said seemed to marry what he'd seen. That was really good."*

Those pathologists that were less actively involved in the sessions seemed to have a less positive view, although they could still see the value:

"I think that's always good, to keep the link between the dissector and the pathologist, enhance that and I think that will strengthen the relationship between the dissector and pathologist and

ensure that whatever the pathologist deem is important for them to report is fed back to the dissectors."

Others, who were more engaged, found they got more out of the experience; the BMSs attending these sessions also reported getting more from the sessions with these pathologists:

"I thought they were very useful. I thought that, again, it gave an opportunity for feedback, which is always a good thing. And it was also a mini teaching opportunity, in that people were able to ask why we do things in a certain way for a certain specimen. It wasn't just a tick box exercise, in that there were sometimes issues with a specimen, in that margin wasn't very well orientated, or not enough blocks had been taken from a particular area, or sometimes too many blocks taken from a particular type of specimen. So for that I thought it was very useful. I know that [….] members of staff have given that direct feedback."

One of the pathologists was very enthusiastic regarding feedback, and the feedback events specifically. They have been key in making these sessions happen and a driving force for these to become a routine part of departmental practice:

"In terms of feedback, I think having the direct feedback sessions with the operators, with the band 6 and 7s, I think it's useful, the more contact the 6s have with the medical staff and the consequences of what they do, it's realising that it's not just taking a block, this block is then going to go on and formulate a part of this patients record. So it's having that insight and realising the importance of that, and I think sometimes that can be enhanced by having those feedback sessions with those end point users, which in this case would be the pathologists, to say I was able to do x, y & z because of what you've given me. And then explaining why they need to take certain blocks, so having that clinical feedback will only enhance the service. Direct pathologist feedback to the dissectors is a valuable part of the training."

Microscopy – "The amount I learnt is amazing!"

The advanced BMS had not considered the implications of slide review, or what might be learnt from doing so. The expert BMS had given this area considerable thought, and were passionate in their desire for more slide review.

"I think the only way to get stronger now is by having more slide review"

"I do feel that there's a big gap [in knowledge] and that needs to be improved. Slide review sessions, I think they need to be more often and more structured."

"One on one slide sessions with pathologists [are not happening regularly]. And I think the fact that when that does happen it usually has to be in our own time, that's definitely something that needs to be looked at.

"…lack of slide review time. It is important, I don't think you realise how important it is until you do the microscopy pilot. The amount I learnt [dissection applicable knowledge] *is amazing.*

The expert BMS were unanimous in their desire for more slide review, and in the importance they placed on it. There is a newly created professional pathway for BMS – microscopic reporting (Liebmann, 2015). This is separate from the microscopic slide review that forms a part of dissection training and is outside the scope of this investigation, although it is of considerable interest to the dissectors. The participant comments suggest that reviewing a number of cases that an individual has dissected, with the pathologist that has reported them, enables the dissector to better appreciate the needs of the pathologist and understand how the information they are communicating is being interpreted by the pathologist. It also serves as a valuable educational tool, topics are encountered and explored by an informal question and answer session, and this highlights any areas of weakness in knowledge, allowing the dissector to then study further in this area. This provides more than isolated pathological or clinical knowledge it allows the dissector (whether junior pathologist or BMS) to understand how their dissection practice effects the microscopic interpretation and report.

The pathologists had, in the main, been trained to dissect and report cases; the more recent transition to reporting cases without having seen them macroscopically has been undertaken successfully. This leaves the vast majority of dissection performed by BMS, without the pathologists ever seeing the specimen. The pathologists did comment that despite the BMS role being limited to dissection, there was great value to regular in-depth microscopic review of cases.

"I think one of the main ways you know how to cut up, is by reporting the specimens you cut up. There are obviously very good guidelines and now the tissue pathways from the college are all useful, but I still think that the only way to know how to cut up is to report a reasonable number of specimens that you've cut up."

"I think it's vitally important that we do go back to slide review, so dissectors who have dissected specimens, they need to have adequate time in the week for slide review. I think that is lacking in the department, that will enhance the way the person will approach the specimen."

Summary

The interviews showed a clear progression in thought process, in line with the complexity of the dissected specimens. The advanced BMS, largely, lacked an awareness of the wider picture in which their practice sat; there was also no consideration of their practice on a deeper level, their thinking was largely confined to that of following a protocol. The expert BMS, however, showed clear evidence of wanting to look more deeply into their areas, they were keen to become involved with clinicians and to expand their areas of knowledge. The consultants had a good level of knowledge, appropriate to their specialism. They also had knowledge of the wider clinical picture, something that the BMS lacked. One way of addressing this lack has been participation in microscopic slide review, something which has become increasingly *ad hoc* and time constrained within this laboratory.

The level of knowledge required to safely practice increases in line with the complexity of the cases being handled. Dissectors begin with simple tissue transfer, where a simple description is sufficient. They progress to parts of organs and whole organs, where a deep knowledge of the anatomy, physiology and pathology is required to enable the specimen to be placed appropriately within its clinical context. Section 3.20 of the Barnes Report (2014) clearly states the need for an appropriate level of knowledge, with on-going updates and development. This is something which is the participants feel is being neglected, as a consequence of time pressures. Whilst the baseline and checklist data indicate that practice is currently at a safe level, neglecting professional responsibilities can ultimately lead to serious negative consequences as seen in the Francis report (2013) and the Bristol Royal Infirmary Heart Surgery Inquiry (Kennedy, 2001).

Feedback and microscopic slide review were keenly sought, as a route to improving knowledge and practice, with much of this being done in the dissectors' own time. Time to perform the additional, quality enhancing, duties was felt to be in short supply, with dissectors just barely able to keep ahead of the practical dissection workload. The expert BMS all felt that there was insufficient time to complete the required paperwork, audits etc. and that slide review was a far lower priority than it ought to be. The strong desire for more microscopy fell outside any desires for reporting. Two of the expert BMS were involved in the IBMS / RCPath BMS reporting pilot, and were able to convey how much difference that had made to their understanding of their practice. However, the microscopy training that they were receiving as part of this pilot is not the same as case review and they both felt that case review was of vital importance to a high quality diagnostic service. The other strong theme was the benefit of the feedback events. The advanced BMS got more from these sessions than the expert BMS, this being a consequence of the sessions being pitched to cover specimens that all dissectors would handle, they were a little simplistic for the more experienced of the expert BMS. However, they could still see the benefit and welcomed further sessions, with the hope that more complex cases would be included. Francis (2013) reports that there should be "Regular comprehensive feedback on performance", whilst speaking in that instance about nursing, the point clearly applies across the professions. He also acknowledged the need for timely feedback, even suggesting real time feedback is desirable. In his conclusion he noted that "learning opportunities were denied through lack of feedback", something which is clearly happening in this laboratory.

The consultants showed a definite desire for the BMS, at all levels, to show greater standardisation and, during the dialog, began to realise that they were, in part, a cause of that lack of consistency. Their own variations in practice started to become more apparent, with an acknowledgement that this was not conducive to good training. The pathologists were very supportive of this investigation as a tool for quality control amongst the BMS, but seemed to feel it was somewhat beneath them. The data gathered would indicate that the checklists may be more relevant to their practice than to the BMS. The Expert BMS also seemed to view the checklists with an amount of condescension, in that that they knew what they were doing. One stating "I know that I'm doing it, I know. Because I do, I'm very methodical", however, the results at baseline and after introducing the checklists show very clearly that no-one was working fully to protocol showing a lack of awareness of their own practice. The advanced BMS were the most enthusiastically engaged, they responded very well to the introduction of the checklists and embraced the new methodology. The results after the introduction of the training intervention demonstrate, that despite the somewhat dismissive attitude from some quarters, everyone showed a noticeable increase in conformance to protocol.

The consultants were not the most resistant to monitoring and assessment, the long held attitude of "Doctor knows best" has translated into a desire for similar autonomy amongst some of the expert BMS, with a resistance to objective assessment and standardisation. However, the strength of the data produced in this investigation appears to have demonstrated the value of a standard approach to both the consultants and the expert BMS. This is acknowledged in the report into pathology quality assurance by Barnes (2014). He report that there was too much variation in pathology practices, which was unacceptable to patients and service users. Further, he called for the relevant professional bodies to produce national standards and protocols to reduce variation and increase standardisation.

The overarching desires were for regular, structured feedback sessions and slide review; it was thought that this would enhance knowledge and further standardisation. The desire for the feedback sessions was such that, despite the previously stated time pressures, each session was very well attended.

At the end of study 3, three interventions had been trailed (checklists, training intervention and guide diagrams), with a series of conversations to allow for adaptation during the investigation, and the interviews. The investigation was brought to a close by formally thanking the participants for their contribution and providing an overview of the results achieved.

Chapter Five – Discussion

Summary

The thesis this far has covered a lot of ground. From concerns about patient welfare leading to reviews into quality in pathology, to the concept of KPIs backed up by evidence based practice and how to ameliorate poor performance. A comprehensive assessment of the scientific literature around specimen dissection and the importance of standard practice has been performed in the literature review. The importance of evidence based practice has been discussed, along with the utility of Key Performance Indicators. How to use this information in order assess practice has been investigated in the studies performed, revealing a great deal of variation in practice. This variation was then addressed by three interventions (the checklists, the training event and the diagrams). The interventions have been developed after careful consideration of the areas discussed in the literature review, namely learning theory and change management. The interventions are constructed in such a way as to encourage a team approach and to foster a collaborative atmosphere to the development of the dissectors. The effect of each of these interventions and combinations of interventions, and also the absence of the interventions, has been assessed in the studies forming this research.

The results

The results from the data collection, indicating the starting point, show considerable variation in the way that individuals handle and describe specimens. The appendix analysis demonstrated a clear split in the BMS group, with different sampling practices between the two groups. The differences did not have any appreciable outcome on diagnosis or workload, but do highlight variation in practice, which, as established in the literature review, leads to greater error rates and worse patient outcomes (NHS England, 2014b; Shia, 2012; Ludeman & Shepherd, 2006; Verrill, 2004). The data from the pathologists demonstrated a broad conformity; one pathologist was noted to show the same variance in sampling seen in one BMS group. Investigation into the discrepancy revealed that the difference was due to a change in the SOP, which some people were unaware of. The change had been made over a year previously, to bring the sampling in line with the RCPath guidelines; however, these staff members were somehow unaware of the change. The results from the gallbladder show a similar split in sampling and description across two groups. This variance with the dissectors revealed a difference in training of the BMS staff. BMS 1, 2 & 5 had been trained by one consultant and BMS 3 & 4 had been trained by a different consultant. The difference related to the site of sampling – the fundus is the area that should be sampled, BMS 1, 2 & 5 had been doing this, however, BMS 3 & 4 had been taking a transverse section through the body of the gallbladder. The fundus should be sampled as this is considered by the lead GI pathologist as the most likely site of any incidental pathology. This triggered a review of the SOP and the underlying reason for the preferred sampling was stated in the SOP. The updated SOP was communicated to the dissectors in a group meeting and the reason for this explained.

The colorectal data clearly demonstrates the application of the checklist and feedback sessions. There are far more data points for the colorectal than in the other specimen types, indicating the higher level of complexity in these specimens; the wide variation in data seen from the first round of data collection shows how much variation in practice there is. All dissectors should be working in the same way, yet the data clearly shows that this is not the case. Even amongst the BMS dissectors that have been trained by the same people, there is still a variation. This variation completely disappeared from the BMS group with the introduction of the checklists and this change persisted with the introduction of the training intervention. Two of the pathologists showed the same response, the others showed a more variable response. The two BMS are both in training and working towards an advanced level dissection examination, as such, they are both invested in their training and professional development. The pathologists are used to working under their own direction and making their own individual judgements, rather than following a protocol. As such, it is perhaps unsurprising that their data output is more variable.

Whilst there is no direct indication that these variations have had an impact on diagnosis, it does show unnecessary variation in practice.

The variations are clear to see, as are the improvements with the introduction of the checklists (Figure 6 on page 81 to Figure 9 on page 84). Comparison between the baseline and first round shows a distinct reduction in variation. The introduction of the checklists resulted in standardisation in practice. Having the checklists available at the point of dissection appears to have focused attention on the process of dissection and allowed dissectors to think more specifically about the specimen without distraction. Discussion with several of the dissectors has indicated that reading the checklists highlighted requirements that they had not been aware of and that some used the checklist as a memory prompt. The introduction of the checklist allowed dissectors to become aware of what information was being collected, this prompted dissectors to ask questions and check the requirements of the SOP. One of the pathologists felt that the presence of the checklists enabled the dissector to focus on the specific requirements of the complexities of the individual specimen, whilst using the checklist to ensure they were performing all of the mandatory operations and satisfying the demands of protocol.

The introduction of the training feedback intervention (Figure 10 on page 87 to Figure 13 on page 90) continues the trend of standardisation of practice between the BMS dissectors. However, the pathologist dissectors, after showing an initial improvement, do not respond as well. Part of the reason for this is that whilst there has been a full and enthusiastic engagement from the BMS dissectors, the engagement by the pathologists has been more variable. Some pathologists appear to have taken the view that this is a worthwhile and important exercise for the BMS, but that they are above such assessment. It is these pathologists that show the highest variation in practice. Those that have keenly engaged and are open to assessing their work are those that have shown the greatest change. This links in with some of the points noted in the literature review, in relation to attitudes. The attitudes of medical doctors have come increasingly under focus in recent years, this is not the large headline hitting activities of a rogue doctor, such as Shipman, but the routine, day to day attitudes of the profession and how that reflects on the best patient outcomes. The historic approach of "doctor knows best" (Kennedy, 2001) must continue to change, with more collaborative working and a more developed team dynamic. Each successive report into the NHS, and there have been many, Walshe (2001) details 10 major inquires leading up to 2001. Only the earliest study referenced in this work (Kennedy, 2001) is included, Francis (2013), King's Mill (RCPath, 2013) and Barnes (2014) have all occurred since then, showing that whilst changes have been made, there is still work to be done. As noted in the literature review, Dixon-Woods (2011) provides an in depth commentary on the changes in the public perception and status of medical doctors. As such, it behoves the pathologists to accept that their own status has changed. Clearly, they are highly skilled, knowledgeable and extremely important to the patient pathway; what they are not, is beyond question. The pathologists and BMS must work more closely as a team, with the goal of the best patient outcome and a shared responsibility for that. In aviation a catastrophic error in flight is likely to result in the death of all on board, who is responsible for this is something of a moot point if everyone has died. As such, a more collaborative approach is seen in the cockpit, with far less hierarchy and rigid deference to rank. Ornato and Peberdy (2013) particularly noted the difference in attitudes between pilots and surgeons. They, along with Sexton *et al.* (2000) reinforced the importance of open communication, flat structure and shared goals in high risk environments. This is something which we have seen develop over the course of this investigation, with the increased communication leading to greater regard for the skills of the BMS by the pathologist; however, this appears in some cases to have fostered the attitudes previously seen in the pathologist in the newly competent BMS dissector. Clearly, this is not the flattening of structure that is desired. More work in this area, by continuing the Feedback Event and extending its scope and utility is hoped to address this.

I stated above that the data is almost overwhelming in scale, Figure 2 on page 75 to Figure 33 on page 116 all detail variation through the different studies, with different specimen types. Thirty two graphs is a great deal of data, the key graphs are Figure 34 on page 117 to Figure 38 on page 131. Figure 34 to Figure 37 each show the trends over time for each individual, separated by specimen type. Figure 34 shows a near immediate transformation in appendix dissection practice by all the BMS dissectors, whilst some improvement is also noted from the pathologists, it is not as pronounced. Figure 35 portrays a similar picture, this time for gallbladder dissection. A more chaotic pattern is seen from the pathologists, whereas the BMS dissectors converge towards 100% conformance very quickly. I note below that the colorectal cases are more complex, despite this, Figure 36 shows the BMS dissectors immediately moving to 100% conformance, and staying there. The pathologists also move towards 100%, although with less speed. Figure 37 shows a less clear cut response, but again, the trend is towards 100% conformance, that is to say, lack of variation. In Figure 37 almost all the dissectors move towards 100%; pathologist 4 shows a rather erratic pattern of practice. The most important graph though, is the final one. Figure 38 on page 131Figure 37 shows the average conformance to SOP for all individual dissectors over all studies. The solid lines are BMS dissectors and the dashed lines are pathologist dissectors. The solids lines almost immediately reach over 75% conformance, and remain there. By the final round, all the BMS dissectors are returning an average conformance of at least 90%. The pathologists also show a reduction in variation, those who remain in the programme throughout all converge towards 100% by the final rounds, those who drop out in study 2, part 5 are at least now showing over 50% conformance. Figure 38 very clearly demonstrates that this programme works, it has achieved its main goal.

The checklists & training event

The first intervention was the introduction of the checklist. The literature review discussed the use of checklists extensively. They have been used to great effect in aviation, with a more limited use in medicine, despite their clear potential. Part of the reason for this discrepancy, as was noted in the literature review, was the team approach seen in aviation, in contrast to the individualistic autocratic approach more traditionally seen in medicine. This intervention was seen to reduce variation in practice (study 3), although there was still variation noted.

Study 2, part 2 led to the second intervention, which was the introduction of the Training Event. The aim of this intervention was to enable a structured feedback forum, where all dissectors could engage in an open dialogue. This enabled a conversation regarding how to describe and sample specimens, where BMS dissectors could speak with each other and with pathologists to reach an agreed approach. Whilst a uniform approach should have been in place, as there are SOPs based on RCPath guidance, the data clearly shows that this was not occurring. The intervention allowed engagement from the dissectors as a team, rather than an instruction directing how they must act. This further reduced variation (study 2, part 3).

The third intervention was introduced in study 2, part 5, this was the use of guide diagrams (appendix 4). The aim of this intervention was to reduce variation in those who had not engaged with the feedback event, notably several of the pathologists. The diagrams were not well received, and did not appreciably alter the level of variation in practice and so were removed after two rounds of data collections (study2, parts 5 & 6).

The combination of the checklists running with the training event appears to be the most effective, both in terms of the level of reduction in variation and in terms of the level of engagement from the dissectors. Using the checklists to generate anonymous data to demonstrate what is occurring, rather than working from assumptions, but actually being able to demonstrate hard evidence, provides an intellectual "hook" upon which the individual can hang the new ideas and practices. The training event satisfies the BMS desire for feedback, and creates a closer working relationship with the pathologists. As the pathologists seldom attend the training sessions run by another pathologist, this provides an opportunity for the BMS to make the pathologist aware of conflicting requirements – *e.g.* they have indicated that a procedure should be performed in a certain way, whilst their colleague has indicated it must not be done this way. This has sparked discussion between the pathologists, leading to discussion of their intent and motivation behind those decisions, ultimately resulting in a standard approach from the pathologists. There remains some hope that some of the pathologists will attend at least some of the sessions run by another pathologist.

One of the aims at the outset of this research was to investigate the use of KPI in dissection and see if they could be applied to create a dataset indicating performance standards. This has been achieved, the dissection checklists are based on the recommendations of the RCPath and local protocols, with best practice in surgery guidance used as a starting point. The specific data points on the checklist are less important that the checklist itself. As demonstrated in the Pronovost study (2006) checklists can be modified to suit the specific requirements of the individual environment, whilst still remaining a powerful tool for regional or national data collection. The checklists used here (Appendix Four – Dissection Checklists, on page 210) are discussed in detail later in this chapter, but it is worth noting at this point how customisable they are. If this work forms the basis of a national framework to address the deficiencies highlighted by Barnes (2014), a consensus on a set of key data points would need to be reached. Once these were agreed, the checklist might contain some optional points, and space for local protocol to add points that were important to that specific laboratory or region. As Bosk *et al.* (2009) takes great pains to point out, there was not one single checklist for the Keystone study (Pronovost, 2006), there were in fact over 100 versions. The checklists used in their study covered one procedure, the insertion of a central line catheter, and contained five key items. The ICU departments taking part in the study were each encouraged to customise and develop the checklist to address the issues and culture within their own environment. In this study four distinct checklists have been used for four clearly differentiated specimen types, clearly, there is room for further development of the dissection checklists, enabling users in other laboratories to customise them according to their own needs is a feature which has been considered from the outset.

Another aim was to use the KPI data to demonstrate variation and use this data to reduce that variation. This has clearly been achieved, with an abundance of graphs showing variation from all practitioners across all specimen types. The data is almost overwhelming in its scale, however, what is clear is that substantial variation in practice occurs at the beginning of this research, and the level of variation is reduced with the intervention of the checklists and the training event. The data gathered from the checklists enables demonstration of the variation, and demonstrating this to the dissectors at the training event is sufficient in many cases to eliminate that variation entirely. For others it is the dialogue at the training event, with the data to back it up, that engenders the change. For those that do not change, the checklist data then enables the final aim to be met, that of remedial and preventative action. Whilst the training event is sufficient to provoke a sustained change from most, some dissectors make a deliberate choice not to conform. Whilst there is an argument to be made for allowing autonomy in practice and allowing the dissector to use their judgement, this must be within the confines of good professional practice and the guidance given by the appropriate professional body (*e.g.* the RCPath and IBMS). This investigation has developed the training event, which has had a powerful remedial and preventative effect when the issue was a lack of knowledge or training, but where the issue has been a deliberate departure from recommended procedure, there are no sanctions in place for addressing deliberate variation. This lack of sanctions for poor performance is something which was highlighted in the Barnes report (2014), and something that would need to be included if this work is to be developed further.

The pathologists have largely been keen to be involved in the delivery of the training event, however, less keen to participate. Very few of the pathologists have attended an event delivered by another pathologist, reinforcing the isolation and self-view of being "above" the BMS. Whilst clearly the consultant pathologists are more highly trained than the BMS dissectors, this attitude of being more important is reinforcing the "doctor knows best" isolationist issue. Most of the pathologists in post at the beginning of this investigation had considerable experience and a certain way of working. Those that join the investigation in the final studies are more recently qualified and are perhaps more engaged with the most recent literature. They are, at any rate, more open to suggestions and changing their working practice. The traditional workflow within histopathology would see a pathologist dissect cases, and the perform the microscopic reporting some days later once the laboratory had processed the tissue samples on to slides. More recently, with BMS led dissection, the pathologists would report cases that were dissected in a specific manner (a single approach was agreed for the BMS dissectors, regardless of which pathologist would be reporting the case) by any suitably trained and qualified individual. In cases of staff shortage, *e.g.* sickness or annual leave, pathologists are asked to assist by providing cover in the dissection room. With current workflow practices, the pathologist may now not report the cases that they have dissected, meaning that it is equally important that they follow the designated protocols. This was the situation during study 2, part 8, the practice of pathologist 9 is clearly deviant from the standard protocol – as can be clearly see in Figure 30 on page 113 and Figure 31 on page 114). They neither provide complete measurements nor take appropriate blocks for any cases of Appendix for the Gallbladder there is more variation, less than 10% of cases receive compete measurements, 55% receive a description of the external surface, 72% of cases have a known abnormality described, meaning that in less than 10% is the SOP followed. If all of the cases dissected by pathologist 9 were reported by them, and they possessed a prodigious memory, capable of holding all the information that they omitted from the macroscopic report, this may not be an issue. However, as the majority of these cases were reported by a different pathologist, this does become an issue. It is noteworthy that the microscopic reports of these cases were substantially longer than would normally be expected. As the specimens had received a cursory macroscopic description, which in some cases was contradictory, the microscopic report was, by necessity, very detailed. In some cases the reporting pathologist needed to view the remaining tissue from the specimen for themselves to clarify an issue / omission with the macroscopic description.

Having mentioned that (in this institution) consultant pathologists are largely called to the dissection room to cover shortages in BMS dissectors, we ought to consider the effect that this may have on their skills. As consultant pathologists, of many years of experience, they have a wealth of knowledge and skills in this area, however, by not practicing these skills they become deskilled. Their knowledge is unlikely to diminish, but some degree of practical skill will be lost. As noted in the study by Shaw (2008), specialist surgeons, specialist histopathologist and specialist BMS perform better, with significantly better patient related outcomes than generalists. By removing this activity from the routine practice of our consultant pathologists, this risks that the consultants will become generalists, performing at a lower level of quality than the BMS dissectors. This is not necessarily a negative of BMS dissection, as consultant dissection can be a routine event, it need not be of a high frequency in order to maintain proficiency – use of the systems developed here would enable an assessment of performance to ensure that practice was being undertaken with sufficient regularity. An additional area of practice being undertaken by the BMS now is histopathological reporting. Again, this raises the question of the scope of BMS practice, and how that relates to the practice of the medically qualified pathologists. Whilst beyond the scope of this work, some consideration might be given to how far the role of the BMS might be extended, and the impact that might have on the role of the consultant pathologist. It is the opinion of the author that there is no single area of practice that the BMS could not take on, however, the BMS (having undergone a very different training route) would not be able to take on the full breadth of all the duties of the consultant pathologist. The ever advancing BMS role can be considered to be akin to that of the registrar in histopathology and the advanced practitioner in cytology. Both are able to function with a degree of autonomy and take responsibility for their own cases, but work within a more restricted framework than the consultant pathologist.

It is worth giving some consideration to the construction of the checklists, and how they might be developed to cover other specimen types. A common theme to all four specimen types is a requirement to orientate the specimen, this may be proximal / distal, anterior / posterior, base / tip *etc*, it is important to be able to consider the specimen in relation to its surrounding anatomy. This is especially true in the context of a pathology that may involve adjacent organs *e.g.* colitis involving one resection margin or colorectal cancer involving one of the circumferential resection margins. However, it may not be possible to orientate all specimens. A ragged, distorted and ruptured appendix may be so effected that the base cannot be clearly seen and the tip may not be recognisable; a gallbladder may have been cut into several times by the surgeon, it may be distorted by stones, rendering the cystic duct hidden and the fundus unrecognisable. A uterine corpus may be so distorted by fibroids that the relative positions of the anterior and posterior reflections may not be used to orientate the specimen. There are a number of possible situations in which orientation of the specimen may not be possible, however, these situations are not encountered particularly frequently and ought to be encountered with a roughly similar frequency by all dissectors. If any individual dissector is noted to deviate substantially from the mean rate, they may need further training, or be able to provide training to others.

Orientation is also important in regard to benign conditions. For example in cases of ischemic bowel, the surgical margins may not be viable, which could lead to a failure of the surgical anastomosis. A requirement for complete measurements is also a part of the checklists. Depending on the point of view of the dissector, this may be considered obvious or unnecessary. Most dissectors would provide full dimensions for the organ unprompted, whilst some feel it necessary to only supply a largest dimension. Clearly an appendix 70 mm in length and 4 mm in diameter is different to one that is 12 mm in diameter, something that would not be communicated by some of the dissectors who fail to record full dimensions. The same applies to a gallbladder specimen, where both length and maximum diameter should be recorded.

An external description of the specimen ought to be attempted, this may be as simple as "congested appendix" or "intact gallbladder", or may be an in depth description of some unusual external feature. An appendix that appears unremarkable microscopically, which was been described as such, may be considered to correlate; however, an appendix that that appears unremarkable microscopically, which lacks an external description, may not convince the pathologist of its unremarkable nature, necessitating revisiting the specimen. As with a gallbladder, if gallstones are suspected and none are found, but the specimen is described as having been received open, the stones may be presumed to have been removed in theatre and their absence noted on the report. If the macro does not record whether the gallbladder is received open or closed, then consideration must be given to the possibility that the stones are lodged further in the bile duct, which would necessitate further surgery.

The checklists for the uterine resections indicate the requirement for a description of the endometrium and myometrium, in the case of a macroscopically benign resection the expectation would be that the endometrial thickness would be recorded and a simple description of the myometrium would made, *e.g.* the myometrium contains intramural fibroids, the myometrium shows features of adenomyosis, the myometrium appears unremarkable *etc.* In cases of known or suspected malignancy the maximum macroscopic dimension of the tumour should be recorded, this being a specific requirement of the minimum dataset (RCPath, 2014b). A minimum requirement of the microscopic report is to indicate whether the tumour shows no myometrial invasion, myometrial invasion of less than 50% of the thickness of the myometrium or myometrial invasion of more than 50% of the thickness of the myometrium. Whilst this is an RCPath minimum requirement of the microscopic report, it is a local requirement of the macroscopic report. This absence is noted in a number of the reports in studies 2 and 3, whilst study 4 shows all dissectors providing this information. Study 5 and 7 each show a slight variation in the provision of this information, in all other cases the dissectors now provide this information. This is echoed in the colon checklists, where a description of the macroscopic penetration of the tumour is requested by local protocol. The minimum dataset (RCPath, 2014a) simply calls for a microscopic measurement of invasion of the tumour beyond the muscularis propria (if applicable), however, this macroscopic description is mandated in local protocol, and should therefore always be provided. In study 2 we can see variation in who provides this information, in study 3, with the introduction of the checklists, this variation is reduced. By study 5 all variation in relation to this KPI is lost, with all dissectors recording this information in all cases. Again this is an important feature to note macroscopically, and speaks of more than simply whether the tumour does, or does not reach the fat. If a dissector is stating that the tumour is not breaching the bowel wall macroscopically, yet clear unequivocal evidence is seen microscopically, one may consider that this was perhaps not visible macroscopically. However, if this was happening regularly, one may consider that the dissector is either unable to recognise when tumour is penetrating the bowel wall, or is perhaps not examining the specimen with an adequate degree of thoroughness. Alternatively, the dissector may be mistaking other features for tumour penetration and over calling the stage of the tumour. In any case, the discrepancy might be identified by an audit correlation between the macroscopic and microscopic report – something that is only possible if the information is recorded in the macroscopic report in the first instance.

The colonic checklists also call for a description of the background mucosa. The third edition of the RCPath dataset for colorectal cancers (2014a) states a need to describe any background abnormalities, this is also stated in the local SOP for dissection of benign or malignant colorectal resections. The local protocol also calls for a description of the background mucosa in the absence of any background abnormalities, therefore there should always be some description of the background mucosa, even if that description is as simple as “the background mucosa is unremarkable”. The reason this is important is that if, for example, a tumour is noted on a background of diverticular disease, the pathologist is aware of the presence of diverticula elsewhere and will then be aware of the possibility that an area of tumour that appears directly adjacent to fat, may not represent true breach of the muscularis propria, in that it may have breached the muscularis mucosae in the region of a diverticulum. Other features of note may be that the bowel wall is thickened away from the tumour, this could indicate that the tumour is stenotic, leading to hypertrophy of the bowel wall due to the increased resistance. If the received specimen has a thickened wall and incudes an obvious polypoid lesion and no other abnormality, consideration must be given to the possibility that a further stenosis exists distally, whether that be a further tumour or a diverticular stricture caused by fibrosis. Either of these circumstances may lead to more surgery. In the case of a further tumour, a resection to remove the tumour is quite likely, in the case of a fibrotic stricture, the thickened bowel wall indicates increased intraluminal pressure and that the bowel wall is under greater strain in trying to pass faecal matter. This places additional strain on the new surgical join, the anastomosis, which may then leak, leading to possible peritonitis, septicaemia or death. It is the wider picture surrounding the main pathology that is omitted by failing to record this information. The provision of the background description shows some variation early on, however, by study 5 only pathologist 6 continues to omit this data.

Knowing what needs to be sampled from each specimen type, and why, is also important. As previously noted, there was a discrepancy in sampling protocol for the gallbladder. This was brought to light in the course of this investigation, and prompted a review of the protocol. Whilst in this case (fundal vs corpus sampling) there is no strong evidence in favour of either approach, the decision taken by the lead pathologist for GI pathology in the department was for a single section to be taken through the fundus, and a section of the cystic duct. As such, this is what should have been occurring, and any deviation from this *e.g*. when working with a disrupted specimen where the fundus was damaged, should be noted on the specimen description. This was echoed with the sampling of the appendix. At a departmental meeting of the pathologists involved in gastrointestinal pathology reporting, a consensus was reached that we should change our sampling protocol from the current practice (two representative transverse sections from the body and one longitudinal section from the tip) and take a single transverse section from the body and one longitudinal section from the tip. This was communicated to the dissectors, most of whom changed their practice, however this is the source of most of the variation on the “appropriate blocks” KPI for pathologists. Subsequently, a review of the RCPath guidelines indicated that a longitudinal block of tip should be taken and one transverse section from the body, along with a transverse section of the base. Again, the BMS showed a quick and sustained change to the new protocol, whilst the pathologists were slower to respond - in Study 2 part 2; the BMS practice hits, and maintains, 100%. This only drops for BMS 2, whilst the pathologists practice shows more variance. Part of this may be due to familiarity in dissection. As the BMS dissectors are predominantly based in the dissection room, any changes are quickly put into practice and are established as routine, whereas the pathologists are infrequent visitors to the dissection room. This means that changes to practice may have been made some time before they next perform dissection, at which time they continue with their established practice – in the absence of any form of prompt. The checklists demonstrated their ability to serve as a prompt, although they were deliberately constructed in a simple non-directive manner. If the checklists were to state outright what constituted “appropriate blocks”, perhaps a greater level of conformance would have been seen. An attempt to be more communicative in terms of what was required was attempted with the use of diagrams. However, the diagrams did not have much impact.

The concept of acceptable / expected frequency could be expanded on. Uterine polyps are not an unusual incidental finding at dissection, Goldstein (2002) indicates a frequency of 16.6% within a representative asymptomatic population. Many of these polyps are benign and are of no consequence to the patient, however, they may be the focus of malignant disease, being both a potential source (Childs, 2005) of malignant cancer and a potential site of metastatic cancer (Hooker, 2011). If the checklists were amended to require that the presence or absence of a polyp is recorded then it would be possible to chart the frequency with which individual dissectors recognise the presence of a polyp, and compare this against the mean for that group. The accuracy of description and macroscopic assessment may become even more important in the future; with increasing calls to reduce waiting times, the 62 and 31 day treatment targets (Department of Health, 2013), and reductions in funding, there are more and more pressures on the diagnostic histopathology department. These pressures are part of the drive for the increase in BMS led dissection, and are likely to have further effects. Salmon *et al.* (2012) calls for apparently unremarkable hysterectomy specimens to receive only a macroscopic description. They concluded that performing microscopic assessment of macroscopically normal hysterectomy specimens did not contribute to patient management. This is a radical suggestion, and one that is unlikely to be universally welcomed, however, it does open a dialogue and encourage consideration of how much utility and value is created by some of the practices in pathology. An ongoing discussion regarding the value of examining macroscopically unremarkable specimens continues with some advocating that some specimens, *e.g.* appendix and gallbladder, should not be submitted to the laboratory (Taylor, 1998) and others recommending that the laboratory should examine all resections of this type (RCPath, 2005). A possible third route would be to do as Salmon *et al.* suggest, and have a BMS perform a macroscopic assessment only; performing sampling for microscopy only where deemed necessary. Clearly, this is a radical step. In their study, only those cases examined by a consultant grade pathologist were eligible to be reported on the macroscopic description only. Further training, assessment, regulation and indemnity would need to be put in place to enable BMS dissectors to do this, however, it is certainly an avenue that the current work could help to achieve. If the frequency with which various pathological features were encountered were to be recorded and plotted, for an individual dissector against a local group mean, this would enable the individual practice to be assessed. Any individual showing notable deviation could then receive closer scrutiny to ensure full competence. This form of ongoing audit would provide an excellent form of individualised quality data, as called for by both Barnes and the Royal College (Barnes, 2013; RCPath, 2013).

The lymph node yield achieved is another area where an average rolling plot could be generated from a modified version of the audit sheets. We saw in the literature review just how extensive the evidence for sampling all the lymph nodes was, and that a minimum average of 12 nodes was expected. Using the audit sheets or an electronic system to log the number nodes retrieved per case would allow the individual to compare their data against a departmental mean. In the right team, the use of the leader board as noted by Ludeman and Shepard (2006) could serve to motivate diligent examination and provide a motivational "target" to aim for. In the wrong team it could act as a divisive factor, causing disharmony, therefore careful consideration would need to be given to its introduction. The lymph node yields within this department show that at baseline the BMS mean yield was 16.75 lymph nodes per cancer resection, and the pathologist mean yield was 16.77 lymph nodes per cancer resection. The BMS and pathologist dissectors show a near identical average yield, however, the range is interesting. The range of means for the BMS dissectors is 15 – 18, showing that none of the BMS have a mean below the recommended minimum, whilst the range for the pathologist dissectors is 11 – 23. One of the pathologist dissectors shows a mean yield below the recommended mean, whilst one of the pathologist dissectors shows a mean far in excess of the others, at 23 lymph nodes per cancer resection. This level of information would fit with the calls for individual quality data noted above and also provides a training opportunity. The pathologist dissector returning a mean of 23 lymph nodes per cancer resection has since been asked to lead one of the BMS feedback events, specifically into colorectal cancers and lymph node yields. This, it is hoped, will lead to an improvement in BMS harvest from all those who attend. However, based on the attendance at previous BMS feedback sessions those who might benefit most are unlikely to attend, *e.g.* the pathologist returning a mean yield of 11 lymph nodes per cancer resection.

Diagrams

The guide diagrams (appendix 4) were not received well by the dissectors. When compared to the diagrams in published text books, these are perhaps somewhat amateurish. They were the best that could be obtained at the time, with no talented artists to hand and no suitable diagrams that might have been adapted from elsewhere. However, the diagrams did contain all the important information, with lines to indicate the measurements that should be supplied and markers indicating what sections should be taken. The diagrams were annotated with additional information, indicating what features should be considered for the macroscopic description.

No-one openly criticised the diagrams, yet one BMS dissector disliked them so much they removed the diagrams from the wall on the first day they were introduced. After a conversation with that dissector, the diagrams were replaced on the wall, but there was little enthusiasm for them from any of the dissectors. In the interviews with the dissectors, two the pathologists specifically indicated their enthusiasm for using guide diagrams, but did not recall encountering these in the dissection room. Unfortunately, there were no specific objections to the diagrams, making it difficult to understand the resistance to them and the reluctance to engage with them.

The diagrams are all, like the checklists, based on the RCPath guidance and local protocol. The appendix diagram indicated the need to measure the length and diameter, indicated serially sectioning through the body to examine the cut surface and taking a longitudinal section through the tip. It also notes some macroscopic features to look out for. The same is true for the gallbladder, colon and uterus. The diagrams were envisaged as a simple graphical equivalent to the checklists, however, despite allowing time for the dissectors to get used to the diagrams, the dislike and disdain persisted, so they were removed.

Attitudes, responsibility & change management

One item noted in the results section was that pathologist 5 always failed to sample the background mucosa. This was highlighted in a discussion between the pathologist and the lead

BMS for colorectal dissection. The pathologist determined that there was no point in sampling normal mucosa on the premise that it is normal and therefore does not need to be sampled. However, the 2nd edition of RCPath dataset for Colorectal Cancer (RCPath, 2007) specifically states the requirement for a block of normal background mucosa, the 3rd edition (RCPath, 2014) repeats this statement, with the explanatory note that this is for microsatellite instability testing or germline testing. Despite this, pathologist 5 continues in their practice of not sampling the background mucosa. Clearly, this is a deliberate choice, not an error or accidental omission – something that will not be changed by a checklist or training event. However, as this work has highlighted, standardisation in practice and reduction in variation is in itself a worthy goal. The aim of this work is to reduce variation wherever possible, whilst allowing for professional autonomy and judgement; a further discussion with pathologist 5, presenting the data gathered here, might be hoped to engender a more positive outcome. Barnes (2014) calls for sanctions where standards fall below an acceptable level, clearly there is an opportunity here for a discussion to determine what constitutes an acceptable level. Perhaps failing to follow the explicit recommendations of one's own professional body may be considered to be below the acceptable level; in which case a further discussion regarding what sanctions might reasonably be considered is order. In the case of deliberate failure to follow recommendations a conversation between the individual and their clinical lead might be in order, highlighting the omission and stressing why this is unacceptable. A lack of conformance after this might then be considered a management issue, and the local capability / disciplinary procedure invoked. Clearly, this would be a last step and a more collaborative, team led approach with shared goals and agreed standards would render this unnecessary.

Continuing on the theme of deliberately departing from standard practice, pathologist 9 appears for the first time in study 2, part 8 (training event and checklists). They had been asked to help cover staffing shortages and, as discussed briefly above, their performance is clearly deviant from standard protocol. They made a choice to ignore the checklists, indicating in strong terms that they did not have time for such things and that they knew what they were doing without bits of paper. However, whilst they may well know what they are doing, they clearly are not doing what they should be doing. Their deviation from protocol is a deliberate act, and one that checklists and training events will not be able to rectify. Again, an individual meeting presenting the appropriate evidence may be more influential. Both of these cases are of an individual determining that their own desire to do as they wish is more important than working to the recommendations of their own professional body, and the agreed standard protocol within the department. This, clearly, does not fit with the modern NHS ethos of collaborative working, and echoes back to the "doctor knows best" days of the old health service.

This links into the area discussed in the literature review, that of change management, and also touches on the points raised by Frances (2013) and Barnes (2014), on the subject of adequate sanctions for dealing with poor performance. The use of the checklists in this investigation have shown clearly that this is a viable method for demonstrating variation in practice, the feedback events then provide an effective method of communication to correct variance. However, in the event that this variation persists, due to either an unwillingness or inability to change, we are no further forward than the situation Frances noted with Mid Staffordshire Trust where he called for "*standards and measures of compliance ….. with rigorous and clear means of enforcement*". Thanks to the RCPath and their minimum datasets and tissue pathways there are standards, but until now there has been no method of measuring compliance. The work presented here demonstrates that whilst a measure of compliance is now available, a means of enforcement is still required, although if this were addressed as a management issue, the standard NHS capability or behavioural procedures could be invoked. The tone of the Francis (2013) and Barnes (2014) reports indicate that something more powerful, with powers to apply professional censure, is desired. Simply removing a poor practitioner from their post appears to be insufficient, the tone of the reports and the current patient–doctor dynamic calls for a more powerful and authoritative oversight. As this work was a trail to establish proof of concept for the checklists and to explore a method of corrective action, such a structure was outside its scope. However, the political and social tone is ready for such a structure, the GMC, the RCPath, the Royal College of Nursing (RCN) the HCPC all hold the capacity to remove the right of an individual to practice within that profession, in the event of malpractice. Should, then, failure to act in accordance to the best professional guidance be considered as such? It clearly constitutes a failure to provide the best possible service to our patients, and the level of censure that invokes is best left to a wider discussion. As Dixon-Woods (2011) noted, the collegiate model of regulation is open to abuse and is unable to adequately protect the profession from this abuse. This has led to a slow diminishing of the self-regulatory powers previously possessed by the professions, and led to more formal legislated regulation. As such, pressing the professional bodies in to service to be the authoritative voice called for above, is unlikely to be successful, indeed such may be contradictory to our goals, as public trust has been sorely abused by scandals like Mid Staffs (Francis, 2013) The public may now not be receptive to being told that the professional bodies, made up of members of the professions, now has additional powers to censure its own members. An independent body with the will to enforce legal sanction may be the most appropriate method of dealing issues of deliberate or wilful poor performance. The demonstration of KPI data will engender greater trust in the abilities and practices of the medical team, whilst the formal oversight of an independent body will foster greater confidence in the organisation providing medical care.

The preferred method of ensuring compliance must be not be authoritative, but must be education and discussion. In this study the feedback event provided this opportunity; however, if a non-compliant individual chooses not to attend or participate in the feedback event one can follow up the individual with a specific discussion regarding their deviation from recommended practice, however, in the event of no change little more can currently be done. If, as Ludeman & Shepherd (2006) suggest, we accept that the accuracy of the diagnosis relies on the quality of the dissection, we must accept the requirement for some form of standard or quality check.

Considering that Foy (2002) reported that changes that could be implemented on a trial basis were most likely to be adopted long term, any structured intervention such as the one detailed here ought to be introduced with collaboration and discussion with the team. The need for this team approach is very strongly highlighted by the work of Pronovost (2006) and Bosk *et al.* (2009), and builds on the information discussed in the literature review in relation to parallels with airline safety, particularly that of Kao and Thomas (2008).

In Barnes (2014) recommendation 4.13 he encouraged training and education of the pathology workforce in quality management. If such a system is to be developed, it is worth giving serious consideration at the initial stages to the inclusion of change management within this system. Surely one goal of a quality management system to address deficiencies or identify areas for improvement, which would be expected to require some form of change. If we are to train our pathology staff in the management of quality, it seems logical that we should also train them in how to address the changes that may be needed.

New knowledge

This thesis contains a great deal of new knowledge. The data in study 1, indicating the relative frequencies of various pathological features, is information that has never previously been collated. Whilst this is a limited initial study, at a single site, it clearly sets a benchmark for the frequency for the presence of exudate, perforation or diverticula in an appendix; mucin, perforation or cholesterolosis in gallbladder; mean staging of colorectal tumours at point of resection, mean lymph node yields, perforation, diverticula and polyps in colorectal resections; the presence of fibroids and adenomyosis in uterine resections. This is limited data, and should not be used to state with confidence that x% of colorectal resections will contain background polyps. However, this new knowledge is a foundation that can link up with data from other centres and further data from this centre, such as that gain in the other studies.

Study 2, parts 1 to 8, all generated new knowledge, there were three main areas of new knowledge; KPI can be used to demonstrate good and poor practice, there is substantial variation in practice by and between individuals, an appropriate feedback system can reduce or eliminate this variation. Selecting the KPI has been done with reference to the RCPath guidance, and the evidence on which they are based, reference to local SOP has also been made in the selection of the KPI. If this work were to be expanded to a larger scale, the selection of the KPI would have to be discussed by an oversight group and a consensus reached before new checklists were developed. The graphs from study 2, parts 1 to 8 all show a progressive reduction in variation, something which is clearly highlighted in Figure 6 on page 81. There has never before been a structured assessment of variation in the practice of histological dissection, the numerous papers in the literature review that refer to variation in practice all indicate that variation in practice leads to more errors and, in those relating to patients, worse patient outcomes. The feedback and training event has a clear and sustained effect, demonstrated in the graphs presented in the results section. In most cases the amount of variation by individuals shows a rapid reduction, with the remaining variation being more slowly eliminated, Those few cases that do not show this pattern have been discussed previously and these relate to deliberate choice, where some form of management action or censure may be required to compel the change, something which is clearly outside the scope of this investigation. A more structured system, either locally or nationally, with the full support of the department and directorate may create an opportunity for those individuals who do make a deliberate choice not follow the protocol to engage in a constructive conversation with the programme leader. Chisholm (2012) noted a reluctance for some medical professionals to engage in behaviour change conversations, citing a desire to prioritise the doctor-patient relationship. This is undoubtedly true in other areas, where difficult conversations are delayed or ignored from a desire to maintain professional relationships. However, this concern can be contained by working within a more structured framework, where an agreement to work to certain standards has already been made.

Limitations

As with all research, this study does have its limitations. The first, and largest, limitation is that this was an individual led, single centre study. The more this study developed, the more important the team aspect became and the more apparent it became that it was too large for an individual to implement without the enthusiastic support of the rest of the department. The introduction of the training event opened the study up tremendously, after the first four of these events the BMS dissection team was very enthused and keen to be part of the team, making suggestions on how to develop and what should come next. However, the involvement of the pathologists was more limited than would have been ideal, and this is something that should be considered before developing this work further or elsewhere.

The study took place over a number of years, as such the dissectors taking part changed over time, as well as the participants changing in their levels of knowledge, skill and experience. As such there is a development of ideas, awareness and confidence that is due to the individuals own professional development, and not due to the checklists or training event, it is not possible to separate for these effects. As this was an exploratory work, one that developed during its execution, the timeline is perhaps longer than would have otherwise have been the case. Also, the rather fluid make-up of the dissection team may have exacerbated this. If being trialled or developed elsewhere, a more condensed timeline would be possible, as the exploratory work has been performed. Additionally, as well as taking a more team led approach at the outset as mentioned above, selecting a core team of dissectors would simplify the approach and enable a more streamlined trial. However, once the development work is complete, extending the scheme to cover all dissector staff would ensure a full complement of data.

The checklists themselves proved to be very adaptable. They were deliberately constructed to be as simple as possible, however, it is possible that more explicit statements would have produced a greater changed. For example, instead of a checklist point indicating "Appropriate blocks", the checklist could state was is meant by appropriate blocks, the appendix checklist could state "1 x LS from tip, 1 x TS from Base, 1 x TS from Body". A space might be left for the dissector to state their justification in the event they felt it necessary to deviate from this standard sampling. Balancing the conflicting aims of a simple checklist, with a specific checklist is a difficult process and would be refined over successive iterations.

Further work

I was privileged to be invited to speak at the 2015 annual conference of the Academy of Clinical and Medical Laboratory Scientists, in Kilkenny. Whilst there I attended a presentation by Richard Crocker, Head of Medicines Optimisation for the NHS Clinical Commissioning Group (CCG) in Northern, Eastern and Western Devon. Crocker detailed the approach taken within his CCG, where the pharmacy had become far more involved in primary care. The pharmacists are far better placed to keep abreast of current developments in medicines, to know what the most appropriate drug is, when a generic drug will perform as well, at a fraction of the cost, to know the long terms side effects *etc.* He detailed a number of cases where a suboptimal medicine had been prescribed simply because the general practitioner was unaware that one of the myriad of alternatives was now the preferred choice. They provided an electronic formulary, whereby the GP entered the condition they wished to treat, or the drug they wished to prescribe, and the system would indicate the preferred choice, and the reasons why that was the preferred choice. The GP was still free to make a different choice, but had to record their reason for their choice. This clearly enhances clinical decision making, utilising the skills of the professionals within the group to the best advantage of the patient and saves money. One challenge in all areas of the NHS is saving money, if we can perform our specimen dissection to the upmost clinical and cost effectiveness, that will provide time and cost savings which we are then able to use to benefit out patients elsewhere. This has clear utility elsewhere in pathology, notably in the blood sciences. Clinicians often take the approach of simply ticking each test request box on the request form, rather than giving a true evaluation to what is needed. A trial run by Crocker saw the clinicians stating the clinical question, and leaving the repertoire of tests to be selected by the laboratory, who then provided clinical advice to the clinician. In essence, this is what we already do in histopathology. We receive an organ with the clinical information of "Crohn's" or "tumour" and we investigate that specimen in the most appropriate way. This then puts us in a position of leading the clinical integration of the pathology service.

However, there is further work to be done. The Joint Working Group on Quality Assurance in Pathology is currently following up on the Barnes Report, and this work may be of interest to them. The calls from Barnes and Francis for individualised, transparent quality data are clearly met in this work; however, this is a single site study and needs to be replicated. A further multicentre study, where core items for the checklists are agreed across all centres, would validate the data gained here and form the basis for a stepwise introduction of a national quality framework. This work can go further, the calls from Barnes apply to all of pathology, not simply to histopathological dissection. The concept of KPI can be extended further into the histopathology laboratory, covering areas such as section cutting, immunocytochemistry, etc. Collating these KPI may require a different approach to using checklists, and may be generated directly from the Laboratory Information Management System (LIMS), this again can provide the individualised, transparent quality data, but would also allow the automated collation of accurate workload statistics. Moving to other areas of pathology, perhaps in microbiology one might have a rolling count of contaminated cultures, the frequency of repeat tests, and adherence to the Standards for Microbiological Investigations (SMI) *etc*. In blood sciences the practices are somewhat clearer cut, and so the KPI may need to translate to errors *e.g.* errors in centrifugation, refrigeration, pipetting *etc*. It must be stressed that errors are expected and an individual making occasional errors is acceptable, the point here would be to enable trends by and between individuals to be identified on a local, regional and national scale. This would provide the individual and transparent quality data that is being called for.

Chapter Six – Conclusions

The checklists are very clearly an effective intervention, audit and management tool. In the current climate of "More for Less" and the requirements for more accountability, and the needed change in ethos towards the team dynamic seen in the aviation industry, this shows a great deal of promise. The checklist is highly adaptable and can be modified to suit local practices, although it might be hoped that the checklist might be picked up by the Joint Working Group on Quality Assurance. A national framework incorporating the checklists as a method of providing QA in histopathological dissection is entirely feasible.

The training intervention was very popular, takes minimal organisation, occupies a small amount of time and uses virtually no resources other than time. It increases communication between the BMS and pathologists; and between the BMS dissectors. The only real lack in the training event is that they are delivered by pathologists, to BMS; meaning that the needed increase in communication between pathologists is missed. It is hoped that in future more pathologists will attend sessions delivered by other pathologists and the BMS will deliver sessions to other BMS and to the pathologists.

The combination of checklists and training intervention has produced a noticeable and sustained reduction in variation. It has enabled the identification of both inadvertent poor practice (low lymph node yield) and deliberate deviation from agreed practice (pathologists 5 and 9). Prior to this study there was no reason to suspect poor performance, and there was no evidence of deviation. This then allows these issues to be tackled, increasing standards in the department and improving patient outcomes.

This work has relied heavily on the identification of substandard performance by Barnes (2014). It is fitting then to consider how this work seeks to meet some of his recommendations.

2.22. Overall the quality assurance framework in pathology lacks several key factors without which we cannot say the best interests of the patient are being served: transparency, integration, key assurance indicators, oversight and effective triggers for sanction and reward.

This work focuses extensively on demonstrating the use of KPIs, demonstrates the facility for transparency and oversight. All that remains is for a decision on thresholds for sanction and reward.

4.28. "Further consideration must be given to the ways in which individual performance can be assessed, monitored and competence-assured. The National Medical Director will ask the professional bodies, led by RCPath, to review these issues and report back within twelve months on their findings."

Individual performance is monitored clearly here, and can be compared against other individuals, local or national means. Competence assurance is currently based on gateway qualifications, the data here could easily be used to demonstrate ongoing competency in any, or all, areas.

4.32. The professional bodies, led by RCPath, should develop methodologies for assessing the performance of individuals in EQA schemes that will give a fair and accurate picture of their competency to practice.

This work could integrate with LIMS and allow automatic data collection for KPIs. This could be collated, analysed and reported by an EQA scheme, allowing for independent analysis and reporting, based against a local, regional or national standard. The power for sanction and reward could rest with the CQC, NHS England or the Professional Standards Authority.

> *4.44. "The quality and governance systems of pathology providers must be integrated with trust governance and quality structures. This should include the measurement of appropriate quality assurance indicators and the identification of an accountable board member within the organisation. CQC and the Chief Inspector of Hospitals have indicated that robust information on the quality of pathology services could contribute to the overall assessment of quality under the new hospital inspection model."*

Clearly, there is plentiful scope for this work to develop further. The Joint Working Group on Quality Assurance is currently determining how to address the recommendations of Barnes, in the background of changes being made in response to Frances. The author hopes that this investigation may demonstrate the gap in knowledge currently, the potential risk to patients it presents and the feasibility of this method to address it.

> *1.7. The current pathology quality assurance framework lacks several key factors: transparency, integration, scrutiny, oversight and effective triggers for reward and sanction, without which we cannot say the best interests of patients and healthcare generally are truly being served.*

This work sets out the framework to provide just such a system, and proof that it works.

References

ACOG (2012) Standardization of Practice to Improve Outcomes. Committee Opinion No. 526. American College of Obstetricians and Gynaecologists. *Obstetrics and Gynaecology*. 119 pp.1081-1082.

Annon, (1942) Cockpit conversation. *Life*. August 24 pp. 62.

Archer, J. (2010) State of the science in health professional education: effective feedback. *Medical Education*. 44 pp.101-108.

Barnes, I., (2010) *Pathology Quality Assurance Review.* NHS England.

Barr, W. and Williams, E.Value of external quality assessment of the technical aspects of histopathology. *Clinical Pathology*. 1982 (33), pp.1050-1056.

Beard, J., Jolly, B., Southgate, L., Newble, D., Thomas, E. and Rochester, J. (2005) Developing assessments of surgical skills for the GMC Performance Procedures. *Annals of the Royal College of Surgeons of England*. 87 (4), pp.242-7.

Bennett, C., Howe, C. and Truswell, E., (2002) *Small Group Teaching and Learning in Psychology - A Review of Research in Small-Group Teaching and Suggestions for Good Practice.* University of York.

Berwick, D., (2013) *A Promise to Learn – a Commitment to Act Improving the Safety of Patients in England National Advisory Group on the Safety of Patients in England.* Crown Copyright.

Bilimoria, K., Bentrem, D., Stewart, A., Talamonti, M., Winchester, D., Russell, T. and Ko, C. (2008) Lymph Node Evaluation as a Colon Cancer Quality Measure: A National Hospital Report Card. *Journal of the National Cancer Institute*. 100 (18), pp.1310-1317.

Bosk, C., Dixon-Woods, M., Goeschel, C. and Pronovost, P. (2009) The art of medicine. Reality check for checklists. *The Lancet*. 374 pp.444-445.

Bosley, S. and Dale, J. (2008) Healthcare assistants in general practice: practical and conceptual issues of skill-mix change. *British Journal of General Practice,*. 58 (547), pp.118-124.

Branch, W. and Paranjape, A. (2002) Feedback and Reflection: Teaching Methods for clinical settings. *Academic Medicine*. 77 (12 Pt 1), pp.1185-1188.

Braun, V. and Clarke, V. (2006) Using thematic analysis in psychology. *Qualitative Research in Psychology*. 3 (2), pp.77-101.

Bridgewater, B., Grayson, A., Brooks, N., Grotte, G., Fabri, B., Au, J. and Keogh, B. (2007) Has the publication of cardiac surgery outcome data been associated with changes in practice in northwest England: an analysis of 25 730 patients undergoing CABG surgery under 30 surgeons over eight years. *Heart*. 93 (6), pp.744-748.

Cai, J., Liu, X., Xiao, Z. and Liu, J. (2009) Improving supply chain performance management: A systematic approach to analyzing iterative KPI accomplishment. *Decision Support Systems*. 46 (2), pp.512-521.

Cancer Research UK (2012) *Cancer Research UK, UK Cancer Incidence (2010) by Country Summary, December 2012.* Available from: cruk.org/cancerstats [Accessed 25/07/2015].

Childs, A., Burke, J., Perry, M. and Gallup, D. (2005) Metastatic uterine serous carcinoma originating in an endometrial polyp: a report of 2 cases. *Journal of Reproductive Medicine*. 50 (3), pp.209-212.

Chisholm, A., Hart, J., Lam, V. and Peters, S. (2012) Current challenges of behavior change talk for medical professionals and trainees. *Patient Education and Counseling*. 87 (3), pp.389-394.

Cobb, P. (2002) Theories of Knowledge and Instructional Design: A Response to Colliver. *Teaching and Learning in Medicine: An International Journal*. 14 (1), pp.52-55.

Colliver, J. (2002) Constructivism: The View of Knowledge That Ended Philosophy or a Theory of Learning and Instruction? *Teaching and Learning in Medicine: An International Journal*. 14 (1), pp.49-51.

Coombs, I., Stowasser, D., Reid, C. and Mitchell, C. (2009) Impact of a standard medication chart on prescribing errors: a before-and-after audit. *Quality and Safety in Health Care*. 18 pp.478-485.

Crawford, L., Morris, P., Thomas, J. and Winter, M. (2006) Practitioner development: from trained technicians to reflective practitioners. *International Journal of Project Management*. 24 (8), pp.722-733.

Crawford, L. and Nahmias, A. (2010) Competencies for managing change. *International Journal of Project Management*. 28 (4), pp.405-412.

Croft, P., Malmivaara, A. and van Tulder, M. (2011) The pros and cons of evidence-based medicine. *Spine*. 36 pp.1121-1125.

Cross, S. (2005) Aptitude testing and assessment of training progress in histopathology. *Current Diagnostic Patholog*. 11 (5), pp.209-307.

Daykin, N. and Clark, B. (2000) 'They'll still get the bodily care'. Discourses of care and relationships between nurses and health care assistants in the NHS. *Sociology of Health & Illness.* 22 (3), pp.349-363.

Department of Health, (2013) *The Handbook to the NHS Constitution.* Crown Copyright.

Dhingra, K., Elms, A. and Hobgood, C. (2010) Reducing Error in the Emergency Department: A Call for Standardization of the Sign-out Process. *Annals of Emergency Medicine*. 10 (56), pp.637-642.

Dixon-Woods, M., Yeung, K. and Bosk, C. (2011) Why is UK medicine no longer a self-regulating profession? The role of scandals involving "bad apple" doctors. *Social Science & Medicine*. 73 pp.1452-1459.

Donnelly, M. and Woolliscroft, J. (1989) Evaluation of clinical instructors by third-year medical students. *Academic Medicine*. 64 pp.159-164.

Duthie, F., Nairn, E., Milne, A., McTaggart, V. and Topping, D. (2004) The impact of involvement of biomedical scientists in specimen dissection and selection of blocks for histopathology: a study of time benefits and specimen handling quality in Ayrshire and Arran area laboratory. *Journal Clinical Pathology*. 57 pp.27-32.

Ellis, I., Pinder, S., Bobrow, L., Buley, I., Coyne, J., Going, J., Humphreys, S., Jasani, B., Lakhani, S., Lowe, J., Miller, K., Rhodes., A., Walker, R. and Wells, C., (2005) *PATHOLOGY REPORTING OF BREAST DISEASE. A Joint Document Incorporating the Third Edition of the*

NHS Breast Screening Programme's Guidelines for Pathology Reporting in Breast Cancer Screening and the Second Edition of the Royal College of Pathologists' Minimum Dataset for Breast Cancer Histopathology. Report number: 58.NHSBSP.

Ferran, N., Metcalfe, A. and O'Doherty, D. (2008) Standardised proformas improve patient handover: Audit of trauma handover practice. *Patient Safety in Surgery*. 2 pp.24.

Fleming, S. and Griffiths, D. (2005) Best Practice No 180 Nephrectomy for renal tumour; dissection guide and dataset. *Journal of Clinical Pathology*. 58 (1), pp.7-14.

Foy, R., MacLennan, G., Grimshaw, J., Penny, G., Campbell, M. and Grol, R. (2002) Attributes of clinical recommendations that influence change in practice following audit and feedback. *Journal of Clinical Epidemiology*. 55 (7), pp.717-722.

Frakes, M. and Van Voorhis, S. (2007) Effectiveness of a Challenge-and-Respond Checklist in Ensuring Safety Behavior Compliance by Medical Team Members at a Rotor-Wing Air Medical Program. *Air Medical Journal*. 26 (5), pp.248-251.

Francis, R., (2013) *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry.* Her Majesty's Stationary Office.

Gawande, A. (2007) The Checklist. *The New Yorker*. December 10, 2007.

Glasziou, P., Ogrinc, G. and Goodman, S. (2011) Can evidence-based medicine and clinical quality improvement learn from each other? *BMJ Quality & Safety*. 20 (Suppl 1) pp.i13-i17.

GMC, (2013) *Good Medical Practice – Working with Doctors, Working with Patients.* General Medical Council.

GMC, (2012) *Continuing Professional Development Guidance for all Doctors. 2012.* General Medical Council.

Goldstein, S., Monteagudo, A., Popiolek, D., Mayberry, P. and Timor-Tritsch, I. (2002) Evaluation of endometrial polyps. *American Journal of Obstetrics and Gynecology*. 186 (4), pp.669-674.

Gonzalez-Gil, A., Palacin, R. and Batty, P. (2014) Optimal energy management of urban rail systems: Key performance indicators. *Energy Conversion and Management*. 90 (0), pp.282-291.

Hannan, E., Cozzens, K., King III, S., Walford, G. and Shah, N. (2012) The New York State Cardiac Registries: History, Contributions, Limitations, and Lessons for Future Efforts to Assess and Publicly Report Healthcare Outcomes. *Journal of the American College of Cardiology*. 59 (25), pp.2309-2316.

Hastings, R. and Howell, R. (2010) The importance and value of EQA for diagnostic genetic laboratories. *Journal of Community Genetics*. 1 (1), pp.11-17.

Haynes, A., Weiser, T., Berry, W., Lipsitz, S., Breizat, A., Dellinger, E., Herbosa, T., Joseph, S., Kibatala, P., Lapitan, M., Merry, A., Moorthy, K., Reznick, R., Taylor, B. and Gawande, A. (New England Journal of Medicine) A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. *2009*. 360 pp.491-499.

Hill, A., Yu, T., Barrow, M. and Hattie, J. (2009) A systematic review of resident-as-teacher programmes. *Medical Education*. 43 pp.1129-1140.

Ho, J., Pattanittum, P., Japaraj, R., Turner, T., Swadpanich, U. and Crowther, C. (2010) Influence of training in the use and generation of evidence on episiotomy practice and perineal trauma. *International Journal of Gynecology & Obstetrics*. 111 (1), pp.13-18.

Hooker, A., Radder, C., van de Wiel, B. and Geenen, M. (2011) Metastasis from breast cancer to an endometrial polyp; treatment options and followup. Report of a case and review of the literature. *European Journal of Gynaecological Oncology*. 32 (2), pp.22830.

HPC, (2012) *Continuing Professional Development and Your Registration.* Health and Care Professions Council.

Hunt, J., (2013) *Patients First and Foremost: The Initial Government Response to the Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry.* The Stationary Office.

IBMS, (2005) *Principles of Good Practice for Biomedical Scientist Involvement in Histopathological Dissection.* IBMS.

IBMS, (2009) *Biomedical Scientist Training Logbook for the Institute Diploma of Expert Practice in Histological Dissection.* Institute of Biomedical Science.

IBMS, (2010a) *Training Logbook for the Advanced Specialist Diploma in Specimen Dissection, Breast Pathology.* Institute of Biomedical Science.

IBMS, (2010b) *Training Logbook for the Advanced Specialist Diploma in Specimen Dissection, Lower Gastrointestinal Pathology.* Institute of Biomedical Science.

IBMS, (2014a) *IBMS CPD.* Institute of Biomedical Science.

IBMS, (2014b) *IBMS CPD – Reflective Practice.* Institute of Biomedical Science.

Ibrahim, M. (2012) Immunocytochemistry Run 99 24th September – 11th October 2012. *UK NEQAS ICC & ISH*.

Jayram, S., (2014) *Joint Press Statement – the Royal College of Pathologists, Institute of Biomedical Science, Association for Clinical Biochemistry and Laboratory Medicine.* Royal College of Pathologists.

Kantele, A., Kanerva, M., Seppänen, M., Sutinen, J., Skogberg, K., Pakarinen, L., Jääskeläinen, I., Aho, I., Järvinen, A., Finnilä, T. and Ollgren, J. (2010) Do as I say, not as I do: Handwashing compliance of infectious diseases experts during influenza pandemic. *American Journal of Infection Control*. 38 (7), pp.579-580.

Kao, L. and Thomas, E. (2008) Navigating Towards Improved Surgical Safety Using Aviation-Based Strategies. *Journal of Surgical Research*. 145 (2), pp.327-335.

Kaul, P., Gong, J. and Guiton, G. (2014) Effective Feedback Strategies for Teaching in Pediatric and Adolescent Gynecology. *Journal of Pediatric and Adolescent Gynecology*. 27 (4), pp.188-193.

Kennedy, I., (2001) *The Report of the Public Inquiry into children's Heart Surgery at the Bristol Royal Infirmary 1984-1995. Learning from Bristol.* Crown Copyright.

Kim, Y., Suh, J., Cha, H., Jang, S., Kim, M., Yoon, S., Kim, B., Chang, H., Kwon, Y. and Hong, E. (2007) Additional lymph node examination from entire submission of residual mesenteric tissue in colorectal cancer specimens may not add clinical and pathologic relevance. *Human Pathology*. 38 (5), pp.762-767.

Kingsbury, K., (2008) Scientists & thinkers – Peter Pronovost.. *Time Magazine*. (The 2008 TIME 100,)

Kitis, G. and Maris, T., (2005) Dysplastic area in ulcerative Colitis. Endoscopic resection or total colectomy. *Annals of Gastroenterology*. 18(2):112-113.

ten Kleij, F. and Musters, P.A.D. (2003) Text analysis of open-ended survey responses: a complementary method to preference mapping. *Food Quality and Preference* [online]. **14** (1), pp.43-52.

Lawrence, J. (2009) Peter Pronovost: champion of checklists in critical care. *The Lancet*. 374 (9688), pp.443.

Levy, A., Murakata, L. and Rohrmann, C. (2001) Gallbladder Carcinoma: Radiologic-Pathologic Correlation. *Radiographics*. 21 (2), pp.295-314.

Liebmann, R. (2015) Breaking new ground: the pilot of biomedical scientists histopathology reporting. *The Biomedical Scientist*. 59 (1), pp.9-12.

Lim, A., Nakamura, B., Higa-McMillan, C., Shimabukuro, S. and Slavin, L. (2012) Effects of workshop trainings on evidence-based practice knowledge and attitudes among youth community mental health providers. *Behaviour Research and Therapy*. 50 (6), pp.397-406.

Lowe, J., (2014) *The Role of the Lead Pathologist and Attending Pathologists in the Multidisciplinary Team.* Report number: G087.The Royal College of Pathologists.

Ludeman, L. and Shepherd, N. (2006) Macroscopic assessment and dissection of colorectal cancer resection specimens. *Current Diagnostic Pathology*. 12 pp.220-230.

Mesmer-Magnus, J. and Viswesvaran, C. (2010) The role of pre-training interventions in learning: A meta-analysis and integrative review. *Human Resource Management Review*. 20 (4), pp.261-282.

Naeger, D., Wilcox, C., Phelps, A., Ordovas, K. and Webb, E. (2014) Residents Teaching Medical Students: How Do They Compare With Attending Educators? *Journal of the American College of Radiology*. 11 (1), pp.63-67.

Nakhleh, R. (2013) Diagnostic error in surgical pathology. *Diagnostic Histopathology*. 19 (12), pp.433-437.

Newble, D. (2004) Techniques for measuring clinical competence: objective structured clinical examinations. *Medical Education*. 38 (2), pp.199-203.

NHS England, (2014b) *Standardise, Educate, Harmonise. Commissioning the Conditions for Safer Surgery. Report of the NHS England Never Events Taskforce.* NHS England Never Events.

NHS England, (2014a) *Information Security Policy*. NHS England.

NHSBSP, (2003) *EXTERNAL QUALITY ASSESSMENT SCHEME FOR BREAST SCREENING HISTOPATHOLOGY - General Description and Standard Operating Procedures,*. Report number: 57.NHSBSP.

NIH, (2012) *Policies and Guidelines Relating to the P30 Cancer Center Support Grant. National Institutes of Health/ DHHS National Cancer Institute Office of Cancer Centers.* National Institute of Health.

Ornato, J. and Peberdy, M. (2014) Applying lessons from commercial aviation safety and operations to resuscitation. *Resuscitation*. 85 (2), pp.173-176.

Persson, J. (2009) Semmelweis's methodology from the modern stand-point: intervention studies and causal ontology. *Studies in History and Philosophy of Science Part C: Studies in History and Philosophy of Biological and Biomedical Sciences*. 40 (3), pp.204-209.

Pronovost, P., Needham, D., Berenholtz, S., Sinopoli, D., Chu, H., Cosgrove, S., Sexton, B., Hyzy, R., Welsh, R., Roth, G., Bander, J., Kepros, J. and Goeschel, C. (2006) An intervention to decrease catheter-related bloodstream infections in the ICU**.** *New England Journal of Medicine*. 355 (26), pp.2725-2732.

Pugel, A., Simianu, V., Flum, D. and Dellinger, E. (2015) Use of the surgical safety checklist to improve communication and reduce complications. *Journal of Infection and Public Health*. 8 (3), pp.219-225.

Quirke, P. and Williams, G., (1998) *Standards and Minimum Datasets for Reporting Common Cancers. Minimum Dataset for Colorectal Carcinoma Histopathology Reports.* Royal College of Pathologists.

Quirke, P., Steele, R., Monson, J., Grieve, R., Khanna, S., Couture, J., O'Callaghan, C., Myint, A., Bessell, E., Thompson, L., Parmar, M., Stephens, R. and Sebag-Montefiore, D. (2009) Effect of the plane of surgery achieved on local recurrence in patients with operable rectal cancer: a prospective study using data from the MRC CR07 and NCIC-CTG CO16 randomised clinical trial. *The Lancet* [online]. 373 (9666), pp.821-828.

Radford, P., Derbyshire, L., Shalhoub, J. and Fitzgerald, J. (2015) Publication of surgeon specific outcome data: A review of implementation, controversies and the potential impact on surgical training. *International Journal of Surgery*. 13 (0), pp.211-216.

Rakha, E., Lee, A., Roberts, J., Vilena Salinas, N., Hobi, Z., Reis-Filho, J. and Ellis, I. (2012) Low–Estrogen Receptor–Positive Breast Cancer: The Impact of Tissue Sampling, Choice of Antibody, and Molecular Subtyping. *Journal of Clinical Oncology*. 30 (23), pp.2929-2933.

RCPath, (2004) *Implementation of the Extended Role of Biomedical Scientists in Specimen Description, Dissection and Sampling – Final Report.* Royal College of Pathologists.

RCPath, (2005) *Histopathology and Cytopathology of Limited or No Clinical Value*. The Royal College of Pathologists.

RCPath, (2007) *Curriculum for Specialist Training in Histopathology and Related Subspecialties. Joint Committee on Pathology Training.* Royal College of Pathologists.

RCPath, (2009) *Tissue Pathways for Gastrointestinal and Pancreatobiliary Pathology.* Royal College of Pathologists.

RCPath, (2010.) *GUide to the CPD Scheme.* Royal College of Pathologists.

RCPath, (2013) *Review of Cellular Pathology Governance, Breast Reporting and Immunohistochemistry at Sherwood Forest Hospitals NHS Foundation Trust. A Report Prepared for the Care Quality Commission in Respect of Diagnostic and Screening Procedure.* Royal College of Pathologists.

RCPath, (2014a) *Standards and Datasets for Reporting Cancers Dataset for Colorectal Cancer (3nd Edition).* Royal College of Pathologists.

RCPath, (2014b) *Standards and Datasets for Reporting Cancers Dataset for Endometrial Cancer.* Royal College of Pathologists.

RCPath, (2015) *Tissue Pathways for Gynaecological Pathology.* Royal College of Pathologists.

Salmon, H., Smith, J. and Balsitis, M. (2002) Is microscopic assessment of macroscopically normal hysterectomy specimens necessary? *Journal of Clinical Pathology*. 55 (1), pp.67-68.

Sanders, S., Smith, A., Carr, R., Roberts, S., Gurusamy, S. and Simmons, E. (2009) Enhanced BMS BMS cut up role in colonic cancer reporting. *Journal of Clinical Pathology*. 65 pp.474.

Scholl, R. (2013) Causal inference, mechanisms, and the Semmelweis case. *Studies in History and Philosophy of Science Part A*. 44 (1), pp.66-76.

Sciacovelli, L., Secchiero, S., Zardo, L. and Plebani, M. (2010) The role of the External Quality Assessment. *Biochemia Medica*. 20 (2), pp.160-164.

Scotland for Health, (2011) *The Role of Assistant Practitioners in the NHS: Factors Affecting Evolution and Development of the Role. Skills for Health Expert Paper.* Skills for Health.

Scott, K. and Grace, R. (1989) Detection of lymph node metastases in colorectal carcinoma before and after fat clearance. *British Journal of Surgery*. 76 pp.1165-1167.

Scottish Cancer Task Force, (2014) *Colorectal Cancer Clinical Quality Performance Indicators.* Scottish Government and Healthcare Improvement Scotland.

Seifert, P. (2009) Checklists and Safety Improvements. *Association of periOperative Registered Nurses*. 89 pp.653-655.

Sexton, J., Thomas, E. and Helmreich, R. (2000) Error, stress, and teamwork in medicine and aviation: cross sectional surveys. *British Medical Journal*. 320 pp.745-749.

Shah, H. and Chung, K. (2009) Archie Cochrane and his vision for evidence-based medicine. *Plastic and Reconstructive Surgery*. 124 (3), pp.982-988.

Shaw, A., Collins, W., Fakis, A., Patel, P., Semeraro, D. and Lund, J. (2008) Colorectal surgeons and biomedical scientists improve lymph node harvest in colorectal cancer. *Techniques in Coloproctology*. 12 pp.295-298.

Shia, J., Wang, H., Nash, G. and Klimstra, D. (2012) Lymph Node Staging in Colorectal Cancer: Revisiting the Benchmark of at Least 12 Lymph Nodes in R0 Resection. *Journal of the American College of Surgeons*. 214 (3), pp.348-355.

Simmonds, E., Sanders, D. and Carr, R. (2011) Current experience and attitudes to biomedical scientist cut-up: results of an online survey of UK consultant histopathologists. *Journal of Clinical Pathology*. 64 pp.363-366.

Stefansson, I., Salvesen, H., Immervoll, H. and Akslen, L. (2004) Prognostic impact of histological grade and vascular invasion compared with tumour cell proliferation in endometrial carcinoma of endometrioid type. *Histopathology*. 44 (5), pp.472-479.

Syred, K. (2005) Learning histopathology: A trainee's viewpoint. . *Current Diagnostic Pathology*. 11 (5), pp.323-328.

Taylor, H. and Huang, J. (1998) ‘Routine’ pathological examination of the gallbladder is a futile exercise. *British Journal of Surgery*. 85 (2), pp.208.

Thomas, J. (2006) Retrieval, handling and assessment of lymph nodes in cancer resection specimens. *Current Diagnostic Pathology*. 12 (1), pp.75-82.

Thorpe, A., Al-Jafari, M., Allen, D., Carr, R., Helliwell, T. and Sanders, S., (2012) *Guidelines on Staffing and Workload for Histopathology and Cytopathology Departments (3rd Edition).* Report number: G107.Royal College of Pathologists.

Torre, D., Daley, B., Sebastian, J. and Elnicki, M. (2007) The Reply. *The American Journal of Medicine*. 120 (11), pp.13.

Torre, D., Daley, B., Sebastian, J. and Elnicki, M. (2006) Overview of Current Learning Theories for Medical Educators. *The American Journal of Medicine*. 119 (10), pp.903-907.

UKNEQAS, (2011a) *UKNEQAS for Cellular Pathology Technique – Participants Manual. Edition 5.* UNNEQAS,

UKNEQAS, (2011b) *UKNEQAS for Immunocytochemisty and in Situ Hybridisation – Participants Manual. Edition 5.* UNNEQAS.

UKNEQAS, (2015) *UK NEQAS for Cellular Pathology Technique Participant Manual 2015 -16 (Edition 12)*. UKNEQAS.

Verrill, C., Carr, N., Wilkinson-Smith, E. and Seel, E. (2004) Histopathological assessment of lymph nodes in colorectal carcinoma: does triple levelling detect significantly more metastases? *Journal of Clinical Pathology*. 57 pp.1165-1167.

Walshe, K. and Higgins, J. (2002) The use and impact of inquiries in the NHS. *British Medical Journal*. 325 pp.895.

Wamsley, M., Julian, K. and Wipf, J. (2004) A literature review of “resident-as-teacher” curricula: do teaching courses make a difference? *Journal of General Internal Medicine*. 19 pp.574-581.

West, K. (2005) Early training in histopathology. *Current Diagnostic Pathology*. 11 (5), pp.317-322.

Westenend, P., Meurs, C. and Damhuis, R. (2004) Tumour size and vascular invasion predict distant metastasis in stage I breast cancer. Grade distinguishes early and late metastasis. *Journal of Clinical Pathology*. 58 (2), pp.196-201.

Whittaker, L., Estes, N., Ash, J. and Meyer, L. (2006) The value of resident teaching to improve student perceptions of surgery clerkships and surgical career choices. *American Journal of Surgery*. 191 pp.320-324.

Williams, G., Quirke, P. and Shepard, N., (2007) *Standards and Datasets for Reporting Cancers. Dataset for Colorectal Cancer (2nd Edition).* Royal College of Pathologists.

Yamamoto, M., Nakajo, S. and Tahara, E. (1989) Dysplasia of the Gallbladder: Its Histogenesis and Correlation to Gallbladder Adenocarcinoma. *Pathology - Research and Practice*. 185 (4), pp.454-460.

Zabar, S., Hanley, K. and Stevens, D. (2004) Measuring the competence of residents as teachers. *Journal of General Internal Medicine*. 19 pp.530-533.

Appendix One – Tissue Pathways and Minimum Datasets

The range of RCPath tissue pathways and minimum dataset documents is listed below:

- General Introduction to cancer datasets
- Breast
- Bone and Soft Tissue
- Cardiovascular System
- Cytopathology
- Central Nervous System
- Endocrine System
- Eye
- Gastrointestinal Tract
- Gynaecological Tract
- Head and Neck
- Lung
- Paediatric
- Lymph Nodes & Bone Marrow Lymphomas
- Skin
- Urinary Tract and Testis

Appendix Two – IBMS & RCPath Dissection Categories

Taken from IBMS, 2005.

Specimen Categories

Specimen dissection – guidelines for categorisation of specimens according to complexity.

These are intended to be broad guidelines definitions to act as a base line, which departments and individual consultants may see fit to modify. The review system will permit the recognition of situations in which clinical or anatomical circumstances indicate the category as per protocol is inappropriate.

Basic definitions:

A Specimens only requiring transfer from container to tissue cassette.
B Specimens requiring transfer but with standard sampling, counting, weighing or slicing.
C Simple dissection required with sampling needing a low level of diagnostic assessment and/ or preparation.
D Dissection and sampling required needing a moderate level of assessment
E Specimens requiring complex dissection and sampling methods

Category A

All small biopsies (endoscopic, synovial etc.), uterine curettings, simple products of conception, bone marrow trephines, testicular biopsies, cervical punch biopsies, needle biopsies (excluding those requiring special procedures e.g. renal, muscle), skin curettings and skin biopsies not requiring dissection.

Category B

Vasa deferentia, temporal arteries, sebaceous cysts, Small lipomas, unremarkable tonsils, unremarkable nasal polyps, thyroglossal cysts, fallopian tubes, molar pregnancy, prostatic chippings, transcervical endometrial resection, lymph nodes.

Category C

Placenta, uterus – routine hysterectomy, diverticular disease, femoral head, parathyroidectomy, ischaemic bowel, small soft tissue tumours, meckel's diverticulum, thyroid – non-tumour, muscle and cardiac biopsy, large gastrointestinal polyps, renal biopsy, appendix, skin biopsies – benign – requiring dissection, gallbladder, simple small benign breast biopsies, salivary gland – non-tumour.

Category D

Orchidectomy – non-neoplastic, gastrectomy – benign ulcer, simple small ovarian cysts & tumours, salivary gland – tumours, pigmented skin lesions, thyroid – tumours, complex (non-neo-plastic) gastrointestinal resections.

Category E

Uterine carcinoma, gastro-intestinal carcinomas, oesophagectomy, bladder resections, renal resections, vulvectomy, penile carcinoma, mastectomy, localised wide lump breast excisions, neck dissection, bone tumours, prostatectomy, orchidectomy – neoplastic, ovarian tumours, mandibulectomy.

Appendix Three – Baseline Data Collection Sheets

Appendix Specimen Number:	
Time from receipt to dissection (working days, mean)	
Need for extra investigations (*e.g.* levels, ICC)	
The number of blocks (mean)	
The need for and number of extra blocks	
A record of any errors in the macroscopic description	
Whether the manner of dissection and macroscopic description allows the minimum dataset to be completed.	
Whether the following are described in the macro:	
Length	
Diameter	
Serosa	
Exudate	
Perforation	
Mucin	
Fibrosis	
Appearance suggestive of malignancy	
Faecolith	
Pus	
Diverticula	
Normal / unremarkable appendix	
If there is agreement between the macroscopic description and the microscopic report.	

Gallbladder Specimen Number:	
Time from receipt to dissection (working days, mean)	
Need for extra investigations (*e.g.* levels, ICC)	
The number of blocks (mean)	
The need for and number of extra blocks	
A record of any errors in the macroscopic description	
Can the minimum dataset be completed.	
Whether the following are described in the macro:	
Length	
Width	
Depth	
Received open / unopened	
Serosal surface	
Lumenal contents	
Presence or absence of stones	
Type of stones (if present)	
Exudate	
Perforation / incision	
Fibrosis	
Mucin	
Wall thickness	
Polyps	
Appearance suggestive of cholesterolosis	
Empyema	
Rokitansky-Aschoff sinuses	
Cystic duct lymph node	
Suspicious of malignancy	
Mucosa	
Agreement between the macroscopic description and the microscopic report.	

Colon Specimen Number:	
Time from receipt to dissection (working days, mean)	
Need for extra investigations (*e.g.* levels, ICC)	
The number of blocks	
Pathological staging under the TNM classification	
The number of lymph nodes recovered	
The incidence of requests for extra blocks	
A record of any errors in the macroscopic description	
Whether the manner of dissection and macroscopic description allows the minimum dataset to be completed.	
Whether the following are described in the macro:	
Full measurements	
Background mucosa	
Polyps	
Diverticula	
Ulceration	
Fissuring	
Loss of fold pattern	
Thickening / thinning of wall	
Oedema	
Perforation	
Serosal puckering	
Exudate	
Agreement between the macroscopic description and the microscopic report	

Uterus Specimen number:	
Time from receipt to dissection (working days, mean)	
Need for extra investigations (*e.g.* levels, ICC)	
The number of blocks	
The need for and number of extra blocks	
A record of any errors in the macroscopic description	
Whether the manner of dissection and macroscopic description allows the minimum dataset to be completed.	
Whether the following are described in the macro:	
The presence of fibroids	
The appearance of the serosal surface	
The thickness of the endometrium	
The appearance of the myometrium	
The presence of adenomyosis	
The presence of endometriosis	
If there is agreement between the macroscopic description and the microscopic report.	

Appendix Four – Dissection Checklists

Dissection Checklist – Uterus, benign and malignant

Case number__________________ Dissector__________ Assistant______________

		Yes	No	N/A
1	Clean / tidy work area and instruments			
2	Specimen number and name checked			
3	Cassette numbers checked			
4	Specimen orientated			
5	Measured in three dimensions			
6	Tubes & ovaries measured (if present)			
7	External abnormalities on surface described (if present)			
8	Cervix described			
9	Cervix measured			
10	Polyp described (if present)			
11	Endo/myo described, endometrial thickness recorded			
12	Blocks of:			
	Cervix			
	Endo/Myo			
	Fundus			
	Fibroid (if present)			
	Polyp (if present)			
	Posterior reflection (if endometriosis)			
13	Is the minimum dataset complete (if appropriate)			
14	Was SOP followed			

Dissection Checklist – Colorectal, benign and malignant

Case number__________________ Dissector______________

Assistant_______________

		Yes	No	N/A
1	Clean / tidy work area and instruments			
2	Specimen number and name checked			
3	Cassette numbers checked			
4	Specimen orientated (*e.g. Proximal & distal margins)*			
5	Complete measurements given			
6	External abnormalities on surface described (if present)			
7	Involvement of margins stated			
8	Appearance of mucosa described			
9	Presence / absence of appendix recorded (if appropriate)			
10	Macroscopic penetration of tumour recorded (if appropriate)			
11	SOP followed			
12	Blocks of:			
	Margins			
	Appendix, if present			
	Background			
	Back ground abnormalities sampled, *e.g.* diverticulae, polyps			
	Pathology sampled, *e.g.* inflammation, tumour			
	Apical node (for cancer cases)			
	At least 12 nodes (for cancer cases)			
13	Is the minimum dataset complete (if appropriate)			

Dissection Checklist – Appendix

Case number__________________ Dissector______________

Assistant_______________

		Yes	No	N/A
1	Clean / tidy work area and instruments			
2	Specimen number and name checked			
3	Cassette numbers checked			
4	Specimen orientated (*e.g. tip & base)*			
5	Complete measurements given			
6	External surface described			
7	Abnormality described (if present)			
8	SOP followed			
9	Appropriate blocks			
10	Is the minimum dataset complete (if appropriate)			

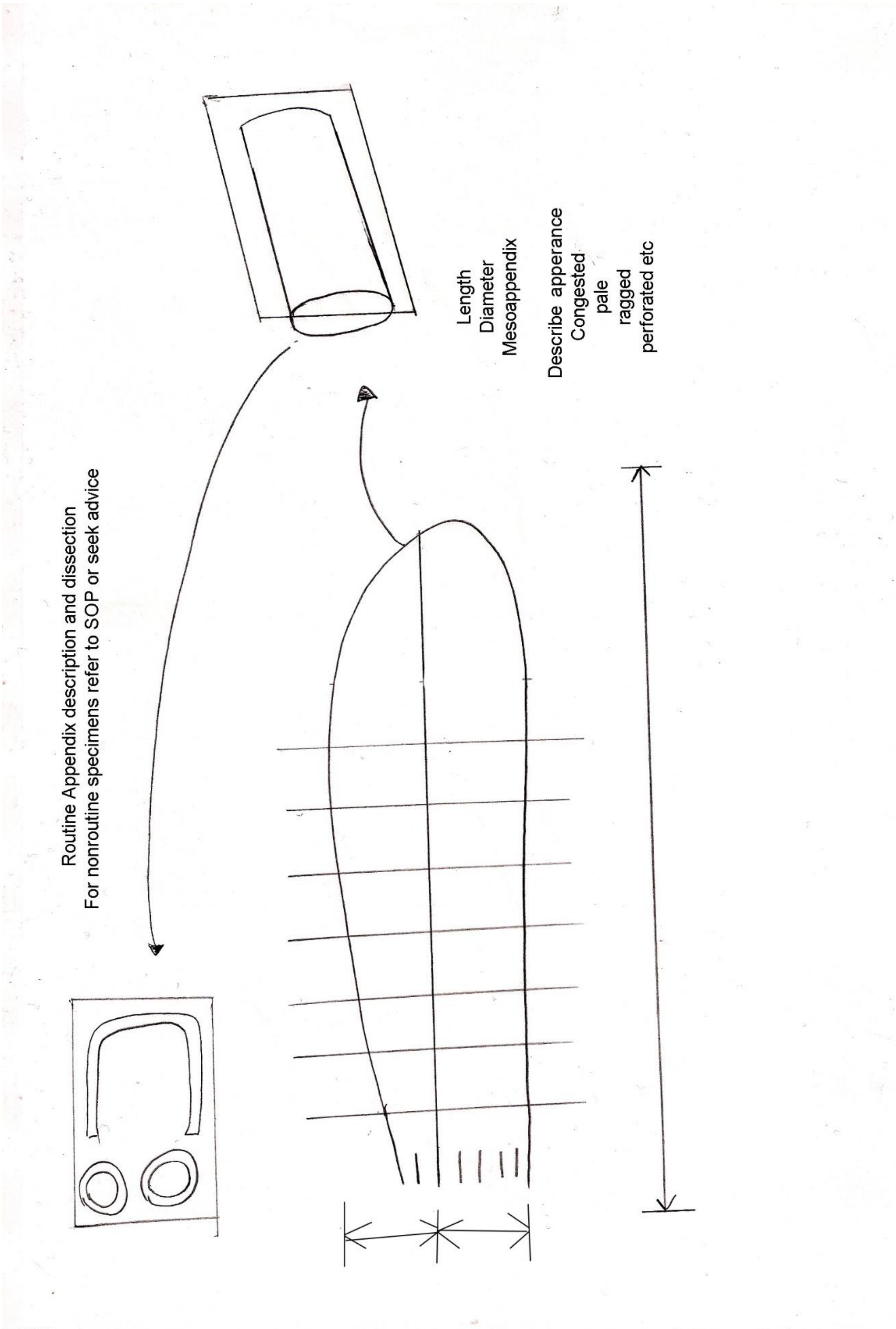
Dissection Checklist – Gall Bladder

Case number__________________ Dissector______________

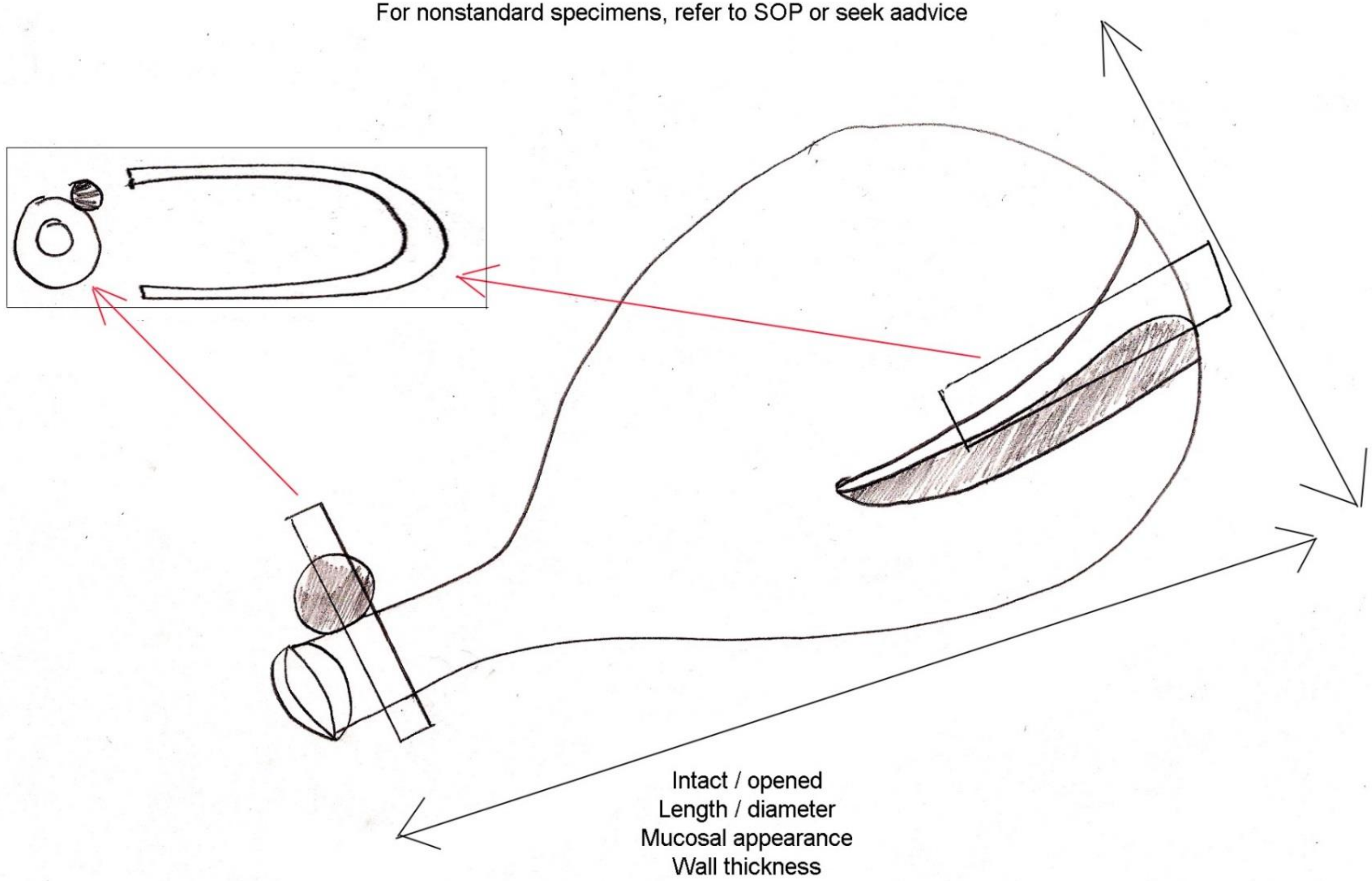
Assistant_______________

		Yes	No	N/A
1	Clean / tidy work area and instruments			
2	Specimen number and name checked			
3	Cassette numbers checked			
4	Specimen orientated (*e.g. duct & fundus)*			
5	Complete measurements given			
6	External surface described			
7	Abnormality described (if present)			
8	SOP followed			
9	Appropriate blocks			
10	Is the minimum dataset complete (if appropriate)			

Appendix Five – Dissection Guide Diagrams

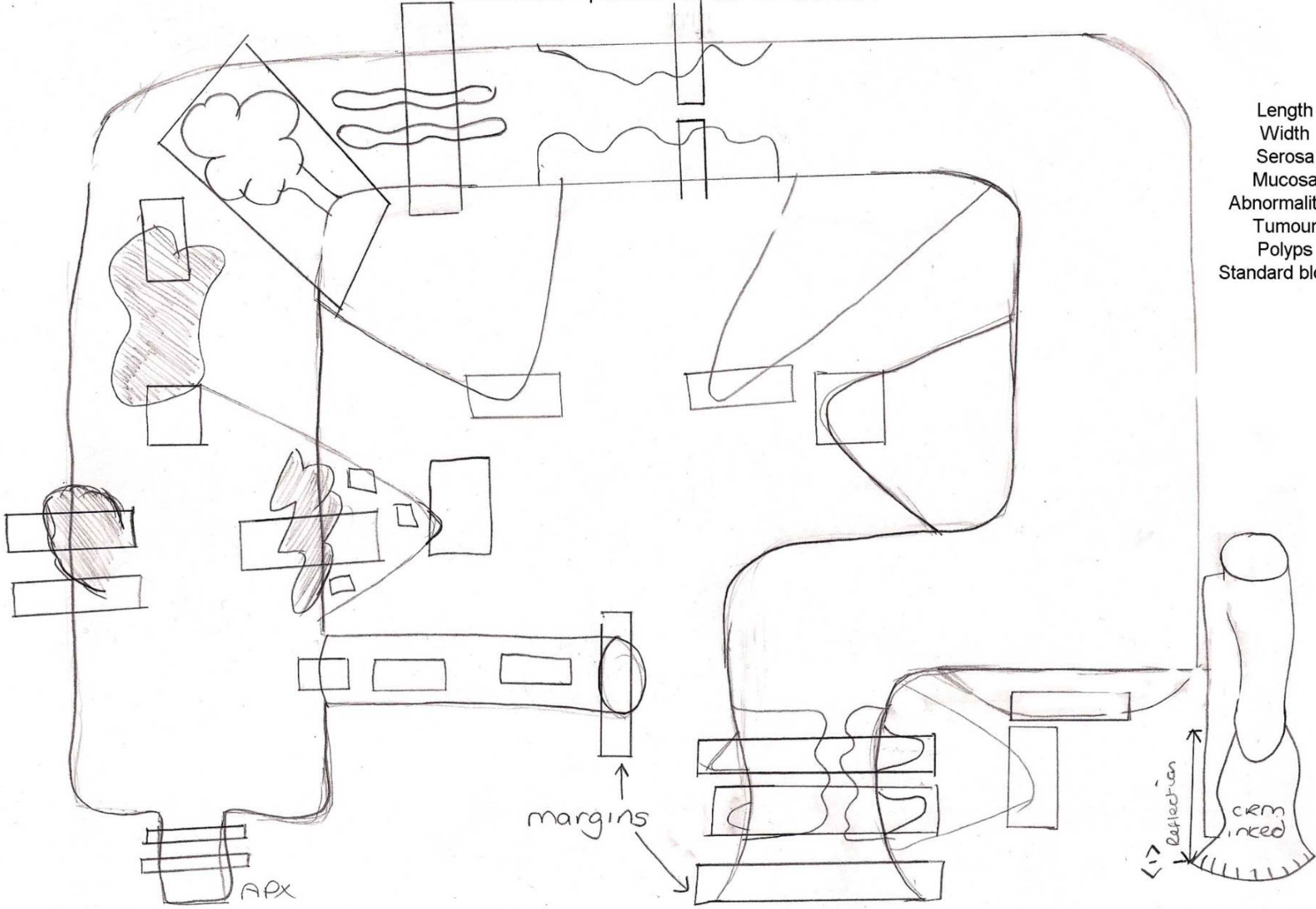


Routine Gallbladder dissection and description
For nonstandard specimens, refer to SOP or seek aadvice

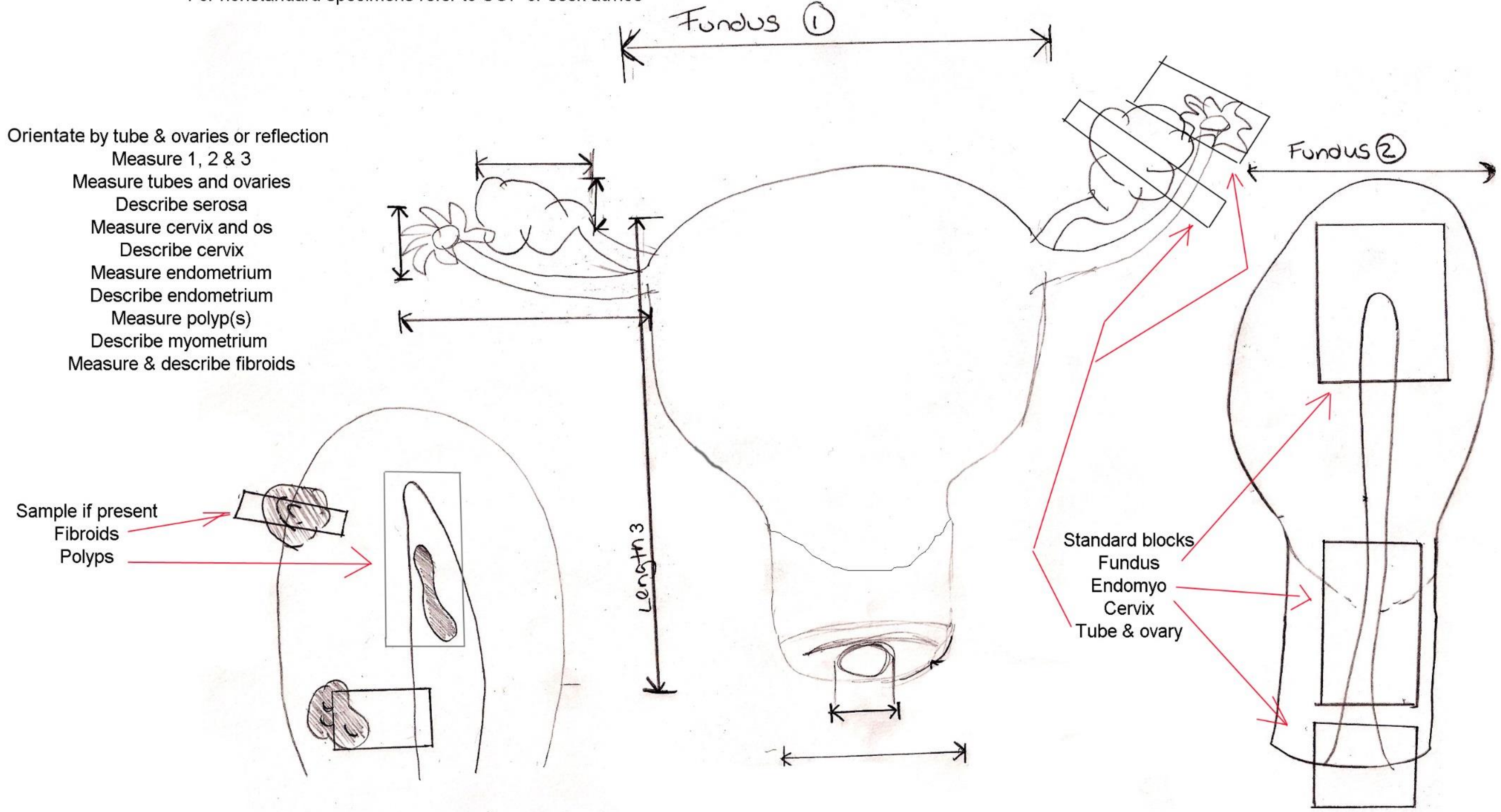


Standard description and dissection of large bowel specimens
For nonstandard specimens see SOP or seek advice

Length
Width
Serosa
Mucosa
Abnormalities
Tumour
Polyps
Standard blocks



Routine uterus dissection and descriotion
For nonstandard specimens refer to SOP or seek advice



Appendix Six – Participant Information Pack and Question Sheet

The following pages show the sheets provided to the participants in the interviews, and also show the questions asked – the questions (page 223) were not disclosed in advance to the participants.

The questions were developed in conjunction with the project supervisor, a chartered psychologist. The intent was to explore the attitudes and opinions of the participants to dissection within the department and their views on the work undertaken. The work thus far had appeared promising, and with the requirement for personally identifiable quality data from the Barnes report (2014) and the King's Mill enquiry (RCPath, 2013), this scheme might be able to be extended to other hospitals – as such, views on how the scheme might be improved and introduced in an improved fashion elsewhere were sought. The work of Braun and Clarke (2006) was instrumental in considering the type of question, and how they might be structured. As these were face to face interviews, rather than a questionnaire, the questions could be further explored after an initial answer.

The questions were designed to be open ended, and as discussed on page 138, participants were encouraged to digress and explore their attitudes and experiences in this area.

Information Sheet

Study Title: The use of key performance indicators as quality assurance in histological dissection.

What is the purpose of the service evaluation?

The aim of this service evaluation is:

- To examine the histological dissection standards following the introduction of the feedback and training intervention.

Do I have to take part?

Data generated within the department from dissectors is anonymously used. Your participation in the interview portion of this study is entirely voluntary.

What if I change my mind?

If you do decide to take part you are still free to leave the study at any time and without giving reason. If you decide to withdraw, please contact me through the details given below and I will remove your information from the study.

What will I have to do if I take part?

This study involves firstly filling out and returning a consent form. We will then have a semi structured conversation regarding the aims of the study. The conversations can be as long or short as you feel appropriate, with as much detail as you feel comfortable giving. The conversations will be carried out through a recorded informal interview. Additional information can be added if you later think of other points.

Will my participation in this study be kept confidential?

All information which is collected from you during the course of the study will be kept strictly confidential. Any names that you may mention in your personal account including your own will be changed and not used in the write up of the study. Direct quotes may be used; however no one will be able to link the information to you personally. The e-mail address that you provide will only be available to me and no printed copies will be generated.

Contact Details:

Mr Matthew Griffiths
Dept of Histopthology
Royal Derby Hospital
Uttoxter Road
Derby
DE22 3NE

E-mail: matthew.griffiths4@nhs.net

Director of Studies: Rachel.Gillibrand@uwe.ac.uk Tel: 0117 328 3385

Thank you for taking the time to read the information above and if you are interested in taking part in the study please complete and return the consent form, which you will find attached.

Many Thanks

Matthew Griffiths

University of the West of England
BRISTOL

Consent Form

The use of key performance indicators as quality assurance in histological dissection.

Please read the following list of statements and enter yes (Y) or no (N) in the boxes.

- I have read and understood the nature of the service evaluation as outlined in the participant information sheet. ☐
- I feel as though I have received enough information about the service evaluation. ☐
- I feel as though I have had sufficient time to come to my decision. ☐
- I understand that I am free to withdraw from the interviews at any time without reason. ☐
- I agree to participate in the service evaluation. ☐

Sign/Print name:

Date:

Debriefing Form

The use of key performance indicators as quality assurance in histological

dissection.

The service evaluation so far has demonstrated a great deal of variation in practice, when working to the same SOPs. The amount of variation was tremendous, and after the introduction of the checklists and then the feedback event, the variation dropped to almost nothing. Standardisation in practice allows us to be certain we are working to a high standard, review of the SOPs allows us to know we are working to the latest RCPath datasets and tissue pathways.
The current data allows us to visualise anonymous individual practice in comparison to their peers. We hope to structure this so that the individual will be able to see their own data and compare this to the mean data for the laboratory. This can be used to audit their dissection, allowing them to identify areas where they could improve their own practice.

If you have any queries about the service evaluation or have any further questions please do not hesitate to contact me on the details below.

I would like to take this opportunity to say thank you for your contribution to the service evaluation. Your help is invaluable to enabling this service evaluation to take place. All participants will be able to access a copy of final write up, should they wish to.

Contact Details:

Mr Matthew Griffiths
Dept of Histopthology
Royal Derby Hospital
Uttoxter Road
Derby
DE22 3NE

E-mail: matthew.griffiths4@nhs.net
Or Rachel.Gillibrand@uwe.ac.uk

University of the West of England
BRISTOL

Interview Questions

1. What do you think the dissection standards are within the department?
2. Are there any specific weaknesses in the department?
    a. Do you feel you have any specific areas of weakness?
3. Are there any specific strengths in the department?
    a. Do you feel you have any specific areas of strength?
4. How do you know how to dissect specimens?
5. What was your opinion of the checklists? What do you think they achieved?
6. What is your opinion of the feedback meetings? What do you think they achieved?
7. What else should we be doing?
8. We want to introduce this programme at another hospital, what can we do better?