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REACT Study: do RandomisEd trials Alter Clinical pracTise? A Qualitative Study

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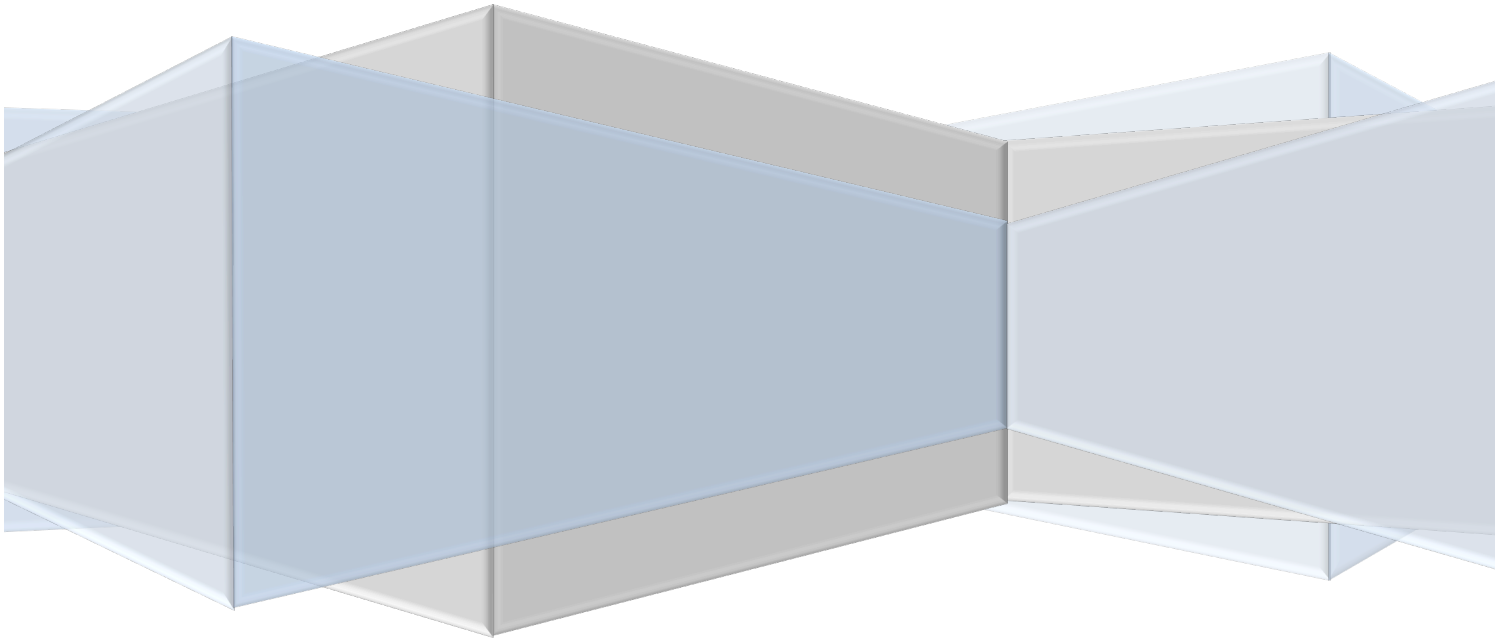

REACT Study: do RandomisEd trials Alter Clinical pracTise? A Qualitative Study

A qualitative study of the closure of midline laparotomy wounds by surgeons and the effect of randomised evidence of their choice of closure technique

Abstract

Background
The STITCH trial published high quality randomised data demonstrating the superiority of small bite over mass closure for the reduction of incisional hernias following elective laparotomy. Previous research has shown time taken for the implementation of evidenced based practise is, on average, 17 years. We aim to understand barriers to implementation of small bite closure into clinical practise.

Methods
Semi-structured interviews were completed with surgeons at a single institution in South West England. Interview transcripts underwent thematic analysis with themes identified following coding and subsequent iterative discussions within the research team.

Results
Nine interviews of eight general surgical consultants and registrars and one urological consultant were performed. Average duration of the interviews was 22:49 minutes (14:20-36.37). Three themes were identified as barriers to the introduction of small bite closure. ‘Trusting the Evidence & Critical Appraisal’ highlighted issues with the published trial and access to data. ‘Surgical Attitude to Risk’ identified differences in personality traits and the importance of guidelines from professional bodies to support practise change. ‘Adopting Evidence in Practise’ discussed training availability, system and patient issues within local hospitals.

Conclusion
Surgeons have to manage the balance between pushing boundaries to improve outcomes and a safety first approach. This influences the adoption of new techniques, such as small bite closure. This study has identified three themes that result in differences in the adoption of a new technique for midline closure. There are possible areas for intervention, to decrease the adoption time for randomised evidence.

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List of Abbreviations

ACPGBI	Association of Coloproctologists of Great Britain and Ireland
ASGBI	Association of Surgeons of Great Britain and Ireland
BMI	Body Mass Index
CCT	Certificate of Completion of Training
CI	Confidence Interval
EBM	Evidence Based Medicine

EHS	European Hernia Society
ESCP	European Society of Coloproctology
HRA	Health research Authority
LB	Large Bite
LMIC	Low and Middle Income Countries
MATCH	Meta-analysis on Materials and Techniques for Laparotomy Closure
NIHR	National Institute of Health and Care Research
PIS	Participant Information Sheet
RCT	Randomsied Controlled Trial
RD&E	Royal Devon and Exeter Hospital
RR	Risk Ratio
PIS	Patient Information Sheet
SB	Small Bite
SL	Suture Length
SSI	Surgical Site Infection
STITCH	Suture Techniques to Reduce the Incidence of The inCisional Hernia
UGI	Upper Gastrointestinal
WL	Wound Length

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Chapter 1: Background and Introduction

1.0 Evidence Based Practise in Surgery

Over the last 20 years, surgical practise has mostly shifted from being based on surgical dogma and case series to data from cohort studies and randomised controlled trials (RCTs); over this time, surgeons have worked to produce this data to allow an evidenced based approach to clinical practise[1]. This evidence has highlighted alternative management strategies for disease and surgical techniques, which can improve patient outcomes such as post-operative morbidity, mortality and quality of life. However, the uptake of this new practise is not always homogenous and research often does not have an implementation strategy following publication.

1.1 Surgery within the UK

Data published by the Royal College of Surgeons for the year 2013/14 demonstrated that there were almost 25,000 surgeons in the UK, with 4941 general surgeons of all grades[2]. In 2016/17, 7631 incisional hernias were repaired in the UK, though this will under-estimate the prevelance as a significant proportion of patients with an incisional hernia do not ungergo surgical fixation[3].

1.2 Incisional Hernia Formation

An incisional hernia is the protrusion of bowel through a weakness in the abdominal wall created by surgical site incision. Incisional hernias occur after abdominal closure in up to 20% of patients post-operatively[4-6]. The aetiology of an incisional hernia is poorly understood but certain risk factors have been identified[6-10]. Patient factors, rather than surgical technique have been identified as the primary cause of incisional hernia formation[8]. Patients with a Body Mass Index (BMI) over 25 and those who get

a surgical site infection (SSI) post-operatively are at increased risk of incisional hernia formation[11 12]. SSI incidence varies from 0.9% to 8.7% dependent on surgical procedures; with the highest rates occurring following large bowel surgery[13]. SSI is a key issue following incisional hernia repair, although laparoscopic technique may reduce the incidence[7].

Other risk factors that increase the risk of incisional hernia formation include; the formation of an ostomy (risk ratio 5.2 (1.9-14.7)), post-operative pulmonary problems (risk ratio 2.87 (1.2-6.9)) and post-operative bowel obstruction (risk ratio 3.5 (1.2-10.9)) [12]. An ostomy is a stoma, which is the opening of a hollow viscera through a surgical incision made in the abdominal wall. This is almost always small or large bowel. Post-operative pulmonary complications include a chest infection or pneumonia and a pulmonary embolus, which is a blood clot on the lung. Other studies have suggested that steroid therapy, malnutrition, nicotine abuse, and other connective tissue diseases also contribute to the formation of incisional hernias[14].

Incisional hernias form a significant part of overall post-operative morbidity. They can be painful and affect patient quality of life. Elective repair of incisional hernias has significant morbidity and post-operative hernia recurrence occurs in 5-32% of cases[15 16]. Seroma formation occurs in 5.4-100% of incisional hernia repairs and no good evidence exists to reduce their formation [17].. Emergency repair of incisional hernias contributes to patient morbidity. Observational data from the Netherlands suggested 33% of patients who were planned for non-operative management of their incisional hernia required subsequent emergency intervention. Emergency surgery was associated with an increased risk of fistula formation (7% vs 0%, P = 0.002) and intra-operative bowel perforation (13% vs 2%, P=0.002)[18]. The morbidity and

mortality associated with an incisional hernia and the associated repair demonstrates the importance of a attempting to reduce the incidence.

1.3 Closure of Abdominal Wall & Incisional Hernia Prevention

Traditional teaching (the so called Jenkin's rule) suggests that to reduce incisional hernia formation sutures should be 1cm apart and 1cm from the wound edge through the fascia; this is the connective tissue that offers strength following surgical incisions[19]. Although there was little evidence supporting the use of the Jenkin's rule this method was used by the vast majority of surgeons internationally. In part this is due to surgical training being akin to an apprenticeship; the surgical trainee learns techniques from a consultant but also their surgical dogma; be that a particular surgical approach or a certain nuance to avoid complications. The result of this is that the accepted methods within surgical practice, but not ones necessarily based on the best evidence, have been passed on from individual to individual.

Data already exist to aid surgical decision making in the closure of abdominal incisions to reduce their incidence. Monofilament sutures were demonstrated in Guinea Pig model to reduce wound infection rate from 48% to 27% when compared to braided nylon[20 21]. A subsequent Cochrane review, published in 2017, on the evidence of wound closure following midline laparotomy demonstrated the use of monofilament over polyfilament sutures reduced incisional hernia rate (Risk Ratio (RR) 0.76, 95% Confidence Interval (CI) 0.59 to 0.98, I^2 = 30%); however, the review states many of the included studies were of very poor quality. Furthermore, this review suggested no benefit was provided by the use of continuous versus interrupted sutures (RR 1.01, 95% CI 0.76 to 1.35), absorbable versus non-absorbable sutures (RR 1.07, 95% CI 0.86 to 1.32) or slow versus fast absorbable

sutures (RR 0.81, 95% CI 0.63 to 1.06)[22]. The same review looked at closure technique and showed no difference between mass closure of the abdomen (suturing all the layers of the abdomen together) versus layered (closing each layer of the abdominal wall) (RR 1.92, 95% CI 0.58 to 6.35). However, other published studies have come to different conclusions. The INLINE meta-analysis demonstrated the benefit of using continuous rather than interrupted suturing (odds ratio 0.59; P=0.001) and the use of slowly rather than rapidly absorbed sutures (odds ratio 0.65; P=0.009) reduce incisional hernia formation in the elective setting[4]. Other reviews and research suggests that mass closure of the abdomen offers the best outcomes with reduced incisional hernia formation[23-25].Observational evidence in the emergency setting suggests that this technique is appropriate with a reduction in incisional hernia formation from 27.0% to 15.0% ($p = 0.02$), however the evidence in this area is not as conclusive[26]. The use of a blunt needle was demonstrated to reduce needle stick injuries with a reduction of glove perforation from 28% with a sharp needle to 12% for a blunt needle (p=0.003); the use of this needle, however, has little supporting evidence for reduction of an incisional hernia[27].

The original Jenkin's paper regarding suture length was published in 1976; this suggested using large bite (LB) closure (1cm apart and 1cm from the fascial edge) and continuous suturing. Jenkins found that non-absorbable sutures at 1cm with a suture length to wound length (SL:WL) ratio of 4:1 can reduce chance of wound disruption and that using a SL:WL ratio of 2:1 or less increased chance of wound disruption[28].

No other significant developments were published until in 2001 when data was published to suggest that stitches placed 3 to 6mm from the wound edge produced a stronger wound after 4 days. This was a study in rats that focused on the burst

pressure following midline laparotomy closure[29]. Midline wounds were closed at 3mm, 6mm or 10mm distance from the wound edge and the burst pressure of the wounds was measured. Immediately after wound closure, bursting pressure was higher in the 10mm group. At 4 days following wound closure, however, the bursting pressure was greater in the groups who had 3mm or 6mm closure when compared to the 10mm group ($P < 0.05$). The 10mm group were the only group to have a statistically significant drop in the bursting pressure 4 days post operatively ($P = 0.02$). Other in vivo data supports the use of small bite (SB) closure; the use of SB closure was demonstrated to increase the tensile strength of abdominal wall closure ($P = 0.006$)[30]. A recent RCT showed increased tensile strength with a stitch every 5mm, however this paper used 16mm stitches as the control[31].

A prospective single centred RCT was completed in 2009[32]. Patients undergoing elective operation using a midline incision were randomised to SB or LB closure. SB closure was defined as a suture 0.5cm away from the edge of the wound and every 0.5cm along the wound; LB closure used a 1cm gap as per Jenkin's Rule. 737 patients were included and demonstrated a reduction in SSI (LB 35/343 (10.2%) vs SB 17/326 (5.2%) p=0.02) and incisional hernia (LB 49/272 (18.0%) vs SB 14/250 (5.6%) p<0.001) occurrence with the use of SB closure. In multivariate analysis, LB closure was an independent risk factor for both SSI and incisional hernia. The study confirmed Jenkin's findings that a SL:WL ratio of greater than 4:1 reduces herniation risk.

1.4 The STITCH Trial

In 2015, the results of the 'Small bites versus large bites for closure of abdominal midline incisions (STITCH) Trial' were published in The Lancet[33]. This was a multi-

centre, double-blinded RCT investigating closure method following mid-line incisions for elective surgery. They compared the same technique used in the initial RCT against standard practice. 545 patients were included in the final analysis and the study demonstrated that with SB closure, patients had a reduced incidence rate of incisional hernia at 1 year (LB 57/227 (21%) vs SB 35/268 (13%),p=0.0220). There was no difference in surgical site infection (LB 68/284 (24%) vs SB 58/276 (21%), p=0.419), which was different to the previous single centre SB RCT. Patients who underwent SB closure had a statistically significant increased number of sutures and increased length of suture. There was no difference in adverse post-operative complications (Ileus (LB 12% vs SB 10% 0.590), pneumonia (LB 14% vs SM 13%, p=0.710), cardiac event (LB 11% vs SB 9%, p=0.573), burst abdomen (LB 1% vs SB 1%, p=0.573) or length of hospital stay (LB 14 vs SB 15, p=0.585) but there was a time increase of 4 more minutes to close the abdominal wall (LB 10 min vs SB 14 min, p<0.0001).

Further analysis of a subset of the STITCH trial patients has revealed further data which support the use of SB close. The distance between the rectus abdominis muscles, which is associated with incisional hernia, at one month is reduced by SB closure (P = 0.005)[34]. Other studies have confirmed the findings of the STITCH trial. Since the publication of the STITCH trial, meta-analysis of data with the MATCH (Meta-analysis on Materials and Techniques for Laparotomy Closure) review demonstrated the reduction of incision hernia with the use of SB closure[35]. This would provide strong evidence to support the use of SB closure in clinical practise. The European Hernia society in 2015 changed their recommendations to ‘A SB technique with a suture to wound length (SL/WL) ratio at least 4/1 is the current recommended method of fascia closure’[36]. A recent British Journal of Surgery

editorial supported the use of SB closure and highlighted the importance of SB closure as part of clinical practise[37].

1.5 Current Surgical Practise

Although the single centre RCT was published in 2009 and then the multi-centre RCT in 2015 and the meta-analysis in 2018, few surgeons seem to have changed their clinical practise. No published data is available on this, however an international survey of 94 colo-rectal surgeons demonstrated a 34% uptake of SB closure of midline laparotomy; this survey was conducted on Twitter and therefore may not be a true reflective sample of surgical practise however it does match the rates found at a local level[38]. A more recent Twitter survey of 1163 American surgeons, demonstrated 63% were a fan of STITCH, though 9.8% had still never heard of the trial; this did not ask surgeons about whether or not they used this as part of routine clinical practise[39]. Surgeons on Twitter are often those who are more actively engaged in the national and inter-national surgical research community and therefore may be more inclined to keep their practise in line with the latest evidence suggesting 34% may be an overestimate of the whole surgeon population. An informal discussion at the study site revealed the split in the colorectal surgical department was roughly that half haven't changed their practise for midline laparotomy closure and the other half had. Following discussion with colleagues from across the southwest, the number using SB closure is roughly 20%, though this data is not published.

1.6 Implementation Theory

The field of implementation science looks at the adoption of new evidence-based medicine into every day practise and is an area of research that has emerged over the previous 10 years. The National Institute of Health in the USA defined implementation science as 'the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health'[40].

Different works have been completed within the field of implementation science. This is a field that concentrates on the use of evidenced based research in clinical practise and aims to reduce the time delay and between publication and use of new evidenced based practise[41].

Implementation science can be broken down into different approaches to achieve more evidenced based practise in the clinical setting. Process models are a stepwise model approach to understand the steps required to introduce evidence. They look at specific steps and then an action model can be used to provide practical support for introduction of different. This includes models such as the quality improvement framework and the Action-To-Model framework. Quality improvement methodologies have been used in the surgical context, with work looking at surgical site infection rate recently published[42]. Determinant frameworks are used for identification of themes. These can act as either a barrier or as enablers of implementation and so can lead to further understanding of implementation outcomes and can potentially be used as a target for intervention. Theoretical domains theory has been used in pre-operative assessment and opioid prescription post operatively[43 44]. Classic theories are theories that originate externally from field of implementation science. These include psychology and sociology, though they can be used to improve

understanding of implementation or may act as an explanation. This includes theories such as Theory of Diffusion and social cognitive theories. This has been used to improve antibiotics stewardship in general surgery[45]. Implementation theories are theories created and developed from scratch by implementation scientists. This includes Implementation Climate Evaluation framework which was used to evaluate the implementation of evidence based

The time from publication of RCTs to the widespread adoption is surprisingly long and estimates show that only half of EBM is adopted into general clinical practise[46-48]. These figures are based on conceptual models, with the timeframe quoted reflecting the journey of research from pre-clinical work, to undergoing evaluation in the clinical setting, to forming guidelines before finally becoming widely practised. Systematic reviews of published analysis identified an average of 17 years between the availability of evidence and it becoming used in clinical practise. These delays inevitably affect clinical care and mean doctors and surgeons do not offer the best evidenced based care to patients. Identifying possible barriers to increase speed of translation from research to clinical practise is important in order to continue to provide high quality care.

Implementation science aims to identify and address quality gaps at the provider, clinic, or healthcare system level that lead to EBM not being practised. Issues with the adoption of EBM can be due to the research itself or due to other clinical factors. The findings of one previous study demonstrated that some of the issues cited as barriers to adoption were the use of inappropriate research questions, inappropriate methods, inaccessibility of a paper, biased findings or unusable reporting[49]. Issues affecting the uptake of EBM can occur at different stages that are not related to the design of the original research; a lack of awareness of the research itself, a

misalignment of research and clinical priorities or a lack of skills or resources can all contribute to EBM not being taken into clinical practise[50-52].

1.7 Barriers to Implementation in Surgery

A recent BJS editorial has highlighted the importance of the use of implementation science within the surgical field[40]. However, little research, has been previously carried out looking at the barriers to adoption of new practice within surgery and further work in this area could improve outcomes for our patients [53 54]. In general surgeons have different personalities compared to other areas of medicine and technical ability plays a greater part in clinical duties and therefore these barriers may differ[55]. A systematic review of published work on surgical personalities identified higher levels of conscientiousness (self-discipline, thoughtfulness), extraversion (sociability, emotional expression) and openness (creative, conventional). The comparisons within the review compared surgical personalities to a normal adult population or a medical student population[56].

Qualitative analysis completed in Australia identified surgical culture as an important component in the implementation of evidence into clinical practise[57]. This study involved semi-structured interviews with 22 surgeons from a variety of surgical specialities, including general surgery, vascular and urology. Different surgical roles were identified; the scientist, the clinician and the entrepreneur. The acceptability of the use of new methods within clinical practise between the three groups varied. This paper identified that surgical culture and training have a significant impact on the use of new practises. The apprenticeship model of surgical training, means if surgical

trainees see their trainers using evidenced based practise, this is likely to be passed on to future consultant surgeons.

Surgical culture is complex and often hierarchical with different political, cultural and social structures, but is often viewed in a negative light, with high levels of blame and fatigue [58] [59]. However, this is starting to shift with a modernisation of the culture and a change in demographics [60].

1.8 Technology Adoption Life Cycle

Other work may be relevant to the surgical field. The 'Technology Adoption Life Cycle' is a theory based upon 20 various studies on the practises of farmers in the United States[61]. This study identified different groups depending on their willingness to utilise new technology within their farms. These groups were innovators, early adopters, the early majority, the majority and non-adopters. These groups all introduced new technologies at different rates.

This landmark paper suggested that the farmers went through different stages prior to the introduction of this technology; these stages were awareness, interest, evaluation, trial and adoption. Different individuals go through these stages at different rates and therefore this affects the adoption of new techniques. These different stages and groups of individuals may to also apply to surgeons.

1.9 Aims & Hypothesis

This study primarily aims to understand the reasons and barriers to surgeons changing their practice with regards to closure of midline laparotomies. Although the study will look at the specific topic of closure of abdominal wounds, many of these findings will likely be transferable to other areas of surgical practice.

Our secondary aim is to identify specific aspects of the published research that concern practising surgeons and form a barrier to their adoption in clinical practise. This could lead to identification of factors that can increase penetration of future work.

Our initial thoughts requiring further exploration were that a lack of awareness of the new data, participants not trusting the data or participants believing the technical skill is different in their hands would be important barriers to the introduction of EBM. The role of surgical culture, as with previous published research, will also be important. This was based on based on informal discussion with colleagues and research group discussion,

Chapter 2: Rapid Literature Review

2.0 Background

A rapid review of the literature was completed to appreciate the current understanding regarding barriers to implementation of EBM within surgery in order to inform topic guide design. The aim was to identify any themes that existed within the literature and so was completed as background work to the MByRes project. The identification of previously identified factors was to ensure our topic guide was evidenced based, though as we were taking a exploratory approach, it was the view of the research team that a thorough systematic review was not required. In addition to this, risk of bias analysis was not thought to be necessary given this review was to identify and not to use these works to draw conclusions, and this was a further reason a systematic review was not performed.

2.1 Rapid review methods[62]

A comprehensive search of EMBASE and MEDLINE used OViD search platform was planned. These were selected to provide a comprehensive search of published work. The search strategy can be seen in Table 1.

Table 1: Search Terms (AND)
surg* or operat* or intervention* or procedur* or resect*
barrier* adj2 implement*

Pre-determined inclusion and exclusion criteria to identify papers of interest were used.

The inclusion criteria were:

- Research identifying barriers to implementation of EBM

  AND

- Evidence affecting surgical pathology in a surgical environment

- Surgical pathology including general, vascular, gynaecological or urological

AND

- Implementation affecting an adult population (age >18years)

The exclusion criteria were:

- Reviews/Opinion Pieces
  - Include barriers identified based solely on author opinion within a paper or referencing other papers analysis of barriers
- Specific data on Low/Middle Income Countries (LMIC)
- Solely community-based research

We wanted to identify research barriers in surgery; as there are significant differences between surgery and medicine we excluded non-surgical and community publications. The evidence for SB closure was in adults and therefore we excluded purely paediatric populations. Papers specifically looking at LMIC were excluded as the factors affecting implementation of EBM are likely to be significantly different; resource availability and pre-existing dogma/protocols are likely to be different and therefore were not included in this rapid review. We wanted evidenced based outcomes to be identified and therefore opinion papers were excluded.

Searches were completed in June 2020. Data were extracted using an excel spreadsheet. A single researcher reviewed each abstract and title with data extracted into an excel spreadsheet. A single author read and reviewed all whole papers; a second author subsequently reviewed these papers independently. Differences were resolved by consensus. Data extracted included paper information,

research methodology and barriers to implementation. Barriers were reviewed following the completion of data extraction from all papers and collated into groups by a single author.

2.2 Results

2879 papers were identified from two databases (Figure 1). Initial screening of the article titles identified 144 papers, which was further reduced to 57 following review of the abstracts. 22 papers met our final inclusion criteria following review of the full text (Table 2) [63-82].

Different methods of data collections were used within the included studies; focus groups, online surveys, semi-structured interviews and paper surveys were all used to identify barriers (Table 2). Different barriers to the implementation of EBM within surgical practise were identified from these papers and these were grouped into six categories, including one for miscellaneous factors.

The six categories identified were

- Human factors
- The impact of the patient
- Awareness and understanding of the evidence
- Belief in the evidence
- Resources
- Other

2.2.1 Human Factors

Human factors refer to environmental, organisational and job factors, and human and individual characteristics, which influence behaviour at work"[83]. Leadership style, communication and teamwork were identified as barriers to the implementation of

different aspects of EBM by many of the studies identified within our rapid review. Communication and teamwork were both key barriers that were identified by both Eskicioglu et al. and Springer et al.[73 80]. Leadership and culture were identified as key factors in the implementation of EBM and these could easily become barriers if not managed correctly. These factors were also identified by Russ et al. and Wilson et al[77 82]. Bernstein et al. and Russ et al. recognised that staff attitudes and behaviours were significant barriers to the implementation of EBM[65 77]. Brynes et al. identified communication as a potential barrier as well[68]. Colossi et al. and Lebares et al. identified the culture staff and clinicians work are important factors in whether new evidence is brought into clinical practise[71 75]. Colossi et al. pointed to organisation culture and the importance of the power structure in the introduction of the surgical safety checklist. Lebares et al. found the culture surrounding key stakeholders was important in the adoption of new practises[75].

2.2.2 Impact of the Patient

Patient factors were identified by many different studies as barriers to implementation of EBM. Fear of litigation was identified by Scales et al. and Thamyongkit et al. as a major barrier to implementation[79 81]. Bernstein et al. recognised the aversion of clinicians to risk was a patient factor that means EBM was not implemented[65]. Lyon et al. acknowledged that patient and family acceptability was also a major barrier to EBM implementation[76]. Alawadi et al. suggested patient specific factors but also patient understanding was a barrier to implementation[63].

2.2.3 Awareness and Understanding of the Evidence

A lack of knowledge or understanding of the evidence is a major barrier to the implementation of it. If surgeons or other healthcare professionals are not aware of

the evidence, they will not be able to implement it[80]. This may be because healthcare professionals do not have intricate understanding and specialist knowledge of all areas of medicine, such as in Byrnes at al. looking at specialist nutritional knowledge of general members of the team[68]. Awareness of an intervention was also identified as a possible barrier, such as of checklists in hospitals identified by Colussi et al. or of a specific course in Dhillon et al.[71 72]. Coughlin et al. identified this as an issue when trying to minimise opioid prescriptions in the USA[84].

2.2.4 Belief in Evidence

The belief in the evidence by the clinical staff was identified as a key barrier to the implementation by Ryu et al., Lyon et al., Aveling et al., Caldon et al. and Scales et al.[64 69 76 78 79]. Despite the evidence stating that a new intervention would produce better outcomes, if staff did not believe in the intervention or the evidence then this was a major barrier to implementation. Some of these papers suggested if other strong evidence existed for alternative interventions, then this may provide a barrier to implementation.

2.2.5 Resources

Issues around resources were identified as a barrier to implementation [65 67 69-72 76-80 82]. This was the most frequently identified implementation barrier. These resources were identified as time, financial issues or equipment availability.

Staffing was a resource that had a significant impact on implementation. Clarke et al. identified staff availability as a key factor in implementing new protocols for kidney transplant[70]. Thamyongkit et al. identified staffing logistics as a major barrier to implementation[81]. Lebares et al. and Budacan identified infrastructure as a resource that can be a barrier to the implementation of a new evidence base[67 75].

2.2.6 Other

Other factors were identified as part of this rapid review that can be a barrier to the implementation of EBM within surgery. Bhandari et al. acknowledged that both surgical character and the technical aspects of any intervention can act as a barrier to its implementation[66].

2.3 Rapid Review Summary

The barriers to implementation identified as part of this rapid review can be separated into 6 different groups; human factors, impact of the patient, awareness and understanding of the evidence, belief in evidence, resource availability and other. Although these barriers to the implementation of EBM have been identified, not all are relevant to the technique of midline laparotomy closure.

2.4 Rapid Review Conclusion

There was a paucity of evidence looking at the barriers to implementation specifically within an adult surgical population. This rapid review only identified 22 papers that met our inclusion criteria and may reflect that further work needs to be done in this area. The rapid review has, however, identified knowledge of the evidence, belief in the evidence, resources and patient factors as possible barriers to implementation of EBM. These could be relevant to the use of SB vs LB closure for midline laparotomies for the surgeons in the UK.

A single author initially performed the paper screening and extraction and this could be seen as a weakness of the review. A second author subsequently reviewed all the papers that underwent full paper review; two excluded papers were included however no new themes were identified. This was a rapid review designed to gain an appreciation of the published work and not a thorough systematic review. The initial

use of only a single author could, however, introduce bias into the review and therefore this should therefore be considered.

Knowledge of the evidence and belief of the evidence are intuitive barriers to implementation of new practise. If surgeons are not aware of the new evidence or think that the evidence is of insufficient quality or poorly conducted, then they are unlikely to change their practise. The availability of certain resources are evidently important to the introduction of new practise; this doesn't necessarily have to be equipment, but time and staffing required to change practise are important in the introduction of EBM.

Human factors are key in any environment, especially in healthcare as communication, leadership and teamwork are vital in the multidisciplinary team that provides care. The impact of the patient is important, as not all patients are suitable or willing to undergo a novel technique.

These factors have been demonstrated in the published literature to be a barrier to introduction of evidenced based surgical practise. We will ensure these areas are further scrutinised within our study.

Chapter 3: Methodology

3.0 Study Setting

The Royal Devon and Exeter Foundation trust is an 842 bedded hospital in the United Kingdom with a tertiary referral service that offers both elective and emergency general surgical care. 204 emergency laparotomies were performed at the RD&E in the year 2018/19. Roughly 150-200 colonic resections are performed

each year, though the proportion of those undergoing open surgery was not possible to quantify due to coding difficulties[85]. The colorectal unit is a tertiary referral centre for rectal cancers and abdominal wall reconstructions. At the time of the interviews, there were 14 general surgeons on the on-call rota, 10 of whom were colorectal and 4 were UGI specialists. The urology service provides a tertiary oncology service with 9 consultants. The gynaecological service provides tertiary oncological service with 3 oncological consultant surgeons.

The RD&E is a university-affiliated hospital and therefore has an increased research presence compared to some other hospitals. The proportion of surgeons using SB closure (50%) is much higher than other hospitals in the region (roughly 20% after informal discussion with surgeons across the south-west) and therefore this must be taken into consideration during the interview process. The interviewer was well known to those who were interviewed; he was a junior trainee embedded within the department and had worked there intermittently for three years. This may have affected the information that surgeon participants were willing to give during the interview. There may have been parts of the interview that surgeons felt more comfortable discussing with someone well known to them, however there will have been topics that inevitably surgeons were less open about because the person interviewing them was someone who they knew and worked with on a regular basis. The interviewer was also a surgeon and so although this will have provided beneficial insight into some of the nuances of the discussion, this will have inevitably changed the dynamic of the interview and therefore the topics that were discussed.

3.1 Participants

Inclusion criteria of the study were:

- Surgical consultant or registrars

  AND

- Surgical specialities including but not limited to general, vascular, gynaecological and urological surgeons

  AND

- Perform midline laparotomy closure as part of clinical duties

Suitable participants were identified through the hospital on-call rota from the RD&E, which is produced as part of clinical care and available to all employees of the trust.

3.2 Data Collection

3.2.0 Interview Design following rapid review

A topic guide was created to guide the interview process however this continually evolved throughout the project following reflection on interviews that had been completed. The rapid review identified possible barriers to implementation of evidenced based practise within surgery. This was then utilised to aid the design of the semi-structured interviews.

Resources were identified within the review and a potential barrier to the use of SB closure could be the correct suture availability. The SB closure technique does also take longer and therefore this may be an important factor in surgical decision-making and so was planned for discussion. Leadership at both a local and national level could take the form of role modelling or creating a climate in which innovation was accepted or encourage and therefore needed to be explored. Both knowledge of the evidence and belief in the evidence could be significant factors in the use of small or LB closure; this is an area that was then included within the semi-structured interview prompt sheet. Patient factors are another area that was discussed during

the review and could be relevant to the implementation of SB closure and therefore were planned to be brought up during the semi-structured interviews.

3.2.1 Sampling

Senior surgical registrars and consultants in the fields of general surgery, vascular surgery, urology and gynaecology were approached for involvement in the study. Surgical registrars and consultants were invited, as they are the clinicians making decisions regarding abdominal wall closure. Maximum variation sampling was used to ensure surgeons with differing opinions on SB closure and of different seniority were approached for inclusion in the study; the study team were embedded into the clinical team as part of their clinical roles and therefore understood the roles and opinions of different surgeons.

Potential participants were contacted either through face-to-face discussions or by e-mail and provided with the participant information sheet (PIS); if participants agreed to take part then a face-to-face interview was arranged soon afterwards. Potential participants were approached a maximum of three times. Recruitment was targeted to attempt coverage of all different surgical specialities, with varying levels of surgical experience, gender and grades in each speciality were covered.

3.2.2 Information Sheets and Consent Forms

A PIS was developed prior to the ethical application (Appendix 1). Its purpose was explanatory for participants to understand how data would be collated and analysed. Participants were informed of the implications of taking part. A consent form (Appendix 2) was also signed by all participants prior to their interviews to ensure that their agreement to take part in the study was well understood and properly documented.

3.2.3 Interviews and Transcription

Interviews were conducted following the acquisition of written consent. SL completed all the interviews having undergone formal training as part of the preparation for this study. Each participant was given a unique randomly allocated 3-digit identifier that was used to pseudo-anonymise all recordings. Interviews were recorded on a digital recording device; the recording device was stored in a secure office with limited access on the NHS site. Basic demographic details of the participant including surgical speciality and date of CCT (Certificate of Completion of Training) were recorded at the beginning of the interview though no name was taken.

A pilot interview with RB, consultant surgeon and supervisor on the project, was completed to ensure that the topic guide (Appendix 3) and projected interview time of 20-30 minutes were accurate.

Recordings were downloaded from the recording device onto secure NHS servers after the interviews and deleted from the recording device. Interviews were transcribed by an external company with a confidential agreement in place. The transcribed data was stored on an NHS computer and was available for access to the study team. Once transcription was completed, original audio files were deleted.

3.3 Data Analysis

SL completed the data analysis and had undergone formal qualitative data analysis training. Data analysis was completed prospectively using thematic analysis on the interview transcription[86]. Coding was completed iteratively from the transcripts with the identification of specific barriers not planned.

We anticipated there would be some variation between surgeons and therefore we looked at each individual transcript separately to identify our themes before bringing the analysis together once this was completed. Instead of a theoretical approach, we have taken an inductive approach. We had no pre-standing ideas about what the themes identified would be and therefore the use of inductive analysis was appropriate[87]. The rapid review had identified possible themes, however was not used as a source for them and we were open to new themes, given the lack of previous research in this area.

Thematic analysis was completed using NVIVO software (QSR International, USA). In vivo coding was used to identify nodes by a single investigator. Individual themes were listed and then further grouped into over-arching themes. Sets were then combined using mind maps to provide over-arching themes as the final aspect of the analysis. Initial themes were presented and discussed within the research team and further shaped the analysis.

3.4 Ethical and HRA Approval

Study protocol was reviewed prior to application for surgical review by two external qualitative researchers at the University of Exeter. Ethical approval was required for this project due to the possible identification of participants and collection of their confidential information (IRAS 255295 & University of Exeter RG/CB/19/4/210). The interviews themselves discussed contentious issues, the possible identification and requirement for data sharing meant approval was required. Approval was sought from both the Health Research Authority (HRA) and the University of Exeter Research Ethics Committee. The research was registered with the Research & Development department at the RD&E prior to commencing the study.

Chapter 4: Results

4.0 Interviews

Nine interviews were completed between 7th June and 18th July 2019. Eight surgeons were General Surgeons with an interest in colorectal and one was a Urologist. No general surgeons with an interest in upper gastro-intestinal surgery at the RD&E met the inclusion criteria. Three surgeons were registrars in training, one was a fellow who had completed their general surgical training and the remaining five were consultants. One interviewee had an academic career otherwise the other participants had no or minimal active academic involvement. Average duration of the interviews was 22:49 minutes (range 14:20 to 36.37). Demographics can be found in Table 3.

Table 3 – Participant Demographics	
Date of Graduation	1988-2008
CCT Date (if applicable)	2000-2016
Stage of Career	
Registrar	3
Fellow	1
Consultant	5
Speciality	
General Surgery (Upper Gastrointestinal Surgery)	0
General Surgery (Colorectal Surgery)	8
Urology	1
Research Involvement	
University Professor	1
Postgraduate Degree (completed or current)	6
On-going research	8
Use of Small Bite Closure	
Use Routinely	3
Use Occasionally	3

Do not use routinely	3

4.1 Themes

Three themes were identified following thematic analysis of the interview transcripts. These were 'Trusting the Evidence & Critical Appraisal', 'Surgical Attitude to Risk' and 'Adopting Evidence in Practise' (Figure 2). Quotes within the manuscript are reported with a unique identifier, surgeons grade (C=consultant and R=registrar). The urological surgeon is identified; otherwise quotes are from a general surgeon.

4.1.0 Trusting the Evidence & Critical Appraisal

4.1.0.0 Awareness

Awareness of the evidence was an important part of whether surgeons had changed their practise. Surgeons broadly were aware of it, but there were many who had not read the paper itself.

> *"I think two-fold, I knew about the STITCH trial before but hadn't really read it" (Interviewee 783,R)*
>
> *"I've come across 'The Stitch Trial', it's on my list of things to do, but I haven't read it" (Interviewee 272,C,Urol)*

This accessibility of results was raised as an issue. As many papers, including the STITCH trial, exist behind a paywall, surgeons who do not have an official affiliation with a university struggled to access different papers to inform their practise. These can be accessed through a library but create another barrier between surgeons and papers to inform their practise.

The journal articles that were accessible, however, were able to inform practise.

> *"A lot of the journal articles are informing me about my clinical decision-making" (Interviewee 272,C,Urol)*
>
> *"like, the New England Journal of Medicine and got a lot of publicity" (Interviewee 186,R)*

Surgeons raised the issue of knowledge about new techniques due to publicity surrounding new data. New papers with a higher almetric factor, a combined measure of citations, how the paper influences news/guidelines and is discussed on social media, were potentially more likely to be moved into clinical practise.

> *"It depends on how I would hear about it. If it's, like, the front-page news in the BMJ or the Lancet and that it says, Everyone should be doing this" (Interviewee 186,R)*

Surgeons discussed their attendance at conferences as an important way of coming across new evidence to inform practise. With ever increasing pressure on clinical commitment and a variety of continued professional development (CPD) required from consultants, not all surgeons attend conferences regularly and therefore do not have access to this information to keep their practice up to date.

> *"I went to the European Hernia Society meeting in Ghent, that I first started to come across the work of Leif Israelsson* [who conducted the initial research]*" (Interviewee 253,C)*
>
> *"I don't go to enough conferences anymore" (Interviewee 186,R)*
>
> *"at the time when the STITCH study was discussed at the EHS meeting" (Interviewee 253,C)*

4.1.0.1 Perceptions of the STITCH Trial

Surgeons spoke on details about how specifics of the STITCH trial had affected their choice to utilise SB closure of elective laparotomies. The surgeons here showed good awareness and understanding of the trial and an ability to critically appraise the data.

There were some surgeons who had an intimate knowledge of the evidence base around SB closure and had actually been using it prior to the STITCH trial. They saw the trial as more validation of the technique they had been already using. The

suggestion was the surgeons had a preconceived idea whether the technique would work or not, and the data was simply a validation of this.

> *"I'd already been doing it, then, a couple of years, and when the results came out confirming a lower rate of incisional hernia, I thought, "That's it. It's confirmed what many of us suspected might be true all along, and it's probably the right thing to do"" (Interviewee 253, C)*

The STITCH trial was a double-blinded randomised trial and it was therefore pointed out:

> *"this was a well-designed trial" (Interviewee 783, R)*

The fact that this was a multi-centre trial was seen as a strength of the trial as single centre trials are less reliable;

> *"but you've got single-centre studies that suggest that it was the right thing to do" (Interviewee 911, C)*
>
> *"Because until they've gone down the true multicentre pathway, then actually, you're no further forward" (Interviewee 253, C)*
>
> *"There are many people who will say to you that a single-institution randomised controlled trial is nothing more than a case series" (Interviewee 253, C)*

Some surgeons were critical of the initial research question posed by the STITCH trial and that this was the reason that some of the surgeons had decided not to change their practise. These surgeons felt the comparator used within the study was mass closure and this meant that surgeons felt the trial was not applicable to their practise, because this was not the surgical technique they used.

> *"It's been looking at mass closure, taking all layers including the muscle, as opposed to small bite. As far as I know, I can't think of anybody really who does mass closure nowadays in this country. Certainly not in this hospital. What those original trials looked at was comparing a technique which I don't use, with a technique which I don't use." (Interviewee 412, C)*
>
> *"I felt that in order to ask the right question, you should define the anterior sheath and then do it, rather than looking at mass closure versus small bite and defining the anterior sheath. I think, obviously, to get the small bite, you*

> *need to define the anterior sheath. That is a given, but if there is no apposition in a mass closure of the anterior sheath, you are likely to get a hernia anyway. So, I think the question and the methodology could have been improved" (Interviewee 463, R)*

The quote regarding mass closure not being used in the hospital was not accurate, as other surgeons were using this technique in both the elective and emergency setting. It is commonly used in other hospitals across the region.

There was criticism as the trial was a RCT of a package of interventions and not a single intervention. This was similar criticism to those who spoke about issues with the research question. The closure method in the STITCH trial was multi-step and some surgeons were less willing to change as they were unclear what was causing the improvement in outcomes.

> *"There are quite a few variables in it, and I think that it's not clear what part, in the STITCH trial, actually improves it, whether it's undermining the skin, or whether it's the type of suture, or the bite size" (Interviewee 783, R)*

> *"It interests me with that that this is defining, generally, a group of techniques" (Interview 911, C)*

> *"the view amongst us is that it is not the small bite itself, but what makes a difference is the definition of the anterior sheath" (Interviewee 463, R)*

> *"They threw lots of different sorts of modifications and sold it as a package, rather than saying that one particular facet was the most important" (Interview 911, C)*

> *"I think it's multi-factorial, and I think a lot of the benefit, I think, is from actually clearing the fascial edge and making sure that you've definitely got the fascia, which I sometimes think, in some of the mass closure techniques, is not the same" (Interviewee 704, R)*

This, however, could be considered a strength of the RCT, as it compared a whole technique against what is current standard practise and wasn't a simple modification or minor alteration that may have resulted in no difference being identified between the groups.

There was criticism that the control group was inadequate and did not reflect true clinical practise.

"The initial data I've seen really has been comparing apples with pears" (Interviewee 412, C)

The limited inclusion criteria were discussed. This was the fact that the inclusion criteria were very specific and therefore the evidence only applies to certain patients. It was the perception from those interviewed that there can be elements of mission creep from surgeons, with some starting to use the technique outside of the group of patient having extrapolated this from the original trial population.

> *"Again, the case selection within the inclusion criteria was very limited" (Interviewee 253, C)*
>
> *"I've extended it out to people beyond the BMIs that were in any of the studies, and I've taken it into people with body mass indices well into the 30s, and diabetics and smokers, I haven't done it in emergency surgery, unless it's very exceptional circumstances" (Interviewee 253, C)*

The use of trial data was identified as important for technique selection, however on-going analysis on the difference in outcomes was important. The outcomes selection and time of follow up were important factors in surgeon interpretation of the trial. The selection of a radiological proven hernia formation as an outcome was also controversial.

> *"a lot of research needs to get some QI [quality improvement] ideas back in terms of, you know, more, sort of, rolling assessment and run charts, rather than looking at that finite end point that you're only going to measure at the end of the study" (Interviewee 911, C)*
>
> *"As we've discussed, some of the new techniques, like small-bite closure, what are the outcomes that matter? Is it 12-month clinical examination? Is it 2-year radiological? Is it just quality of life? All those types of things" (Interviewee 253, C)*
>
> *"There's a lot of move, of late, to have things like core outcome datasets, where we know what it is that's important to measure" (Interviewee 253, C)*

The lack of depth of reporting was an issue for some surgeons as they felt they could not truly interpret the data that was presented to them. The trial included all patients undergoing elective midline laparotomy, including patients with a gynaecological or vascular pathology. This mix of patients was a particular concern for one surgeon:

> *"I think, if they want to encourage adoption within the colorectal sphere, they need to give us more granularity" (Interviewee 253, C)*

Surgeons had slightly different take away lessons from the published paper and felt that there were aspects of the research, which did not make sense to the participants. Some of this was simply a personal view on the research that has been published so far.

> *"I couldn't quite figure out, at the time, why the lower rate of wound infection should occur, because that wasn't straightforward" (Interviewee 253, C)*
>
> *"I haven't been convinced by the studies that have been published so far" (Interviewee 412, C)*

There were surgeons whose description of the evidence demonstrated a lack of understanding of the technique in question and this could lead to inappropriate use of SB closure. This highlights the importance of safe introduction of new or alternative clinical method. Interviewee 186 did not understand the STITCH paper and interview 543 suggested the correct suture could not be found in the UK, however this was incorrect.

> *"But the small bite closure had higher burst pressures when they were testing it in a laboratory, and then they subsequently found that there was a lower rate of acute dehiscence and a lower rate of incisional hernias, I think" (Interviewee 186, R)*
>
> *"what some of us do here when we are doing small bite closure isn't technically the same as what the trials …… because we can't get the suture in the UK that they had actually used for the trials" (Interviewee 543, R)*

4.1.0.2 Conflict elsewhere within the Literature

The confliction about the paper and the alternative evidence that has been published previously means that there was some confusion and frustration amongst surgeons. For registrars, the variation in techniques used by consultants meant they were unsure which technique should be used.

> *"it's really frustrating reading all the different papers and then speaking to all these different consultants who all know what they're talking about ……. even though it's completely at conflict with what someone else believes" (Interviewee 186, R)*

4.1.1 Attitudes to Risk

Individual attitude to risk was the second of the themes to be identified from our analysis. The differences in how risk was perceived affected whether surgeons changed their technique. This was down in part to surgeon personality, but the perception of risk was affected by the support of colleagues, authoritative bodies and the possibilities of future medico-legal repercussions of their work.

4.1.1.0 Personality

Individual surgeons act differently and are likely to be on different parts of the adoption curve. Personalities varied between the surgeons who were interviewed. Some individuals embraced shifts in practice and view risk differently as well and this is reflected by their personality. Others are more resistant to change.

> *"I mean…….. it comes down to personalities, as well …… There are definitely some people who are more likely to pioneer new things than others, and those people are maybe more resilient" Interviewee 543, R)*
>
> *"I think I'm more cynical" (Interviewee 412, C)*
>
> *"I always tend to, unless there is overwhelming evidence, stick to what has worked in the past there in that regard" (Interviewee 463, R)*
>
> *"I'm definitely not the first person, or the quickest person." (Interviewee 704, R)*

> *"I'm probably not necessarily a pioneer at this stage" (Interviewee 783, R)*
>
> *"I'm probably a bit of a luddite in terms of new things" (Interviewee 911, C)*
>
> *"Some people are very much; they want to be first at everything. I'm not like that" (Interviewee 253, C)*
>
> *"there were some dinosaurs …….. the old guards would not change their ways, regardless." (Interviewee 783, R)*

The difference in surgical behaviours is important in the variation between some surgeons using SB closure and others not changing to a new technique. The above quotes are examples of surgeons identifying their own personalities, on different parts of the adoption curve, playing an important role of their utilisation of the new SB technique and this is likely to apply across the board with regards to other evidenced based changes in practise. Surgeons who changed their practise more often were in a better position to use a novel technique such as SB closure.

> *"I'm probably still at the stage where I'm still adopting quite a lot of new things on a fairly regular basis" (Interviewee 543, R)*
>
> *"I think I tend to be someone who doesn't necessarily change, especially if it has given me good results in the past" (Interviewee 463, R)*
>
> *"I think once you feel that you are doing something the optimum way, and then a new technique comes out, and especially if you've been doing that for a while, I think it's more difficult to change" (Interviewee 704, R)*

Individual preference and opinion on a new technique plays a role in a new technique becoming part of everyday practise and in the utilisation of new techniques. A surgeon who found the new technique cumbersome said this played a part in not using the technique;

> *"I also think when you use a loop you end up with too much stitch in the wound. There's too much string around the place" (Interviewee 412, C)*

The surgeon's individual learning curve and their perspective on this are also important. The learning curve with any new technique will mean initial patients might have worse outcomes and this is an ethical dilemma that surgeons will view differently and will affect whether they change their practise.

> *"If I'm going to start doing something new and something different, when I know I'm getting good, acceptable outcomes using the old technique, then why should I put my practice and my patients at risk potentially of doing something new?" (Interviewee 412, C)*
>
> *"Part of it was the learning curve" (Interviewee 412, C)*
>
> *"I think it was definitely a learning curve" (Interviewee 704, R)*

Individuals also placed importance on the time the technique took, though this was not important for others and this affected the uptake of the SB closure technique.

> *"then in the interest of saving time, or in what I deem lower risk patients, then I would go for the easier and simpler option" (Interviewee 272, C, Urol)*
>
> *"It* [small bite closure] *wasn't a difficult thing to do. It's not technically difficult; it just takes longer" (Interviewee 253, C)*
>
> *"It does slightly depend on the patient and the time, and the other situations, but if there is time for a small bite closure then I would do that" (Interviewee 704, R)*

4.1.1.1 Authoritative bodies

The position statements from different specialist bodies and other surgical authorities such as the Royal College are important to many surgeons. Their statement can reduce the perceived risk that each individual surgeon takes upon himself or herself when they utilise a new technique. This may reflect some surgeons wanting the choice to be made by someone else.

"I guess I see it perhaps as their role to advise their members on when there's been sufficient high-quality evidence that there should be a change in practice" (Interviewee 543, R)

"I think if I had a wider group of people that I …… genuinely trusted and respected. Then, yes. I think that would make me- because then, again, I wouldn't feel like I was going out on my own" (Interviewee 543, R)

"if there is a general consensus and implementation is put out, then you would have to follow it" (interviewee 463, R)

"I keep trying to find time to read up-to-date NICE guidelines on different subject areas" (Interviewee 272, C, Urol)

"if there had been a diktat from the college or somewhere to say, thou most close laparotomies using a small bite closure, then you would have no choice" (Interviewee 911, R)

"So, in terms of updating myself on current practice, if guidelines come around from big organisations saying, this is the way you should be doing something, then fine" (Interviewee 911, R)

"Royal College of Surgeons gave you instructions and said, this is how you're supposed to do things, that would be excellent" (Interviewee 186, C)

"So, it's almost, the evidence for you is less important, and the guidelines from those kinds of governing bodies are more important?
Respondent*: Probably. Yes, I think in terms of influence on my practice, I would take more notice of guidelines" (Interviewee 911, R)*

This, however, should be seen in the context that the European Hernia Society guidelines recommend the use of SB closure for midline laparotomies[36]. Participants may not be aware of these guidelines, but they do exist.

4.1.1.2 Colleagues

Surgical colleagues influenced the perception of risk for many participants. The change in practice of certain surgeons was determined by whether others were changing in their local department. The feeling that other surgeons were also doing the same thing would reduce the perception of risk as they were not practising in isolation.

"if I, on my own, is the only one in my department who has read this randomised controlled trial and decided to make a change, I would speak to my colleagues about it" (Interviewee 543, R)

"I say, for me, I'm probably being a bit of a chicken, if I was on my own, the only person doing a particular closure, let's say, then that would worry me" (Interviewee 911, C)

"I think you have to just go on respected seniors opinion, if they've read the literature and they say, This is why we're doing it, I think that's reasonable to go with that" (Interviewee 704, R)

"in consideration with the department I'm working in. I wouldn't do anything necessarily out on my own" (Interviewee 783, R)

"Part of me wouldn't mind that much if everybody else, or the majority of people, said, Yes, we should be doing this" (Interview 911, C)

"I would rather that we all sort of moved together at one point, rather than maybe going individually" (Interviewee 543, R)

"do you think if you'd gone and worked in a different department where people hadn't been talking about it as much, do you think you would have changed? Respondent: No, I probably wouldn't have done. I would have carried on with what I was doing." (Interviewee 783, R)

"being an early adopter of something in a department would be quite a difficult thing to do, unless you were very sure of yourself" (Interviewee 186, R)

There were surgeons who felt that if others within the wider surgical community had adopted a new technique the feelings of local surgeons were less important; however, it was imperative that other surgeons were also using the technique.

"And I'd heard a lot of people from my colleagues in the Netherlands who were saying that they were doing small-bite closure at that time" (Interviewee 253, C)

"I was at the stage [when I started using the technique] *where I'd heard enough other people saying that they'd moved over and that they were doing it" (Interviewee 253, C)*

4.1.1.3 Medico-legal issues

Surgical views on adopting new techniques and the risk associated with that were affected by medico-legal issues and concerns over litigation. This reduces uptake of new technique as surgeons fear complications following utilisation of this puts them at increased risk.

> *"If you're going to adopt a new technique you have to be able to justify it to yourself because if you can't justify it to yourself, you certainly won't be able to justify it to the patient or to the patient's lawyer if something goes wrong. That's key really" (Interviewee 412, C)*

> *"Interviewer: Why do you think that is?*
> *Respondent: Defensive thinking, I guess" (Interviewee 911, C)*

> *"But if you're going to take it up as being normal practice, you're far better off doing it as a group because, you know, you can defend yourself better from that point of view" (Interviewee 911, C)*

> *"From a medical/legal point of view, I think it makes a lot of sense, because you absolve yourself of any individual responsibility" (Interviewee 911, C)*

> *"You'd be a brave man, medico-legally, in this country, at the moment" (Interviewee 253, C)*

4.1.2 Adopting Evidence in Clinical Practice

The third theme to emerge from the analysis was the issues of adoption into clinical practise. This included issues with local culture, the impact of seeing the work in clinical practise, the issues surrounding patients and ongoing questions about training.

4.1.2.0 Clinical work

Surgeons talked about the impact of their clinical practise had on their decision making to use SB closure. The balance between anecdotal evidence from clinical practise and published evidence was discussed widely and different surgeons had varying opinions on this; these factors evidently had an important role in their uptake

of SB technique. Some surgeons balanced the evidence against what they saw as part of their clinical practise when using a novel technique.

> *"Because at the end of the day, part of it is evidence-based as well as anecdotal evidence based on your own practice" (Interviewee 463, R)*
>
> *"I guess from my practice looking at evidence-based medicine that is published, especially new studies, versus your own anecdotal evidence and if there is a difference in between the results" (Interviewee 463, R)*
>
> *"Then towards the end of my training it became more apparent that the way that seemed to be working best was to just take the anterior rectus sheath" (Interviewee 412, C)*
>
> *"I have to say I ignored that because I looked at my dehiscence rate and my hernia rate and saw it was no different to anyone else's" (Interviewee 412, C)*
>
> *"we weigh our own personal experience against what we, I guess, know to be true, from all what we believe to be- whether or not we believe it to be true from the research" (Interviewee 543, R)*

A difference in clinical perspective was noted; an immediate complication of SB closure is abdominal dehiscence, and this is likely to have a greater impact on practise compared to a reduction of long-term complications such as hernias that surgeons often do not see.

> *"you're looking at short-term outcomes, which if you're looking at things like, you know, early wound dehiscence may be an issue" (Interviewee 911, C)*
>
> *"If I start doing small bite closure and then I get a wound dehiscence, I'll be mortified. I can only think of one dehisced wound that I've had in the last 10 years." (Interviewee 412, C)*
>
> *"the main thing I'd be concerned about is whether the wound dehisced, like, a week or two, while they were still an inpatient, and then you could come in for criticism from other people" (Interviewee 186, R)*
>
> *"if you follow those patients up longer, all you're seeing is that you might have delayed the inevitable by a year or so" (Interviewee 253, C)*

"in a lot of hernia studies, lately, that one-year data is really insufficient" (Interviewee 253, C)

"Yes, probably, [bearing in mind] *how difficult I found this recurrent case, the use of the small bite technique, it almost put me off it altogether, but that was largely due to scar tissue" (Interviewee 704, R)*

4.1.2.1 Patients

The opinions of patients of the utilisation of novel techniques were an important factor for surgeons when deciding to change their practise. The acceptability of novelty and the new technique to patients was important for some.

"if you've maybe told a patient that you've tried something new and then they've had a problem with it. I think it feels different and you maybe feel more vulnerable" (Interviewee 543, R)

"I think it's maybe more difficult to speak to the patient about that and not feel like you've made the wrong decision" (Interviewee 543, R)

"Whereas, if you go to a patient and say, everybody does it this way, they're automatically happier. I think selling evidence of patients if very difficult" (Interviewee 911, C)

Conversely, there is patient expectation that surgeons will be using modern and novel techniques. Although this quote was from whilst discussing laparoscopic surgery, it highlights that patient expectations are important for surgical decision making.

"I think its [laparoscopic surgery] *because if it goes well it goes very well …… Patients expect it." (Interviewee 412, C)*

Patient specific factors are an important part in surgical decision-making. The STITCH trial was for a specific group of patients with strict exclusion criteria and therefore some surgeons felt that SB closure had to be used selectively.

"Then I think it would depend on the patient" (Interviewee 543, R)

"So, I think it's about using it appropriately, and not necessarily using it for all cases whatever" (Interviewee 704, R)

"are they overweight, have they had previous incisions, is this revision surgery? What's their nutritional state like, generally? Are they people who are a little bit catabolic, because they've got cancer on board, and therefore need to make sure that the wounds are closed adequately? Had they had previous radiotherapy?" (Interviewee 272, C, Urol)

"I think doing it for higher risk patients seems a reasonable thing, that's why I've approached it that way, really." (Interviewee 272, C, Urol)

"degree of contamination, other factors of the patient, whether they've had previous surgery, what the quality of the tissues are like" (Interviewee 911, C)

4.1.2.2 Criticism & Peers

The opinions of peers and criticism of other surgeons in the clinical environment was an important factor in the uptake of the novel technique. The concern about criticism within the clinical environment is important. This does link in with the theme of risk; however, plays an important role within the theme of adopting evidence in clinical practise as local colleagues will differ from hospital to hospital and this will affect surgeon experience depending on where they are working.

"I've already talked about people being concerned about criticism from their colleagues" (Interviewee 543, R)

"then you could come in for criticism from other people" (Interviewee 186, C)

"I think it does because we're all subject to peer review" (Interviewee 412, C)

There are those, however, who do not see criticism as a problem and therefore this is not an issue that is important for all surgeons.

"I am very happy with being criticised for adoption of new techniques if it results in complications" (Interviewee 463, R)

4.1.2.3 Training

Surgeons discussed the impact of training on their ability to adopt a novel technique. This training took many different forms.

4.1.2.3.0 Clinical training

The role clinical training took in surgeons being able to modify their practise was identified as being important by many interviewees. This mostly involved surgeons needing someone to demonstrate a novel technique prior to utilisation in the clinical environment. Interestingly, it was predominantly registrars who perceived this to be a barrier.

"I think as a registrar, you're constantly having to do different consultants' techniques for varying things, so consequently it doesn't matter so much if you do one thing with one person, one thing with someone else" (Interviewee 704, R)

"I mean, I'm aware of the backdrop and the evidence-base to this project, but that doesn't really come into my mind, because I don't feel that anyone has, like, sat me down and taught me about it" (Interviewee 186, R)

"So, I think that's a technical aspect of it, but unless it's specifically taught to you, or you specifically think about it" (Interviewee 543, R)

"I don't think I've had enough personal experience since then of other small bite closures for me to, I guess, be confident in my use of the method to put myself out there" Interviewee 543, R)

4.1.2.3.1 Critical Analysis & Implementation

There was discussion about ongoing training in critical analysis and how this impacts the adoption of new clinical practise. There were however differing opinions on the effectiveness of this. There was discussion that this training was insufficient to make a genuine difference to clinical practise.

"I think the current situation of, "Here are two papers. Critically appraise them for your exit exam," is lip service" (Interviewee 253, C)

There was, however, a much larger school of thought that there was good training on the critical appraisal of evidence.

"Well, I think evaluate evidence, we had quite a lot of training on it" (Interviewee 911, C)

"It's something you learn as you go along, because at audit meetings, or journal clubs, they will discuss papers and you'll hear senior surgeons talk about the weaknesses of a study, or the strengths of a study" (Interviewee 272, C, Urol)

Despite the mixed opinion on the quality of training on the appraisal of evidence, there was consensus that there was little on the implementation of that evidence into clinical practise. This was thought to be insufficient and did not allow for changing surgical technique.

"In terms of how you then translate that to everyday practice, probably not an awful lot" (Interviewee 911, C)

"translational stuff from research to clinical practice, I've not had specific training about" (Interviewee 186, R)

4.1.2.4 Local culture & Systems

Adapting to local clinical environments was important and several different surgeons noted this was an issue. The availability of certain kit was important. The stitch used in the trial was available in the UK and is a commonplace suture, however the work completed prior to the trial in Israelesson's original work was a different suture type.

"what some of us do here when we are doing small bite closure isn't technically the same as what the trials …… because we can't get the suture in the UK that they had actually used for the trials" (Interviewee 543, R)

"I suppose the difficulty here is that I've always tended to 2-0 PDS, and certainly, that's what was used in the STITCH study. But …..the STITCH study …….. is not was Israelsson originally did" (Interviewee 253, C)

There were local barriers that were discussed. Many of these were a cultural issue within the workplace and that this often was a barrier to trying to change practice. Working in a place with other surgeons who also change their practice meant surgeons felt more comfortable changing their practice. There was discussion about how newly qualified surgeons with modern training are more adaptable and aware of the evidence continuing to change as their understanding improves.

> *"So, again, that kind of almost comes back to what you were saying earlier about culture, and if other people are changing, it makes it easier for you to change" (Interviewee 543, R)*
>
> *"I think it's probably definitely a changing culture. I think some of the more senior consultants; it would take a lot to get them to change their practice. So, yes, I think things are changing" (Interviewee 704, R)*
>
> *"there were some dinosaurs there that- I shouldn't say that. Yes, the old guards would not change their ways, regardless" (Interviewee 783, R)*

When discussing other research projects, the issue of patient pathways was discussed. These are factors that affect clinical practise at a local level and will vary from hospital to hospital. There was, however, no identification of what these barriers are.

"Can we implement that? We can't. There are systemic barriers" (Interviewee 253, C)

"Do we have the capacity to implement that study? Emphatically, no" (Interviewee 253, C)

Chapter 5: Discussion

5.0 Results

The qualitative interviews in this project centred on the introduction of the SB laparotomy closure into clinical practise following the publication of the STITCH trial. The aims of this study were to understand reasons for and barriers to surgeons changing their practice with regards to closure of midline laparotomies. Thematic analysis of the semi-structured interviews identified 'Trusting the Evidence & Critical Appraisal', 'Surgical Attitude to Risk' and 'Adopting Evidence in Practise' as barriers to change. Surgeons were not concerned about changing their practise and wished to provide the best care for their patients. This was best highlighted by "I think if you are [afraid to change], then you shouldn't be practicing". The threshold at which surgeons changed however varied considerably due to personality, clinical experience and research exposure. The other aim was to identify aspects of research that concern practising surgeons and form a barrier to their adoption of EBM in clinical practice. This formed part of the 'Trust the Evidence and Critical Appraisal' theme.

'Trusting the Evidence and Critical Appraisal' focused mainly on the individual interpretation of the results of STITCH trial and the effect this had on the patient demographics being operated on in Exeter. Issues with outcomes, length of follow up and the comparator meant take up of the new technique was varied. The specific factors regarding the published trial were that the comparator arm was not a relevant technique and not having data with suitable granularity to make evidence applicable to a specific patient group. Some of these concerns could, however be viewed as strengths; the testing of the SB closure as a package against current standard of care provides a good comparison against current practise rather than needing

multiple different RCTs for smaller changes that may never identify a change. Another relevant issue was access to the publication, with this and many other surgical publications, being behind a pay wall and therefore not accessible to surgeons without a university affiliation. There is currently a shift to open access publication, which is being driven by policies of funding bodies such as NIHR (National Institute of Health and Care Research) demanding that papers published as a result of their funding are open access. The threshold for changing practise varied; some surgeons were happy with a single RCT, however there were others who were “watching it”, before committing to change.

‘Surgical Attitude to Risk’ was identified as a barrier to the introduction of new, evidenced based practise. This theme had different aspects to it and varied significantly between surgeons. The surgeons themselves identified personality as being a significant determinant as to how early surgeons were willing to change their practise. The burden of possible litigation following complications when a new technique had been used played a role in assessing the risk of a new technique as well as the criticism from colleagues following any complications of a new technique. The role of authoritative bodes was discussed with the possibility of them offering advice, which would be a way of mitigating the risks to an individual surgeon. The role of these bodies however is challenging and unclear. The European Hernia Society recommendations that were published in 2015 concluded it was reasonable to “promote…..SB closure” and that SB technique was “suggested”, though stronger language than this was not used. However, this is a specialist group and so not all surgeons closing midline laparotomies will read their published guidelines. The ACPGBI (association of coloproctologists of Great Britain and Ireland), ASGBI (association of surgeons of Great Britain and Ireland) or the ESCP (European

society of coloproctology) do not have any guidelines for the technique to close midline laparotomies, which may contribute to some surgeons being reluctant to change their practise. These bodies often write guidelines or produce guidance on controversial topics, such as trans-anal total mesorectal excision or use of mesh for urinary incontinence[88 89], however there is a lack of guidelines to cover routine surgical practise. The shift of responsibility to these bodies is challenging as there are so many facets to the practise their surgeon members are responsible for, that it is almost impossible for these groups to maintain complete up-to-date guidelines an all aspects of practise.

The final theme identified was ‘Adopting Evidence in Practise’. These were issues identified with local culture and the actual implementation within a hospital. The issues mentioned were the training individuals received, patient factors and the availability of specific kit. Local culture included things as simple as the wrong suture being opened already or questions being raised when a different technique was being used. The increased time associated with SB closure means a change in attitude from anaesthetists, as prolonged anaesthetics are required to support the new technique. Historically, standard practise was consultants left closure to the surgical trainees and a change in focus from ‘closure time is not coffee time’ is required[90]. The training discussed was varied. There is little training as part of the surgical curriculum for assessing and introducing new techniques into surgical practise. The use of journal clubs allows for the assessment of the quality of papers; however, the next step of when to introduce new techniques into practise is not covered. This, however, is probably an oversimplification of the issue; there is no guidance or teaching for surgical trainees on how they should introduce any new technique into their practise when they are consultants, irrespective of whether this is

an innovative technique or an established technique being completed for the first time. There are different guidelines for this, though there is no established pathway[91]. It is difficult, however, to understand where this would fit in surgical training and how this would be delivered. The apprentice model of surgical training often means using the technique the consultant wants to use. The creation of peri-CCT (certificate of completion of training) courses for senior surgical trainees to discuss these issues may be beneficial, however these trainees are already under significant pressures with exams, consultant jobs and fellowships that the course may not have its intended consequence. There is the problem of how a consultant should be taught a new technique. Peer supervision is often challenging in an overburdened NHS for consultant colleagues and so safely learning and then introducing a new technique is challenging. Increasing use of simulation training moving forward may make this safer however this is not yet established. The use of a new technique in clinical practise can be challenging due to strict inclusion criteria of trials limiting their applicability. The STITCH trial was in non-obese patients who did not smoke and therefore the use within the UK population is restricted. It is unclear how these findings can be extrapolated to different patient groups in the clinical setting. Practise shift was discussed with the technique initially being used solely within the included population, but following the inclusion in practise, the technique can then be used on a wider range of patients.

5.1 Results in context of previous literature

The key implementation science model that is reflected in this research is determinant framework[41]. This is used to describe domains that influence implementation outcomes. This model does not address causal mechanisms or how changes have taken place, and although this forms part of the discussion, was not

an intrinsic part of the research project. Three classes were identified as part of this study as providing hindrance to the uptake of EBM. These results, however, were only relevant to the adoption of the RE-AIM framework[92]. This framework is one the most common implementation science models used in the last 20 years. It was conceptualised 20 years ago to address the delay of translation of scientific evidence into practise. RE-AIM is an acronym standing for reach, effectiveness, adoption, implementation and maintenance, though a lot of this framework is beyond the scope of this project.

The rapid review completed as part of this project identified knowledge of the evidence, belief in the evidence, resources and patient factors as possible barriers to implementation of EBM. There is significant overlap with the findings of this review and the outcomes of the qualitative analysis. This alignment further increases the validity of the work completed. 'Trusting the Evidence and Critical Appraisal' falls within the realm of knowledge and the belief of evidence; some surgeons had not read the manuscript, while others had incorrect re-call of the paper. 'Adopting Evidence in Practise' includes similar barriers to the barriers included within the resources and patient factors themes. 'Surgical Attitude to Risk', however, is a novel factor identified from the qualitative interviews. The two themes were identified in our initial rapid review and the primary research completed may mean that these are two areas that could be targeted to improve the implementation of future evidenced based practise, as they are likely to be widely applicable. With regards to the STITCH trial, data from colorectal patients comparing SB closure to closure with the anterior sheath would provide practise-changing evidence to many of the surgeons interviewed. The availability of the correct suture and possible demonstrations of the

new technique at conferences/teaching sessions may then increase uptake of SB closure.

Other general themes, which can affect the introduction of evidenced based practise, have been identified in the literature and are relevant to the STITCH trial[93]. The limited external validity of a study can lead to non-adoption of a new technique. This is particularly relevant to the STITCH trial, as included patients were non-obese, non-smoking Scandinavian patients who are phenotypically different to patients seen in the UK. Frontline provider competing demands is relevant here, with the different clinical demands, culture of letting surgical trainees close midline wounds and the extra time required are demands that may lead to SB closure being used.

5.2 Strengths and Limitations of the study

This was an ethically approved, well-planned and conducted study with targeted recruitment of surgeons from general surgery, with one urologist. Nine interviews were completed, which was over 50% of eligible general surgeons at the RD&E. The clinical experience of the research team meant there was a greater understanding of clinical context of the evidence and this may have lead to greater detail within the interviews. The interviewee as well known to the surgeons being interviewed which may have lead to a more relaxed discussion with surgeons being less worried to express their opinions. However, this may have had a negative impact on the discussions and could have affected the topics discussed or the assumptions made.

The surgeons in this study were from a single institution with ethical approval limited to the single site. Although the benefit of having single institution surgeons meant that we were able to target recruitment more than if the study was multi-centre, the themes identified may have been limited by surgeons coming from a single institution with the similar experiences, training and culture. However, with the identification

that local culture can act as a barrier to the introduction of new, evidenced based practise, the inclusion of surgeons from other hospitals may have lead to a greater insight into the impact different local cultures can have. Surgical registrars, however, move hospitals as regularly as every 6 months and so were able to provide experience of cultural variation between hospitals.

We were limited to the number of surgeons we were able to recruit to this study. We had initially hoped to get multiple surgeons from different specialities. There were no upper gastrointestinal (UGI) surgeons that met the inclusion criteria of performing elective laparotomies at our single site and so therefore were not included in this study. Prior to the commencement of the study, the research team thought there would be some members of the UGI team who met the inclusion criteria. Interviewing UGI surgeons at alternative sites may provide a different point of view from the colorectal surgeons who were interviewed as part of this study. There was only one urology surgeon included; several urologists were approached, however of those who responded, only one met the inclusion criteria and therefore was included in the study. None of the urology registrars met the inclusion criteria. The study initially aimed to include gynae-oncology surgeons, however this proved challenging and therefore was none were included. This means that the results of this study are limited to reflecting the viewpoint of colorectal surgeons working at a single institution and is reflective of the 9 surgeons that were recruited, which is less than the 12 we had initially aimed to enrol in the study. Although there are interesting findings from this piece of research, further work in different specialities and at different sites would be useful to further validate these findings and to identify potential novel themes. This, however, was beyond the scope of this study due to ethical and time constraints.

Although a researcher with qualitative analysis training completed the coding, there was no dual coding and therefore there is always the possibility that nodes were missed. This single coding, completed by the same researcher who completed the interviews, may have lead to coding being completed differently; this may have reduced the trustworthiness of the research. The researcher had training as a surgeon as well, and so was in the beneficial position of being able to understand the clinical context of the discussion, however this may have altered the interpretation of some of the discussions that were had. The codes identified from the transcripts were discussed within the research team to ensure other researchers with qualitative experience were involved to try and increase trustworthiness.

5.3 Identification of future interventions

The three themes identified within this piece of work can be used to identify targets for future interventions to improve the introduction of evidenced based research.

The theme of ‘Surgical Acceptability of Risk’ can be used to identify the possible use of guidelines as a way to mitigate risk. They would provide broad consensus guidelines for best practise. The problem associated with this is those writing guidelines are heavily involved in research and will inevitably have a different perspective on the work being released compared to other surgeons. The research orientation of those writing the guidelines may mean they are more inclined to be pioneering surgeons and this may influence the guidelines that are written. These perspectives will be reflected in the guidelines as surgeons with a greater degree of research involvement often write them and therefore may affect their mass uptake by jobbing non-academic surgeons. There is no consensus as to whether pioneers or those late adopters offer their patients the safest and optimal approach. This

threshold for adoption of new practise is certainly not agreed upon and therefore would be a contentious issue for if and when guidelines could be updated. This other issue is the volume of work that would be required to create these guidelines; there are so many facets to surgical practise and therefore producing these guidelines and then most importantly keeping them up-to-date would be a challenge. There is no funding currently available for this volume of work and so expecting this to be completed on a volunteer basis by surgeons is unrealistic on a continual basis.

A teaching intervention as part of surgical training regarding perception and management of risk may provide benefit to surgeons moving forward. This is not something that is currently tackled as part of surgical curriculum. This is, however, something surgical trainees pick up ad hoc from different consultants and in clinical scenarios they come across throughout their training. This understandably leads to huge variety in practise. This area is controversial as there is little consensus, but this intervention would need to be more about the practicalities of managing risk and how surgeons can cope with managing risk, rather than the right thing to do in a specific circumstance. Such an intervention may lead to a change in culture; this is important as many surgeons during the interviews stated that their peers heavily influenced them and working in an environment where change was the norm aided the modification of their practise.

An improvement in surgical training is required to tackle the theme “adopting evidence in practise”. The inclusion of implementation work alongside simple critical analysis is imperative if surgical practise is to keep up with the research being produced to continue to improve patient care. There is currently a requirement for surgical trainees to demonstrate understanding of research methodology through publication and attendance at courses, and this is assessed in the final surgical

fellowship exams. This is important, as surgeons need to understand the research that is being completed and published and be able to critically appraise this. However, the step from understanding this research and putting it into clinical practise is not an area currently covered in surgical training and this being improved may aid the implementation of EBM.

The use of surgical input prior to the design of surgical trials could improve the issues highlighted by the 'Trusting the evidence and critical appraisal' theme. There is currently a drive for more PPI (patient and public involvement) in the design of surgical studies and trials. This provides more patient relevant research questions and outcomes, which improve research. The identification of this theme highlights the importance of the inclusion of non-academic surgeons in the design of these trials. This would ensure that the research question and outcomes are relevant to their practise. One of the interviewees stated that the research question did not include their usual clinical practise and the involvement of only academic surgeons in the design of these trials may provide a different perspective from most other surgeons.

5. 4 Implications for future research

The threshold for which new techniques are introduced varies between surgeons. The STITCH was a multi-centre RCT, however it was the first of its kind. There were surgeons included in this study who changed their practise before the publication of this trial or as a result of the trial and there are those who still remain cynical of the technique and its results.

One of the barriers to the uptake of novel techniques is that surgeons will want more evidence than a single study to change their practise. This requires time and

significant investment. There is no agreed threshold internationally for evidence leading to a change in practise; multiple meta-analyses for the use of antibiotics in uncomplicated diverticulitis suggest antibiotic treatment is not required, however this is still commonplace in the UK[94 95]. The quality and volume of data suggesting the superiority of a technique over another will impact the introduction of a new technique into practise, but the point at which this is acceptable is not defined or agreed upon.

The introduction of new techniques is a controversial topic within surgery, and the IDEAL collaboration is working on the safe introduction of innovation within surgery, though the work of this group is beyond the scope of this project[91]. The IDEAL collaboration is looking at publishing guidelines and consent process for the introduction of innovative or new procedures. This, however, is mainly focused on early stage research and less so on implementing the results of large scale RCTs.

Improving the implementation of evidenced based work is of upmost importance if we are to reduce research waste and improve outcomes for patients. Although this is currently poor, a shift in culture is currently underway. Rapid dissemination of data prior to publication through online webinars and reports is currently being utilised by surgical research collaborative across the country (COVIDSurg, GLOBALSurg, COVIDHAREM). These are research groups of surgeons from different hospitals who work together to collect large datasets for analysis. The rapid availability of this information can improve individual surgeons access to high quality data and allow practise to be modified. These groups publish their work through traditional peer-review process, however this initial presentation can sometimes be before this process has taken place. The validity of this data, however, has been demonstrated

and reflects real world practise. This may result in surgeons being more willing to use this to change their practise, as it is not from a controlled trial environment.

There are already some policies that are already being introduced that will aid the implementation of EBM, and these should be encouraged. There has been a shift from funding bodies, who wish to reduce research waste, and there is now a requirement for an implementation plan as part of a grant submission. At the point of applying for funding for surgical research, this implementation plan needs to demonstrate how researchers will ensure that surgeons become aware of the results and therefore enable change in practise. With time, the effect of these plans will hopefully improve dissemination and lead to a more rapid change in practise. Surgical mentorship, although not an entirely new concept, is currently being used for the introduction of robotic surgery. Surgical proctors are initially present when consultants are becoming comfortable with the new technique, with surgeons having attended training courses prior to starting. This is, however, expensive. This is part funded by the companies who make the robots and so is not available for other aspects of EBM .The use of a different stitch and method for the closure of the abdominal wall, for example, is not associated with an increase in profit for private companies and so they are unlikely to provide funding for additional training. The increasing use of open access journals should allow surgeons access to high quality data. These journal articles no longer being hidden behind pay walls should allow non-academic surgeons and those without university affiliations to access publications to inform and improve practise. NIHR mandate that these open access journals be used to increase the accessibility of the work they fund.

Chapter 6: Conclusion

Through rapid review, we designed a topic guide for use within our semi-structured interviews. The transcripts from these underwent qualitative analysis and led to the identification of barriers to the implementation of SB closure of midline laparotomies.

Our primary aim was to understand the reasons and barriers to surgeons changing their practice. The three themes of 'Trusting the Evidence & Critical Appraisal', 'Surgical Attitude to Risk' and 'Adopting Evidence in Practise' were identified as barriers to the introduction of EBM to clinical work. Surgeons were generally happy to change practise, but the threshold at which they changed varied considerably due to personality, clinical experience and research exposure. The secondary aim to identify aspects of research that concern practising surgeons and form a barrier to their adoption in clinical practise was more challenging. Surgeons wanted data that was relevant to their practise and sufficient evidence to create a reason to change.

The threshold for which new techniques should be introduced into surgical clinical practise is controversial, with opinions within the surgical community differing and no consensus exists. Innovators and pioneers are required within surgery to push the boundaries, though this has to be tapered by a safety first, evidenced based approach. Once high-quality evidence exists, though the definition of this in itself varies, the introduction into clinical practise offers patients the best chance of good outcomes.

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Appendix 1 – Patient Information Sheet

A qualitative evaluation of surgeon decisions to change or not to change their surgical techniques in the face of new evidence from randomised controlled trials

INFORMATION SHEET FOR PARTICIPANTS

VERSION NUMBER 4 DATE 16/05/2019

Thank you for showing an interest in this project. Please read this information sheet carefully before deciding whether or not to participate.

What is the aim of the project?

The time from publication of new evidence supporting a clinical change to widespread adoption takes a long time and a figure of 17 years has been quoted in the past. Factors causing this delay have been identified, however little research has been previously carried out looking at the adoption of new practice within the field of surgery. This may differ when compared to medicine.

There are a variety of opinions on the best methodology to close midline laparotomy wounds and we are interested in these opinions and why some surgeons use one technique and others use another.

This project is being undertaken as part of a Masters by Research

Why me?

As a member of the surgical team at the Royal Devon and Exeter NHS Foundation Trust, we are interested in your opinions regarding surgical practise and how new evidence influences your practise.

Description of participants required

Consultant surgeons and senior registrars will be interviewed as part of this study.

Those who perform midline laparotomies as part of their clinical practice

What will participants be asked to do?

You will be asked to attend a one to one interview with the researcher, which will be audio- recorded. This interview is expected to take up to half an hour of your time. This interview will be transcribed and analysed together with the transcripts of other interviews in order to identify themes. All transcriptions will be non-attributable and pseudo-anonymised. Any quotes used will be anonymised in any reports. Transcriptions will be completed by a member of the research team or by an external company.

If you are interested in taking part, please contact the research team by responding to the e-mail this was attached to. We will contact you again after a minimum of one week if we don't hear from you to check if you are interested in taking part; please let us know if you do not wish for us to contact you again.

What are the possible disadvantages and risks of taking part?

This study does not aim to explore particularly sensitive or personal aspects of a patient's care or surgical practise. The main potential risks to the participant are considered to be potential professional sensitivities from discussing issues within the interview. To alleviate this, interviews will be anonymised and not linked back to individual participants.

Payment/reward to volunteers/interviewees
No expenses will be paid.

Can participants change their mind and withdraw from the Project?

You may withdraw from participation in the project at any time without any disadvantage to yourself of any kind. If you wish to withdraw, please contact one of the research team named below.

Your rights to access, change or move your information are limited and may not be possible once data has been analysed. If you withdraw from the study, we will remove any personal data we have held however we will keep other research data that has been collected such as the analysed transcripts. To safeguard your rights, we will use the minimum personally-identifiable information possible.

For the purposes of this study we will also use consent to protect your confidentiality and provide you with choice in your participation. All information collected in this study will be kept strictly confidential and stored either on an encrypted password protected computer, or in a locked office at the hospital. You will be allocated a unique participant number, which will ensure the information from your interview will be protected and cannot be identified by anyone else. Any personally identifiable information will be stored separately and securely from information obtained from the research. Personal data will be kept for a maximum of 3 months following the completion of the project and research data will be kept for a maximum of 5 years after the completion of the project.

What will happen to the interviews I give?

Interviews will be recorded on a recording device and stored on a secure NHS computer. Once the interview has been transcribed, all audio recordings will be deleted.

How will my information be kept confidential?

The University of Exeter processes personal data for the purposes of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot

be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection.

What data or information will be collected and what use will be made of it?

Your personal data will be stored on a secure NHS computer; this will remain for 3 months after the completion of the study and then be deleted. Research data will then be stored at the University of Exeter for a maximum of 5 years. Due to recent regulatory changes in the way that data is processed (General Data Protection Regulation 2018 and the Data Protection Act 2018) the University of Exeter's lawful basis to process personal data for the purposes of carrying out research is termed as a 'task in the public interest'. If you have any concerns about how the data is controlled and managed for this study then you can also contact the Sponsor Representative, Pam Baxter, Senior Research Governance Officer.

What if participants have any questions?

If you have any questions about our project, either now or in the future, please feel free to contact either:-

Samuel Lawday	or	Robert Bethune
Royal Devon and Exeter Hospital		Department of Surgery
slawday@nhs.net		rob.bethune@nhs.net

Complaints

If you have any complaints about the way in which this study has been carried out please contact the Chair of the University of Exeter Medical School Research Ethics Committee:-

Ruth Garside, PhD

Chair of the UEMS Research Ethics Committee

Email: uemsethics@exeter.ac.uk

This project has been reviewed and approved by the

University of Exeter Medical School Research Ethics Committee

Appendix 2 – Consent Form

A qualitative evaluation of surgeon decisions to change or not to change their surgical techniques in the face of new evidence from randomised controlled trials

CONSENT FORM FOR PARTICIPANTS

VERSION NUMBER 5 DATE 28/05/2019

Participant Identification Number:

Name of Researcher:

Please initial box

1. I confirm that I have read the information sheet dated 16.05.2019 version no 4.0 for the above project. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my legal rights being affected. However, I understand that this may not be possible once the data has been analysed. ☐

3. I understand that relevant sections of the data collected during the study, may be looked at by members of the research team, individuals from the University of Exeter/Royal Devon & Exeter Hospital or a Transcription service where it is ☐

relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I understand that taking part involves partially anonymised interviews, being audio recorded and transcribed. These will be stored for 3 months after the completion of the project and for a maximum of 5 years at the University of Exeter ☐

5. Research data, including anonymised quotes, may be shared with other researchers for use in future research projects and that only anonymised quotes may be used ☐

6. A report, including anonymised quotes may be published in an academic publication ☐

7. I understand that the data collected during the study will be retained in secure storage on an NHS drive and will be stored after the study at the University of Exeter. ☐

8. I understand that an open questioning technique will be used and I can decline to answer any particular question(s). ☐

9. I agree to take part in the above project. ☐

.....	……..	.....
(Printed name of participant)	(Signature of participant)	(Date)
.....	……..	.....
(Printed name of researcher taking consent)	(Signature of researcher)	(Date)

This project has been reviewed and approved by the University of Exeter Medical School Research Ethics Committee

UEMS REC REFERENCE NUMBER: May19/D/210

When completed: 1 copy for participant; 1 copy for researcher/project file

Appendix 3

QI Project – REACT

Semi-Structured Interview Schedule

Open ended Question	Prompts (use if not covered by initial response)
General demographics and background info	
Gender Where and when did you graduate as a doctor? What is your area of speciality? To what degree are you involved in research yet?	 Job plan, attending conferences, publishing, reading journals
Training	**Prompt**
During your surgical training, how were you taught to close a midline laparotomy?	
Closure of Surgical Laparotomy	**Prompt**
Can you tell me how you would go about closing a midline laparotomy wound? Is this the way you have always closed a midline wound or has this changed over time? Why has this/hasn't this changed? What has effected your decision making regarding bite size for midline laparotomy closure?	What size bite do you use?
Culture of Change	
How easy was it/would it be to change your practise? To what extent do you feel as though you	

would need to justify your changes? How do you feel about criticisms as a result of complications following a change in practise?	
Evidence Basis	**Prompt**
Have you heard the STITCH trial and what is your knowledge of it? Has this affected your decision making regarding closure of midline laparotomy? What are your thoughts of the paper?	Positive and Negative
The Future	**Prompt**
What changes to current studies would you have wanted to see in order to change your practise?/ Why has your practised changed following this study compared to others RCTs in other areas? What evidence or change in evidence would you need to see in order to change your practise? Are you someone who changes their practise a lot and will you continue to do this in the future? To what extent do you think surgical training should include aspect of evidenced based medicine? Is there anything else you would like to add about anything we have talked about today? Do you have any questions about anything we have talked about today?	