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Evidence based spinal surgery or the “journal of anecdotal medicine?” Using qualitative interviews with spinal surgeons to understand how the drivers of orthopaedic decision making can influence the creation and adoption of surgical trial evidence

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ABSTRACT

Background: There is uncertainty regarding the best available treatment for stable thoracolumbar fractures without spinal cord injury. We explore what influences surgical decision making for the treatment of stable thoracolumbar fractures in the UK and discuss the implications of variation in spinal surgical work on the creation and adoption of future evidence.

Methods: Qualitative semi-structured interviews with 19 spinal surgeons from 13 UK hospitals. Data were collected as part of a mixed methods randomised pilot study (PRESTO). A conceptual framework of drivers of variation in orthopaedic surgical work informed how we analysed and reported our findings.

Results: We identified various patient, surgeon, organisational and cultural factors to influence surgical decision making and variation in the treatment of stable thoracolumbar fractures. We then use our findings to present the ‘cycle of uncertainty,’ to illustrate how a lack of evidence is a justification for a Randomised Controlled Trial (RCT) and the reason why a trial is not deemed feasible.

Conclusion: Surgical decision-making is complex, particularly in the absence of robust evidence. The reliance on informal sources to inform decision making and the limited role of evidence, have implications for the likelihood that RCT evidence will be created and/or adopted. To break this cycle of uncertainty we suggest focussing earlier in the research cycle to develop context-specific strategies that are designed to avoid equipoise from deeming future surgical trials unfeasible and high quality evidence being created. This could include separate pieces of implementation research and/or targeted qualitative research conducted prior to RCTs to encourage evidence based surgical decision-making.

Trial registration: PRESTO: (ISRCTN12094890).

1. Introduction

The evidence-based medicine movement aimed to create a culture where medical decisions are based on a combination of high quality empirical evidence, clinical expertise and the needs and wishes of patients (Greenhalgh et al., 2014). There are numerous examples of how evidence from high quality research has subsequently changed clinical practice (Beard et al., 2018; Costa et al., 2016; Lau & Haut, 2014). Additionally, there are various funding streams (National Institute for Health Research (NIHR), 2021; Medical Research fund, 2021; National Institutes of Health, 2021) and career pathways available to facilitate

embedding research within clinical practice. In the UK, the introduction of initiatives such as the National Institute for Health Research (NIHR) Academic Clinical Fellowship; NIHR Applied Research Collaborations (ARCs); dual academic and clinical roles and NIHR Associate Principal Investigator Schemes have provided incentives for health professionals to be research active and have encouraged research to be embedded within clinical practice. Despite this, the extent that research is used to inform clinical practice is variable in the surgical community (Grove et al., 2021a; Pope, 2003).

A mixed methods systematic review identified eight main factors as driving variation in orthopaedic surgical practice, which the authors present in a conceptual framework: formal codified and managerial knowledge, medical socialisation, cultural normative and political

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influence, training and formal education, experiential factors, individual patient and surgeon factors (Grove et al., 2016, 2018). The conceptual framework provides a useful way of understanding how and to what extent evidence may inform surgical decision-making and its use in routine practice. This reflects the clinical decision making literature more broadly, which has focussed on facilitating the adoption of published evidence into clinical practice (Greenhalgh et al., 2014; Grove et al., 2021a; Guyatt et al., 1992; Halladay & Bero, 2000).

Less attention has been given to understanding how the drivers of variation in surgical work and the extent to which evidence is used to inform surgical decision making can influence the *generation* of high quality evidence and this warrants further exploration. In this paper, we apply the Grove et al. conceptual framework (Grove et al., 2016) of the factors influencing variation in orthopaedic surgical work to qualitative findings from the PRESTO (Pragmatic Randomised Evaluation of Stable Thoracolumbar fracture Treatment Outcomes) mixed methods feasibility study (Cook et al., 2020). PRESTO was commissioned by the NIHR Health Technology Assessment (HTA) programme to establish whether it is feasible to deliver a large-scale trial comparing the clinical and cost-effectiveness of surgical fixation to initial non-operative management for patients with a stable thoracolumbar fracture without spinal cord injury (Cook et al., 2020, 2021). At the time that the PRESTO study was commissioned (commissioning brief published 2016), there was informal consensus that simple compression fractures without neurological complications can be managed without surgery and that fractures which are obviously unstable with neurological damage or at an increased risk of damage require surgical fixation (Wood et al., 2015). The commissioning brief stated that there was a known 'zone of uncertainty' where variation between surgeons and centres occurs as to whether surgical or non-operative treatments (e.g. surgical brace) are best for stable thoracolumbar fractures without spinal cord injury (Wood et al., 2015) for outcomes including: pain, speed of recovery, return to normal activities, prevention of kyphosis (spinal deformity) and other associated problems with chronic back pain and balance. As a result, there was variation in practice throughout the UK, with the boundaries that this variation operated within also being unclear. Following a Cochrane review (Abudou et al., 2013), which concluded that a large multi-centre RCT to address these uncertainties and variation in practice was required, a NIHR HTA programme commissioning brief for an external pilot study to assess the feasibility of a full scale was published to address this evidence gap and the PRESTO study was funded.

PRESTO included an embedded qualitative study, the main focus of which was to explore recruitment and consent processes to inform the design of a full-scale, multi-centre RCT. In this paper, we present findings from an additional exploratory, in-depth analysis of data collected as part of the PRESTO qualitative study. Through this analysis we aimed to: i) explore current treatment of stable thoracolumbar fractures within the UK and what underpins or is used to inform surgical decision making for the treatment of stable thoracolumbar fractures without spinal cord injury ii) use our qualitative findings to understand the role of decision making and the implications of variation in practice on the creation and adoption of future RCT evidence in spinal surgery.

2. Materials and methods

2.1. Design

Qualitative data were collected as part of the PRESTO study. Feasibility was assessed through a randomised external pilot study, a national survey of surgeons and a qualitative study. The PRESTO qualitative study took place during the 12-month pilot RCT recruitment period and was designed to explore patients, surgeons and local recruiting staff's views and experiences of the interventions (operative and conservative management) and trial processes. Qualitative findings were used in conjunction with findings from the randomised pilot study and survey to assess feasibility and identify areas that would need to be addressed

ahead of funding a full-scale trial. Further details of the PRESTO study and findings from the qualitative process evaluation pertaining to recruitment optimisation are published elsewhere (Cook et al., 2020, 2021; Scantlebury et al., 2021).

The interviews we conducted during the PRESTO qualitative study explored, as pre-specified in the commissioning brief, whether clinicians were willing to randomise and adhere to randomisation. These conversations inevitably included surgeon views on the current treatment for stable thoracolumbar fractures and discussion of what influenced their decision as to whether to recommend operative or non-operative management for patients with stable thoracolumbar fractures without spinal cord injury. Whilst we originally asked these questions to understand in more depth the variation in UK practice and the potential impact this may have on equipoise and recruitment to a future full-scale RCT, our initial analysis, which was conducted for the main funder report highlighted that we had rich and detailed data on this issue and resulted in the more in-depth analysis which is reported in this paper.

2.2. Sampling

Spinal surgery is a subspecialty of orthopaedics (approximately 5000 surgeons in England) and neurosurgery (700 surgeons in England) (Durst & Ahuja, 2021). As a result, the number of spinal surgeons managing thoracolumbar fractures in the UK is relatively small in comparison to other medical specialties (Durst & Ahuja, 2021), with many surgeons known to one another. As such, we chose to adopt a convenience sampling frame. Initially, surgeons from the three PRESTO study sites were interviewed. We then used snowball sampling to ensure that our sample represented a diverse sample of surgeons from across the UK that represented different hospitals (geographical areas and hospital types), specialties (orthopaedics, neurosurgeons) and grades (consultants, spinal fellows) (Braun & Clarke, 2021; Ghaljaie et al., 2017). This involved asking interviewees to forward recruitment emails to surgical colleagues both within and outside of PRESTO study sites. We also advertised for participants through: British Association of Spine Surgeons (BASS) newsletter, a regional network of spinal surgeons and by sending an invitation email to those who expressed an interest in the qualitative study through the PRESTO survey.

2.3. Data collection

Data collection took place during the PRESTO study's 12 month recruitment phase (April 2018–March 2019). Ethical approval was obtained from the North East – Newcastle and North Tyneside Research Ethics Committee (REC reference 18/NE/0008). Informed consent was obtained from all participants. Data collection was undertaken by AS, an experienced qualitative health researcher who at the time, had no prior research or clinical experience of orthopaedic surgery or surgical trials.

All interviews were semi-structured, conducted via telephone and were audio-recorded. The research team and clinical co-applicants developed a topic guide (additional file 1) for the purposes of the PRESTO process evaluation and so questions are broader than the data that are reported here. Key topics that were explored during interviews included: current treatment of stable thoracolumbar fractures (specifically related to the eligibility criteria for the trial), surgeon and treatment preferences; barriers and facilitators to running a full-scale trial; surgeon's willingness to randomise and views on approaching and consenting patients to the PRESTO study. Whilst topic guides provided a framework for interviews, they were used flexibly to allow for probing and for participants to discuss topics that were of importance to them.

2.4. Participants

Nineteen surgeons and health professionals, from 13 UK hospitals were interviewed. One participant was no longer working in the NHS. Participants represented a range of staff groups (surgeons,

physiotherapists and research associates), grades (e.g. consultants, spinal fellows) and 13 hospital sites the majority of which were in England, Wales and Northern Ireland. 12 participants were considered by the authors (based on discussions held during interviews) to have research experience either through their role in the PRESTO study (e.g. PRESTO PI) or because they discussed having published, obtained research funding or involvement in the delivery of research projects (additional file 2). Participants were either surgeons who routinely treat patients with thoracolumbar fractures, or health professionals involved in recruiting patients to the PRESTO study.

2.5. Analysis

Following transcription, interviews were analysed using the method of thematic analysis outlined by Braun and Clarke (Braun and Clarke, 2019, 2020). This initial thematic analysis was descriptive and conducted for the purposes of the report to the funder. As a result, themes concentrated on highlighting issues with trial processes such as recruitment and their development was largely deductive and derived from the topic guide. However, we also allowed for inductive theme development and actively sought to identify new themes or topics within our data. During this initial thematic analysis, we identified rich and detailed data relating to the current treatment of stable thoracolumbar fractures in the UK and factors influencing surgical decision making. To explore this in more detail, we used Grove et al.'s conceptual framework (Grove et al., 2016) to explore the themes and sub-themes that we identified as relevant from our original analysis (e.g. current treatment of thoracolumbar fractures; changing clinical practice; factors influencing clinical decision making; defining stability) to provide a more detailed understanding of current practice and what underpins surgical decision making.

During this process, differences or similarities in our findings and those of Grove et al., were actively sought. However, we found that given the broad nature of the conceptual framework and our broad application of it, our findings mapped onto those of Grove et al.'s. Following our thematic analyses, we reflected as a team, through regular discussions and the writing process, on the implications of our findings for future feasibility studies and the impact of uncertainty on evidence creation and adoption. This enabled us to 'go beyond' a descriptive account of our findings, to present and understand them at a conceptual level and resulted in the development of the 'cycle of uncertainty' as a new way of considering the implications of decision making and variation in practice on the future conduct of orthopaedic surgical trials.

3. Results

First, we briefly describe current treatment for stable thoracolumbar fractures without spinal cord injury in the UK. For some types of thoracolumbar fractures there is disagreement and uncertainty surrounding the best available treatments and so describing this context is important for allowing readers to understand the resultant drivers of variation in practice that we identified. We then present our findings according to Grove et al.'s conceptual framework of drivers of variation in orthopaedics surgical work: informal experiential knowledge; socialisation and association with colleagues; cultural normative and political influence norms; individual patient and surgeon factors; managerial knowledge; formal codified knowledge (Grove et al., 2016). Lastly, we consider our qualitative data and the various factors, which underpinned decision making for the treatment of stable thoracolumbar fractures in the context of the PRESTO trial. As a result, we propose the cycle of uncertainty to illustrate how a lack of evidence can be the justification for a RCT (e.g. PRESTO). However, this uncertainty and reliance on informal knowledge sources can, through issues with equipoise, also act as a barrier to conducting RCTs and the creation of the evidence needed to challenge the practice variation, which drives the need for evidence in the first place.

3.1. Working in a 'surgical grey zone' - current treatment for stable thoracolumbar fractures in the UK

There is variation in usual practice for the treatment of stable thoracolumbar fractures without spinal cord injury globally, with treatments including surgery (open spinal surgery or minimally invasive surgery) or conservative (early mobilisation with bracing or early mobilisation without bracing) management (Cook et al., 2020, 2021). There is informal consensus that simple compression fractures without neurological complications can be managed conservatively (Wood et al., 2015). This was reflected in our sample where the majority of interviewees reported a preference for managing stable thoracolumbar fractures non-operatively.

"In our unit we believe in conservative treatment for this, which is obviously the prescribed mode of treatment at this moment, but again treatment varies based on individual consultant's preferences." (06)

Despite a view that there is 'no treatment for a stable thoracolumbar fracture' (08) and that surgeons are in agreement that conservative management is preferred for this fracture, differences in definitions of stability were reported to be driving variation in practice. Indeed, surgeons described how there is a known 'zone of uncertainty' where optimum treatment is unclear and so variation between surgeons and centres occurs as to whether surgical or non-operative treatments (e.g. surgical brace) are used for stable thoracolumbar fractures without spinal cord injury. The parameters for this surgical grey area were widely debated and varied according to individual surgeons, with decisions as to whether to operate or not strongly tied to how stability was defined.

"I think the controversy might be that some people are treating fractures with surgery which other people might consider stable. The discrepancy is, is it stable or not." (08).

In addition to the debate as to what constitutes a stable fracture, surgeons held strong treatment preferences, which were widely recognised to vary between surgeons and hospitals throughout the UK. Therefore, despite the majority of interviewees agreeing that both surgical and non-operative management are routinely provided, some felt that there are no circumstances where operating on a stable fracture is appropriate. The result is considerable variation in practice in the treatment of stable thoracolumbar fractures without spinal cord injury throughout the UK

"I've answered from my perspective, it doesn't mean that it reflects off all of spinal surgeons in the UK. But the thing is you will find most of the surgeons have a one-sided view because this topic, your topic, is not a balanced topic. That's why there's no way, except for those surgeons you're talking to who operate left, right and centre for all stable fractures and you will find more conservative view from most of the surgeons." (09)

Irrespective of whether a surgeon advocated operative or non-operative management, treatment preferences were strong and were widely recognised to vary between surgeons and hospitals throughout the UK. For the remainder of the results section we use Grove et al.'s framework to describe and explore the various factors that underpin and drive this variation in treatment of stable thoracolumbar fractures in the UK. (Grove et al., 2016)

3.2. Informal experiential knowledge – the journal of anecdotal medicine

As noted above, opinions regarding treatment for stable thoracolumbar fractures were often strong, with surgeons attributing the variation in surgeon preferences and treatment to the lack of consensus as to how stability is defined. Surgeons described a range of methods, which were used to determine stability in routine practice, which included the fracture pattern, neurological deficit, angle of kypnosis and pain. However, whether some or all of these criteria are used, along with

surgeon's interpretations of the criteria and the extent that imaging (e.g. MRI or CT scans), and/or various definitions or classification systems for defining stability e.g. whether or not the AO spinal classification system was used varied. Surgeons also cited difficulties with operationalising existing definitions of stability, for patients who were perceived to fall into a surgical grey-area, where optimum treatment is unclear. However, without universally agreed criteria for patients that fall into this surgical grey-area, deciding on the optimum treatment for a patient was often a decision, which was based in part by definitions of stability, but also tacit knowledge that surgeons develop because of years of experience and training – *informal experiential knowledge*.

"Your seniority helps you in a way to treat these patients comfortably, whereas us, we for instance, we've been consulting for the past 3, 4 years, they find it difficult not to use braces on a patient like that because if something happens, I don't have a leg to stand on. I'm not saying any patient is different, but it is the comfort in your own practice, they're reading the literature, but comfort in your own practice that you've seen which makes you go, "No, my experience tells me this" That's what we rely on, isn't it? Of course, we rely on the evidence, but we rely on our own experience over the years and you go, "No, this will be fine," and that's what we do there that this will work because I know this will work. That's the grey zone whether we operate or we don't operate. (Surgeon 12)

When describing how decisions are made, surgeons described being reliant on their 'gut instinct', 'comfort of their own experience' and the tacit knowledge that surgeons develop as a result of years of surgical experience and training. It was these tacit factors, which were perceived to give surgeons a belief that an approach will be effective and confidence in their decision making even when working in known grey areas. There also appeared to be a sense of 'cumulative collective comfort', from adopting and persisting with practices that were advocated during training and/or which had been used over time and so became organisational or individual practice norms.

"I think in most cases it's a product of who you trained with, what you've seen and actually I'm sure people have said it but one of the most powerful things is probably the "Journal of Anecdotal Medicine" and burnt fingers but I think you can have one case that you get your fingers burnt with doing one thing or another and it's very hard to look past, oh I did this and we had a really bad experience. As a clinician it's sometimes very hard to un-see that." (18)

3.3. Socialisation and association with colleagues

Treatment for stable thoracolumbar fractures was perceived to be heavily influenced by *where* patients receive their treatment. Surgeons categorised hospitals and geographical areas throughout the UK as being 'pro-surgery' or 'pro-conservative treatment.' There was therefore an organisational influence on what treatment was likely to be recommended based on the organisational norm at a given hospital. In some areas of the UK surgeon consensus was perceived to be so strong that patients *"don't even get offered the chance of bed rest. They just get operated on."* (08)

"Surgery has probably very little role to play in stable thoracolumbar fractures except in some areas of the UK where they operate more. Because every place is different isn't it? Some places they operate more, some they operate less. Definitely we want better outcomes for patients." (09)

Whilst the majority of stable thoracolumbar fracture patients are treated either by a neurosurgeon or orthopaedic surgeon, patients may also receive treatment from Emergency Department (ED) doctors. Specialty-norms were therefore also considered important in considering influences on clinical decision making, with ED doctors reported to prescribe braces due to pressures on ED to discharge patients to avoid negatively affecting ED performance targets.

"I think that, obviously, the consultant ... One in particular prefers to do a surgical approach, but most of the patients, or quite a few patients, are seen by a neuro-surgeon, so they don't even come to ortho. I think neurosurgery would tend to give a brace and send home I think there are different preferences depending on which team you sit in. I think neurosurgery, maybe, have a slight preference towards bracing and I think that's 'it in A&E as well because patients come into A&E, being diagnosed with a [bone 0:02:10] fracture, then they'll prefer to discharge and then organise for a brace Otherwise, I think if they come into orthopaedics then they potentially ... I mean, it's difficult to say because we've not had tons of patients, but potentially they'd be more likely to get a surgical approach." (15)

3.4. Individual patient and surgeon factors

3.4.1. Patient and surgeon factors – the personality of the fracture

Surgeons opposed one-size fits all approaches to clinical decision making and instead emphasised the importance of considering each patient and fracture, on an individual, case-by-case basis - "the personality of the fracture".

"The personality of the fracture takes into account what the fracture itself looks like on an X-ray or an imaging, but also the environment that hints at how it actually occurred in the first place, the patient factors and then the ongoing patient factors. First of all, it might be a smoker. It might be a drug addict. They might be someone who is a championship motorcyclist. There are all sorts of different things and all those have different demands. All of those things feed into what we term the 'personality of the fracture', its likelihood of healing and the likelihood of the outcome." (13)

Whilst certain clinical factors such as whether a patient has osteoporosis, or poly-trauma were seen as pivotal in a surgeon's decision to operate or not on stable thoracolumbar fractures, a large number of patient lifestyle considerations were also considered when making treatment decisions. Particular emphasis was placed on the patient's employment status. Surgeons described how they associated surgical fixation with quicker recovery times and being able to mobilise more quickly and so factors such as whether patients were self-employed and/or have 'high-flying careers', were often influential during consultations and patients developed preferences for surgery.

"Yes, it just highlights the uniqueness of each situation. You might have people who might be a 45-year old male, but actually, because of their personality, they're all different. They all have a uniqueness about them, and I think that's the one thing that I learnt as an orthopaedic trainee: to just look at things on an individual basis and try and find the different patterns that try and push me towards or guide me towards the best outcome for that patient." (13)

Surgeons also considered "what patients were trying to avoid through surgery" and described how some patients were recommended for, or opted for surgery to avoid developing kyphosis (spinal deformity) or to try and tackle long term chronic pain.

"If someone has got a neurological deficit, they'll definitely need an operation. If they've got lots of arthritis in their spine which has joined some of the bones together ... There are a few different conditions. One of them is inflammatory arthritis called ankylosing spondylitis, which causes some of the bones to join together. Another one is called DISH, diffuse idiopathic skeletal hyperostosis. Again, that causes a number of the bones to join together. If you have a fracture through one of those levels, then what you've got are two long lever arms moving. Then, that reduces the likelihood of that fracture healing up. So I'd have a much lower threshold for fixing those ones, even if the fracture line itself looked the same as in a mobile spine." (13)

Additionally, the role of patient preference was discussed, with this patient group considered to hold particularly strong preferences. However, whilst surgeons described how in situations where there is a grey area surrounding treatment, there is a degree of pressure to 'give people what they want', it was felt that patients could in most cases be guided towards a certain treatment.

"The concern about the risks of surgery. I think also, our population that we serve, we're in the [location], we've got an older population. So, they may be more middle aged, they're more established in their jobs, they're less worried about losing their jobs perhaps. My previous practice [location], where you've got city workers and people in high-flying careers and things. They're perhaps a little bit more worried about the impact on their employment of taking time out and things like that. They would tend to be more aggressive in trying to get back on their feet." (03)

There was little mention of surgeon factors such as the surgeon's gender, age, personality type or surgical volume (Grove et al., 2016) influencing decisions to recommend surgical or non-operative treatment for stable thoracolumbar fractures amongst our participants. However, for some surgeons, views that they would not be happy to wear a brace themselves and concerns surrounding compliance were considered to reduce the likelihood that they would recommend conservative management for their patients.

"There are issues around bracing. [describes personal experience] I abandoned it, I ignored my colleague's instructions and didn't wear it, so I'm a bad patient myself. I think if you're going to depend on bracing, you've somehow got to check up on compliance, that some patients might say ... They might admit to you but maybe not to the surgeon that they didn't actually wear it." (01)

3.5. Managerial knowledge – treatment costs and resource use

Whilst one surgeon described that should a treatment be proven to be more cost-effective that surgeons may be put under pressure from commissioners and hospital managers to use that approach, treatment costs were not considered as a powerful enough reason to influence treatment in isolation.

"The economic argument alone is unlikely to directly influence many surgeons, because it's a small part of it." (03)

For those that were influenced by the costs of treatment, much of the conversation surrounded the potential cost and resource implications of prescribing a brace. There was a "clinical ease" associated with braces, which were perceived to require less clinical input when compared to surgery. However, for others, concerns surrounding patient adherence with wearing a brace caused them to view braces as a 'waste' of resources if unworn. This was not perceived as a risk with surgery, which was considered to have 'inevitable compliance'.

"I mean from the health economics point of view, braces are pretty expensive. An operation obviously costs some money, a big operation, but the braces may cost £1,000 or so, so if you prescribe a brace and then they never wear it, you really have wasted a lot of money. If you prescribe an operation and then once all the stuff is in there, there's not much you can do about it, so you have inevitable compliance." (01)

3.6. Cultural normative and political influence norms

There was little discussion from interviewees about how the wider orthopaedic and neurosurgical profession influences decision-making – cultural normative and political influence norms. This may be in part because spinal surgeons include multiple specialties (neurosurgery, orthopaedics) and so cultural norms may be challenging to establish. As discussed, we found that whether surgeons recommended surgical or

conservative management for patients within the 'zone of uncertainty' was underpinned by the interplay of various clinical (e.g. definitions of stability) patient (e.g. patient lifestyle), surgeon (tacit knowledge) and organisational (where a patient receives treatment) factors and evidence.

Despite this, there was some discussion about how, especially for conditions for which there are multiple treatment options and a grey area surrounding what is the 'best' available treatment, decision making can be a balancing act where the risks of surgery are compared with conservative management. Interestingly, despite acknowledging that they have a "vested interest in surgery", and conservative management being the most commonly used treatment for stable thoracolumbar fractures, conservative treatments were perceived to leave surgeons more "exposed" from a medico-legal perspective. These feelings of exposure were also tied in with a cultural expectation that surgeons treat people through actively intervening and concern that treating patients conservatively or "doing nothing" can lead to judgement from clinical colleagues and/or patients. For instance, even if a surgery does not go to plan this was viewed more positively than a patient experiencing negative outcomes without intervention. Consequently, there was a perception that surgeons sometimes operate to avoid the potential regret that can occur when a patient receives conservative management and then has a bad outcome.

"I think they have a very low threshold for operating because they feel more exposed. If you do nothing, you're obviously more exposed than if you do something, even if you do something wrong." (08)

3.7. Formal codified knowledge – using evidence to inform clinical decision making

The publication of recent high profile RCTs (Costa et al., 2016) along with the increasing number of surgeons involved in multi-centre RCTs were considered by interviewees to have created a "shift" in the clinical community and an openness to using evidence to inform clinical decision making. However, for a number of injuries and conditions, a lack of high quality evidence (e.g RCTs) was perceived to have meant that in the past surgeons have been reliant on lower quality evidence and audit. Emphasis was placed on the need for more, rigorous RCTs to be conducted by academics with good track records which are then published in high quality journals. Without this evidence to guide practice in a clear direction, there was a perceived ambiguity surrounding treatment, requiring surgeons to rely on their own preferences for specific treatments.

"If you definitely show that one treatment is superior to the other, then I think lots of people will have an open mind and then they will, just like your findings, direct their treatment calls. I think one of the main problems you'll find is there's not a lot of evidence-based, you know, which absolutely states 'this is the right thing to do'. And I think, because everything is retrospective or prospective, there's never been any randomised trials, or there's very few So I think this will be very, very helpful." (17)

Despite this, even where RCTs had found one treatment to be superior over another, on a given outcome, it was acknowledged that there is often only partial uptake of this evidence into practice. As such, there is perceived to be no guarantee that high quality evidence will be used in clinical decision making, with the influence of individual surgeon preferences and the various types of knowledge that underpin them considered key drivers of decision making. The importance of disseminating findings through key clinical conferences and organisations (e.g. Brit-Spine, BASS) and of engaging well respected surgeons were suggested as potential methods of overcoming this and encouraging greater adoption of evidence into practice.

"I think we're increasingly, as a community, becoming aware of the value of evidence. I think we've seen through the impact of the [Distal Radius Acute Fracture Fixation Trial] DRAFFT trial ... patients with the

orthopaedic surgeons, we've seen a change in practice where obviously it's been a partial uptake on that. The overall savings for the health service as a consequence of that trial have been quite substantial. It's a shame, if more people had taken it up, obviously it would be much bigger." (03)

3.8. The cycle of uncertainty-a barrier to trial feasibility?

The uncertainty surrounding current practice for stable thoracolumbar fractures in the UK was the main justification for the PRESTO feasibility study (Guyatt et al., 1992). This uncertainty, stemmed from a lack of robust evidence regarding the best available treatment for stable thoracolumbar fractures without spinal cord injury, which in the absence of high quality evidence meant clinicians were reliant on other 'anecdotal' beliefs and factors to inform their decision making (i.e. the cultural, organisational, surgeon and patient factors that we discuss earlier). The impact of this during PRESTO was that the lack of consensus within the clinical community surrounding treatment options resulted in issues with equipoise.

"I personally don't think that offering surgery is equally as good as non-operative treatment for such fractures because surgery is probably over-kill. If you don't offer to your own self or your own family, then you don't offer to patients either. So if you say there are 500 spine surgeons in the UK, all 500 spine surgeons if they have stable thoracolumbar fractures, you won't find a single spine surgeon going for an operation, I can tell you that, so why patients then? This is my feeling, so I'm just wondering that it may be difficult to convince patients to go for the surgery, because both are not equally viable." (09)

On a practical level, the uncertainty surrounding treatment for stable thoracolumbar fractures meant that staff involved in recruitment during PRESTO were acknowledging equipoise by agreeing to take part in the PRESTO study and randomise patients but then, were perceived to be "hiding behind personal biases" when making decisions about a patient's eligibility for the trial.

"The feasibility element to this trial was the fact that, on the face of it, even if you look at the data in a moderate level of detail, without doing the trial, beforehand you would still have seen a very large number of patients coming through. It's only when you get to the real nitty-gritty of each person, you look in there and, "Oh, this person has metastases." Or, "This person is very old and frail, and has a pacemaker, and just wouldn't be good to go under general anaesthetic." You really dive into the notes and you find these reasons that they aren't appropriate for the trial. It may just be an unlucky year, but there is so much data now for that, it does seem like it's a bit of a pattern." (04)

Additionally surgeons gave examples of situations where a surgeon's preferences for one of the available treatments had been communicated to patients during recruitment consultations (Scantlebury et al., 2021). Ultimately, equipoise underpinned many of the barriers to trial recruitment that we encountered during the PRESTO study (Scantlebury et al., 2021) and caused surgeons to rely on their personal preferences and the individual characteristics of each patient and fracture when making decisions about a patient's suitability for the study.

"In my practice I don't honestly think that I've seen many patients who truly fit that description apart from the ones that have already got an unstable fracture and you're in no doubt at all that it needs fixing. I suppose depending on how firm you want to be with your lines you could argue ... I think this is where it's incredibly difficult because you could say, pain increases on mechanical loading but what do you define as your increase and can you have a strictly defined criteria." Because otherwise it's incredibly subjective to what we call, "does that mean sitting up in bed supported to a certain angle," does that mean sitting in a chair, sitting upright with no support, standing. It's a difficult one and I suppose this is the issue why everyone is varied in their practice. It's a very personal thing

how you interpret the kind of definitions and how you feel you should apply them." (18)

The PRESTO study concluded that a large, multi-centre effectiveness RCT comparing operative and non-operative management for stable thoracolumbar fractures in the UK is currently unfeasible (Cook et al., 2021). In the case of PRESTO, there was uncertainty amongst the clinical community about whether to treat patients through operative or conservative management for stable thoracolumbar fractures without spinal cord injury and through the commissioning brief a recognised need for a RCT - community equipoise existed (Rooshenas et al., 2016). As a result, the surgical community were theoretically willing to randomise patients and acknowledged a need for robust evidence as demonstrated through the findings of the PRESTO study survey (Cook et al., 2021). However, in practice there was a substantial gap between community and personal equipoise and when faced with the reality of randomisation surgeons were less balanced and willing to randomise. Instead, our qualitative data suggest that individual surgeons were not in equipoise and relied on tacit, experiential forms of knowledge to make decisions about treatment and a patient's eligibility for the PRESTO study.

We present this as a 'vicious cycle of uncertainty' and use Fig. 1 to illustrate how uncertainty, from a lack of formal evidence e.g. RCTs, surrounding the best available treatment is a justification for a RCT, and a key reason as to why full-scale effectiveness trials are considered unfeasible. As our findings demonstrate, surgeons draw on a multitude of types of knowledge in order to inform their surgical decision making which, as we have noted, can vary across individuals and organisations. These tacit variations in practice result in a lack of equipoise, which blocks the creation of new evidence. The result is that there remains a lack of robust evidence as to the best available treatment, continued reliance on anecdotal evidence and variation in practice. We suggest that to embed research into clinical decision making and facilitate the adoption of new, high quality evidence, it is important that any strategies which are developed consider the entire research cycle and attempt to break the 'vicious cycle of uncertainty.'

4. Discussion

There is a lack of robust empirical evidence as to what is the best available treatment for stable thoracolumbar fractures without spinal cord injury (Abudou et al., 2013; Wood et al., 2015). We explored surgeon willingness to randomise and adherence to randomisation and the grey area surrounding treatment for stable thoracolumbar fractures. More specifically, we applied Grove et al's conceptual framework of drivers of variation in orthopaedic surgical work (Grove et al., 2016) to the qualitative data collected during the PRESTO study. As a result, we identified that there is a limited role of evidence and a reliance on preferences of individual surgeons, practices at different hospitals and other informal sources of evidence to inform the treatment of stable thoracolumbar fractures without spinal cord injury in the UK.

Early critics of the evidence-based medicine movement were concerned that emphasising the importance of experimental evidence would devalue the role of tacit knowledge that accumulates with clinical experience (Greenhalgh et al., 2014). However, in our study surgeons placed particular emphasis on considering the 'personality of the fracture' and identified tacit knowledge and individual patient factors (e.g. lifestyle, employment status) as key drivers of clinical decision making. Comparatively less importance was placed on evidence. This may be because in the case of stable thoracolumbar fractures without spinal cord injury there is a lack of high-quality evidence (RCTs) guiding clinicians towards a single 'best treatment', which when combined with the uncertainty as to how fracture stability is defined adds to the complexity of decision making in this area. However, our findings also suggest that even where an RCT has found one treatment to be superior over another, there is no guarantee that this evidence will be used to inform clinical decision making. This is consistent with previous evidence, which

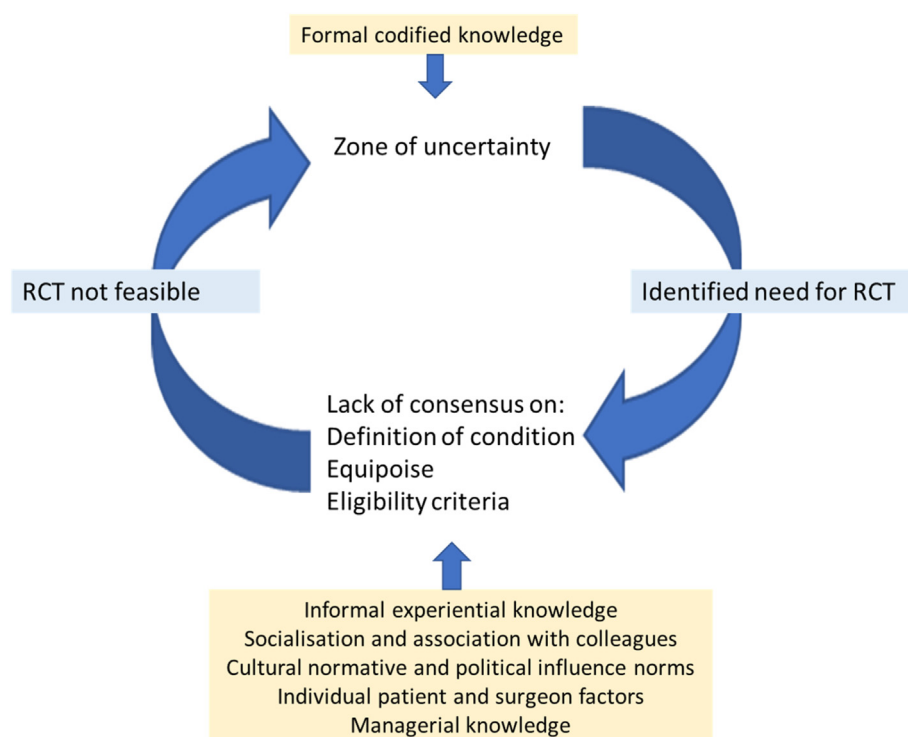


Fig. 1. The cycle of uncertainty.

reported that surgeons legitimised using more nebulous types of knowledge to inform decision making irrespective of whether evidence was available, by viewing surgery as an art (Pope, 2003). A more recent qualitative case study has highlighted the importance of professional identity and the organisation where a surgeon is based on surgical decision making and the use of evidence. The paper, which categorises surgeons as ‘paragons, innovators and mavericks’ argues that where an individual falls on the spectrum of these three identities influences their likelihood of adhering to evidence based practice and their response to standardisation (Grove et al., 2021a). It is therefore perhaps unsurprising that there are reports of scepticism amongst surgeons towards the applicability of RCT evidence to surgical decision making as by averaging the benefits of an intervention for a group of people, RCTs ignore the complex variation and individuality of medical work and decision making – i.e. the personality of the fracture is randomised out (Grove et al., 2021a).

We also used our findings to conceptualise the ‘cycle of uncertainty’ (Fig. 1) as a means of considering the role of equipoise in the creation and adoption of evidence and more specifically its influence on our ability to conduct feasibility and pilot trials. PRESTO, like most RCTs and pilot/feasibility studies, was commissioned on the basis of clinical uncertainty. However, ingrained variations in practice across individuals and organisations resulted in equipoise being compromised and are one of the main reasons why full, effectiveness trials can prove unfeasible, with many of the commonly identified barriers to trial recruitment underpinned by a lack of equipoise (Wood et al., 2015). During PRESTO, surgeons demonstrated this by acknowledging community equipoise through their willingness to participate in the feasibility study, but then communicating treatment preferences and/or using their own experience or individual characteristics of patients to determine their ineligibility, suggesting a lack of personal equipoise. RCTs therefore require surgeons to move further away from relying on tacit knowledge sources and the comfort of their experience and embrace uncertainty and equipoise through the randomisation process. Surgeons understand and are aware that community equipoise exists and that a trial is necessary to address this, but remain reliant on informal knowledge sources (e.g.

organisational and specialty norms, surgeon and patient preferences and characteristics) to inform decision-making and recruitment decisions, which ultimately creates a barrier to trial recruitment and the creation of evidence.

Our findings highlight that non-evidence based variation in practice creates a need for evidence, but is also a key barrier to the creation of this evidence and the conduct of RCTs. In light of this, we agree with Grove et al. that a new method for facilitating evidence based knowledge in surgical work is required (Grove et al., 2016). However, we suggest that to embed research into surgical decision-making and facilitate the adoption of new, high quality evidence, it is important that any strategies which are developed, consider the entire research cycle and attempt to break the ‘cycle of uncertainty.’ Previous attempts to tackle issues with equipoise have aimed to optimise recruitment *during* the pilot or feasibility stage, by educating those involved in recruitment on issues such as randomisation, equipoise and consent (Donovan et al., 2016). For instance, when designing and conducting RCTs, clinicians and academics may wish to consider incorporating strategies or methods to support the adoption of evidence into clinical decision-making either as part of the main RCT or as a separate piece of implementation research at the pilot, feasibility, or even ‘pre-feasibility’ stage. This suggestion is in keeping with the new Medical Research Council (MRC) guidance for evaluating complex interventions, which recommends an ‘evaluability assessment’ consisting of collaborations with stakeholders to determine whether and how an intervention can be evaluated (Skivington et al., 2021). Targeted qualitative research which shifts away from identifying common barriers and facilitators to trial recruitment, for which there is already a wealth of literature (Realpe et al., 2021; Scantlebury et al., 2021), to in-depth, context specific explorations of the drivers of surgical decision making in relation to the clinical problem under investigation could be an important element of an evaluability assessment. Undertaking this work early in the research cycle could potentially maximise the chances that a trial is deemed feasible and that the evidence which is needed to inform decision making is created. This may also have the potential added benefit of avoiding funding costly feasibility and/or pilot studies in situations where equipoise is known or suspected to be a particular

problem. In these situations, there may be a need to look to other research methodologies, which may more easily align with the way that surgeons use RCTs. For instance, decision analysis (Howard, 1988).

4.1. Strengths and limitations

This study adds to a small but growing number of qualitative studies that have been conducted in orthopaedic surgery. In this paper, the use of qualitative data from the PRESTO feasibility study and Grove et al.'s conceptual framework enabled us to consider the role of surgical decision making in the context of feasibility studies. This is a novel contribution to the evidence base, which has highlighted a potential way of addressing one of the most commonly identified barriers to RCT recruitment – equipoise. Through this work, we have suggested a number of potential avenues for future research to explore, which may lead to improvements in the design and conduct of future orthopaedic surgical trials. Mapping our findings onto those of a mixed methods systematic review also enabled us to place them in the context of the broader evidence on drivers in variation of orthopaedic surgical practice. Grove et al., state that the themes they identified should not be viewed hierarchically, but as a series of complex and inter-related factors which influence treatment decisions differently for any given patient. We therefore used the framework flexibly as a way to explain our findings, rather than as a rigid set of pre-determined factors that influence clinical decision making. For example, the influence of training and formal education was only discussed by our participants briefly and in the context of other themes (e.g. informal experiential knowledge) and so we chose not to report this separately, but to embed it within relevant themes as appropriate. Limited mention of these themes by our interviewees, should not be viewed as absence of evidence, but may reflect that the original aims of the PRESTO qualitative study were broader than a focus on current practice and surgical decision making.

Spinal surgeons were recruited via snowball sampling, a technique, which is useful when the number of experts in a given field is small and individuals are known to one another. Although this meant that we were 'limited' to capturing the views of those that agreed to take part, we deliberately aimed to interview surgeons from different geographical settings, hospitals and specialties who represented various genders, professional grades and years' experience. Equally, our findings only represent the views of spinal surgeons in the UK. However, our findings map well onto Grove et al.'s framework (Grove et al., 2016), and are consistent with previous research on surgical decision making (Grove et al., 2018, 2021a, 2021b; Pope, 2003). This suggests that they may be of interest and applicable to surgeons working in orthopaedic surgery more broadly.

5. Conclusions

Our findings suggest that surgical decisions are based on the complex interplay between the different types of knowledge that we identified as influencing surgical decision making. When considering the implications of this in the context of feasibility studies more broadly we describe how in situations where there is no consensus or robust evidence as to the best available treatment a vicious cycle of uncertainty ensues -equipoise and variation in practice create a need for evidence and act as a barrier to evidence being created. For instance, a lack of robust empirical evidence and surgical grey areas surrounding treatment were the drivers for the PRESTO feasibility trial being funded, with many surgeons aware that community equipoise existed and the need for a trial to address this. However, in practice, surgeons were reliant on informal knowledge sources to inform decision making and recruitment decisions, which acted as a barrier to the feasibility trial and creation of evidence. To facilitate the successful conduct of future orthopaedic surgical trials and ensure that the evidence they produce informs decision making, we first need to develop ways to break the cycle; something which may require intervening earlier in the research cycle and/or the use of other forms of evidence either prior to or instead of RCTs.

Ethical statement

North East - Newcastle and North Tyneside Research Ethics Committee approved the PRESTO study on March 20, 2018 (REC reference 18/NE/0008). Written and verbal consent was obtained from all participants before the start of each interview.

Ethics approval and consent to participate

North East – Newcastle and North Tyneside Research Ethics Committee approved the PRESTO study on March 20, 2018 (REC reference 18/NE/0008). Written and verbal consent was obtained from all participants before the start of each interview. Participants were made aware, verbally at the start of each interview and via the consent forms that anonymised quotations may be published.

Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Abbreviations

A&E	Accident and Emergency
ARC	Applied Research Collaborations
BASS	British Association of Spine Surgeons
CT	Computerised Tomography scan
ED	Emergency Department
MRI	Magnetic Resonance Imaging
NHS	National Health Service
NIHR	National Institute for Health Research
PRESTO	Pragmatic randomised evaluation of stable thoracolumbar fracture treatment outcomes
REC	Research Ethics Committee
RCT	Randomised Controlled Trial
UK	United Kingdom

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ssmqr.2022.100092>.

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