PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Study protocol for a randomised controlled trial of consenting processes and their effects on patient decision making when undergoing spinal injections: the Risks In Spinal Consenting for Surgery (RISCS) trial
AUTHORS	Fletcher, James; Khan, Mohsin; Thorpe, Paul

VERSION 1 – REVIEW

REVIEWER	Shona Kalkman University Medical Center Utrecht, the Netherlands
REVIEW RETURNED	17-Apr-2018

GENERAL COMMENTS	The study team aims to address a relevant ethical question: What risks ought to be communicated to patients undergoing a medical procedure? The authors refer tothree English tort law cases, with different rulings about the appropriate level of information provision. In the United Kingdom (UK), there appears to be a difference between "medical informed consent" and "legal informed consent" for invasive procedures. Apparently, if patients suffer from a rare, but serious adverse event following a procedure, which had not been communicated to them beforehand, and if they attest that they would not have undergone the procedure had they known about the potential adverse event, UK tort law finds such patients to be “legally correct” (based on causation). The authors point out that there is no evidence to support the assumption, that if patients are provided extensive information about all (rare, but serious) adverse events, they would actually alter their decision-making (i.e. not undergoing the procedure). The research question is pretty straight-forward: do patients who receive “legal” or “extensive” information about procedure-related risk consent less often to an invasive medical procedure than patients who receive “medical” or “standard” information about procedure-related risk? The authors also list a number of secondary outcomes, such as anxiety levels and pain experience post-operatively. I recommend the following changes to improve the protocol, and subsequent academic reporting: 1. The introduction will require more background to clarify the study’s rationales. Is the distinction between “medical” and “legal” consent a distinction unique to the UK or is this a general concern for medical ethics? And what is exactly so

problematic about the distinction? I think I understand what the authors are getting at, but it will need to be spelled out. It helps to think in terms of the consequences of accepting either one of the consent types as “standard”. What will be won and what will be lost (ethically, practically, socially). I feel the reader also needs a bit more briefing about the UK tort law cases, I had to look those up.

2. Causation appears to refer to patients not wishing to undergo a certain procedure, if they are informed about all reported risks in the literature. But what about opting for an alternative (such as general anesthesia, or an epidural)? In tort law, there seems to be a focus on the risks of not having the surgery versus the risks of the surgery (including anesthetic). In other words, how would a patient have decided had she known about the option of general anesthesia (or something else) as an alternative to a spinal injection, and their comparative risks?
3. What will the results teach us? Of course, it may not be difficult to demonstrate that patients who receive a long list of complications are more anxious and are more likely to decide against having a procedure (they probably really need?) compared to patients who receive “normal” pre-operative information. But what does that actually mean? Are patients in the “legal consent” arm justified in deciding against the procedure? Or are they overreacting? Or, what will the results tellus about the quality of decision-making? What are the implications for (UK/international?) policy and law? How does the concept of causation a posteriori relate to the “reasonable person” standard a priori? The authors do reflect a bit on this on page 9, but I feel that the conclusion about potential outcomes is lacking.
4. I wonder whether the title accurately reflects the study question.
5. Page 2, Strengths and Limitations: “This study provides a methodology of how to use different consent processes for the same procedure.” This suggests that the authors are proposing that practice is benefitted by different types of consent/information provision.
6. I found it unclear to what extent the effect of the accompanying verbal information is taken into account. Written patient information is clearly different, but will the person providing verbal information downplay or overstate risks? A surgeon has interest in convincing the patient that the risks are negligible (which they probably are in light of potential benefits), so how will he/she answer a patient’s question about the relevance of the risk “death”, for example?
7. Would it be of use to send the patient information forms along with the protocol for review?

REVIEWER	Michael H. McGillion McMaster University, Canada
REVIEW RETURNED	05-May-2018

GENERAL COMMENTS	Overall, it was a pleasure to review this protocol, which is well written and in compliance with SPIRIT guidelines. There are a few minor areas that need clarification/edits. Please see below a list of items, as follows: § Page 5: Line 3 "secretaries" and line 27 "spinal secretaries". Are these the same? § Page 6: Line 40 - STAI, According to the study, state anxiety will be measured 2 weeks prior to surgery, while the patient is at home. My concern is will 2 weeks prior to surgery capture the same level of state anxiety as measuring anxiety right before surgery. Given that the patient is still at home, their anxiety may be less, as compared to when surgery is imminent. Can the authors provide some clarification or support that state anxiety will be approximately the same? § Page 7: line 9- measuring EuroQol being measured 6 weeks after surgery, do the authors know baseline of patients? I recognize that change in consent is the primary outcome, but should EuroQol be assessed at baseline, and if so, what correlations do the authors wish to make regarding consenting process and EuroQol measurement? § Page 8: line 23 – Are the surgeons and spinal research team used in data management are they blinded to intervention?

VERSION 1 – AUTHOR RESPONSE

Reviewer 1		
Reviewer Comment	Author response (briefly explained, changes are highlighted in the manuscript)	Author action (page and line)
The introduction will require more background to clarify the study's rationales. Is the distinction between "medical" and "legal" consent a distinction unique to the UK or is this a general concern for medical ethics?	The authors would like to acknowledge the comments and suggestions made by the reviewer, which helped improve the manuscript. This is a general concern using terms that we have created for the project. The legal position is how surgeons would be judged however a 'medical' approach, based on what surgeons think the patient should be informed about, is still commonplace.	Page 3 lines 8 and 9: Patients have been found legally correct, when stating post hoc, that they may not have given consent if certain risks had been presented to them preoperatively. Page 3 lines 15 and 16: These aspects are relevant to all consenting procedures worldwide. Page 3 lines 24-31 The combination of these factors has changed medical negligence outcomes significantly over recent years. This is despite there being no clinical evidence to support the legal view that patient decision making will often materially change based on the preoperative risks presented to them. This has led to a significant shift in how surgeons approach the consent process. The classical

		'medical-styled' consent process aimed to focus the patient on pertinent risks of an operative procedure. We feel the current clinical negligence climate only supports surgeons who adopt a 'legal-styled' approach which presents the patient with an encyclopaedic list of potential operative risks. Page 6 line 5 The standard risks ('medically styled') that a patient is informed of during the consenting process are Page 6 line 11 The intervention consent form ('legally styled') will be encyclopaedic to include all known risks and complications to have ever have occurred from spinal injections following a detailed literature search.
And what is exactly so problematic about the distinction? I think I understand what the authors are getting at, but it will need to be spelled out. It helps to think in terms of the consequences of accepting either one of the consent types as "standard". What will be won and what will be lost (ethically, practically, socially). I feel the reader also needs a bit more briefing about the UK tort law cases, I had to look those up.	That surgeons seem to believe that a medical approach is best for patients, however they are judged in court based on the case law.	Further explanation about the anticipated consequences of a medical or legal based consenting system are explained: Page 9, lines 35-43 If rates of consent do decrease with more information, especially regarding rare risks, then the legal principle is upheld, and all consenting practise in the NHS should change to reflect this. This would often involve significant change in practice, mainly relating to the time allocated to consent processes and the amount of information imparted; also, the time given to patients to reflect on this information. Conversely, if there is no change in the rates of consent despite more detailed explanation of risks, then the premise of the Chester vs Afshar Supreme Court judgement will be shown to be fallible, and this study may be used to justify and defend standard consenting practice for minor procedures.
Causation appears to refer to patients not wishing to undergo a certain procedure, if they are informed about all reported risks in the literature. But what about opting for an alternative (such as general anesthesia, or an epidural)? In tort law, there seems to be a focus on the risks of not having the surgery versus	There is no case law known to the authors that refers to a patient successfully arguing that if they were told about certain risks they would have chosen another operation or anaesthetic. The case law (chester vs afshar) refers to a patient still choosing to have their operation but stating that they would have had it at a different time if they had been	No action needed

the risks of the surgery (including anesthetic). In other words, how would a patient have decided had she known about the option of general anesthesia (or something else) as an alternative to a spinal injection, and their comparative risks?	told of the risks (they would have gone away and reflected, and thus the operation would not have happened on that day, so the complication would not have happened).	
What will the results teach us? Of course, it may not be difficult to demonstrate that patients who receive a long list of complications are more anxious and are more likely to decide against having a procedure (they probably really need?) compared to patients who receive "normal" pre-operative information. But what does that actually mean? Are patients in the "legal consent" arm justified in deciding against the procedure? Or are they overreacting? Or, what will the results tell us about the quality of decision-making? What are the implications for (UK/international?) policy and law? How does the concept of causation a posteriori relate to the "reasonable person" standard a priori? And how does the concept of causation relate to shared decision-making? The authors do reflect a bit on this on page 9, but I feel that the	The results should lead to binary outcomes. Either the premise that the more you tell a group of patients, the more they do not consent will be found to be correct or not. If correct, then consenting practices need to change to reflect the extra information that needs to be imparted preoperatively, as causation will have been confirmed. If no one withdraws consent, then causation does not apply to this group, and not explaining an encyclopaedic list of risks to patients can be justified. This will protect surgeons from disgruntled patients seeking compensation using a retrospective approach to risks they could claim they were not told of.	No action needed

conclusion about potential outcomes is lacking.		
4. I wonder whether the title accurately reflects the study question.	Changed as suggested by the reviewer.	Study protocol for a randomised controlled trial into consenting processes and their effects on patient decision making when undergoing spinal injections: the Risks In Spinal Consenting for Surgery (RISCS) trial
5. Page 2, Strengths and Limitations: "This study provides a methodology of how to use different consent processes for the same procedure." This suggests that the authors are proposing that practice is benefited by different types of consent/information provision.	Changed as suggested by the reviewer.	Page 2, line 34 'Use' has been changed to 'compare'.
6. I found it unclear to what extent the effect of the accompanying verbalinformation is taken into account. Written patient information is clearly different, but will the person providing verbal information downplay or overstate risks? A surgeon has interest in convincing the patient that the risks are negligible (which they probably are in light of potential benefits), so how will he/she answer a patient's question about the relevance of the risk "death", for example?	Limited information is provided verbally regarding the risks in clinic. The patient is informed that an injection is recommended and of the trial at the same time. Before they can consent, they are asked about involvement in the trial, and then upon verbal agreement to the trial, they do not receive any more verbal information about the injection. Once they have consented to the trial and then received their consent pack with the consent form and its written explanation, they have the contact details of the chief investigator and a 24hr phone number to call where they will receive consistent verbal explanation from an experienced spinal surgeon.	No action needed

7. Would it be of use to send the patient information forms along with the protocol for review?	Changed as suggested by the reviewer.	Patient information sheets uploaded

VERSION 2 – REVIEW

REVIEWER	M McGillion McMaster University, Canada
REVIEW RETURNED	29-Jun-2018

GENERAL COMMENTS	I am satisfied with the authors' responses and actions taken. There are minor edits suggested to that may further improve the readability of the paper. Please find these comments below with references to page and line numbers. 1) Under Exclusion criteria for the third bullet, please remove period at end of sentence (page 4, line 29). 2) Under recruitment procedure, (page 4, line 44), I suggest you state "what anxiety, if any, it may cause". At present the statement indicates that anxiety is (implying always) present with obtaining consent. 3) Under recruitment procedure, (page 5 line 3), I suggest it be clarified that spinal secretaries will send out the identified packs 4) Under intervention, (page 6, line 19), please delete extra closed bracket [)] in text. 5) Throughout the article, post operative is used as a separate word (page 7, line 10; line 20; line 30), however, preoperative is used as a combined term (page 3, line 12). 6) Flowchart of participant journey (page 13, line 43) please spell-out BSR abbreviation in flow diagram 7) Figure 2: Trial participant encounters (page 14), please consider including a legend for the abbreviations included.

VERSION 2 – AUTHOR RESPONSE

Reviewer 1		
Reviewer Comment	Author response (briefly explained, changes are highlighted in the manuscript)	Author action (page and line)
We would like to thank the reviewer again for their thorough and detailed review of the manuscript.		
1) Under Exclusion criteria for the third bullet, please remove period at end of sentence (page 4, line 29).	Text changed	Deleted '.' – PubMed page 4 line 20
2) Under recruitment	Text added	Page 4, line 32 changed:

procedure, (page 4, line 44), I suggest you state "what anxiety, if any, it may cause". At present the statement indicates that anxiety is (implying always) present with obtaining consent.		'…decisions made by patients, and what anxiety, if any, it may cause.'
3) Under recruitment procedure, (page 5 line 3), I suggest it be clarified that spinal secretaries will send out the identified packs	Text clarified	Page 5 lines 2 and 3: 'These packs will be randomised, placed in a tray and sent out in a sequential order by the spinal secretaries.'
4) Under intervention, (page 6, line 19), please delete extra closed bracket [)] in text.	I cannot find an extra bracket	No action needed
5) Throughout the article, post operative is used as a separate word (page 7, line 10; line 20; line 30), however, preoperative is used as a combined term (page 3, line 12).	All changed to hyphenated versions – 'pre-' and 'post-'	Page 3 line 9 Page 3 line 27 Page 7 line 10, line 19, line 27
6) Flowchart of participant journey (page 13, line 43) please spell-out BSR abbreviation in flow diagram		BSR and STAI spelt out in full.
7) Figure 2: Trial participant encounters (page 14), please consider including a legend for the abbreviations included.		Abbreviations have been defined