

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Development of a patient decision aid on subacromial decompression surgery and rotator cuff repair surgery: an international mixed-methods study
AUTHORS	Zadro, Joshua; Jones, Caitlin; Harris, Ian; Buchbinder, Rachelle; O'Connor, Denise; McCaffery, Kirsten; Thompson, Rachel; Karunaratne, Sascha; Teng, Min Jiat; Maher, Christopher; Hoffmann, Tammy

VERSION 1 – REVIEW

REVIEWER	Razmjou, Helen Sunnybrook Res Inst
REVIEW RETURNED	05-Jul-2021

GENERAL COMMENTS	<p>Development of a patient decision aid on subacromial decompression surgery and rotator cuff repair surgery</p> <p>The purpose of this study was to develop and test a patient decision aid that presents evidence-based information on the benefits and harms of subacromial decompression and rotator cuff repair surgery, compared to non-surgical option using a mixed-methods study design.</p> <p>The manuscript is well-written and the investigators have taken the appropriate steps to develop this decision aid. The amount of details provided on each step of the study is impressive.</p> <p>The tool seems to have incorporated the majority of important components of a decision aid. I however have some concerns:</p> <ol style="list-style-type: none">1) Some information is redundant and repetitive. In certain cases, identical wording has been repeated on the same page.2) The ambiguity about acute traumatic tears which often need urgent attention needs to be improved.3) The information is too generic and does not incorporate patient's specific data. <p>Suggestions:</p> <ol style="list-style-type: none">1) Remove identical information that has been repeated under different titles (see details below)
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2) Highlight the fact that this decision aid is for impingement syndrome, partial thickness and degenerative full-thickness tears. You have mentioned trauma as an exclusion factor, but you have not mentioned the difference between traumatic acute tears that if left alone my progress to unrepairable tears due to muscle atrophy and fatty infiltration.

3) I am not sure if at this stage of the study you could add more information to the decision aid tool but adding a section on patient individual profile such as age, nature of injury (traumatic vs. insidious), level of disability (e.g. ASES, or any one page disability outcome), imaging findings (e.g. large subacromial spur) will improve the usability of the information from a fancy pamphlet to a meaningful and personalized tool. By adding the personalized patient data, patients can make a more informed decision on the best management.

- a. Age is a significant contributor to necessity for surgery
- b. Degenerative tears are often successfully managed with conservative treatment
- c. You could add a disability outcome and provide some information different levels of disability of that measure.
- d. Acuteness and type of injury affect management
- e. Imaging: plain radiographs in impingement syndrome/partial or small full-thickness tear should exclude a large subacromial enthesophytes (osteophyte) pressing on the rotator cuff tendons.

If this cannot be done, this has to be mentioned in the limitation section, indicating that this aid is generic and does not take into account patient's specific data.

Decision tool:

Page 93: Picture, right upper hand: I suggest revising to "inflamed or torn"

Second box: It makes it difficult to do simple... repetitive information

This decision aid does not apply.... The trauma has been noted as an exclusion criteria but it may be necessary to add traumatic acute tears as an exclusion criteria as well.

Page 94: Please remove (subacromial decompression and or....) after surgery from the title. This information is repeated in the same box.

Left lower box: Non-surgical options: "corticosteroid" may be more accurate than "steroid" which may refer to male hormone-related compounds.

Right lower box: Identical information about subacromial decompression and repair. To avoid overlap, I suggest removing identical sentences from the first box and instead you could note something like both surgical and non-surgical are valid options and the choice depends on patient's individual situation.

	<p>Page 95 and 97: Seem to be clear.</p> <p>Page 96: Please make sure that the statement on RC repair is clear. The sentence sounds too generic and somewhat misleading. Check your evidence and add the info on what type of tears you are referring to. Delaying a repair of an acute large full-thickness tear in a young man is not recommended as within a few months, the fatty infiltration and muscle atrophy may make an easily reparable tear, permanently irreparable.</p>
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REVIEWER	Lewis , Krystina University of Ottawa School of Nursing
REVIEW RETURNED	12-Jul-2021

GENERAL COMMENTS	<p>Dr. J. Zadro and colleagues report the findings of a mixed methods study aimed at developing and user testing a patient decision aid for subacromial decompression surgery and rotator cuff repair surgery, compared to non-surgical options. The manuscript is well organized and well written. I have three main comments, and offer additional, more specific comments below by section.</p> <p>General comments:</p> <ol style="list-style-type: none"> 1. An initial step in designing and developing a patient decision aid is to understand the user, which often provides the justification for developing the PDA. Was any research conducted prior to embarking on the design and prototype development of the PDA to understand the user, their needs, their goals for treatment, strengths, limitations within the specific context? For example, was an informal or formal needs assessment completed? It is noted in Figure 1 that the patients and clinicians' views on decisional needs were elicited in the interviews, however the methods used to uncover these and their findings are not reported in this manuscript. 2. More clarification regarding the decision aid prototype used for this study would be helpful. Specifically: <ol style="list-style-type: none"> a) What are the specific non-surgical options included in the decision aid? b) It is clear what evidence was used to inform the estimates of benefits and harms used in the decision aid. However, it is less clear what sources, literature or otherwise, guided the rest of the PDA content (e.g. the options, values clarification, aspects that are important to users etc) c) What was the decision aid's format? How was it presented to study participants? d) When did the study participants receive the decision aid for review? Did participants have access to it prior to the interview to review on their own time, or was it presented to them at the time of the interview?
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3. The evidence for the IPDAS systematic development process of Patient Decision Aids was recently updated and published in Medical Decision Making. I acknowledge that the reported study was designed, conducted and written up before its publication. Yet, would it be possible to comment on how your PDA's development approach aligns with a user-centered design approach endorsed by IPDAS? How do the methods ascribed to in this study relate to IPDAS' recommended minimal, medium and maximal processes? The UCD-11, a quantitative measure of the user-centeredness of patient decision aids (or other personal health tools), could be a useful way to report this.

Witteman, H.O., Maki, K.G., Vaisson, G., Finderup, J., Lewis, K.B., Steffensen, K.D., Beaudoin, C., Comeau, S. Volk, R.J. (2021) Systematic Development of Patient Decision Aids: An Update from the IPDAS Collaboration. Medical Decision Making. June 19, 2021; 272989X211014163. doi: 10.1177/0272989X211014163. Online ahead of print.

Witteman HO, Vaisson G, Provencher T, et al. An 11-item measure of user- and human-centered design for personal health tools (UCD-11): development and validation. J Med Internet Res. 2021;23(3):e15032

Please see below for additional comments by section:

Methods

1. Eligibility criteria: Eligible health care professionals had to manage/consult at least five people with suspected subacromial pain syndrome per year. Could the authors clarify the minimum of years of experience the HCP had to have?

2. The pre-interview questionnaire was used to purposively sample participants. The authors note that no participant who completed the questionnaire refused an interview. Yet, did the research team turn any potential participant away to achieve a purposive sample?

3. The Ottawa Hospital Research institute questionnaire modified for use in this study is intended to rate the Acceptability rather than useability of Patient Decision Aids. Acceptability refers to ratings regarding the comprehensibility of components of a decision aid, its length, amount of information, balance in presentation of information about options, and overall suitability for decision making (https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Acceptability.pdf) (which is what was collected). Useability, on the other hand, refers to a tool or product's effectiveness, efficiency and satisfaction in a specified context of use (as defined by the International Organization for Standardization).

4. Health professionals and patients and who completed an interview were compensated for their time with a \$100 and \$50

	<p>supermarket gift card, respectively. It is unclear why health care professionals received a greater sum than patients.</p> <p>Results:</p> <p>5. Participating health care providers were from 4 different countries (Australia, Canada, United States and England). Could the authors provide justification for why they recruited internationally, and how participants' different countries of practice may have influenced responses and views of the decision aid given the context in which they practice?</p> <p>6. How many iterative cycles of revisions were conducted?</p> <p>7. As reported 'yes' in the COREQ checklist, how many repeat interviews were carried out? Who participated in the repeat interviews?</p> <p>8. Could the authors specify the number of patients who reported that the DA swayed them away from surgery, and how many were swayed towards surgery? (Lines 333-335)</p> <p>9. The authors state that a limitation of their study is that they only interviewed people who speak English. Yet, if the decision aid is only available in English, then limiting participants based on language in makes sense. May I suggest that the limitation be framed around the fact that only an English language PDA is available at the moment given its in its early development phase, and state any intention for translating the tool in the future.</p> <p>Discussion:</p> <p>10. In the background, the authors provide compelling data for the global increasing use of subacromial decompression surgery and rotator cuff repair surgery. This, paired with the state of the evidence on the effectiveness of these surgical options, the authors suggest that people may not be making informed treatment choices. Hence, it would be of great interest to explore the role of patient decision aids and a shared decision-making process more broadly, to reduce the overuse of these surgical options.</p>
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VERSION 1 – AUTHOR RESPONSE

REVIEWER #1

We thank the reviewer for their positive comments.

COMMENTS TO THE AUTHORS

- 1) Some information is redundant and repetitive. In certain cases, identical wording has been repeated on the same page.
- 2) The ambiguity about acute traumatic tears which often need urgent attention needs to be improved.

3) The information is too generic and does not incorporate patient's specific data.

AUTHORS' RESPONSE

We thank the reviewer for their comments on the decision aid. The challenge with changing the content of the decision aid at this stage is that the current decision aid is the end-product of feedback from 26 health professionals and 14 patients with shoulder pain, as well as extensive discussions and revisions from the multidisciplinary expert steering group. Given the range of views on the topic and content of the decision aid, we could not incorporate everyone's suggestions. Supplementary File 13 outlines feedback from health professionals and patients we chose not to implement and the reason for our decisions. The steering group is happy to incorporate minor edits at this stage. However, making large edits now would undermine the processes we took to arrive at the final version of this decision aid.

We have tried our best to address the reviewer's comments below, but please appreciate this is difficult given the vast amount of feedback we have already received.

COMMENTS TO THE AUTHORS

Suggestions:

1) Remove identical information that has been repeated under different titles (see details below)

a. Second box: It makes it difficult to do simple... repetitive information

b. This decision aid does not apply.... The trauma has been noted as an exclusion criteria but it may be necessary to add traumatic acute tears as an exclusion criteria as well.

c. Page 94: Please remove (subacromial decompression and or....) after surgery from the title. This information is repeated in the same box.

d. Right lower box: Identical information about subacromial decompression and repair. To avoid overlap, I suggest removing identical sentences from the first box and instead you could note something like both surgical and non-surgical are valid options and the choice depends on patient's individual situation.

AUTHORS' RESPONSE

a. RE: "It makes it difficult to do simple..." This is the only statement to describe the symptoms of shoulder pain so we have decided to leave it as it is

b. We have tried to make the language of the decision aid as accessible as possible for patients. As such, we decided to use 'sudden rotator cuff tear' as a more lay description for 'traumatic acute rotator cuff tears'

c. I apologise but I am unsure what the reviewer is referring to. I can't see where this information is repeated

d. For the reasons stated in response to the previous comment, we have decided to keep this information as it is. The information about subacromial decompression surgery and rotator cuff repair surgery in the 'Key messages' box is not identical and was flagged as important by many participants in our study. Footnotes A and B describe how the quality of evidence differs for these surgeries and the population the evidence applies to. There is also additional information about the evidence for rotator cuff repair surgery so people do not extrapolate our message to all types of rotator cuff tears: "Research on rotator cuff repair surgery does not apply to people who tear a tendon following trauma, or people with a full-thickness tear of the subscapularis tendon."

COMMENTS TO THE AUTHORS

2)

a. Highlight the fact that this decision aid is for impingement syndrome, partial thickness and degenerative full-thickness tears.

b. You have mentioned trauma as an exclusion factor, but you have not mentioned the difference between traumatic acute tears that if left alone may progress to unrepairable tears due to muscle atrophy and fatty infiltration.

AUTHORS' RESPONSE

a. Many health professionals opposed the term 'impingement' (see 2nd row of the table in Supplementary File 13) so we decided not to include it. This decision aid is for anyone with "persisting shoulder pain that is likely due to issues with rotator cuff tendons that move and support the shoulder (eg. inflammation, tears)." This includes partial thickness and degenerative full-thickness tears. However, we wanted to keep the language accessible for patients since they may read this decision aid before seeing a health professional (e.g. if they find it on a Google search).

b. We decided to use 'sudden rotator cuff tear' as a more lay description for 'traumatic acute rotator cuff tears'. This type of tear was a clear exclusion item. We state under the Key Message box that the evidence we present does not apply to those with 'traumatic acute rotator cuff tears': "Research on rotator cuff repair surgery does not apply to people who tear a tendon following trauma, or people with a full-thickness tear of the subscapularis tendon."

COMMENTS TO THE AUTHORS

3) I am not sure if at this stage of the study you could add more information to the decision aid tool but adding a section on patient individual profile such as age, nature of injury (traumatic vs. insidious), level of disability (e.g. ASES, or any one page disability outcome), imaging findings (e.g. large subacromial spur) will improve the usability of the information from a fancy pamphlet to a meaningful and personalized tool. By adding the personalized patient data, patients can make a more informed decision on the best management.

a. Age is a significant contributor to necessity for surgery

b. Degenerative tears are often successfully managed with conservative treatment

c. You could add a disability outcome and provide some information different levels of disability of that measure.

d. Acuteness and type of injury affect management

e. Imaging: plain radiographs in impingement syndrome/partial or small full-thickness tear should exclude a large subacromial enthesophytes (osteophyte) pressing on the rotator cuff tendons.

If this cannot be done, this has to be mentioned in the limitation section, indicating that this aid is generic and does not take into account patient's specific data.

AUTHORS' RESPONSE

As mentioned in response to an earlier comment, we cannot make major changes to the decision aid at this point. We have included a question on the last page that prompts patients to consider some of the individual circumstances the reviewer mentions above: "Have I considered my situation before making any decisions (eg. age, pain severity, activity levels, job demands, insurance coverage, caring responsibilities, involvement in sport, etc)?"

We have also mentioned in the limitations section that individual circumstances may limit the applicability of this decision aid for some people with shoulder pain.

(Page 19, 1st paragraph)

Limitations include a small sample size for our quantitative usability data, being unable to recruit certain groups of health professionals (e.g. rheumatologists, sports doctors), and the decision aid only being developed in English (the Steering group will consider translating this tool to other languages following its evaluation in a clinical trial). We also acknowledge that individual circumstances may limit the applicability

of the evidence presented in the decision aid (e.g. age, pain severity, activity levels, job demands, insurance coverage, caring responsibilities, involvement in sport).

COMMENTS TO THE AUTHORS

Decision tool:

Page 93: Picture, right upper hand: I suggest revising to “inflamed or torn”

AUTHORS' RESPONSE

We have made this change as suggested.

COMMENTS TO THE AUTHORS

Left lower box: Non-surgical options: “corticosteroid” may be more accurate than “steroid” which may refer to male hormone-related compounds.

AUTHORS' RESPONSE

We have made this change as suggested.

COMMENTS TO THE AUTHORS

Page 95 and 97: Seem to be clear.

AUTHORS' RESPONSE

Thank you.

COMMENTS TO THE AUTHORS

Page 96: Please make sure that the statement on RC repair is clear. The sentence sounds too generic and somewhat misleading. Check your evidence and add the info on what type of tears you are referring to. Delaying a repair of an acute large full-thickness tear in a young man is not recommended as within a few months, the fatty infiltration and muscle atrophy may make an easily reparable tear, permanently irreparable.

AUTHORS' RESPONSE

We acknowledge in several places that this decision aid is not for people with acute traumatic tears (see below statements from the decision aid). Interviews with participants and discussions among the multidisciplinary steering group suggest this information is clear.

(Who should read this decision aid?)

This decision aid does not apply to people who have other causes of shoulder pain like frozen shoulder (which causes pain and severe stiffness), osteoarthritis, or shoulder pain that begins after trauma immediately resulting in loss of movement or strength (eg. sudden rotator cuff tear, fracture, dislocation).

If you're unsure of the cause of your pain, see a health professional

(Key Message: further information)

For rotator cuff repair surgery, we are somewhat confident about this message because there is lack of high-quality research on this surgery. This research was mostly conducted on people aged in their 50s and 60s but is the best evidence we have for all ages. Research on rotator cuff repair surgery does not apply to people who tear a tendon following trauma, or people with a full-thickness tear of the subscapularis tendon.

REVIEWER #2

Dr. J. Zadro

AUTHORS' RESPONSE

We thank the reviewer for their positive comments.

COMMENTS TO THE AUTHORS

1. An initial step in designing and developing a patient decision aid is to understand the user, which often provides the justification for developing the PDA. Was any research conducted prior to embarking on the design and prototype development of the PDA to understand the user, their needs, their goals for treatment, strengths, limitations within the specific context? For example, was an informal or formal needs assessment completed? It is noted in Figure 1 that the patients and clinicians' views on decisional needs were elicited in the interviews, however the methods used to uncover these and their findings are not reported in this manuscript.

AUTHORS' RESPONSE

We assessed patients' and health professionals' views on decisional needs (see newly added Supplementary Files 5 and 6 for the interview guides for health professionals and patients, respectively). Patients' and health professionals' views on decisional needs was integrated with the feedback given on each section of the decision aid to streamline the presentation of the results. For example, if a health professional stated that patients needed to be aware of particular non-surgical treatment options, this feedback was categorised under the section "What are the treatment options covered in this decision aid?" We have added this explanation to the data analysis section.

(Page 11, 1st paragraph)

The mapping of themes and sub-themes was iterative as new data emerged so that the decision aid was continually updated before new interviews were conducted. Over 10 iterative cycles of revisions were performed. However, in some cases these were very minor changes (e.g. correcting typos, re-wording a sentence). Patients' views on decisional needs and health professionals' views on patients' decisional needs were integrated with the feedback given on each section of the decision aid to streamline the presentation of the results. Interviews stopped once no new feedback was being provided (data saturation) and participants had an overall positive impression of the decision aid.

COMMENTS TO THE AUTHORS

2. More clarification regarding the decision aid prototype used for this study would be helpful. Specifically:

- a) What are the specific non-surgical options included in the decision aid?
- b) It is clear what evidence was used to inform the estimates of benefits and harms used in the decision aid. However, it is less clear what sources, literature or otherwise, guided the rest of the PDA content (e.g. the options, values clarification, aspects that are important to users etc)
- c) What was the decision aid's format? How was it presented to study participants?
- d) When did the study participants receive the decision aid for review? Did participants have access to it prior to the interview to review on their own time, or was it presented to them at the time of the interview?

AUTHORS' RESPONSE

We have now included the draft/prototype decision aid in Supplementary File 1 and added the above details as requested by the reviewer.

(Page 6, 2nd paragraph)

We developed a patient decision aid with guidance from the International Patient Decision Aids Standards (IPDAS) using mixed-methods [10, 11]. We began by assembling a multidisciplinary steering group (study authors) including topic experts (IH: orthopaedic surgery; RB: shoulder pain; KM, TH, RT and DO: patient decision aids and shared decision making) and health professionals who manage people with shoulder pain (JZ and SK: physiotherapists; RB: rheumatologist). The first draft of the decision aid was created in PowerPoint and based on decision aids for antibiotics [12] and knee arthroscopy [13] which several study

authors have developed (TH, KM, RB, DO and IH) (Supplementary File 1). Key features adapted from these decision aids included horizontal bar graphs displaying the effects of surgery compared to placebo and non-surgical options (which included injections, physiotherapy, medication and wait and see), icon arrays to help patients understand probabilities, a statement about the source and quality of the evidence, questions for patients to ask their health professional, and practical issues (e.g. time off work, driving restrictions). Decision science evidence suggests these features improve patient decision making [14-18]. Data from the 2019 Cochrane reviews on subacromial decompression surgery [6] and rotator cuff repair surgery [7] were used to inform numeric estimates of benefits and harms used in the decision aid. Expert opinion and consensus from the steering group was used to inform other information presented in the decision aid (e.g. causes and symptoms of shoulder pain, practical issues). The steering group provided feedback on the first draft before we conducted semi-structured interviews with people with shoulder pain and health professionals who manage people with shoulder pain.

(Page 7, 3rd paragraph)

Box 1 describes the data collection process including the pre-interview questionnaires (used to purposively sample participants), semi-structured interviews and useability questionnaires. In accordance with IPDAS guidance [10, 11], semi-structured interviews were used to assess patients' views on decisional needs and health professionals' views on patients' decisional needs, gather feedback on the draft decision aid, and assess useability of the decision aid. Participants were provided the draft decision aid prior to the interview but some participants did not review it beforehand. At the end of each interview, participants were given the opportunity to provide any additional feedback or comments.

COMMENTS TO THE AUTHORS

3. The evidence for the IPDAS systematic development process of Patient Decision Aids was recently updated and published in *Medical Decision Making*. I acknowledge that the reported study was designed, conducted and written up before its publication. Yet, would it be possible to comment on how your PDA's development approach aligns with a user-centered design approach endorsed by IPDAS? How do the methods ascribed to in this study relate to IPDAS' recommended minimal, medium and maximal processes? The UCD-11, a quantitative measure of the user-centeredness of patient decision aids (or other personal health tools), could be a useful way to report this.

Witteman, H.O., Maki, K.G., Vaisson, G., Finderup, J., Lewis, K.B., Steffensen, K.D., Beaudoin, C., Comeau, S. Volk, R.J. (2021) Systematic Development of Patient Decision Aids: An Update from the IPDAS Collaboration. *Medical Decision Making*. June 19, 2021; 272989X211014163. doi: 10.1177/0272989X211014163. Online ahead of print.

Witteman HO, Vaisson G, Provencher T, et al. An 11-item measure of user- and human-centered design for personal health tools (UCD-11): development and validation. *J Med Internet Res*. 2021;23(3):e15032

AUTHORS' RESPONSE

Our decision aid met 6 out of 6 criteria to be considered a decision aid, 6 out of 6 criteria to reduce the risk of harmful bias, and 20 and 23 quality criteria according to the IPDASi checklist (v4.0) (Supplementary File 10). The new papers related to IPDAS are updates of the literature informing each of the existing IPDAS criteria but the process to examine how the IPDAS criteria should be formally changed has not yet occurred (as reflected by no changes on the IPDAS website).

As suggested, we have now also assessed user-centredness of our patient decision aid using the 11-item measure of user- and human-centered design for personal health tools (UCD-11).

(Page 11, 3rd paragraph)

We determined that the decision aid (Supplementary File 9) met 6 out of 6 criteria to be considered a decision aid, 6 out of 6 criteria to reduce the risk of harmful bias, and 20 and 23 quality criteria according to the IPDASi checklist (v4.0) [22] (Supplementary File 10). Our decision aid also met 10 out of 11 criteria for user-centredness (Supplementary File 11), as assessed by the User-Centered Design 11-item measure (UCD-11) [23].

COMMENTS TO THE AUTHORS

Please see below for additional comments by section:

Methods

1. Eligibility criteria: Eligible health care professionals had to manage/consult at least five people with suspected subacromial pain syndrome per year. Could the authors clarify the minimum of years of experience the HCP had to have?

AUTHORS' RESPONSE

There was no restriction on years of experience. This has now been clarified in the revised manuscript.

(Page 7, 2nd paragraph)

Health professionals had to manage/consult at least five people with suspected subacromial pain syndrome per year. There was no restriction on the type of health professional (e.g. orthopaedic surgeon, physiotherapist, general practitioner), work setting or country of practice, or years of experience.

COMMENTS TO THE AUTHORS

2. The pre-interview questionnaire was used to purposively sample participants. The authors note that no participant who completed the questionnaire refused an interview. Yet, did the research team turn any potential participant away to achieve a purposive sample?

AUTHORS' RESPONSE

Yes, we had 156 responses to the health professional pre-interview survey and 33 responses to the patient pre-interview survey. We only interviewed 26 health professionals and 14 patients. We have now added this information to the revised manuscript.

(Page 12, 1st paragraph)

No participant who completed the pre-interview questionnaire refused an interview. However, a number of participants who completed the pre-interview questionnaire were not interviewed since participants were purposively sampled (n=130 health professional and n=19 patient respondents were not interviewed).

COMMENTS TO THE AUTHORS

3. The Ottawa Hospital Research institute questionnaire modified for use in this study is intended to rate the Acceptability rather than useability of Patient Decision Aids. Acceptability refers to ratings regarding the comprehensibility of components of a decision aid, its length, amount of information, balance in presentation of information about options, and overall suitability for decision making (<https://protect-au.mimecast.com/s/CyCDCOMKzVTpPLNZEuk0CNt?domain=decisionaid.ohri.ca>) (which is what was collected). Useability, on the other hand, refers to a tool or product's effectiveness, efficiency and

satisfaction in a specified context of use (as defined by the International Organization for Standardization).

AUTHORS' RESPONSE

We agree with the reviewer. Any reference to 'useability' in relation to the modified Ottawa Hospital Research institute questionnaire has now been changed to 'acceptability'.

COMMENTS TO THE AUTHORS

4. Health professionals and patients and who completed an interview were compensated for their time with a \$100 and \$50 supermarket gift card, respectively. It is unclear why health care professionals received a greater sum than patients.

AUTHORS' RESPONSE

We have added an explanation for this.

(Page 10, 1st paragraph)

Health professionals and patients and who completed an interview were compensated for their time with a \$100 and \$50 supermarket gift card, respectively. Health professionals were compensated with more money to account for potentially sacrificing patient appointments to participate in this study.

COMMENTS TO THE AUTHORS

Results:

5. Participating health care providers were from 4 different countries (Australia, Canada, United States and England). Could the authors provide justification for why they recruited internationally, and how participants' different countries of practice may have influenced responses and views of the decision aid given the context in which they practice?

AUTHORS' RESPONSE

We recruited health professionals from various countries to maximise the acceptability of this tool in various countries. Some information had to be made more general to accommodate characteristics of different health systems. For example, we could not be specific about the costs of surgery and non-surgical options as this varies between countries due to factors like health system and insurance coverage. We also received feedback to not only mention doctors as providers of steroid injections; in the UK, this is within the scope of some advanced practice physiotherapists.

This information has been added to the manuscript.

(Page 21, 3rd paragraph)

We included health professionals practising in various countries to maximise the acceptability of this tool globally. As such, some information had to be made more general to accommodate the characteristics of different health systems. For example, we could not be specific about the costs of surgery or non-surgical options as this varies between countries due to factors like health system and insurance coverage. We also received feedback to mention physiotherapists as providers of injections as this is within the scope of some advanced practice physiotherapists in the UK.

COMMENTS TO THE AUTHORS

6. How many iterative cycles of revisions were conducted?

AUTHORS' RESPONSE

Over 10. However, in some cases these were only very minor changes between interviews (e.g. correcting typos, re-wording a sentence). This information has been added to the revised manuscript.

(Page 11, 1st paragraph)

The mapping of themes and sub-themes was iterative as new data emerged so that the decision aid was continually updated before new interviews were conducted. Over 10 iterative cycles of revisions were performed. However, in some cases these were very minor changes (e.g. correcting typos, re-wording a sentence). Patients' views on decisional needs and health professionals' views on patients' decisional needs were integrated with the feedback given on each section of the decision aid to streamline the presentation of the results. Interviews stopped once no new feedback was being provided (data saturation) and participants had an overall positive impression of the decision aid.

COMMENTS TO THE AUTHORS

7. As reported 'yes' in the COREQ checklist, how many repeat interviews were carried out? Who participated in the repeat interviews?

AUTHORS' RESPONSE

We have now added this information to the revised manuscript.

(Page 12, 1st paragraph)

We interviewed 26 health professionals [11 (42%) physiotherapists, 7 (27%) orthopaedic surgeons, 4 (15%) general practitioners, 3 (12%) chiropractors and 1 (4%) osteopath] and 14 patients. Repeat interviews were conducted with one of these health professionals (physiotherapist) and four of these patients to explore whether initial feedback had been addressed through modifications to the decision aid.

COMMENTS TO THE AUTHORS

8. Could the authors specify the number of patients who reported that the DA swayed them away from surgery, and how many were swayed towards surgery? (Lines 333-335)

AUTHORS' RESPONSE

One patient was swayed towards surgery during the first interview. However, their opinion changed in a repeat interview. This has been added to the revised manuscript.

(Page 18, 2nd paragraph)

Some orthopaedic surgeons felt the decision aid was not balanced and biased against surgery. Most patients stated that the decision aid had swayed them away from surgery. One patient was initially swayed towards surgery after reading the decision aid – to have surgery before the risk of complications increased or pain got worse – but changed their mind after reviewing the decision aid in a repeat interview due to lack of evidence of benefit.

COMMENTS TO THE AUTHORS

9. The authors state that a limitation of their study is that they only interviewed people who speak English. Yet, if the decision aid is only available in English, then limiting participants based on language makes sense. May I suggest that the limitation be framed around the fact that only an English language PDA is available at the moment given its in its early development phase, and state any intention for translating the tool in the future.

AUTHORS' RESPONSE

We have revised this limitation as suggested.

(Page 19, 1st paragraph)

Limitations include a small sample size for our quantitative useability data, being unable to recruit certain groups of health professionals (e.g. rheumatologists, sports doctors), and the decision aid only being developed in English (the Steering group will consider cross-cultural adaptation of this tool following its evaluation in a clinical trial).

COMMENTS TO THE AUTHORS

Discussion:

10. In the background, the authors provide compelling data for the global increasing use of subacromial decompression surgery and rotator cuff repair surgery. This, paired with the state of the evidence on the effectiveness of these surgical options, the authors suggest that people may not be making informed treatment choices. Hence, it would be of great interest to explore the role of patient decision aids and a shared decision-making process more broadly, to reduce the overuse of these surgical options.

AUTHORS' RESPONSE

We completely agree. A randomised controlled trial evaluating whether this decision aid reduces people's intentions to undergo shoulder surgery and facilitates informed treatment choices is underway.

VERSION 2 – REVIEW

REVIEWER	Lewis , Krystina University of Ottawa School of Nursing
REVIEW RETURNED	14-Aug-2021

GENERAL COMMENTS	Thank you to the authors for their complete and thorough responses. I have no further comment.
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