

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	EXPERT CONSENSUS ON A STANDARDIZED DEFINITION AND SEVERITY CLASSIFICATION FOR ADVERSE EVENTS ASSOCIATED WITH SPINAL AND PERIPHERAL JOINT MANIPULATION AND MOBILIZATION: PROTOCOL FOR AN INTERNATIONAL E-DELPHI STUDY
AUTHORS	Funabashi, Martha; Pohlman, Katherine A.; Gorrell, Lindsay; Salsbury, Stacie A; Bergna, Andrea; Heneghan, Nicola

VERSION 1 – REVIEW

REVIEWER	Daniels, Clinton VA Puget Sound Health Care System, RCS
REVIEW RETURNED	10-Apr-2021

GENERAL COMMENTS	<p>Thank you for the opportunity to review the manuscript titled, “Expert consensus on a standardized definition and severity classification for adverse events associated with spinal and peripheral joint manipulation and mobilization: protocol for an international E-Delphi study”. The purpose of this manuscript is to transparently report the methodology for operating a Delphi study to standardize the severity and classification of adverse events following spinal manipulative therapy. The project is well thought out and well written. Strengths of the design are the use of multiple rounds to seek consensus, interferential statistics will evaluate consensus, agreement and stability, and that the authors plan to follow the Guidance on Conducting and Reporting Delphi Studies (CREDES) reporting guide. I believe the methodology described will adequately address the projects aims.</p> <p>This is a timely topic for manual therapy providers and one that is well overdue. I look forward to the eventual results of the study and anticipate sharing them with my trainees. The following suggestions may strengthen the article:</p> <p>Abstract:</p> <ol style="list-style-type: none">1. Ok <p>Introduction:</p> <ol style="list-style-type: none">1. Page 5, Lines 15-17 – consider adding OMT or Maitland mobilization grades to the list of SMT terminology.2. Line 17-24 – The ladder portion of this sentence reads as if it is missing the direct object. Consider revising to something like “While both interventions are applied to spinal or peripheral joints, an important distinction is that manipulation usually consists of the application of a dynamic high-velocity, low-amplitude thrust,
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	<p>whereas, mobilization consists of the application of a cyclic low-velocity and variable amplitude manual force."</p> <p>3. Lines 30-32 – The citation here [1] is almost 10 years old. Are there any newer references that demonstrate an increased use of SMT? Also, does this mean "increased use" by providers or the population.</p> <p>4. Line 37-39 – This sentence needs a reference. There also seems to be a bit of a disconnect in the sentence. The first part of the statement reads very generally, "Patient safety is a top priority within healthcare" but the second portion reads very specific "and focuses on minimizing preventable and/or unexpected...". Is there a specific initiative in patient safety you are referring to here? If not, I would qualify with something like the following, "...within healthcare and generally focuses on..."</p> <p>5. Line 55 – By "hospital patients" do you mean in-patient hospital patients? There is plenty of ambulatory care offered in hospital settings.</p> <p>6. Somewhere in the introduction I would like to see some discussion on what is currently known about the incidence, beliefs, and comparative context of adverse events after SMT. A number of studies have been done in this arena, some by the authorship team, that could be cited here:</p> <p>Walker BF, et al. Outcomes of usual chiropractic. The OUCH randomized controlled trial of adverse events. <i>Spine (Phila Pa 1976)</i> 2013;38(20):1723-9.</p> <p>Funabashi M, et al. Belief, perceptions and practices of chiropractors and patients about mitigation strategies for benign adverse events after spinal manipulation therapy. <i>Chiropr Man Ther</i> 2020;28(1):46.</p> <p>Pohlman KA, et al. Assessing adverse events after chiropractic care at a chiropractic teaching clinic: an active-surveillance pilot study. <i>JMPT</i> 2020;43(9):845-854.</p> <p>Carnes D, et al. Adverse events and manual therapy: a systematic review. <i>Man Ther</i> 2010;15(4):355-63.</p> <p>Carlesso LC, et al. Defining adverse events in manual therapy: an exploratory qualitative analysis of the patient perspective. <i>Man Ther</i> 2011;16(5):440-6.</p> <p>Kranenburg HA, et al. Adverse events associated with the use of cervical spine manipulation or mobilization and patient characteristics: a systematic review. <i>Musculoskeletal Sci Pract</i> 2017;28:32-38.</p> <p>Methodology:</p> <p>1. Page 7, Line 3 – The authors state "no register currently exists for Delphi research" which is true. However, there are non-specific registries available that could be utilized, such as Open Science Framework, https://osf.io/registries/</p> <p>2. Page 8, Line 15-17 – How will the groups be monitored? Will there be monitoring to ensure one group is not dominated by a single profession? For example, how will you make sure the "Manual therapy clinicians" group is not all physical therapist or all chiropractors? Is there a maximum number of panelist that will be included?</p> <p>3. Page 9, Line 43 – Regarding Supplementary File 1, will there be additional instructions sent to the panel participants? Not all of the boxes are intuitive to how they would be selected by participants. Some appear to be yes/no, others require inputting specific numbers.</p> <p>a. Does "Highest degrees/education" include both professional and academic degrees? If they have both, are both reported?</p>
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- b. For “Average number of patients/week”, depending on the setting this number may be significantly impacted by COVID-19 restrictions. Consider qualifying by asking for number of patients per week prior to covid or without covid-related restrictions.
- c. Is age or race/ethnicity going to be collected as part of the demographics?
- 4. Line 43 – Why are the round 1 open ended questions not available now? If I am interpreting correctly, these questions are not dependent on the scoping review that is in preparation, so it seems like the authors could have already developed them before this submission. How many questions likely to make up Round 1?
- 5. I like that way that you are approaching this with the open-ended questions initially and saving the scoping review findings and seed statements for round 2. I believe this will help you receive the unbiased information you want!
- 6. Page 10, Line 18 – Reads awkwardly. Consider dropping the “s” from “events”
- 7. Line 36 – Is the “Executive Committee” the authorship team? The steering committee is described on page 14, but I don’t see any description of the executive committee.
- 8. Line 50 – Authors report that statements that do not receive consensus in round 2 will be discarded, but what about statements that nearly reached consensus? Will these be discarded and not be reworked with panel feedback and reviewed again in round 3? Or would you consider an edited statement to be a “new” statement after revisions are made? Maybe I am just confused on the semantics used here. Please clarify.

Data Analysis:

- 1. Page 12, Line 13 – I like your approach to assessing consensus, agreement and stability. Did the executive team come up with the a priori criteria, or has this been done elsewhere previously? If so, please cite.
- 2. Page 13, Lines 16-21 – Thank you for defining the difference between consensus and agreement. I believe this to be an important distinction and reminds me of the difference between sensitivity and specificity. This will be helpful to readers.
- 3. Analysis plan is good.

Discussion:

- 1. Any anticipated limitations or barriers?

Tables

- 1. Table 1:
 - a. Does inclusion in the “Patients” group require exclusion from all of the other groups? Many practitioners, researchers, and students have likely also been patients receiving SMT in the past, but seems to me their opinions on the matter would confound this category.
 - b. Is the “Medical Doctors” group inclusive or exclusive of Doctors of Osteopathy? This may differ elsewhere, but in the US, the majority of DOs practice relatively the same as MDs. I am speculating here, but I imagine most DOs will self-identify more with the “Medical Doctor” group than they would with the “Manual therapy clinicians” group”.
 - c. In several of the groups the authors list professionals that may qualify, “(e.g., physiotherapists, osteopaths, chiropractors and naprapaths). Is there a rhyme or reason to the order these are listed? Why not alphabetical?

	<p>d. In the "Manual therapy clinicians" group you restrict eligibility to those with 7 or greater years of experience. This would seem reasonable, but strikes me as odd since "Manual therapy students" are an included group. Why are students a stand alone category while practicing providers with 0-6 years experience are not eligible?</p> <p>2. Table 3:</p> <p>a. In what order are these listed? Number of individuals representing each group? Or alphabetical? Or both?</p> <p>Again, thanks for the opportunity to review this article. I believe this is an important study and I hope that these recommendations will be useful to the authors.</p>
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REVIEWER	Corkery, Marie B Northeastern University, Physical Therapy, Movement and Rehabilitation Sciences
REVIEW RETURNED	17-Jun-2021

GENERAL COMMENTS	<p>I welcome this international multidisciplinary effort to provide a standardized definition and classification of adverse events following joint manipulation. The background and methods are clearly described. Best of luck with your study and I look forward to the findings. I had a couple of questions and feedback as follows.</p> <p>Introduction It might be helpful in the introduction to provide some context and background for the study to include a little more detail on the current classification system and definitions/terminology used to report for adverse events and why these are deficient.</p> <p>Is it possible to provide more information about the scoping review of the literature to be used to develop the open ended questions, such as databases and search terms? It would be interesting to review the results of this review and the questions developed to evaluate the delphi study in more depth.</p> <p>Page 8, line 26 "the commonly used abbreviation SMT will be used to be inclusive of all these terms and distinctions" Although you have indicated that the abbreviation "SMT" is meant to be inclusive of manipulation/mobilization of peripheral and spinal joints, the individual letters of the acronym itself are not defined. Given that SMT is frequently used to describe "Spinal Manipulative Therapy" this may lead to some confusion among respondents. Supplementary file 1 uses the term SMT/MOB. Perhaps the term SMT could be more clearly defined or a term more reflective of peripheral and spinal manipulation/mobilization could be used?</p> <p>Table 1 For the expert consensus panel, I would suggest ensure that physicians who are more likely to see patients with adverse events from manipulation such as Emergency Room physicians and neurologists are included in this category.</p>
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VERSION 1 – AUTHOR RESPONSE

<p>Reviewer: 1 Dr. Clinton Daniels, VA Puget Sound Health Care System</p> <p>Comments to the Author: Thank you for the opportunity to review the manuscript titled, “Expert consensus on a standardized definition and severity classification for adverse events associated with spinal and peripheral joint manipulation and mobilization: protocol for an international E-Delphi study”. The purpose of this manuscript is to transparently report the methodology for operating a Delphi study to standardize the severity and classification of adverse events following spinal manipulative therapy. The project is well thought out and well written. Strengths of the design are the use of multiple rounds to seek consensus, inferential statistics will evaluate consensus, agreement and stability, and that the authors plan to follow the Guidance on Conducting and Reporting Delphi Studies (CREDES) reporting guide. I believe the methodology described will adequately address the projects aims.</p>	<p>Thank you very much.</p>
<p>This is a timely topic for manual therapy providers and one that is well overdue. I look forward to the eventual results of the study and anticipate sharing them with my trainees. The following suggestions may strengthen the article:</p>	<p>Thank you – we appreciate your comment.</p>
<p>Abstract: 1. Ok</p>	<p>No action taken</p>
<p>Introduction: 1. Page 5, Lines 15-17 – consider adding OMT or Maitland mobilization grades to the list of SMT terminology.</p>	<p>Both terms were added as suggested: “These interventions, which are described in many ways, include amongst others, high-velocity low-amplitude manipulation, low-velocity variable-amplitude mobilization, spinal manipulative therapy, musculoskeletal manipulation, osteopathic manipulative treatment, Maitland mobilization grades, etc.”</p>
<p>2. Line 17-24 – The ladder portion of this sentence reads as if it is missing the direct object. Consider revising to something like “While both interventions are applied to spinal or peripheral joints, an important distinction is that manipulation usually consists of the application of a dynamic high-velocity, low-amplitude thrust, whereas, mobilization consists of the application of a cyclic low-velocity and variable amplitude manual force.”</p>	<p>This sentence was reworded as suggested: “While both interventions are applied to spinal or peripheral joints, an important distinction is that manipulation usually consists of the application of a dynamic high-velocity, low-amplitude thrust; whereas mobilization consists of the application of a cyclic low-velocity and variable amplitude manual force.”</p>
<p>3. Lines 30-32 – The citation here [1] is almost 10 years old. Are there any newer references that demonstrate an increased use of SMT? Also, does this mean “increased use” by providers or the population.</p>	<p>We agree that the reference cited here [1] is from 2012. However, reference [1] was cited as it focused on the interventions, rather than specific professions. While newer references exist (e.g., [2]), they focus on specific professions. We meant “increase use” by and patients:</p>

	<p>“[...] the use of these interventions <u>by patients</u> have also increased.”</p>
<p>4. Line 37-39 – This sentence needs a reference. There also seems to be a bit of a disconnect in the sentence. The first part of the statement reads very generally, “Patient safety is a top priority within healthcare” but the second portion reads very specific “and focuses on minimizing preventable and/or unexpected...”. Is there a specific initiative in patient safety you are referring to here? If not, I would qualify with something like the following, “...within healthcare and generally focuses on...”</p>	<p>There are several initiatives promoting and supporting patient safety worldwide. The World Health Organization (WHO) recently released an action plan focused on eliminating avoidable harm in all health care, which is in line with the “To err is human” report by Kohn et al. in 2000. These references were added to the sentence. We also incorporated this suggestion: “Patient safety is a top priority within healthcare and <u>generally</u> focuses on minimizing preventable and/or unexpected adverse events following any type of intervention, including SMT and MOB.”</p>
<p>5. Line 55 – By “hospital patients” do you mean in-patient hospital patients? There is plenty of ambulatory care offered in hospital settings.</p>	<p>This sentence was changed to “While <u>hospital in-patients</u> are expected to have more adverse events [...]” as suggested.</p>
<p>6. Somewhere in the introduction I would like to see some discussion on what is currently known about the incidence, beliefs, and comparative context of adverse events after SMT. A number of studies have been done in this arena, some by the authorship team, that could be cited here: Walker BF, et al. Outcomes of usual chiropractic. The OUCH randomized controlled trial of adverse events. Spine (Phila Pa 1976) 2013;38(20):1723-9. Funabashi M, et al. Belief, perceptions and practices of chiropractors and patients about mitigation strategies for benign adverse events after spinal manipulation therapy. Chiropr Man Ther 2020;28(1):46. Pohlman KA, et al. Assessing adverse events after chiropractic care at a chiropractic teaching clinic: an active-surveillance pilot study. JMPT 2020;43(9):845-854. Carnes D, et al. Adverse events and manual therapy: a systematic review. Man Ther 2010;15(4):355-63. Carlesso LC, et al. Defining adverse events in manual therapy: an exploratory qualitative analysis of the patient perspective. Man Ther 2011;16(5):440-6. Kranenburg HA, et al. Adverse events associated with the use of cervical spine manipulation or mobilization and patient characteristics: a systematic review. Musculoskeletal Sci Pract 2017;28:32-38.</p>	<p>Thank you for this suggestion. This section was added to the introduction: “Similar to other health care interventions, adverse events after SMT and MOB have been reported. Adverse events attributed mostly to SMT present great variation, ranging from frequent and expected minor adverse events (such as mild discomfort and increased muscle soreness after treatment) to rare and serious adverse events (such as cauda equina syndrome). An accurate estimation of the incidence of adverse events following SMT and MOB remains challenging for several reasons, including the varied definitions of what constitutes an adverse event, and the use of diverse terminology. Specifically, ‘adverse events’, ‘adverse reactions’, ‘complications’, and ‘side-effects’ have been used interchangeably in studies reporting unintended and undesirable outcomes following SMT. Similarly, ‘mild’, ‘minor’ and ‘benign’, as well as ‘major’, ‘severe’ and ‘intense’ have been used to classify the severity of such events. The use of such diverse terminology precludes not only the accurate estimation of adverse events following SMT and MOB, but also advancements of patient safety.”</p>
<p>Methodology: 1. Page 7, Line 3 – The authors state “no register currently exists for Delphi research” which is true. However, there are non-specific registries available that could be utilized, such as Open Science Framework, https://osf.io/registries/</p>	<p>Thank you for this suggestion. This protocol has been registered at Open Science Framework as suggested: “This protocol has been informed by a rigorous scoping review of the literature (in preparation), is in accordance with the “Guidance on Conducting and REporting DELphi Studies (CREDES)” <u>and was registered at Open Science Framework (osf.io/ex3ha).</u>”</p>

<p>2. Page 8, Line 15-17 – How will the groups be monitored? Will there be monitoring to ensure one group is not dominated by a single profession? For example, how will you make sure the “Manual therapy clinicians” group is not all physical therapist or all chiropractors?</p>	<p>As mentioned earlier in this section, recruitment will include calls for expression of interest, at which point potential participants will provide some information (such as profession). Therefore, if an expert group or a profession is underrepresented, additional invitations will be sent. Additional information were added to this section to clarify this point: “While expressing their interest in participating in this study on a REDCap electronic form, potential participants will be asked to provide eligibility information.” “To prevent overrepresentation from one expert group or profession, expressions of interest from potential participants and their eligibility information will be monitored and, to achieve similar number of responses between all professions and groups, additional invitations will be sent to expert groups or professions who are underrepresented.”</p>
<p>Is there a maximum number of panelist that will be included?</p>	<p>In line with other Delphi studies, there is no maximum number of panelists. Our criteria are sufficiently robust and stipulates the requirements for expertise in this highly specialist field.</p>
<p>3. Page 9, Line 43 – Regarding Supplementary File 1, will there be additional instructions sent to the panel participants? Not all of the boxes are intuitive to how they would be selected by participants. Some appear to be yes/no, others require inputting specific numbers. a. Does “Highest degrees/education” include both professional and academic degrees? If they have both, are both reported?</p>	<p>Supplementary File 1 indicates the demographic information that is going to be collected from participants. This information, however, will be collected through a REDCap online form, which includes branching logic and skip patterns to ensure a comprehensive and smooth process for the participant. In other words, the participant will not input their information in the same format as in the table provided in Supplementary File 1. a. We will collect information on both professional and academic degrees.</p>
<p>b. For “Average number of patients/week”, depending on the setting this number may be significantly impacted by COVID-19 restrictions. Consider qualifying by asking for number of patients per week prior to covid or without covid-related restrictions.</p>	<p>b. this is a great point. This item now reads: “Average number of patients/week prior to COVID-19” on Supplementary File 1</p>
<p>c. Is age or race/ethnicity going to be collected as part of the demographics?</p>	<p>c. Again, good suggestion. Age and ethnicity were added to the demographic information being collected on Supplementary File 1.</p>
<p>4. Line 43 – Why are the round 1 open ended questions not available now? If I am interpreting correctly, these questions are not dependent on the scoping review that is in preparation, so it seems like the authors could have already developed them before this submission. How many questions likely to make up Round 1?</p>	<p>While we anticipate having two sections at Round 1 (one section focused on adverse event definition and a separate section focused on the severity classification), these questions were not included in this submission as they are still being developed and require approval from the Steering Committee.</p>
<p>5. I like that way that you are approaching this with the open-ended questions initially and saving the scoping review findings and seed statements for round 2. I believe this will help you receive the unbiased information you want!</p>	<p>Exactly our thoughts – thank you for your support.</p>
<p>6. Page 10, Line 18 – Reads awkwardly. Consider dropping the “s” from “events”</p>	<p>Revised as suggested.</p>

<p>7. Line 36 – Is the “Executive Committee” the authorship team? The steering committee is described on page 14, but I don’t see any description of the executive committee.</p>	<p>The authorship team includes all Executive and Steering Committee members that made significant scientific contributions to this protocol and engaged in manuscript writing. A description of the Executive Committee was added to the manuscript:</p> <p>“Study Executive Committee</p> <p>The Executive Committee is composed of international and multidisciplinary members with expertise in patient safety and SMT and MOB (Table 3). This committee will lead and conduct this study. Tasks include questionnaire development; management of data collection and questionnaire completion; compilation and summarizing results at each round; proposal of additional statements; and preparing reports of final results, such as summary of findings infographic and manuscripts for publication.”</p> <p>Additionally, based on preliminary results from our scoping review, some Steering Committee members were identified as key researchers in this area. Consequently, not including their expertise and opinions would create a major limitation in our Delphi study. To address that, Steering committee members will be allowed to participate in the Delphi study. Importantly, Steering Committee members who participate in the Delphi Study as panellists will not be involved with reviewing each rounds results, questionnaire feedback or statement development. This was added to the Steering Committee description: “Members in this committee will aid in expert participant identification and either provide their opinions and expertise through i) being a participant in the Delphi panel, or ii) providing feedback on questionnaire development, structure and clarity, reviewing study results at each round and approving additional statement inclusion and review study conduct (selected Delphi expert methodologists mentioned in Methods section). Feedback and changes suggested by the Steering Committee members must be approved by the Executive Committee before implementation. At the end of Round 3, all Steering Committee members will aid in the interpretation of final results and dissemination of findings.”</p>
<p>8. Line 50 – Authors report that statements that do not receive consensus in round 2 will be discarded, but what about statements that nearly reached consensus? Will these be discarded and not be reworked with panel feedback and reviewed again in round 3? Or would you consider an edited statement to be a “new” statement after revisions are made? Maybe I am just confused on the semantics used here. Please clarify.</p>	<p>Thank you for this suggestion. Statements nearly achieving consensus will be revised and included in Round 3:</p> <p>“Statements nearly achieving the <i>a priori</i> criteria for consensus will be reviewed on a case-by-case basis and where appropriate, revised statements based on comments from participants will be carried forward to the next round.”</p>

Data Analysis: 1. Page 12, Line 13 – I like your approach to assessing consensus, agreement and stability. Did the executive team come up with the a priori criteria, or has this been done elsewhere previously? If so, please cite.	Thank you for catching this unintended omission. Our a priori criteria were determined based on previous studies and the appropriate citations were included.
2. Page 13, Lines 16-21 – Thank you for defining the difference between consensus and agreement. I believe this to be an important distinction and reminds me of the difference between sensitivity and specificity. This will be helpful to readers.	Thank you – we also think this is an important distinction to be made.
3. Analysis plan is good.	Thank you
Discussion: 1. Any anticipated limitations or barriers?	Recruitment of participants in specific expert groups are anticipated to be challenging (e.g., lawyers and judges).
Tables 1. Table 1: a. Does inclusion in the “Patients” group require exclusion from all of the other groups? Many practitioners, researchers, and students have likely also been patients receiving SMT in the past, but seems to me their opinions on the matter would confound this category.	That is correct and we will recruit patients whose professions do not provide SMT. This was added to the “Patients” inclusion criteria: “An adult (≥ 18 years old) who <u>has not received any training in SMT or MOB</u> and received SMT or MOB from a health care professional (e.g., chiropractors, naprapaths, osteopaths, and physiotherapists) to manage a musculoskeletal condition in the last 12 months”
b. Is the “Medical Doctors” group inclusive or exclusive of Doctors of Osteopathy? This may differ elsewhere, but in the US, the majority of DOs practice relatively the same as MDs. I am speculating here, but I imagine most DOs will self-identify more with the “Medical Doctor” group than they would with the “Manual therapy clinicians” group”.	Thank you for this comment. “Medical doctors” was intended to be exclusive of Doctors of Osteopathy. Potential participants will be asked to specify their profession at the expression of interest and Doctors of Osteopathy will be grouped within the “Manual therapy clinicians” group.
c. In several of the groups the authors list professionals that may qualify, “(e.g., physiotherapists, osteopaths, chiropractors and naprapaths). Is there a rhyme or reason to the order these are listed? Why not alphabetical?”	We agree with the suggestion and the professions are now listed in alphabetical order throughout Table 1.
d. In the "Manual therapy clinicians" group you restrict eligibility to those with 7 or greater years of experience. This would seem reasonable, but strikes me as odd since "Manual therapy students" are an included group. Why are students a stand alone category while practicing providers with 0-6 years experience are not eligible?	Students are a stand-alone group as they are the future clinicians who will be using the results of this study. Therefore, we would like to include their perspective and have their contribution.
2. Table 3: a. In what order are these listed? Number of individuals representing each group? Or alphabetical? Or both?	These are listed following the same order as Table 1 (researchers/academics and clinicians) with manual therapy professions being listed first in alphabetical order (chiropractor, naprapath, osteopath, and physiotherapist), followed by other professions also in alphabetical order (medical doctors and nurse)
Again, thanks for the opportunity to review this article. I believe this is an important study and I hope that these recommendations will be useful to the authors.	Thank you very much for your support and useful comments.

<p>Reviewer: 2 Dr. Marie B Corkery, Northeastern University</p> <p>Comments to the Author: I welcome this international multidisciplinary effort to provide a standardized definition and classification of adverse events following joint manipulation. The background and methods are clearly described. Best of luck with your study and I look forward to the findings. I had a couple of questions and feedback as follows.</p>	<p>Thank you very much for your support to our study.</p>
<p>Introduction It might be helpful in the introduction to provide some context and background for the study to include a little more detail on the current classification system and definitions/terminology used to report for adverse events and why these are deficient.</p>	<p>Thank you for this suggestion, which aligns with one of Reviewer 1's suggestion. The following section was added to the introduction: "Similar to other health care interventions, adverse events after SMT and MOB have been reported. Adverse events attributed mostly to SMT present great variation, ranging from frequent and expected minor adverse events (such as mild discomfort and increased muscle soreness after treatment) to rare and serious adverse events (such as cauda equina syndrome). An accurate estimation of the incidence of adverse events following SMT and MOB remains challenging for several reasons, including the varied definitions of what constitutes an adverse event, and the use of diverse terminology. Specifically, 'adverse events', 'adverse reactions', 'complications', and 'side-effects' have been used interchangeably in studies reporting unintended and undesirable outcomes following SMT. Similarly, 'mild', 'minor' and 'benign', as well as 'major', 'severe' and 'intense' have been used to classify the severity of such events. The use of such diverse terminology precludes not only the accurate estimation of adverse events following SMT and MOB, but also advancements of patient safety."</p>
<p>Is it possible to provide more information about the scoping review of the literature to be used to develop the open ended questions, such as databases and search terms? It would be interesting to review the results of this review and the questions developed to evaluate the delphi study in more depth.</p>	<p>Round 1 questions were not included in this submission as they are still being developed and require approval from the Steering Committee. Information about the scoping review was added as suggested: "A detailed description of the scoping review is currently under preparation. Briefly, a literature search strategy was developed with assistance of a health sciences librarian and comprised of combinations of indexing terms (MESH and non-MESH), such as musculoskeletal manipulation, adverse event and definition or classification. Databases, such as MEDLINE, EMBASE CINAHL and Scopus were search as well as grey literature and theses and dissertations. Relevant studies were identified and definition and classification of adverse events following after SMT and MOB were extracted."</p>

<p>Page 8, line 26 “the commonly used abbreviation SMT will be used to be inclusive of all these terms and distinctions” Although you have indicated that the abbreviation “SMT” is meant to be inclusive of manipulation/mobilization of peripheral and spinal joints, the individual letters of the acronym itself are not defined. Given that SMT is frequently used to describe “Spinal Manipulative Therapy” this may lead to some confusion among respondents. Supplementary file 1 uses the term SMT/MOB. Perhaps the term SMT could be more clearly defined or a term more reflective of peripheral and spinal manipulation/mobilization could be used?</p>	<p>Thank you for this comment. To avoid confusion and to be more inclusive of peripheral and spinal manipulation and mobilization, the term “SMT” was replaced by “manipulative therapy (SMT)” and “mobilization (MOB)” throughout the manuscript. This was outlined in the introduction: “For the purpose of this manuscript, “SMT” will be used to refer to manipulative therapy and “MOB” will be used to refer to mobilization.”</p>
<p>Table 1 For the expert consensus panel, I would suggest ensure that physicians who are more likely to see patients with adverse events from manipulation such as Emergency Room physicians and neurologists are included in this category.</p>	<p>Thank you very much for this suggestion. We will definitely keep that in mind when recruiting for the study.</p>

VERSION 2 – REVIEW

REVIEWER	Daniels, Clinton VA Puget Sound Health Care System, RCS
REVIEW RETURNED	25-Sep-2021

GENERAL COMMENTS	<p>Thank you for the opportunity to review this revised manuscript. The authors have thoroughly and impressively addressed all of my comments, questions, and concerns. I look forward to reading the results of this study in the coming years.</p>
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REVIEWER	Corkery, Marie B Northeastern University, Physical Therapy, Movement and Rehabilitation Sciences
REVIEW RETURNED	20-Sep-2021

GENERAL COMMENTS	<p>Thank you for enhancing the introduction and providing clarification on the definitions. I believe all of my previous comments have been addressed. Aside from the following minor typos, i have no additional comments or feedback. Best of luck with your study!</p> <p>Under Round 2, Line 20, replace "comprised of" with "composed of" or "comprised" Line 25, change "search" to "searched"</p> <p>References Check reference 3 for formatting.</p>
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