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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

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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

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ABSTRACT

Introduction

Spinal and peripheral joint manipulation and mobilization are widely used and recommended in best practice guidelines for managing spinal pain. Similar to other interventions, adverse events (AEs) have been reported following these interventions. However, a clear AE definition and classification system remains unsettled. With many professionals using spinal and peripheral joint manipulation and mobilization, establishing consensus on a definition and classification system is needed to assist with the assimilation of AEs data across professions and to inform research priorities to optimise safety in clinical practice.

Methods and analysis

This international multidisciplinary e-Delphi study protocol is informed by a scoping review and in accordance with the "Guidance on Conduction and Reporting Delphi Studies". With oversight from an expert steering committee, the study comprises 3 rounds using online questionnaires. Experts in manual therapy and patient safety meeting strict eligibility criteria from the following fields will be invited to participate: clinical, medical and legal practice, health records, regulatory bodies, researchers and patients. Round 1 will include open-ended questions on participants' working definition and/or understanding of AEs following spinal and peripheral joint manipulation and mobilization and their severity classification. In round 2, participants will rate their level of agreement with statements generated from round 1 and our scoping review. In round 3, participants will re-rate their agreement with statements achieving consensus in round 2. Statements reaching consensus must meet the *a priori* criteria, as determined by descriptive analysis. Inferential statistics will be used to evaluate agreement between participants and stability of responses between rounds. Statements achieving consensus in round 3 will provide an expert-derived definition and classification system for AEs following spinal and peripheral joint manipulation and mobilization.

Ethics and dissemination

This study was deemed exempt by Parker University's Institutional Review Board (A-00218). Results will be disseminated through publications and presentations.

KEYWORDS

Adverse event; classification; spinal manipulation; spinal mobilization; joint manipulation; joint mobilization; Delphi technique

ARTICLE SUMMARY

Strengths and limitations of this study

- This study protocol is based on a formal scoping review of the literature and the published "Guidance on Conducting and REporting DElphi Studies (CREDES)"
- Researchers will represent all professional groups who perform spinal and peripheral joint manipulation and mobilization as part of routine clinical practice
- Participants will involve international and multidisciplinary spinal and peripheral joint manipulation and mobilization stakeholder representatives
- Definitions and *a priori* criteria for consensus, agreement and stability are detailed
- Findings will be specific to spinal and peripheral joint manipulation and mobilization, limiting the external validity to other manual therapy techniques

INTRODUCTION

Spinal and peripheral joint manipulation and mobilization are interventions commonly used in the management of many musculoskeletal conditions, including spinal pain, and are most often administered in ambulatory care settings.[1,2] These interventions have a vast array of terms to describe them, including high-velocity low-amplitude manipulation, low-velocity variable-amplitude mobilization, spinal manipulative therapy, musculoskeletal manipulation, among others. Another important distinction is that manipulation usually consists of the application of a dynamic high-velocity, low-amplitude thrust to the spine or peripheral joint, whereas mobilization consists of the application of a cyclic low-velocity and variable amplitude force.[3] For ease of reading, the commonly used abbreviation "SMT" will be used to be inclusive of all these terms and distinctions. With increasing evidence supporting the effectiveness of SMT to reduce pain and improve function in patients with musculoskeletal conditions,[4–6] the use of these interventions have also increased.[1] However, research that demonstrates the safety of these approaches have lagged behind efforts to establish the efficacy of these interventions.

Patient safety is a top priority within healthcare and focuses on minimizing preventable and/or unexpected adverse events following any type of intervention, including SMT. Despite this awareness, efforts to reduce adverse events within the SMT field have been minimal.[7–10] In 2015, a National Patient Safety Foundation expert panel emphasized that patient safety was still a major public health issue.[11] Their key recommendation included the creation of a common set of safety metrics that reflect meaningful outcomes and focused on ambulatory centers, as the usage of such sites is substantially higher than those located in hospital settings (1 billion annual visits versus 35 million annual admissions, respectively).[12]

While hospital patients are expected to have more adverse events due to their acute condition and undergoing more invasive procedures,[13] it is still important to collect adverse events data following SMT interventions in a standardized way.[14] Systematic evaluation and reporting would

significantly facilitate a better understanding of observed adverse events and ideally allow for the development of strategies to prevent the occurrence of such events. More specifically, this standardization includes the operational definition of what constitutes an adverse event and the severity classification system for similar modalities. By establishing consensus on the definition and the use of a standardised severity classification system, adverse event reports following SMT can then be better identified and put into the same frame of reference across professions. This has the potential to significantly advance the knowledge related to adverse events, promoting a fundamental advancement in patient safety and quality of care for SMT.

Aims

The aims of this Delphi study are to determine, by an expert consensus process, a standardized definition and severity classification for adverse events following SMT, within an adult population with musculoskeletal conditions, for use in both clinical care and research studies.

METHODOLOGY

Design and justification

The electronic Delphi (e-Delphi) method is suited to achieving consensus amongst experts through the independent completion of sequential questionnaires that are refined by participant feedback resulting in a convergence of opinion and eventual consensus.[15] An e-Delphi method in this instance overcomes barriers to other consensus approaches e.g., nominal group technique, differences in geographical location, time zones, etc. This method therefore allows us to approach experts globally and without limits to specific participant groups.

This protocol has been informed by a rigorous scoping review of the literature (in preparation), and in accordance with the “Guidance on Conducting and REporting DElphi Studies (CREDES)”.[16] While

no register currently exists for Delphi research, the protocol is being published *a priori* to ensure quality, rigour and transparency. Our three-round e-Delphi procedure is outlined in Figure 1 with data collection taking place between September 2021 and April 2022. Using the Research Electronic Data Capture system (REDCap) platform, all rounds will be completed electronically and confidentially. In round 1, participants will be invited to answer open-ended questions on their working definition and/or understanding of adverse events and their current severity classification for SMT. In round 2, participants will rate their level of agreement with statements generated from round 1 and results from the scoping review of the literature using a 5-point Likert scale. In round 3, participants will re-rate their agreement with statements that achieved consensus in round 2. Statements reaching consensus must meet the *a priori* criteria at rounds 2 and 3.

Expert Eligibility and Sample

Experts will be defined as adult individuals with a high level of knowledge within the area of patient safety and adverse events related to SMT for musculoskeletal conditions which will be confirmed using the eligibility criteria (See Table 1). Potentially eligible participants will be identified through existing professional networks and social media/internet-based searching. They will be recruited worldwide and need to be aged 18 or above, able to read and write in English, and willing to participate by providing signed informed consent. Through email, potential participants will be invited to participate by an author or by their professional network connection. Recruitment will be maximized by encouraging identified experts to snowball the invitation with other potential expert participants, including calls for expressions of interest on social media and professional organisations and networks.

Informed consent will be obtained electronically through REDCap. Recruitment will continue for 8 weeks with a reminder email sent at weeks 2, 4 and 6. Should no contact be made after 8 weeks, no further communication will be sent.[17]

Sample size in previously published Delphi studies and expert panels have ranged from 4 to 3000.[18] Previous Delphi studies with an aim of defining intervention adverse events and complications typically achieved consensus with responses from 30-73[19–22] experts in the final round and therefore a conservative estimate of 75 responses are required. Assuming a response rate of 70%, a minimum of 108 experts are required to complete the consent form to ensure at least 75 responses.[15] To prevent overrepresentation from one expert group or profession, recruitment will be monitored to achieve similar number of responses between all professions and groups.

Table 1. Eligibility criteria for expert consensus panel. Abbreviations – SMT: spinal and peripheral joint manipulation and mobilization.

Expert group	Inclusion criteria
Researchers	• ≥2 peer reviewed publications (scoping or systematic review, randomized controlled trials, prospective cohort, retrospective case-control or case series, qualitative studies, basic science mechanistic) relating to patient safety or adverse events and SMT in the previous 10 years
Manual therapy clinicians	• A clinical professional with ≥7 years of clinical practice experience using SMT to manage musculoskeletal conditions in adults (e.g., physiotherapists, osteopaths, chiropractors and naprapaths)
Patients	• An adult (≥ 18 years old) who has received SMT from a health care professional (e.g., physiotherapists, osteopaths, chiropractors and naprapaths) to manage a musculoskeletal condition in the last 12 months
Medical doctors	• A medical doctor who has a professional interest in SMT (e.g., refers patients to manual therapy providers, has treated patients who presented with an adverse event potentially related to SMT) and/or adverse events following conservative treatments
Manual therapy students	• A student (≥ 18 years old) actively enrolled in a professional program that includes SMT to manage musculoskeletal conditions in adults in their curriculum (e.g., physiotherapists, osteopaths, chiropractors and naprapaths)
Professional regulatory body representatives	• An adult (≥ 18 years old) who is involved with local or federal policy and regulations for professions that use SMT to manage musculoskeletal conditions in adults (e.g., physiotherapists, osteopaths, chiropractors and naprapaths)

Malpractice insurance representatives	• A professional malpractice insurance employee (≥ 18 years old) who is involved with malpractice claims for professions that use SMT to manage musculoskeletal conditions in adults (e.g., physiotherapists, osteopaths, chiropractors and naprapaths)
Lawyers or judges	• A licensed legal professional who has an interest in medico-legal actions involving adverse events following conservative treatment and/or professions that use SMT to manage musculoskeletal conditions in adults (e.g., physiotherapists, osteopaths, chiropractors and naprapaths)
Data analysts or informatics/electronic health record representatives	• An adult (≥ 18 years old) with expertise in collecting standardized health data including, but not limited to adverse events, for professions that use SMT to manage musculoskeletal conditions in adults (e.g., physiotherapists, osteopaths, chiropractors and naprapaths).

Procedure

Round 1

The objectives of round 1 are to collect participant demographic information and generate statements on the definition and severity classification of adverse events following SMT. Participants will complete the "Demographic Information Form" specific to their expert group (i.e., researcher, manual therapy clinician, patient, medical doctor, student, professional regulatory body, malpractice insurance and informatics/electronic health records representatives, lawyers and judges) (Supplementary file 1). The round 1 questionnaire will consist of open-ended questions. Open-ended questions improve content validity as statements are generated by expert opinion.[15,23,24] Statements based on the results of the scoping literature review will be generated and included in round 2, rather than round 1, to allow participants to provide their expert opinion without bias from the literature, thereby reducing experimenter bias.[25] The round 1 questions will ask participants to define their current understanding of adverse events and their severity classification following SMT. This may or may not include providing references or resources to support their definition or classification. Participants will have the opportunity to provide general comments related to this topic

at the end of the questionnaire. The round 1 questionnaire will be piloted for feedback on readability, relevance and appropriateness through the Steering Committee and edited accordingly. Round 1 will be open for 6 weeks with email reminders being provided at weeks 1, 3 and 5.

Round 2

The objectives of round 2 are to evaluate consensus of statements developed from the round 1 questionnaire and scoping review findings regarding adverse events definitions and their severity classification following SMT in adults with musculoskeletal conditions, and to identify any further statements. Participants will be provided with feedback explaining how statements were generated from round 1 and then asked to rate their agreement with the provided statements using a 5-point Likert scale where 1=strongly disagree and 5=strongly agree.[26] A 5-point scale is preferred as it displays acceptable psychometric properties while being quick and easy for participants to complete, thus reducing frustration and demotivation.[27] An open text box will be included for each statement to allow for any additional comments that may generate further statements. All comments will be analysed by the Executive Committee and reviewed by the Steering Committee. All participants will be invited to take part in round 2, including those who did not complete round 1, provided they have not withdrawn from the study. This provides the opportunity for participants to continue their involvement even when unable to complete previous rounds.[15] As per round 1, the round 2 questionnaire will remain active for 6 weeks with email reminders sent at weeks 1, 3 and 5.

Round 3

The objective of round 3 is to further evaluate statements regarding adverse events definitions and their severity classification following SMT. The round 3 questionnaire will include feedback from round 2 using descriptive statistics and qualitative comments, promoting participant reflection before completing the questionnaire. In round 3, participants will be asked to rate their agreement with the

statements achieving consensus from round 2 using the same 5-point Likert scale. Statements that do not achieve consensus in round 2 will be discarded. A free-text box will be provided for participants to clarify responses, but the generation of new statements will not be encouraged. All responses will be analysed by the Executive Committee and reviewed by the Steering Committee. All participants will be invited to participate in round 3, which will again remain active for 6 weeks with email reminders sent at weeks 1, 3 and 5.

Data Analysis

Quantitative data analysis will be conducted using R: A language and environment for statistical computing (R Foundation for Statistical Computing, Vienna, Austria). Qualitative data analysis will be conducted using Microsoft Excel (Microsoft Corporation, USA). Qualitative data will be analysed independently by two researchers (MF/LG) at each round and disagreements will be resolved by discussion and consensus with the consultation of a third reviewer (KP), if needed.

Complete agreement between Executive Committee members is required for statements to be included, with disagreements resolved by discussion.[28] The Steering Committee will have the opportunity to review the data and interpretation of findings at each stage for feedback and editing before dissemination to the e-Delphi participants for the next round.

Round 1

Qualitative data from open-ended questions will be examined using a theoretical thematic analysis to generate statements under themes pre-identified from the scoping review of the literature and then examined inductively for any new themes.[29,30] Wording used by participants will be combined to generate statements that best represent similar statements across participants.[25] Statements generated from the results of the scoping review of the literature not identified from participant responses will also be included. For a statement to be included, it must be described at least once by

any participant or via results of the scoping review of the literature, therefore all standalone statements will be kept and included. The round 2 questionnaire will be constructed using the statements generated.

Round 2

Descriptive and inferential statistics will be used to evaluate agreement and consensus (Table 2). Any statements not achieving the *a priori* criteria for consensus will be discarded (median ≥3.5; interquartile range ≤1.5 & percentage agreement ≥60%). Qualitative data from comments will be analysed using thematic analysis for the emergence of any new statements.

Round 3

Descriptive and inferential statistics will evaluate consensus against *a priori* criteria (median ≥3.5; interquartile range ≤1 & percentage agreement ≥70%) (Table 2). Statements achieving consensus after round 3 will be used to define adverse events and their severity classification following SMT. Statements that fail to achieve consensus in round 3 will be discarded.

Table 2. Definitions and statistical measures of consensus, agreement and stability. Abbreviations – IQR: Interquartile Range; NA: not applicable.

	Definition	**Statistics**	**Round 2**	**Round 3**
Consensus	The extent to which the group of experts share the same opinion	Median IQR Percent agreement	≥3.5 ≤1.5 ≥60%	≥3.5 ≤1 ≥70%
Agreement	A measure of inter-rater agreement where the rating of one expert can be predicted by the rating of another	Kendall's coefficient of concordance	Significant agreement ($p<0.05$)	Significant agreement ($p<0.05$)
Stability	The consistency of responses between successive rounds	Wilcoxon rank-sum test	NA	Significance level $p<0.05$

Consensus, Agreement and Stability

Definitions and statistical measures of consensus and agreement described in the literature for Delphi studies are conflicting.[28,31–33] Specifically, while consensus and agreement have been used interchangeably,[33] unique definitions have also been recommended.[34] Therefore, this study will use the following definitions:

- Consensus – the extent to which the group of experts share the same opinion[33]
- Agreement – a measure of inter-rater agreement where the rating of one expert can be predicted by the rating of another[35]
- Stability – the consistency of responses between successive rounds[33]

Consensus, agreement and stability will be assessed in each round using a combination of descriptive and inferential statistics (Table 2).[28,31,32] Consensus will be evaluated using descriptive statistics of central tendency and dispersion. As the Likert scale is considered an ordinal scale,[36] median and interquartile range (IQR) will be used.[33,36] Percent agreement, defined as the percentage of responses rated agree/strongly agree will also be used to evaluate consensus amongst experts for each statement.[37] Progressively increased criteria will be used between rounds 2 and 3 to encourage convergence and strengthen overall consensus.[37] Agreement between experts across all items and within categories identified after round 1 will be evaluated using Kendall's Coefficient of Concordance (*W*) where 0 is no agreement and 1 is perfect agreement.[35] Stability of the responses between rounds 2 and 3 will be evaluated using the Wilcoxon rank-sum test.[33] Statistical significance will be set at $p < 0.05$.

Data Management

All data will be managed using REDCap electronic data capture tools,[38] which is hosted at Parker University, Dallas, TX, USA. REDCap is a secure, web-based application designed to support data capture for research studies. All personal information and data will be kept secure from any third party

using a password-protected computer during the study. Only members of the study team will have access to the study data. On completion of the study, the data will be kept securely for 10 years at Parker University, Dallas, TX, USA, before being securely destroyed in accordance with the institution's guidelines.

Study Steering Committee

The Steering Committee is composed of international and multidisciplinary members with expertise in patient safety, methodology and SMT (Table 3). This committee will provide overall study oversight and meet at key stages throughout the study to provide feedback on questionnaire development, structure and clarity; aid in expert participant identification; review study results at each round and approve additional statement inclusion; review study conduct; and aid in the dissemination of findings. Feedback and changes suggested by the Steering Committee must be approved by the Executive Committee before implementation.

Table 3. Steering Committee members' background and geographical location.

Background	Geographical Location
Academic chiropractor	Australia, Canada, Switzerland and USA
Academic naprapath	Sweden
Academic physiotherapist	Canada and UK
Academic osteopath	Italy, Switzerland, UK
Academic medical doctor	Canada
Academic nurse	USA
Clinical chiropractor	USA, Australia
Clinical osteopath	Italy
Clinical medical doctor	Canada

Ethics

This study was submitted to Parker University's Institutional Review Board and deemed exempt (A-00218). Freely given e-informed consent will be obtained from all participants prior to participation

through REDCap. Participants will be informed of the withdrawal process and assured anonymity throughout the study and during dissemination.

Patient and Public Involvement

The study was conceived from our experience working with clinicians and patients using SMT and their views were used to highlight the relevance of this research. Our Steering Committee will include a patient representative who will co-design the "Participant Information Sheets", expression of interest emails/social media posts and developing the round 1 questionnaire. It is anticipated that our patient representative will also contribute to reviewing results at each round and support interpretation of findings. Our patient representative will be central to our dissemination strategy including patient cohorts. A summary of results will be disseminated to all professions through professional organizations newsletter, conferences and reports. Feedback from professional groups will be invited to inform future studies and to facilitate the ongoing collaboration of an international, multidisciplinary research working group to support advancement of knowledge in the field of AE. Patient and public involvement in the full study will be reported using the "Guidance for Reporting Involvement of Patients and the Public2-short form (GRIPP2-SF)"[39] when disseminating the study results.

DISCUSSION

This e-Delphi study will provide expert consensus on the definition of adverse events and their severity classification following SMT, that could not be determined from the current literature. Conducting a Delphi study electronically allows the development of expert informed recommendations from a wide range of specialists, regardless of geographical location, and who can participate confidentially, which is considered a strength. Another noticeable strength of this study is the active participation and

collaboration of several professions that routinely perform SMT when treating patients with musculoskeletal conditions (i.e., chiropractic, naprapathy, physiotherapy and osteopathy). Inclusion of international and multidisciplinary experts will ensure that the unique views and opinions of each profession and expert group is taken into consideration, while creating a standardized definition of adverse events and severity classification. Critically establishing standardized definitions and severity classifications across professions will significantly advance the evidence concerning adverse events. Drawing on a single expert multi-professional framework will contribute to enhancing the consistency in recording adverse events and will, in time, improve our understanding of the adverse events following SMT. From this, strategies to prevent and mitigate such events may be developed, which can significantly increase the knowledge related to adverse events, promoting a fundamental advancement in patient safety and quality of care for all professions that use SMT.

AUTHOR CONTRIBUTIONS

MF, KP, LG, AB and NH are leading the protocol development, analyses, and dissemination. Data analysis will be completed independently by MF and LG with oversight by KP, AB and NH. SS is a member of the Steering Committee overseeing protocol development and made significant contributions to this manuscript. All authors and Steering Committee members will be involved in interpretation of the findings and dissemination strategy. All authors have contributed to the design and development of the protocol and have contributed to the manuscript draft. All authors have read, provided feedback and approved the final manuscript.

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PATIENT CONSENT FOR PUBLICATION

Not required

CONFLICT OF INTEREST

The authors declare that they have no competing interests.

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FIGURE LEGENDS

Figure 1. Delphi study procedures

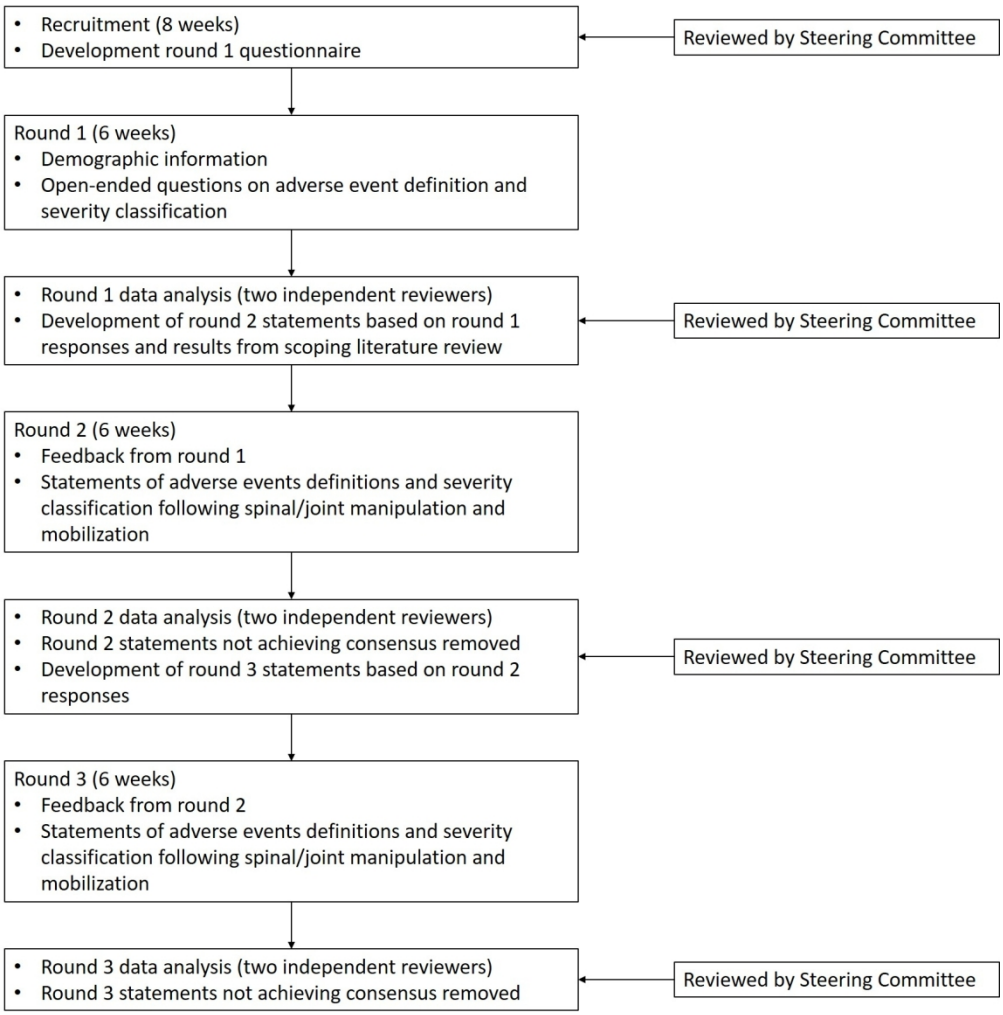

Figure 1. Delphi study procedures

146x148mm (300 x 300 DPI)

SUPPLEMENTARY FILE 1

Demographic information

	Researcher	*Manual Therapy Clinician*	*Medical Doctor*	*Patients*	*Manual Therapy Student*	*Regulatory Body Representative*	*Malpractice Insurance Representative*	*Lawyers and Judges*	*Data analysts or Informatics/ Electronic health records Representative*
Sex									
Country									
Profession/Occupation									
Highest degrees/education									
Highest degree year									
Work/Academic/Patient Care/Regulatory Setting				Patient Care Setting					
Years clinical experience (overall)					Months				
Years clinical experience with SMT/MOB									
Average number of patients/week									
Clinical experience with adverse events following SMT/MOB									

Number of peer-reviewed publications									
Number of publications related to patient safety or adverse events for SMT/MOB in the past 10 Years									
Musculoskeletal condition									
Musculoskeletal condition duration									
Profession received SMT/MOB from									
Have received SMT/MOB as patient									
Experienced adverse event as a patient									
Specialist training/ professional interest in SMT/MOB									

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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

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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

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ABSTRACT

Introduction

Spinal and peripheral joint manipulation (SMT) and mobilization (MOB) are widely used and recommended in best practice guidelines for managing musculoskeletal conditions. Although adverse events (AEs) have been reported following these interventions, a clear definition and classification system for AEs remains unsettled. With many professionals using SMT and MOB, establishing consensus on a definition and classification system is needed to assist with the assimilation of AEs data across professions and to inform research priorities to optimise safety in clinical practice.

Methods and analysis

This international multidisciplinary e-Delphi study protocol is informed by a scoping review and in accordance with the "Guidance on Conduction and Reporting Delphi Studies". With oversight from an expert steering committee, the study comprises 3 rounds using online questionnaires. Experts in manual therapy and patient safety meeting strict eligibility criteria from the following fields will be invited to participate: clinical, medical and legal practice, health records, regulatory bodies, researchers and patients. Round 1 will include open-ended questions on participants' working definition and/or understanding of AEs following SMT and MOB and their severity classification. In round 2, participants will rate their level of agreement with statements generated from round 1 and our scoping review. In round 3, participants will re-rate their agreement with statements achieving consensus in round 2. Statements reaching consensus must meet the *a priori* criteria, as determined by descriptive analysis. Inferential statistics will be used to evaluate agreement between participants and stability of responses between rounds. Statements achieving consensus in round 3 will provide an expert-derived definition and classification system for AEs following SMT and MOB.

Ethics and dissemination

This study was approved by the Canadian Memorial Chiropractic College Research Ethics Board and deemed exempt by Parker University's Institutional Review Board. Results will be disseminated through scientific, professional and educational reports, publications and presentations.

KEYWORDS

Adverse event; classification; spinal manipulation; spinal mobilization; joint manipulation; joint mobilization; Delphi technique

ARTICLE SUMMARY

Strengths and limitations of this study

- This study protocol is based on a formal scoping review of the literature and the published "Guidance on Conducting and REporting DElphi Studies (CREDES)"
- Researchers will represent all professional groups who perform spinal and peripheral joint manipulation and mobilization as part of routine clinical practice
- Participants will involve international and multidisciplinary spinal and peripheral joint manipulation and mobilization stakeholder representatives
- Definitions and *a priori* criteria for consensus, agreement and stability are detailed
- Findings will be specific to spinal and peripheral joint manipulation and mobilization, limiting the external validity to other manual therapy techniques

INTRODUCTION

Spinal and peripheral joint manipulation and mobilization are interventions commonly used in the management of many musculoskeletal conditions, including spinal pain, and are most often administered in ambulatory care settings.[1,2] 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*. 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.[3] For the purpose of this manuscript, "SMT" will be used to refer to manipulative therapy and "MOB" will be used to refer to mobilization.

With increasing evidence supporting the effectiveness of SMT and MOB to reduce pain and improve function in patients with musculoskeletal conditions,[4–6] the use of these interventions by patients have also increased.[1] However, research that demonstrates the safety of these approaches have lagged behind efforts to establish the efficacy of these interventions.

Patient safety is a top priority within healthcare and generally focuses on minimizing preventable and/or unexpected adverse events following any type of intervention, including SMT and MOB.[7,8] Despite this awareness, efforts to reduce adverse events within the SMT and MOB fields have been minimal.[7,9–11] In 2015, a National Patient Safety Foundation expert panel emphasized that patient safety was still a major public health issue.[12] Their key recommendation included the creation of a common set of safety metrics that reflect meaningful outcomes and focused on ambulatory care centers; patient contact in such sites is substantially higher than those located in hospital settings (1 billion annual visits versus 35 million annual admissions, respectively).[13]

While hospital in-patients are expected to have more adverse events due to their acute condition and undergoing more invasive procedures,[14] it is still important to collect adverse events data following SMT interventions in a standardized way.[15] 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).[16–19] 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.[20] Specifically, 'adverse events', 'adverse reactions', 'complications', and 'side-effects' have been used interchangeably in studies reporting unintended and undesirable outcomes following SMT.[21–24] Similarly, 'mild', 'minor' and 'benign', as well as 'major', 'severe' and 'intense' have been used to classify the severity of such events.[25–27] 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.

To address these concerns, the systematic evaluation and reporting of adverse events following SMT and MOB would significantly facilitate a better understanding of such events and potentially allow for the development of strategies to prevent and manage their occurrence. More specifically, this standardization includes the operational definition of what constitutes an adverse event and the severity classification system for similar modalities. By establishing consensus on the definition and the use of a standardised severity classification system, adverse event reports following SMT and MOB can then be better identified and put into the same frame of reference across professions. This has the potential to significantly advance the knowledge related to adverse events, promoting a fundamental advancement in patient safety and quality of care for SMT and MOB.

Aims

The aim of this Delphi study is to determine, by an expert consensus process, a standardized definition and severity classification for adverse events following SMT and MOB, within an adult population with musculoskeletal conditions, for use in both clinical care and research studies.

METHODOLOGY

Design and justification

The electronic Delphi (e-Delphi) method is suited to achieving consensus amongst experts through the independent completion of sequential questionnaires that are refined by participant feedback resulting in a convergence of opinion and eventual consensus.[28] An e-Delphi method in this instance overcomes barriers to other consensus approaches e.g., nominal group technique, differences in geographical location, time zones, etc. This method therefore allows us to approach experts globally and without limits to specific participant groups.

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)"[29] and was registered at Open Science Framework (osf.io/ex3ha). This protocol is also being published *a priori* to ensure quality, rigour and transparency. Our three-round e-Delphi procedure is outlined in Figure 1 with data collection taking place between November 2021 and June 2022. Using the Research Electronic Data Capture system (REDCap) platform, all rounds will be completed electronically and confidentially. In round 1, participants will be invited to answer open-ended questions on their working definition and/or understanding of adverse events and their current severity classification for SMT and MOB. In round 2, participants will rate their level of agreement with statements generated from round 1 and results from the scoping review of the literature using a 5-point Likert

scale. In round 3, participants will re-rate their agreement with statements that achieved consensus in round 2. Statements reaching consensus must meet the *a priori* criteria at rounds 2 and 3.

Expert Eligibility and Sample

Experts will be defined as adult individuals with a high level of knowledge within the area of patient safety and adverse events related to SMT and MOB for musculoskeletal conditions which will be confirmed using the eligibility criteria (See Table 1). Potentially eligible participants will be identified through existing professional networks and social media/internet-based searching. They will be recruited worldwide and be aged 18 or above, able to read and write in English, and willing to provide signed informed consent. Through email, potential participants will be invited to participate by an author or via their professional network connection. Recruitment will be maximized by encouraging identified experts to snowball the invitation with other potential expert participants, including calls for expressions of interest on social media and professional organisations and networks. While expressing their interest in participating in this study on a REDCap electronic form, potential participants will be asked to provide eligibility information.

Informed consent will be obtained electronically through REDCap. Recruitment will continue for 8 weeks with a reminder email sent at weeks 2, 4 and 6. Should no contact be made after 8 weeks, no further communication will be sent.[30]

Sample size in previously published Delphi studies and expert panels have ranged from 4 to 3000.[31] Previous Delphi studies with an aim of defining intervention adverse events and complications typically achieved consensus with responses from 30-73[32–35] experts in the final round and therefore a conservative estimate of 75 responses are required. Assuming a response rate of 70%, a minimum of 108 experts are required to complete the consent form to ensure at least 75 responses.[28] 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.

Table 1. Eligibility criteria for expert consensus panel.

Expert group	Inclusion criteria
Researchers	• ≥2 peer reviewed publications (scoping or systematic review, randomized controlled trials, prospective cohort, retrospective case-control or case series, qualitative studies, basic science mechanistic) relating to patient safety or adverse events and SMT in the previous 10 years
Manual therapy clinicians	• A clinical professional with ≥7 years of clinical practice experience using SMT or MOB to manage musculoskeletal conditions in adults (e.g., chiropractors, naprapaths, osteopaths, and physiotherapists)
Patients	• An adult (≥ 18 years old) who has not received any training in SMT or MOB and has 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
Medical doctors	• A medical doctor who has a professional interest in SMT or MOB (e.g., refers patients to manual therapy providers, has treated patients who presented with an adverse event potentially related to SMT or MOB) and/or adverse events following conservative treatments
Manual therapy students	• A student (≥ 18 years old) actively enrolled in a professional program that includes SMT or MOB to manage musculoskeletal conditions in adults in their curriculum (e.g., chiropractors, naprapaths, osteopaths, and physiotherapists)
Professional regulatory body representatives	• An adult (≥ 18 years old) who is involved with local or federal policy and regulations for professions that use SMT or MOB to manage musculoskeletal conditions in adults (e.g., chiropractors, naprapaths, osteopaths, and physiotherapists)
Malpractice insurance representatives	• A professional malpractice insurance employee (≥ 18 years old) who is involved with malpractice claims for professions that use SMT or MOB to manage musculoskeletal conditions in adults (e.g., chiropractors, naprapaths, osteopaths, and physiotherapists)
Lawyers or judges	• A licensed legal professional who has an interest in medico-legal actions involving adverse events following conservative treatment and/or professions that use SMT or MOB to manage musculoskeletal conditions in adults (e.g.,

	chiropractors, naprapaths, osteopaths, and physiotherapists)
Data analysts or informatics/electronic health record representatives	• An adult (≥ 18 years old) with expertise in collecting standardized health data including, but not limited to adverse events, for professions that use SMT or MOB to manage musculoskeletal conditions in adults (e.g., chiropractors, naprapaths, osteopaths, and physiotherapists).

Abbreviations – SMT: spinal and peripheral joint manipulation and mobilization.

Procedure

Round 1

The objectives of round 1 are to collect participant demographic information and generate statements on the definition and severity classification of adverse events following SMT and MOB. Participants will complete the "Demographic Information Form" specific to their expert group (i.e., researcher, manual therapy clinician, patient, medical doctor, student, professional regulatory body, malpractice insurance and informatics/electronic health records representatives, lawyers and judges) (Supplementary file 1). The round 1 questionnaire will consist of open-ended questions. Open-ended questions improve content validity as statements are generated by expert opinion.[28,36,37] Statements based on the results of the scoping literature review will be generated and included in round 2, rather than round 1, to allow participants to provide their expert opinion without bias from the literature, thereby reducing experimenter bias.[38] The round 1 questions will ask participants to define their current understanding of adverse events and their severity classification following SMT and MOB. This may or may not include providing references or resources to support their definition or classification. Participants will have the opportunity to provide general comments related to this topic at the end of the questionnaire. The round 1 questionnaire will be piloted for feedback on readability, relevance and appropriateness through selected Delphi expert methodologists in the Steering Committee and edited accordingly. Round 1 will be open for 6 weeks with email reminders being provided at weeks 1, 3 and 5.

Round 2

The objectives of round 2 are to evaluate consensus of statements developed from the round 1 questionnaire and scoping review findings regarding adverse event definitions and their severity classification following SMT and MOB in adults with musculoskeletal conditions, and to identify any further statements. 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.

Participants will be provided with feedback explaining how statements were generated from round 1 and the scoping review and then asked to rate their agreement with the provided statements using a 5-point Likert scale where 1=strongly disagree and 5=strongly agree.[39] A 5-point scale is preferred as it displays acceptable psychometric properties while being quick and easy for participants to complete, thus reducing frustration and demotivation.[40] An open text box will be included for each statement to allow for any additional comments that may generate further statements. All comments will be analysed by the Executive Committee and reviewed by selected Delphi expert methodologists in the Steering Committee. All participants will be invited to take part in round 2, including those who did not complete round 1, provided they have not withdrawn from the study. This provides the opportunity for participants to continue their involvement even when unable to complete previous rounds.[28] As per round 1, the round 2 questionnaire will remain active for 6 weeks with email reminders sent at weeks 1, 3 and 5.

Round 3

The objective of round 3 is to further evaluate statements regarding adverse events definitions and their severity classification following SMT and MOB. The round 3 questionnaire will include feedback from round 2 using descriptive statistics and qualitative comments, promoting participant reflection before completing the questionnaire. In round 3, participants will be asked to rate their agreement with the statements achieving consensus from round 2 using the same 5-point Likert scale. Statements that do not achieve consensus in round 2 will be discarded. A free-text box will be provided for participants to clarify responses, but the generation of new statements will not be encouraged. All responses will be analysed by the Executive Committee and reviewed by the full Steering Committee. All participants will be invited to participate in round 3, which will again remain active for 6 weeks with email reminders sent at weeks 1, 3 and 5.

Data Analysis

Quantitative data analysis will be conducted using R: A language and environment for statistical computing (R Foundation for Statistical Computing, Vienna, Austria). Qualitative data analysis will be conducted using Microsoft Excel (Microsoft Corporation, USA). Qualitative data will be analysed independently by two researchers (MF/LG) at each round and disagreements will be resolved by discussion and consensus with the consultation of a third reviewer (KP), if needed.

Complete agreement between Executive Committee members is required for statements to be included, with disagreements resolved by discussion.[41] The selected Delphi expert methodologists in the Steering Committee will have the opportunity to review the data and interpretation of findings at each stage for feedback and editing before dissemination to the e-Delphi participants for the next round.

Round 1

Qualitative data from open-ended questions will be examined using a theoretical thematic analysis to generate statements under themes pre-identified from the scoping review of the literature and then examined inductively for any new themes.[42,43] Wording used by participants will be combined to generate statements that best represent similar statements across participants.[38] Statements generated from the results of the scoping review of the literature not identified from participant responses will also be included. For a statement to be included, it must be described at least once by any participant or via results of the scoping review of the literature, therefore all standalone statements will be kept and included. The round 2 questionnaire will be constructed using the statements generated.

Round 2

Descriptive and inferential statistics will be used to evaluate agreement and consensus (Table 2). Statements nearly achieving the *a priori* 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. Qualitative data from comments will be analysed using thematic analysis for the emergence of any new statements.

Round 3

Descriptive and inferential statistics will evaluate consensus against *a priori* criteria (median ≥3.5; interquartile range ≤1 & percentage agreement ≥70%) (Table 2). Statements achieving consensus after round 3 will be used to define adverse events and their severity classification following SMT and MOB. Statements that fail to achieve consensus in round 3 will be discarded.

Table 2. Definitions and statistical measures of consensus, agreement and stability.

	Definition	Statistics	Round 2	Round 3
Consensus	The extent to which the group of experts share the same opinion	Median IQR Percent agreement	≥3.5 ≤1.5 ≥60%	≥3.5 ≤1 ≥70%
Agreement	A measure of inter-rater agreement where the rating of one expert can be predicted by the rating of another	Kendall's coefficient of concordance	Significant agreement ($p<0.05$)	Significant agreement ($p<0.05$)
Stability	The consistency of responses between successive rounds	Wilcoxon rank-sum test	NA	Significance level $p<0.05$

Abbreviations – IQR: Interquartile Range; NA: not applicable.

Consensus, Agreement and Stability

Definitions and statistical measures of consensus and agreement described in the literature for Delphi studies are conflicting.[41,44–46] Specifically, while consensus and agreement have been used interchangeably,[46] unique definitions have also been recommended.[47] Therefore, this study will use the following definitions and is consistent with earlier research [48]:

- Consensus – the extent to which the group of experts share the same opinion[46]
- Agreement – a measure of inter-rater agreement where the rating of one expert can be predicted by the rating of another[49]
- Stability – the consistency of responses between successive rounds[46]

For each round a combination of descriptive and inferential statistics will be used to assess consensus, agreement and stability (Table 2).[41,44,45,48] Consensus will be evaluated using descriptive statistics of central tendency and dispersion (median and interquartile range (IQR)). Percent agreement of responses rated agree/strongly agree will also be used to evaluate consensus for each statement.[50] To enable convergence and strengthen consensus overall criteria will be increased between round 2 and 3.[50] Kendall's Coefficient of Concordance (*W*) where 0 is no agreement and 1 is perfect agreement will be used to evaluate agreement across all items and within categories identified after

round 1.[49] Wilcoxon rank-sum test will be used to evaluate stability of the responses between rounds 2 and 3 .[46] Statistical significance will be set at $p < 0.05$.

Data Management

All data will be managed using REDCap electronic data capture tools,[51] which is hosted at Parker University, Dallas, TX, USA. REDCap is a secure, web-based application designed to support data capture for research studies. All personal information and data will be kept secure from any third party using a password-protected computer during the study. Only members of the study team will have access to the study data. On completion of the study, the data will be kept securely for 10 years at Parker University, Dallas, TX, USA, before being securely destroyed in accordance with the institution's guidelines.

Study Executive Committee

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.

Study Steering Committee

The Steering Committee is composed of international and multidisciplinary members with expertise in patient safety, methodology, and SMT and MOB (Table 3). 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.

Table 3. Executive and Steering Committee members' background and geographical location.

Background	Geographical Location
Academic chiropractor	Australia, Canada, Switzerland and USA
Academic naprapath	Sweden
Academic osteopath	Italy, UK
Academic physiotherapist	Canada and UK
Academic medical doctor	Canada
Academic nurse	USA
Clinical chiropractor	USA, Australia
Clinical osteopath	Italy
Clinical medical doctor	Canada

Patient and Public Involvement

The study was conceived from our experience working with clinicians and patients using SMT and their views were used to highlight the relevance of this research. Our Steering Committee will include a patient representative who will co-design the "Participant Information Sheets", expression of interest emails/social media posts and developing the round 1 questionnaire. It is anticipated that our patient representative will also contribute to reviewing results at each round and support interpretation of findings. Our patient representative will be central to our dissemination strategy including patient cohorts. A summary of results will be disseminated to all professions through professional organizations newsletter, conferences and reports. Feedback from professional groups will be invited to inform future studies and to facilitate the ongoing collaboration of an international, multidisciplinary research working group to support advancement of knowledge in the field of AE. Patient and public involvement in the full study will be reported using the "Guidance for Reporting

Involvement of Patients and the Public2-short form (GRIPP2-SF)"[52] when disseminating the study results.

DISCUSSION

This e-Delphi study will provide expert consensus on the definition of adverse events and their severity classification following SMT and MOB that could not be determined from the current literature. In this study, we will use the term "adverse event" in accordance with previous studies in this area,[25,26] but consider it an umbrella term representative of other related terms referring to undesirable outcomes of SMT and MOB, such as harms, complications, side effects, etc.

Conducting a Delphi study electronically allows the development of expert informed recommendations from a wide range of specialists, regardless of geographical location, and who can participate confidentially, which is considered a strength. Another noticeable strength of this study is the active participation and collaboration of several professions that routinely perform SMT when treating patients with musculoskeletal conditions (i.e., chiropractic, naprapathy, physiotherapy and osteopathy). Inclusion of international and multidisciplinary experts will ensure that the unique views and opinions of each profession and expert group is taken into consideration, while creating a standardized definition of adverse events and severity classification. Critically establishing standardized definitions and severity classifications across professions will significantly advance the evidence concerning adverse events. Drawing on a single expert multi-professional framework will contribute to enhancing the consistency in recording adverse events and will, in time, improve our understanding of the adverse events following SMT. From this, strategies to prevent and mitigate such events may be developed, which can significantly increase the knowledge related to adverse events, promoting a fundamental advancement in patient safety and quality of care for all professions that use SMT.

Ethics and dissemination

This study was approved by the Canadian Memorial Chiropractic College (CMCC) Research Ethics Board (#2103B01) and deemed exempt by Parker University's Institutional Review Board (A-00218). Freely given e-informed consent will be obtained from all participants prior to participation through REDCap. Participants will be informed of the withdrawal process and assured anonymity throughout the study and during dissemination. Results from this study will be disseminated through scientific, professional and educational reports, publications and presentations.

AUTHOR CONTRIBUTIONS

MF, KP, LG, AB and NH are leading the protocol development, analyses, and dissemination. Data analysis will be completed independently by MF and LG with oversight by KP, AB and NH. SS is a member of the Steering Committee overseeing protocol development and made significant contributions to this manuscript. All authors and Steering Committee members will be involved in interpretation of the findings and dissemination strategy. All authors have contributed to the design and development of the protocol and have contributed to the manuscript draft. All authors have read, provided feedback and approved the final manuscript.

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PATIENT CONSENT FOR PUBLICATION

Not required

CONFLICT OF INTEREST

The authors declare that they have no competing interests.

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FIGURE LEGENDS

Figure 1. Delphi study procedures

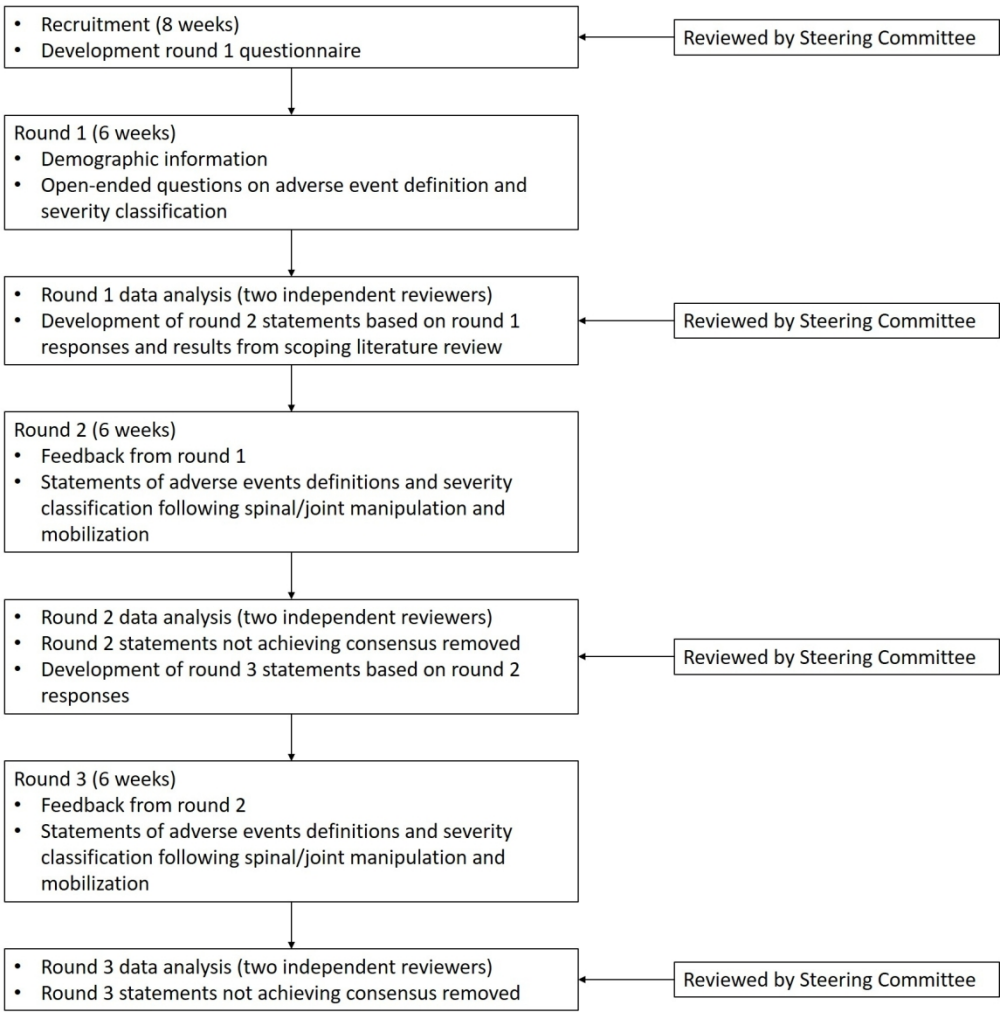

Figure 1. Delphi study procedures

146x148mm (300 x 300 DPI)

SUPPLEMENTARY FILE 1

Demographic information

	Researcher	*Manual Therapy Clinician*	*Medical Doctor*	*Patients*	*Manual Therapy Student*	*Regulatory Body Representative*	*Malpractice Insurance Representative*	*Lawyers and Judges*	*Data analysts or Informatics/ Electronic health records Representative*
Sex									
Age									
Country									
Ethnicity									
Profession/Occupation									
Highest degrees/education									
Highest degree year									
Work/Academic/Patient Care/Regulatory Setting				Patient Care Setting					
Years clinical experience (overall)					Months				
Years clinical experience with SMT/MOB									
Average number of patients/week prior to COVID-19									

Clinical experience with adverse events following SMT/MOB									
Number of peer-reviewed publications									
Number of publications related to patient safety or adverse events for SMT/MOB in the past 10 Years									
Musculoskeletal condition									
Musculoskeletal condition duration									
Profession received SMT/MOB from									
Have received SMT/MOB as patient									
Experienced adverse event as a patient									
Specialist training/ professional interest in SMT/MOB									