Adverse events following cervical manual physical therapy techniques

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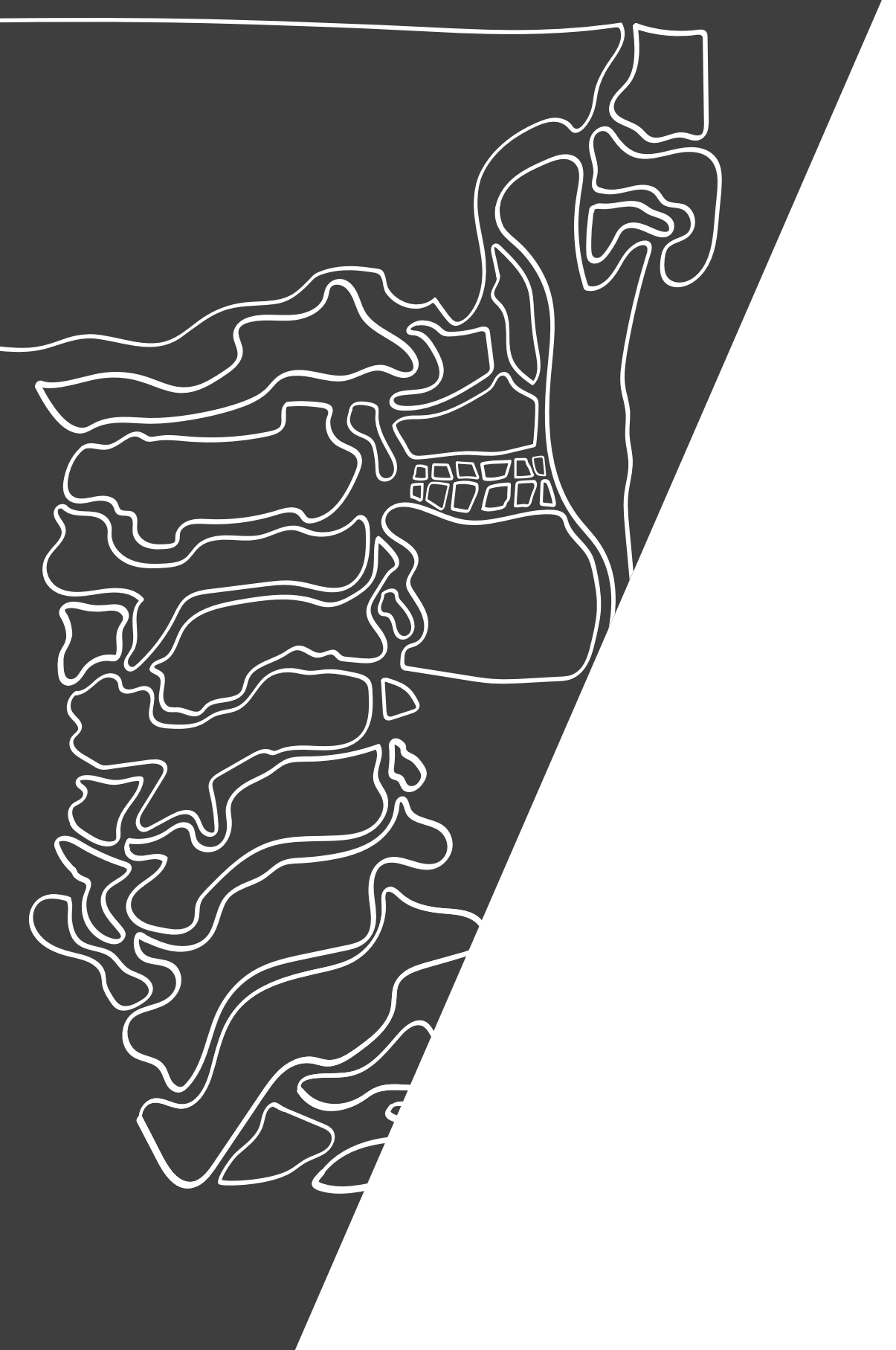

ADVERSE EVENTS FOLLOWING CERVICAL MANIPULATIVE THERAPY: CONSENSUS ON CLASSIFICATION AMONG DUTCH MEDICAL SPECIALISTS, MANUAL THERAPISTS, AND PATIENTS

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ABSTRACT

Objectives: To obtain consensus-based agreement on a classification system of adverse events (AE) following Cervical Spinal Manipulation. The classification system should be comprised of clear definitions, include patients' and clinicians' perspectives, and have an acceptable number of categories.

Method: Design: A three round Delphi-study.
Participants: Thirty Dutch participants (medical specialists, manual therapists, and patients) participated in an online survey.
Procedure: Participants inventoried AE and were asked about their preferences for either a three or a four-category classification system. The identified AE were classified by two analysts following the International Classification of Functioning, Disability and Health (ICF) and the International Classification of Diseases and Related Health Problems (ICD-10). Participants were asked to classify the severity for all AE in relation to the time duration.

Results: Consensus occurred in a three-category classification system. There was strong consensus for 16 AE in all severities (no, minor, and major AE) and all three-time durations [hours, days, weeks]. The 16 AE included anxiety, flushing, skin rash, fainting, dizziness, coma, altered sensation, muscle tenderness, pain, increased pain during movement, radiating pain, dislocation, fracture, transient ischemic attack, stroke, and death. Mild to strong consensus was reached for 13 AE.

Discussion: A consensus-based classification system of AE is established which includes patients' and clinicians' perspectives and has three categories. The classification comprises a precise description of potential AE in accordance with internationally accepted classifications. After international validation, clinicians and researchers may use this AE-classification system to report AE in clinical practice and research.
Level of Evidence: 5

INTRODUCTION

Adverse events (AE) may occur as a consequence of Cervical Spinal Manipulations (CSM). Adverse events are unexpected events that occur following an intervention without evidence of causality.(Carlesso et al., 2010b) Major adverse events such as Cervical Arterial Dissection (CAD), Cerebral Vascular Accident, or death only rarely occur.(Carlesso et al., 2010a; Cassidy et al., 2008) Incidence rates of major adverse events were estimated between 1 to three thousand and 1 to six million.(Assendelft et al., 1996; Magarey et al., 2004; Nielsen et al., 2017) In general, it is likely that the incidence rates of AE are underreported.(Ernst, 2007; Kranenburg et al., 2017; Shekelle, 2007; Wynd et al., 2013) This could possibly be due to the lack of standard definitions of AE and the absence of a clear, uniform classification system that combines the severity and duration of the AE.(Carlesso et al., 2010b; Carnes et al., 2010; Thomas, 2016; Wynd et al., 2013) A note of caution is due in this context since not all AE occur at the time of the intervention. It could happen that the therapist is not aware of an AE when not alerted by the patient. Additionally, a clinician might not always be willing to be open about the presence of an AE. Gorrell et al. (Gorrell et al., 2016) emphasized the importance of a uniform standardized nomenclature classification system and development and validation of AE reporting tools to collect and pool data in the future.

A clear classification system begins with clarifying the construct of an AE. Multiple terms are used to describe the harm caused following cervical mobilization or manipulation. Most have their origin in the pharmacovigilance field but are not completely appropriate for orthopedic physical therapy. Most of the existing terms imply causality with the used technique. Causalities of AE following CSM have been suggested, but are not confirmed.(Carlesso et al., 2010b) A clear classification system with standard definitions, that combines severity and time duration of adverse events is advantageous for implementation as an incident reporting system by professional or national independent associations. Such an unambiguous AE system may facilitate manual therapists in reporting AE.(Carlesso et al., 2010b; Carnes et al., 2010; Dionne et al., 2008; Puentedura et al., 2012) In research, the classification system described by Carnes et al. (Carnes et al., 2010) is regularly used.(Carlesso et al., 2011; Paanalahti et al., 2014) While defining potential AE in that study by means of a Delphi method, consensus was established for only 15 of 36 presented potential AE.(Carnes et al., 2010) There is a myriad of possible reasons why the participants of the latter study did not achieve consensus on a more extensive number of potential AE. For example, first, the response rate of the participants was minimal (Round 1--50%, Round 2--62%, and Round 3--55%). Low response rates may be vulnerable for

selection bias and outlier opinions may be difficult to neutralize. Secondly, the AE were divided into four categories: no, minor, moderate, and major AE. This division may be too complex to use as there is more debate about what is a minor or a moderate AE than what is not an AE or what is a major AE.(Carlesso et al., 2011) Thirdly, definitions of a potential AE may not have been clearly described. A set of more precisely described definitions might enhance clarity between participants. In both research and clinical practice, there is a need for a clear consensus-based classification system of AE following CSM.(Schulz et al., 2010) The aim of this study, therefore, was to develop a system which meets the following criteria: 1] beneficial for research and clinical practice, 2] includes patients' and clinicians' perspectives, 3] has an acceptable number of categories and clear definitions, and 4] is based on an accepted international classification of diseases (ICD-10) and international classification of functioning, disability and health (ICF).

METHOD

DESIGN

A three-round modified digital Delphi study was performed from September 2013 to January 2014 (Figure 1).(Keeney et al., 2011; McKenna, 1994) The Delphi technique is a structured approach that is employed to achieve consensus anonymously among a panel of experts and is a well-established technique for consensus building among participants.(Avery et al., 2005; Keeney et al., 2006; Thompson, 2009) Following each round, the panel members can anonymously observe the group opinions, compare the group opinions with their own responses, and may even reconsider them. The online survey program SurveyMonkey was used to inventory the panel members' opinions.(SurveyMonkey, n.d.)

PARTICIPANTS, THERAPISTS, CENTERS

To achieve a broad perspective of input, a heterogeneous sample of Dutch participants (panel members) was recruited. They were selected from three relevant expert groups: 1] medical specialists; 2] manual physical therapists (MT's); and 3] patients. A total of 30 panel members were included with a quota of ten members per expert group. Medical specialists (i.e., neurologists or orthopedic surgeons) were recruited from four hospitals, patients were recruited from three different private clinics, and the MTs were randomly invited. The first author asked contact persons (medical specialists and manual therapists) through emails to outpatient clinics and hospitals nationwide to invite potential participants in their own institution. The contact persons provided a list of potential participating panel members who were asked through emails to participate. Potential panel members were also

asked to recruit other potential panel members (snowball-sampling method). This recruitment process was executed for both medical professionals and patients. By selecting hospitals and clinics nationally, there was an attempt to create a varied spread of participants during the invitation process.

Prior to the selection of panel members, inclusion criteria were established: 1] medical specialists working with or who could receive patients that experienced AE after CSM. No more than two panel members with the same specialization were allowed; 2] manual therapists; i.e., physical therapists who had graduated from programs accredited by the country's national Orthopedic Manual Therapy organization.; 3] patients over 18 years old who suffered from neck pain and had been treated by a manual therapist and experienced a CSM at least once; and 4] all panel members had to be native Dutch speakers. The panel was limited the Dutch nationality as an international panel would imply multiple translations and interpretations which would reduce the reliability of the results of this study.

DELPHI PROCESS

All panel members signed informed consent and received an individualized unique participation code. In an attempt to ensure quasi-anonymity, only the first author (RK) was aware of this code.(Keeney et al., 2011) This Delphi study was comprised of three rounds. During each round, the survey was available for 21 days. Those members who did not initially respond received a personal reminder by email from the first author after ten, 17, and 20 days. Each panel member could miss one round before being excluded from further participation. All were invited during each round to make further comments on each of the questions.

The following decision criteria were specified a-priori; 1] strong consensus was predetermined at ≥ 75%; 2] in Round 1, participants were asked to select either a system with three or four categories to classify. The number of categories as a result of Round 1 was used in Round 2; 3] if no consensus was reached for ten AE over four categories in Round 2, the three categorical system was employed in Round 3. An independent Medical Ethical Committee of the University Medical Center Groningen, The Netherlands approved a waiver for this research protocol. This waiver stated that the "Medical Research Involving Humans Act" (WMO) did not apply for this study.

INTERVENTION

ROUND ONE

The aim of Round 1 was twofold; 1] to inventory all possible adverse events following CSM, and 2] to reach consensus on either a three or four categorical AE classification system (Figure 1). (Keeney et al., 2011)

1. Identification of adverse events

As Carnes et al. (Carnes et al., 2010) described the most comprehensive list of AE, this list was designated as a base and was provided to the panel members. To translate the AE of Carnes et al.'s (Carnes et al., 2010) list into Dutch, a forward-backward translation strategy was employed by the first author and a native bilingual manual therapist.(Maneesriwongul and Dixon, 2004) During Round 1, panel members were asked to indicate potential AE from Carnes et al.'s list.(Carnes et al., 2010) Panel members were also asked to add items to the list that they considered as possible AE.

2. Categories

Panel members were directed to select one of the two categorical classification systems. The first option was a system of four categories as proposed by Carnes et al. (Carnes et al., 2010): not adverse, minor, moderate, or major AE. The second option was a categorical classification system of three categories instead of four: not adverse, minor adverse, or major AE.

ROUND TWO

Time and severity

Round 2 aimed at obtaining agreement on the influence of the length of time that the AE lasted against the severity of the AE. For the length of time, the time units as described by Carnes et al. (Carnes et al., 2010) (hours, days, and weeks) were used. For severity, the AE were analyzed in accordance with the Carnes et al.'s (Carnes et al., 2010) four categorical classification. If a unanimous preference was reached in Round 1 for our proposed three categorical classification, then the AE were analyzed in the three categorical classification. Using a selection table, the panel members were asked to indicate the severity of an adverse event in relation to the time in which it had occurred.

ROUND THREE

The aim of Round 3 was to validate the answers of Round 2. When proceeded in the four categorical system; for each potential AE, the panel members own opinion

and the group opinion was presented. If a panel member agreed with the opinion provided by the majority of panel members, the next item was presented. If they did not agree with the opinion provided by the majority, they were asked to re-indicate their opinion. If 100% consensus from all the responding panel members in Round 2 was already reached, no question was needed, and the results were shown to all panel members.

However, following the third a-priori specified criteria; if no consensus was reached for ten AE over four categories in Round 2, then the number of categories was adjusted in preparation for Round 3. Panel members' indication of AE as chosen in the four categorical classification system was validated within the three categorical classification system. Validation was performed by asking each panel member again if their indication of Round 2 resembles the third round. This was established by showing each panel member their individual opinion of the second round and the groups' panel opinions of Round 2. If a panel member agreed with the answer provided by the majority of panel members, the next item was presented. If they did not agree with the answer provided by the majority, they were asked to restate their opinion. Also, if 100% consensus from all the responding panel members in Round 2 was already reached, the results were shown to all panel members.

DATA ANALYSES

DATA ANALYSES ROUND ONE

Definitions of adverse events

If one of the panel members indicated that an item in Round 1 was a possible AE, the item proceeded to Round 2. The first author (RK) and the second author (SL) individually linked all the AE from Carnes et al. 's (Carnes et al., 2010) list and the AE that the panel members had added to the ICF or the ICD-10.(World Health Organisation, 2012, 2001) The ICF and ICD-10 provide a systematic coding and clear definitions. In the event of a dispute or uncertainty, the opinion and advice was sought from the last author (CS).

Categories

Panel members were subsequently asked to select one of the two categorical classification systems. Since the four categorical classification proposed by Carnes et al. (Carnes et al., 2010) has been used in published research, the potential AE in Round 2 were presented accordingly. However, if in Round 1 the panel members reached a strong consensus for our proposed three categorical classification system, then the potential AE were presented in that manner.

DATA ANALYSES ROUND TWO

A modification of a linked ICF or ICD-10 definition could occur if one of the participating panel members advised to do so during Round 1. However, it could only be changed if both authors (RK, SL) agreed to the change. In the event of a dispute or uncertainty, the opinion of the last author (CS) was sought. In preparation for the third round, the modes of the groups' AE (exhibited in percentages) were calculated.

If the panel members reached consensus on less than ten AE in Round 2 by using the four categories, AE's were analyzed into the three categories based on the assumption that additional consensus was reached using three categories instead of four. To convert the answers from the classification in four categories to the classification in three categories, the answers of moderate AE were merged with the answers of minor AE and labeled as minor AE. The underlying motivation for this merger was the assumption that these categories overlap the most and, therefore, incite the most debate.(Carlesso et al., 2011)

DATA ANALYSES ROUND THREE

Degree of consensus

A pre-determined level of consensus was employed, which is often referred to as the Majority Rule.(Hasson et al., 2000) The most common percentage for agreement is 75%.(Diamond et al., 2014) Setting direction to consensus was first described in 1995 and later further refined by O'Loughlin and Meskell.(de Loe, 1995; Meskell et al., 2013; O'Loughlin and Kelly, 2004) For this study, mild consensus was established at 60% to 74% agreement (Table 1). Strong consensus was specified whereby at least 75% of the panel members agreed on an AE.(Awad and Alghadir, 2013; Carnes et al., 2010; Glocker et al., 2013)

Table 1. Level of Consensus

Level of Agreement	***Level of Consensus***
0% - <60%	No consensus
60% - <75%	Mild consensus
75% - 100%	Strong consensus

RESULTS

FLOW OF PARTICIPANTS, THERAPISTS, CENTERS THROUGH THE STUDY

A total of 30 experts responded positively to the invitation and signed the informed consent (Table 2). The medical specialist group consisted of two neurologists, one neurosurgeon, one orthopedist, one orthopedic surgeon, one trauma surgeon, one emergency physician, one sports physician, and two general practitioners. All group members in the manual therapy group had obtained a master's degree and were practicing manual therapy in a private setting. Three of them were also teachers at a university of Master Manual Therapy education and three others at a university of Bachelor Physical Therapy education. An eleventh manual therapist was added based on his broader perspective due to his work as a full-time Professor of Rehabilitation Medicine. One of the patient panel members withdrew for unknown reasons after the first round. No panel member was excluded for Round 3. Furthermore, panel members were geographically dispersed nationwide.

Table 2. Three Round Response Rate for Panel Members

Round	*Total response*	*Medical Specialists*	*Manual Therapists*	*Patients*
1	27 (90%)	8 (30%)	11 (41%)	8 (30%)
2	27 (90%)	10 (37%)	11 (41%)	6 (22%)
3	23 (77%)	8 (35%)	10 (43%)	5 (22%)

ROUND 1

Definitions of adverse events

All 37 items listed by Carnes et al. (Carnes et al., 2010) were identified by at least one panel member as a potential AE after CSM. The panel members returned 12 new suggestions for potential AE. Six panel members indicated that they required more specific definitions for some of the suggested potential AE. During the analysis and following the linking of AE to ICF and ICD-10 definitions, some of the items were combined if they had the same ICF or ICD-10 code such as vomiting and puking. The final list comprised 34 items related to ICF or ICD-10 definitions (Appendix 1).

Categories

Of the panel members, 55.6% preferred the four categorical classification proposed by Carnes et al. (Carnes et al., 2010), and 44.4% favored the three categorical classification of events. Therefore, no unanimous preference on the categories of classification was achieved. Following the method section, we preceded the Delphi-

study with the four category classification as proposed by Carnes et al. (Carnes et al., 2010)

ROUND 2

Time and severity

All responding panel members determined that death and stroke were major AE. During the analysis procedure of division into four categories, strong consensus was reached for eight potential AE, and no (strong) consensus was reached for 16 potential AE. Therefore, the study was subsequently continued with the three categorical classification system. Consequently, the answers of minor and moderate AE were merged into minor AE and returned as three categorical answers to the panel members.

Definitions of adverse events

To the definition of AE 'Skin Rash', the following was amended: it concerns a local area at the manipulated segment. The definition of AE 'Fainting' was further specified by addition that it concerns repeated fainting in the specified time. Loss of consciousness generally occurs within one-two minutes. Dizziness was divided into two different AE, namely, ICD-10 H81.9 disorder of vestibular function, unspecified, and ICD-10 R42 dizziness and giddiness. For the AE "migraine", the option of "weeks" was removed because migraine has a maximum duration of three days.(Headache Classification Subcommittee of the International Headache Society, 2004) Two members of the medical panel asked specific questions regarding the AE 'loss of or reduced bladder control' and 'loss or reduced bowel control', as it was important for them to know whether it concerned incontinence or constipation. After consulting with an independent medical specialist for an expert opinion regarding a specification of the definition, it was added that both adverse events primarily concerned incontinence.

ROUND 3

Consensus

After showing the panel members their individual indications of AE in the three categorical classification system and the indications of the majority of panel members, consensus was reached for 29 of the 34 AE for all durations (hours, days, weeks) (Table 3). Regarding the remaining five AE (Depression, Joint pain, Vertigo, Visual disturbance and Panic attack) consensus was obtained for two of the three durations [hours, days, weeks].

Degree of Consensus

For 16 of the 34 AE, a strong consensus (at least 75% of the panel members agreed on an AE) was reached for all durations [hours, days, weeks] (Table 3.1). These AE were: anxiety, altered sensation, coma, death, dislocation, dizziness, fainting, flushing, fracture, increased pain during movement, muscle tenderness, pain, radiating pain, skin rash, stroke and transient ischemic attack. The remaining 13 AE in which consensus was gained, were combined mild-strong consensus results (Table 3.2). Mild consensus (60% to 74% agreement) was only reached in the category Minor AE. Furthermore, six panel members (four physicians and two manual therapists) noted for 14 adverse events that they could not determine the relationship between a CSM and the potential AE. No panel member from the patient panel noted comments to the responses.

Table 3. Consensus Results; severities and time durations.
3.1 Full Consensus (Strong) for all severities and all time durations.

		No Adverse Event	***Minor Adverse Event***	***Major Adverse Event***
Anxiety ICF-B152	*Hours*		*Strong consensus*	
	Days		*Strong consensus*	
	Weeks		*Strong consensus*	
Altered sensation ICF-B279	Hours		Strong consensus	
	Days		Strong consensus	
	Weeks			Strong consensus
Coma ICF-B110	Hours			Strong consensus
	Days			Strong consensus
	Weeks			Strong consensus
Death				Strong consensus
Dislocation ICF-B7150				Strong consensus
Dizziness ICD10-R42	Hours		Strong consensus	
	Days		Strong consensus	
	Weeks			Strong consensus
Fainting ICD10-R55	Hours		Strong consensus	
	Days			Strong consensus
	Weeks			Strong consensus

3.1 Continued

		No Adverse Event	*Minor Adverse Event*	*Major Adverse Event*
Flushing ICD10-R23.2	Hours	Strong consensus		
	Days		Strong consensus	
	Weeks		Strong consensus	
Fracture ICD10-S12				Strong consensus
Increased pain during movement ICF-B2801	Hours		Strong consensus	
	Days		Strong consensus	
	Weeks			Strong consensus
Muscle tenderness ICD10-M79.1	Hours	Strong consensus		
	Days		Strong consensus	
	Weeks		Strong consensus	
Pain ICF-B2801	Hours		Strong consensus	
	Days		Strong consensus	
	Weeks			Strong consensus
Radiating pain ICF-B2803	Hours		Strong consensus	
	Days		Strong consensus	
	Weeks			Strong consensus
Skin rash ICD10-L98	Hours		Strong consensus	
	Days		Strong consensus	
	Weeks		Strong consensus	
Stroke ICD10-I69				Strong consensus
TIA ICD10-G45				Strong consensus

3.2 Full Consensus (Mild or Strong) for all severities and all time durations

		No Adverse Event	***Minor Adverse Event***	***Major Adverse Event***
Breathing difficulties ICF-B440	Hours		Mild consensus	
	Days			Strong consensus
	Weeks			Strong consensus
Control of voluntary movements ICF-B760	Hours		Strong consensus	
	Days		Mild consensus	
	Weeks			Strong consensus
Deafness ICD10-H91.9	Hours		Mild consensus	
	Days			Strong consensus
	Weeks			Strong consensus
Fatigue / Yawn CD10-R53	Hours	Strong consensus		
	Days		Mild consensus	
	Weeks		Strong consensus	
Headache ICF-28010	Hours		Strong consensus	
	Days		Strong consensus	
	Weeks		Mild consensus	
Loss of movement ICF-B710	Hours		Strong consensus	
	Days		Strong consensus	
	Weeks		Mild consensus	
Loss or reduced bladder control ICF-B6200	Hours		Mild consensus	
	Days			Strong consensus
	Weeks			Strong consensus
Loss or reduced bowel control ICF-B5253	Hours		Mild consensus	
	Days			Strong consensus
	Weeks			Strong consensus
Migraine ICD10-G43	Hours		Strong consensus	
	Days		Mild consensus	
Nausea ICF-5350	Hours		Strong consensus	
	Days		Strong consensus	
	Weeks		Mild consensus	
Palpitations ICD10-F45.3	Hours		Strong consensus	
	Days		Mild consensus	
	Weeks			Strong consensus

3.2 Continued

		No Adverse Event	*Minor Adverse Event*	*Major Adverse Event*
Severe sweating ICD10-F45.3	Hours		Mild consensus	
	Days		Strong consensus	
	Weeks		Mild consensus	
Vomiting ICD10-R11	Hours		Strong consensus	
	Days		Mild consensus	
	Weeks			Strong consensus

3.3 Partial consensus for all severities and all time durations

		No Adverse Event	*Minor Adverse Event*	*Major Adverse Event*
Depression ICD10-F32	Hours		Mild consensus	
	Days	No consensus	No consensus	No consensus
	Weeks		Mild consensus	
Joint pain ICD-M25.5	Hours		Strong consensus	
	Days		Strong consensus	
	Weeks	No consensus	No consensus	No consensus
Panic attack ICD10-F41	Hours		Mild consensus	
	Days	No consensus	No consensus	No consensus
	Weeks			Strong consensus
Vertigo ICD10-H81.9	Hours		Strong consensus	
	Days	No consensus	No consensus	No consensus
	Weeks			Strong consensus
Visual disturbance ICF-B210	Hours	No consensus	No consensus	No consensus
	Days		Mild consensus	
	Weeks			Strong consensus

DISCUSSION

A consensus-based classification system of AE following CSM was established. It includes patients' and clinicians' perspectives, it comprises an acceptable number of categories (no, minor, and major AE), it incorporates a precise description of potential AE, and it is based on internationally accepted classifications (ICD-10 and ICF). Mild to strong consensus was achieved on 29 of the 34 AE for all durations [hours, days, weeks]. For the remaining five AE, consensus was reached for two of the three durations [hours, days, weeks].

For use in daily practice, it is essential for clinicians that AE can be rapidly classified and without too much difficulty, i.e., the fewer the choices, the better the consensus. In our study, a three categorical classification system was developed in which the word 'moderate' was not included, and patients' opinions were included in the Delphi process. Patient opinions were included, because they are considered an important part of shared decision making. Therewith, we added a new perspective to the previous Delphi process as described by Carnes et al.(Carnes et al., 2010) Furthermore, in our classification we integrated all durations for all AE when applicable and reached consensus on 29 AE for all the durations. Because symptoms of AE such as vomiting and puking can be considered as one and the same, we used ICF/ ICD-10-linking rules. Aligning nomenclature for symptoms creates a better understanding of the variety between symptoms and may also simplify the reporting of AE. To the authors' knowledge, this is the first study in which AE were linked to other classification systems (ICF and ICD-10) whereby a wide-ranging expert panel participated. Also, the introduction of two levels of consensus (mild and strong consensus) is new and supports transparency in the quality of consensus.

The results in this study are strengthened the consistent high overall response rate during all three rounds. i.e., 90% for the first two rounds and 77% for the third round, which indicates substantial validity of the results.
Even though this study was not internationally performed, and the ICF and ICD-10 were followed, the results may not be generalizable to other world regions but the suggested definitions could be used for international research towards validating the results within clinicians and researchers of other countries. Additionally, before this classification system can be considered internationally useful, it should produce valid interpretations of datasets in several languages.
Although all described AE were identified by the panel as possible AE following CSM, the causality of AE after CSM is complex and not supported by all criteria of causation.(Haynes et al., 2012; Tuchin, 2014) Despite the importance, the causality of AE is not addressed in this study.

There are several limitations in this study that should be critically appraised. Although potential AE were accumulated over a period of time, the severity of AE themselves remains undefined. For example, pain could be described more accurately by using the Numeric Rating Scale (NRS). The next point of consideration is that this study approached all potential AE as isolated AE even though the simultaneous occurrence of more than one minor AE might be considered as a major AE from a patient's or a therapist's perspective.(Carnes et al., 2010) Sampling

bias may have occurred; the sample of manual therapists may have been prejudiced since more than half of the (n=6) panel members were also teaching to physical and manual therapy students. Finally, statistics were not applied to the detailed results. (Appendix 2). However, contrary to what other studies indicate, it seems no differences in opinions were ascertained between the patient panel versus the medical and manual therapy panels (Appendix 2).(Rajendran et al., 2012; Weissman et al., 2008)

In order to improve the feasibility of the list in daily practice or research, it is proposed that: 1] the quality of the list of AE should be internationally tested for validity; 2] clinicians add new AE to the current list and assess the time of this newly defined AE by the severity, as was done in this study; 3] a distinction between causes (i.e., fracture or arterial dissection) and signs/symptoms (i.e., pain and vomiting) be performed.

Additionally, it might be advisable to assist manual therapists in classifying and/or reporting AE with additional education. It is also recommended to obtain agreement on specific AE that should then be reported to a central organization. If, after international validation, our classification is used as a base for an incident reporting system, it could fill a gap between science and everyday practice.

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APPENDICES

APPENDIX 1

Appendix 1. Adverse Events: linked ICF/ ICD10 codes and definitions.

Adverse Event	*Code*	*Definition*
Altered sensation	ICF-B279	Additional sensory functions, other specified and unspecified
Anxiety	ICF-B152	Specific mental functions related to the feeling and affective components of the processes of the mind. Incl.: functions of appropriateness of emotion, regulation and range of emotion; affect; sadness, happiness, love, fear, anger, hate, tension, anxiety, joy, sorrow; lability of emotion; flattening of affect
Breathing difficulties	ICF-B440	Functions of inhaling air into the lungs, the exchange of gases between air and blood, and exhaling air. Incl.: functions of respiration rate, rhythm and depth; impairments such as apnoea, hyperventilation, irregular respiration, paradoxical respiration and bronchial spasm and as in pulmonary emphysema.
Coma	ICF-B110	General mental functions of the state of awareness and alertness, including the clarity and continuity of the wakeful state. Inclusions: functions of the state, continuity and quality of consciousness; loss of consciousness, coma, vegetative states, fugues, trance states, possession states, drug-induced altered consciousness, delirium, stupor
Control of voluntary movements	ICF-B760	Functions associated with control over and coordination of voluntary movements. Incl.: functions of control of simple voluntary movements and of complex voluntary movements, coordination of voluntary movements, supportive functions of arm or leg, right left motor coordination, eye hand coordination, eye foot coordination; impairments such as control and coordination problems, e.g. dysdiadochokinesia

Appendix 1. Continued

Adverse Event	*Code*	*Definition*
Deafness	ICD10-H91.9	Hearing loss, unspecified. Incl.: Deafness: NOS, high frequency, low frequency
Death		NOS
Depression	ICD10-F32	In typical mild, moderate, or severe depressive episodes, the patient suffers from lowering of mood, reduction of energy, and decrease in activity. Capacity for enjoyment, interest, and concentration is reduced, and marked tiredness after even minimum effort is common. Sleep is usually disturbed and appetite diminished. Self-esteem and self-confidence are almost always reduced and, even in the mild form, some ideas of guilt or worthlessness are often present. The lowered mood varies little from day to day, is unresponsive to circumstances and may be accompanied by so-called "somatic" symptoms, such as loss of interest and pleasurable feelings, waking in the morning several hours before the usual time, depression worst in the morning, marked psychomotor retardation, agitation, loss of appetite, weight loss, and loss of libido. Depending upon the number and severity of the symptoms, a depressive episode may be specified as mild, moderate or severe. Incl.: single episodes of: depressive reaction psychogenic depression reactive depression
Dislocation	ICF-B7150	Functions of the maintenance of structural integrity of one joint.
Dizziness	ICD10-R42	Dizziness and giddiness Incl.: Light-headedness, Vertigo NOS
Fainting	ICD10-R55	Syncope and collapse Incl.: Blackout, Fainting
Fatigue / Yawn	ICD10-R53	Malaise and fatigue
Flushing	ICD10-R23.2	Flushing, Excessive blushing
Fracture	ICD10-S12	Fracture of neck Incl.: cervical: neural arch, spine, spinous process, transverse process, vertebra, vertebral arch

Appendix 1. Continued

Adverse Event	*Code*	*Definition*
Headache	ICF-28010	Sensation of unpleasant feeling indicating potential or actual damage to some body structure felt in the head and neck.
Increased pain during movement	ICF-B2801	Sensation of unpleasant feeling indicating potential or actual damage to some body structure felt in a specific part, or parts, of the body during movement
Joint pain	ICD-M25.5	Pain in joint
Loss of movement	ICF-B710	Functions of the range and ease of movement of a joint. Inclusions: functions of mobility of single or several joints, vertebral, shoulder, elbow, wrist, hip, knee, ankle, small joints of hands and feet; mobility of joints generalized; impairments such as in hypermobility of joints, frozen joints, frozen shoulder, arthritis
Loss or reduced bladder control	ICF-B6200	Functions of voiding the urinary bladder. Incl.: impairments such as in urine retention
Loss or reduced bowel control	ICF-B5253	Faecal continence Functions involved in voluntary control over the elimination function
Migraine	ICD10-G43	Migraine
Muscle tenderness	ICD10-M79.1	Myalgia Excl.: myositis
Nausea	ICF-5350	Sensation of needing to vomit
Pain	ICF-B2801	Sensation of unpleasant feeling indicating potential or actual damage to some body structure felt in a specific part, or parts, of the body
Palpitations	ICD10-F45.3	Somatoform autonomic dysfunction
Panic attack	ICD10-F41	Disorders in which manifestation of anxiety is the major symptom and is not restricted to any particular environmental situation. Depressive and obsessional symptoms, and even some elements of phobic anxiety, may also be present, provided that they are clearly secondary or less severe.

Appendix 1. Continued

Adverse Event	***Code***	***Definition***
Radiating pain	ICF-B2803	Unpleasant sensation indicating potential or actual damage to some body structure located in areas of skin served by the same nerve root.
Severe sweating	ICD10-F45.3	Somatoform autonomic dysfunction
Skin rash	ICD10-L98.9	Disorder of skin and subcutaneous tissue, unspecified
Stroke	ICD10-I69	Sequelae of cerebrovascular disease
Transient Ischaemic Attack (TIA)	ICD10-G45	Transient cerebral ischaemic attacks and related syndromes Excl.: neonatal cerebral ischaemia
Vertigo	ICD10-H81.9	Disorder of vestibular function, unspecified
Visual disturbance	ICF-B210	Sensory functions relating to sensing the presence of light and sensing the form, size, shape and colour of the visual stimuli. Incl.: visual acuity functions; visual field functions; quality of vision; functions of sensing light and colour, visual acuity of distant and near vision, monocular and binocular vision; visual picture quality; impairments such as myopia, hypermetropia, astigmatism, hemianopia, colour-blindness, tunnel vision, central and peripheral scotoma, diplopia, night blindness and impaired adaptability to light
Vomiting	ICD10-R11	Vomiting
Abbreviations:	NOS	Not Otherwise Specified

APPENDIX 2

Appendix 2. Specified answers per group, severity and adverse event

	Duration	*No Adverse Event*			*Minor Adverse Event*			*Major Adverse Event*		
		Med	**MT**	**Pat**	**Med**	**MT**	**Pat**	**Med**	**MT**	**Pat**
Altered sensation ICF-B279	Hours	0%	0%	20%	100%	100%	80%	0%	0%	0%
	Days	0%	0%	20%	100%	90%	80%	100%	10%	0%
	Weeks	0%	0%	20%	0%	10%	0%	100%	90%	80%
Anxiety ICF-B152	Hours	0%	20%	20%	100%	80%	80%	0%	0%	0%
	Days	0%	20%	20%	100%	80%	80%	0%	0%	0%
	Weeks	0%	20%	20%	87.5%	70%	80%	25%	10%	0%
Breathing difficulties ICF-B440	Hours	0%	0%	20%	75%	50%	80%	25%	50%	0%
	Days	0%	0%	20%	0%	0%	0%	100%	100%	80%
	Weeks	0%	0%	20%	0%	0%	0%	100%	100%	80%
Coma ICF-B110	Hours	0%	0%	20%	0%	0%	0%	100%	100%	80%
	Days	0%	0%	20%	0%	0%	0%	100%	100%	80%
	Weeks	0%	0%	20%	0%	0%	0%	100%	100%	80%
Control of voluntary movements ICF-B760	Hours	0%	0%	20%	100%	80%	80%	0%	20%	0%
	Days	0%	10%	20%	75%	60%	60%	25%	30%	20%
	Weeks	0%	10%	20%	0%	0%	0%	100%	90%	80%
Deafness ICD10-H91.9	Hours	20%	0%	12.5%	80%	80%	62.5%	0%	20%	25%
	Days	20%	0%	12.5%	0%	10%	0%	80%	90%	87.5%
	Weeks	20%	0%	12.5%	0%	10%	0%	80%	90%	87.5%

Appendix 2. Continued

	Duration	*No Adverse Event*			*Minor Adverse Event*			*Major Adverse Event*		
		Med	**MT**	**Pat**	**Med**	**MT**	**Pat**	**Med**	**MT**	**Pat**
Death		0%	0%	0%	0%	0%	0%	100%	100%	100%
Depression ICD10-F32	Hours	25%	30%	20%	75%	50%	80%	0%	20%	0%
	Days	25%	30%	20%	75%	40%	60%	0%	30%	20%
	Weeks	25%	30%	20%	0%	10%	0%	75%	60%	80%
Dislocation ICF-B7150		0%	0%	20%	0%	0%	0%	100%	100%	80%
Dizziness ICD10-R42	Hours	12.5%	0%	20%	87.5%	90%	80%	0%	10%	0%
	Days	0%	0%	20%	37.5%	80%	80%	62.5%	20%	0%
	Weeks	0%	0%	20%	0%	10%	60%	100%	90%	20%
Fainting ICD10-R55	Hours	0%	0%	20%	75%	80%	80%	25%	20%	0%
	Days	12.5%	0%	20%	0%	0%	0%	87.5%	100%	80%
	Weeks	12.5%	0%	20%	0%	0%	0%	87.5%	100%	80%
Fatigue / Yawn ICD10-R53	Hours	100%	80%	100%	0%	20%	0%	0%	0%	0%
	Days	12.5%	30%	40%	87.5%	70%	60%	0%	0%	0%
	Weeks	12.5%	0%	20%	75%	80%	80%	12.5%	20%	0%
Flushing ICD10-R23.2	Hours	87.5%	100%	100%	12.5%	0%	0%	0%	0%	0%
	Days	0%	10%	20%	87.5%	90%	80%	12.5%	0%	0%
	Weeks	0%	0%	20%	75%	90%	80%	25%	10%	0%
Fracture ICD10-S12		0%	0%	20%	0%	0%	0%	100%	100%	80%

Appendix 2. Continued

	Duration	*No Adverse Event*			*Minor Adverse Event*			*Major Adverse Event*		
		Med	**MT**	**Pat**	**Med**	**MT**	**Pat**	**Med**	**MT**	**Pat**
Headache ICF28010	Hours	0%	20%	20%	100%	70%	80%	0%	10%	0%
	Days	0%	0%	20%	100%	90%	80%	0%	10%	0%
	Weeks	0%	0%	20%	75%	50%	20%	25%	50%	20%
Increased pain during movement ICF-B2801	Hours	0%	10%	20%	100%	90%	80%	0%	0%	0%
	Days	0%	10%	20%	100%	90%	80%	0%	0%	0%
	Weeks	0%	10%	20%	0%	0%	0%	100%	90%	80%
Joint pain ICD10-M25.5	Hours	12.5%	0%	20%	87.5%	100%	80%	0%	0%	0%
	Days	12.5%	10%	20%	87.5%	70%	80%	0%	20%	0%
	Weeks	12.5%	10%	20%	62.5%	30%	80%	25%	60%	0%
Loss of movement ICF-B710	Hours	0%	10%	40%	100%	90%	60%	0%	0%	0%
	Days	0%	0%	20%	100%	90%	80%	0%	10%	0%
	Weeks	0%	0%	20%	87.5%	50%	60%	12.5%	50%	20%
Loss or reduced bladder control ICF-B6200	Hours	0%	0%	20%	87.5%	40%	80%	12.5%	60%	0%
	Days	0%	0%	20%	0%	0%	0%	100%	100%	80%
	Weeks	0%	0%	20%	0%	0%	0%	100%	100%	80%
Loss or reduced bowel control ICF-B5253	Hours	0%	0%	20%	100%	40%	80%	0%	60%	0%
	Days	0%	0%	20%	0%	0%	0%	100%	100%	80%
	Weeks	0%	0%	20%	0%	0%	0%	100%	100%	80%
Migraine ICD10-G43	Hours	12.5%	0%	20%	87.5%	70%	80%	0%	30%	0%
	Days	12.5%	0%	20%	75.0%	60%	80%	12.5%	40%	0%

Appendix 2. Continued

	Duration	*No Adverse Event*			*Minor Adverse Event*			*Major Adverse Event*		
		Med	**MT**	**Pat**	**Med**	**MT**	**Pat**	**Med**	**MT**	**Pat**
Muscle tenderness ICD10-M79.1	Hours	100%	90%	100%	0%	10%	0%	0%	0%	0%
	Days	0%	10%	40%	100%	90%	60%	0%	0%	0%
	Weeks	0%	10%	20%	100%	90%	80%	0%	0%	0%
Nausea ICF-5350	Hours	0%	0%	20%	100%	100%	80%	0%	0%	0%
	Days	0%	0%	20%	100%	90%	80%	0%	10%	0%
	Weeks	0%	0%	20%	50%	70%	80%	50%	30%	0%
Pain ICF-B2801	Hours	0%	20%	20%	100%	80%	80%	0%	0%	0%
	Days	0%	0%	20%	100%	80%	80%	0%	20%	0%
	Weeks	0%	0%	20%	0%	0%	0%	100%	100%	80%
Palpitations ICD10-F45.3	Hours	0%	10%	20%	100%	70%	80%	0%	20%	0%
	Days	0%	10%	20%	87.5%	50%	40%	12.5%	40%	40%
	Weeks	0%	10%	20%	12.5%	0%	20%	87.5%	90%	60%
Panic attack ICD10-F41	Hours	12.5%	30%	20%	87.5%	50%	80%	0%	20%	0%
	Days	12.5%	30%	20%	75%	40%	60%	12.5%	30%	20%
	Weeks	12.5%	30%	20%	0%	0%	0%	87.5%	70%	80%
Radiating pain ICF-B2803	Hours	0%	0%	20%	100%	100%	80%	0%	0%	0%
	Days	0%	0%	20%	100%	90%	80%	0%	0%	0%
	Weeks	0%	0%	20%	0%	10%	0%	100%	100%	80%

Appendix 2. Continued

	Duration	*No Adverse Event*			*Minor Adverse Event*			*Major Adverse Event*		
		Med	**MT**	**Pat**	**Med**	**MT**	**Pat**	**Med**	**MT**	**Pat**
Severe sweating ICD10-F45.3	Hours	12.5%	30%	40%	87.5%	70%	60%	0%	0%	0%
	Days	12.5%	20%	20%	87.5%	80%	80%	0%	0%	0%
	Weeks	12.5%	10%	20%	50%	80%	80%	25%	10%	0%
Skin rash ICD10-L98	Hours	25%	10%	40%	75%	90%	60%	0%	0%	0%
	Days	12.5%	0%	20%	87.5%	100%	80%	0%	0%	0%
	Weeks	12.5%	0%	20%	87.5%	80%	80%	0%	20%	0%
Stroke ICD10-I69		0%	0%	0%	0%	0%	0%	100%	100%	100%
Transient Ischaemic Attack (TIA) ICD10-G45		0%	0%	20%	0%	0%	0%	100%	100%	80%
Vertigo ICD10-H81.9	Hours	12.5%	0%	20%	87.5%	90%	80%	0%	10%	0%
	Days	0%	0%	20%	37.5%	70%	60%	62.5%	30%	20%
	Weeks	0%	0%	20%	0%	0%	20%	100%	100%	60%
Visual disturbance ICF-B210	Hours	0%	0%	20%	75%	50%	40%	25%	50%	40%
	Days	0%	0%	20%	25%	30%	40%	75%	70%	40%
	Weeks	0%	0%	20%	0%	0%	20%	100%	100%	20%
Vomiting ICD10-R11	Hours	0%	0%	20%	100%	100%	80%	0%	0%	0%
	Days	0%	0%	20%	75%	70%	60%	25%	30%	20%
	Weeks	0%	0%	20%	0%	0%	0%	100%	100%	80%

Abbreviations: MED: Medical specialists, MT: Manual Therapists, PAT: Patients