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Original article

## Development and validation of providers' and patients' measurement instruments to evaluate adverse events after spinal manipulation therapy

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### Abstract

**Introduction:** Spinal manipulation therapy (SMT) is used throughout the world by chiropractors, osteopaths, physiotherapists and other manual therapists, yet there are no systematic data collection mechanisms in place to monitor and evaluate adverse events (AE) that occur after SMT. We established a reporting and learning system ("SafetyNet") to fill this void and to address several aims, one of which is a prospective population-based active surveillance study to (a) document AE after SMT, (b) identify potential risk factors, and (c) develop potential strategies to mitigate risk. The purpose of this paper is to describe the development and validation of provider and patient measurement instruments to identify potential SMT AE in provider offices.

**Methods:** Instrument development and validation occurred in a step-wise fashion: (1) definition of terms (e.g. adverse event, seriousness); (2) identification and development of key domains, items, and sub-items; and (3) assessment of relevant measurement properties.

**Results:** Two provider short instruments, a provider long instrument, and a pre and post treatment patient comment instruments were developed, refined, and pilot tested with 12 providers and 300 patients.

**Conclusions:** The development and validation of instruments to evaluate SMT AEs may benefit the SMT research community as well as clinicians and their patients by providing rigorous prospective assessment of potential SMT-related AEs and their risk factors, thus enhancing patient safety and the promotion of a safety culture. Placing the instruments in providers' offices for use on consecutive patients is next on the SafetyNet research agenda.

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**Keywords:** Spinal manipulation therapy; Chiropractic; Physiotherapist; Validation; Instrument; Adverse event

### Introduction

The patient safety movement began in earnest with the 1991 report, *To Err Is Human: Building a Safer Health System* which found that U.S. hospital medical errors killed between 44,000 and 98,000 patients each year [1]. This report called for a shift in health care culture, moving away from a "blame and shame" culture toward a systems-based approach, promoting

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the identification and mitigation of adverse events. However, cultural shift is multifactorial and highly complex [1]. Barriers include litigation, professional protection, peer criticism, and potential respective governing body disciplinary actions. Understanding the multidimensionality and dynamic nature of culture particularly in community-based primary care is required if transformation to a safety culture is to occur [2]. Spinal manipulation therapy (SMT) is a regulated treatment, practised in community-based settings by several health care professions, such as chiropractors, osteopaths, naturopaths, physiotherapists, and physicians. The potential for an adverse event (AE) related to the delivery of SMT exists within all of these professions. Although the need to improve the identification of SMT AEs has been documented [3,4] no formal safety reporting and learning mechanisms exist in North America to monitor, assess and reduce SMT-related AEs.

Reporting and learning systems have emerged as a key strategy to identify and mitigate risks associated with health care delivery [5,6]. They are typically anonymous and confidential methods of monitoring the occurrence of clinical or administrative incidents, and used to develop improvement strategies to address the cause of the incidents. Good reporting and learning systems move beyond pure reporting element and lead into an environment of continuous learning [2]. Most often these systems are found in association with hospital-based quality assurance and patient safety initiatives; community-based reporting and learning systems remain quite scarce. This gap is relevant, as the majority of health care delivery occurs in the community, not in hospitals [7]. As the first step in developing a reporting and learning system, AE identification, reporting, and assessment are vital to patient safety, as the identification of modifiable risk factors can reduce harms system.

AEs associated with SMT have been studied in different research designs, including clinical trials [8–10]. Clinical trials are not the optimal design to collect rare AEs [10] and most observational studies lack standardized instruments and operational definitions for relevant terms [11]. Reported AEs following SMT in adult patients are most often self-limiting and usually consist of symptoms such as radiating musculoskeletal pain, nausea, dizziness, or tiredness [11–13]. There have been other more serious, but rare AEs, such as cauda equina syndrome [13,14] and stroke. A recent case control study suggests the “association between manipulation and stroke is confounded by indication”, raising doubt about a causal relationship [15].

To help overcome the absence of high quality data about SMT AE in North America, we developed SafetyNet. It is comprised of a number of research projects that aim to support the development of a patient safety culture for SMT providers. SafetyNet reflects the efforts of a large multidisciplinary research team with expertise in physiotherapy, chiropractic, and various medical specialties. SafetyNet has several coordinated objectives, including conducting a prospective population-based active surveillance study to document AEs after SMT, identify potential risk factors, and develop potential strategies to mitigate risk. The team is based in Alberta, Canada, with steering committee members from across Canada, as well as from the United States and Europe. As chiropractors and physiotherapists provide the

majority of SMT care in Alberta, our team has focused on developing instruments for use in their practices. We describe one of the first projects undertaken by members of this team to develop and validate provider and patient measurement instruments to allow for assessment of potential SMT AE in provider offices.

## Research approach

The research approach we took was to develop standardized instruments with clear definitions of relevant terms. This development and validation occurred in a step-wise fashion: (1) definition of terms (e.g. adverse event, seriousness, etc.); (2) identification and development of key domains, items, and sub-items; and (3) assessment of relevant measurement properties. The instruments needed to be brief enough to facilitate their implementation, yet detailed enough to be informative. A multi-disciplinary team of content and/or SMT experts and providers ( $n = 16$ ) were involved, as their experience was needed at each step. The completion of a step was not considered to have been achieved until consensus was reached. This took a period of about 18 months.

## Methods and findings

### Step 1: Definition of terms

Unclear definitions are one of the major methodological flaws when reporting on manual therapy adverse event data [4,11]. Our team’s first step was to define AE and determine other variables that needed to have operational definitions to allow for meaningful study. As shown in Table 1, we identified existing definitions of AE from relevant organizations. The team adapted the definition of AE from the International Conference of Harmonisation (ICH) [16,17]: *Any unfavorable sign, symptom, or disease temporally associated with the treatment, whether or not caused by the treatment.*

Our team decided the following variables were necessary for meaningful AE assessment: (i) seriousness; (ii) causality (i.e. relatedness); (iii) preventability; and (iv) patient disposition. Similar to the AE process, definitions for these variables were sought from relevant organizations and the published literature. Table 2 provides all the definitions that were considered for seriousness. For our study’s purposes, we adapted the definition proposed by the National Cancer Institute [24]:

*Mild:* Asymptomatic or mild symptoms, self-care only (e.g. ice/heat, over-the-counter analgesic);

*Moderate:* Limiting age-appropriate activities of daily living (e.g. work, school) OR sought care from a medical doctor;

*Severe:* Medically significant but not immediately life-threatening; temporarily limits self-care (e.g. bathing, dressing, eating); OR urgent or emergency room assessment sought; and

*Serious:* Results in death OR a life-threatening adverse event OR an AE resulting in inpatient hospitalization or prolongation of existing hospitalization for more than 24 h: a persistent or significant incapacity or substantial disruption of the ability

Table 1  
Definitions of adverse event.

SafetyNET[18]	Any unfavorable sign, symptom, or disease temporally associated with the treatment, whether or not caused by the treatment (adapted from the ICH definition).
International Conference on Harmonisation (ICH) [19]	Any untoward medical occurrence in a patient or clinical investigation and which does not necessarily have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the treatment, whether or not related to the treatment.
World Health Organization (WHO) [16,20]	An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable.
US Food and Drug Administration (FDA) [21]	An adverse event is any undesirable experience associated with the use of the medical product in a patient.
Institute for Health Improvement (IHI) [22]	(Harm): Unintended physical injury resulting from or contribute to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death.
Agency for Healthcare Research and Quality (AHRQ) [23]	An untoward and usually unanticipated outcome that occurs in association with health care.
Common Terminology Criteria for Adverse Event (CTCAE) [24]	Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure.
Canadian Institute for Patient Safety (CPSI) [25]	1. An unexpected and undesired incident directly associated with the care or services provided to the patient; 2. An incident that occurs during the process of providing health care and results in patient injury or death; 3. An adverse outcome for a patient, including an injury or complication.

to conduct normal life functions; a congenital anomaly/birth defect.

For causality, we modified the definition proposed by the WHO, de-emphasizing health products and making the language more inclusive of practice-based health care interventions [27] (see Table 3):

*Certain*: A clinical event occurring in a plausible time relationship to treatment, and which cannot be explained by concurrent disease or other drugs or therapies;

*Probable/likely*: A clinical event with a reasonable time sequence to treatment, unlikely to be attributed to concurrent disease or other drugs or therapies;

*Possible*: A clinical event with a reasonable time sequence to treatment, but which could also be explained by concurrent disease or other drugs or therapies; and

*Unlikely*: A clinical event with a temporal relationship to treatment which makes a causal relationship improbable, and in which drugs, other therapies or underlying disease provide plausible explanations.

For patient disposition, we adopted the definition proposed by the National Institute of Arthritis and Musculoskeletal and Skin Diseases [30]:

- 1: Resolved, no sequelae
- 2: AE still present – no treatment
- 3: AE still present – being treated
- 4: Residual effects present – no treatment
- 5: Residual effects present – treated
- 6: Death
- 7: Unknown

We also adopted a definition of preventability from Baker and Norton [34]:

- 1: Virtually no evidence of preventability
- 2: Slight to modest evidence of preventability
- 3: Preventability not quite likely (less than 50/50, but “close call”)
- 4: Preventability more than likely (more than 50/50, but “close call”)
- 5: Strong evidence of preventability
- 6: Virtually certain evidence of preventability

*Step 2: Identification and development of key domains, items, and sub-items*

To be able to assess the relationship between exposure and outcome, separate patient and provider instruments were developed. We included the following domains: (i) details of the intervention, including anatomic location and dose; (ii) details of any AE reported, including time to occurrence, seriousness, patient disposition; and (iii) potential confounders, including patient’s underlying health concerns and other therapies used.

For feasibility reasons, the measurement instruments also needed to: (a) be easy to complete by the users; (b) collect essential information without being too burdensome; (c) avoid promoting hypervigilance or stress about potential AE; and (d) collect information for a reasonable duration. Finally, we balanced our desire to collect all potential related AE with recognizing the diminishing return from AEs that occurred more than a week after treatment.

We used an iterative process for developing and refining items and sub-items until consensus was reached on both the questions and response options. Five instruments were developed (see Appendices A–C):

- (a) *Two provider short instruments*: Since terminology differs amongst SMT professions, the treatment section was designed to be profession-specific; thus both a physiotherapy and chiropractic versions were developed. We designed

Table 2  
AE severity definitions from major organizations (not an exhaustive list).

SafetyNET [18]	<p><b>Mild:</b> Asymptomatic or mild symptoms, self-care only (e.g. ice/heat, over-the-counter analgesic). <b>Moderate:</b> Limiting age-appropriate activities of daily living (e.g. work, school) OR sought care from a medical doctor. <b>Severe:</b> Medically significant but not immediately life-threatening; temporarily limits self-care (e.g. bathing, dressing, eating); OR urgent or ER assessment sought. <b>Serious:</b> Results in death OR a life-threatening adverse event OR an AE resulting in inpatient hospitalization or prolongation of existing hospitalization for more than 24 hours; a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; a congenital anomaly/birth defect.</p>
National Cancer Institute (NCI) Common Toxicity Criteria [24]	<p><b>Mild:</b> Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated. <b>Moderate:</b> Minimal, local, or non-invasive intervention (e.g. ice/heat pack, analgesic, anti-inflammatory meds) indicated; limiting age-appropriate activities of daily living (ADL). <b>Severe:</b> Medically significant, but not immediately life-threatening; hospitalization; disabling; limiting self-care ADL. <b>Serious:</b> Results in death; OR a life-threatening adverse event; OR an adverse event that results in inpatient hospitalization or prolongation of existing hospitalization for &gt;24 h; a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; a congenital anomaly/birth defect. Of note, important medical events that may not result in death, be life threatening or require hospitalization may be considered serious when, based upon medical judgment, they jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.</p>
International Conference on Harmonisation (ICH) [19]	<p><b>Serious:</b> Any untoward medical occurrence that at any dose: (a) results in death, (b) is life-threatening. Life threatening refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.</p>
WHO International Classification for Patient Safety (ICPS) [20]	<p><b>Minor temporary:</b> Minor patient injury or increased patient monitoring or change in treatment plan (with or without injury), length of stay increased by less than 1 day. Examples: Error in setting or monitoring heparin levels requiring increased number of lab tests, missed insulin dose requiring change in dosing for next administration and/or increased glucose checks. Bruising, abrasions, skin tear, complaints of pain, small number of non-facial sutures. Minor self-inflicted injury (scratches or cutting). <b>Major temporary:</b> A temporary injury that exceeds minor temporary or increases length of stay one day or more. Examples: Facial sutures, minor fractures, severe drug reaction. <b>Minor permanent:</b> A permanent injury that does not compromise basic functions of daily living. Examples: Loss of finger, loss of testicle or ovary, removal of bowel due to circulatory compromise, loss of teeth, second-degree sexual conduct (forced sexual contact via threat of violence or weapon, forced sexual contact that causes injury, or sexual contact with someone under 16 years old), retained sponge/needle. <b>Major permanent:</b> Permanent injury that affects basic functions of daily living. Examples: Hip fracture, nerve damage from improper surgical positioning, missing limb, damage to sensory organ, first-degree sexual assault (forced sexual penetration via threat of violence or weapon, forced sexual penetration that causes injury, or sexual penetration of someone under 16 years old).</p>
Institute for Healthcare Improvement [22]	<p><b>Category E:</b> Temporary harm to the patient and required intervention. <b>Category F:</b> Temporary harm to the patient and required initial or prolonged hospitalization. <b>Category G:</b> Permanent patient harm. <b>Category H:</b> Intervention required to sustain life. <b>Category I:</b> Patient death.</p>
National Health Services (NHS) [26]	<p><b>Low:</b> Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care. <b>Moderate:</b> Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care. <b>Severe:</b> Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care. <b>Death:</b> Any patient safety incident that directly resulted in the death of one or more persons receiving NHS funded care.</p>

these instruments to be completed on all consecutive patients seen during the study period; hence the majority of information is collected through check boxes. This design allows the instruments to only take a few seconds to complete (Appendix A).

- (b) *Provider long instrument:* This instrument is designed to be completed for all moderate, serious, or severe patient reported AEs (Appendix B). It contains text boxes to allow for narrative descriptions allowing for better understanding of the events leading to the AE [16].
- (c) *Two patient instruments:* The first version of this instrument was a two-sided document to collect information about the SMT visit from the patient's perspective. Patient feedback was evaluated by our study team, and the instrument

was modified into two separate pre- and post-treatment instruments. The pre-treatment instrument addresses items such as medical history and current symptoms. At the recommendation of SMT provider groups, the post-treatment instrument gathers information about overall patient satisfaction, treatment sought and overall experience, positive or negative. Only patients, who report a negative experience, are asked additional questions regarding a potential AE and its nature, severity, and duration as well as follow-up care required and current disposition. Both paper and web-based versions were created for the post-treatment instrument; they are identical except for 6 extra questions on the web-based version allowing for more space for patient responses (Appendix C).

Table 3  
Causality (e.g. relatedness) and patient disposition terms.

Relatedness	
SafetyNET [18]	<p><b>Certain:</b> A clinical event occurring in a plausible time relationship to treatment, and which cannot be explained by concurrent disease or other drugs or therapies.</p> <p><b>Probable/likely:</b> A clinical event with a reasonable time sequence to treatment, unlikely to be attributed to concurrent disease or other drugs or therapies.</p> <p><b>Possible:</b> A clinical event with a reasonable time sequence to treatment, but which could also be explained by concurrent disease or other drugs or therapies.</p> <p><b>Unlikely:</b> A clinical event with a temporal relationship to treatment which makes a causal relationship improbable, and in which drugs, other therapies or underlying disease provide plausible explanations.</p>
WHO Collaborating Center for International Drug Monitoring [28]	<p><b>Certain:</b> A clinical event, including laboratory test abnormality, occurring in a plausible time relationship to drug administration, and which cannot be explained by concurrent disease or other drugs or chemicals.</p> <p><b>Probable/likely:</b> A clinical event, including laboratory test abnormality, with a reasonable time sequence to administration of the drug, unlikely to be attributed to concurrent disease or other drugs or chemicals, and which follows a clinically reasonable response on withdrawal (dechallenge).</p> <p><b>Possible:</b> A clinical event, including laboratory test abnormality, with a reasonable time sequence to administrations of the drug, but which could also be explained by concurrent disease or other drugs or chemicals. Information on drug withdrawal may be lacking or unclear.</p> <p><b>Unlikely:</b> A clinical event, including laboratory test abnormality, with a temporal relationship to drug administration which makes a causal relationship improbable, and in which other drugs, chemicals or underlying disease provide plausible explanations.</p> <p><b>Conditional/unclassified:</b> A clinical event, including laboratory test abnormality, reported as an adverse reaction, about which more data is essential for a proper assessment, or the additional data is under examination.</p> <p><b>Unassessable/unclassifiable:</b> A report suggesting an adverse reaction which cannot be judged because information is insufficient or contradictory, and which cannot be supplemented or verified.</p>
European Union Pharmacovigilance [29]	<p><b>Category A:</b> Reports including good reasons and sufficient documentation to assume a causal relationship, in the sense of plausible, conceivable, likely, but not necessarily highly probable.</p> <p><b>Category B:</b> Reports containing sufficient information to accept the possibility of a causal relationship, in the sense of not impossible and not unlikely, although the connection is uncertain and may be even doubtful, e.g. because of missing data, insufficient evidence or the possibility of another explanation.</p> <p><b>Category O:</b> Reports where causality is, for one or another reason, not assessable, e.g. because of missing or conflicting data.</p>
<i>Patient disposition</i>	
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) [30] and SafetyNET** [18]	<p>1 = Resolved, no sequelae 2 = AE still present – no treatment 3 = AE still present – being treated 4 = Residual effects present – no treatment 5 = Residual effects present – treated 6 = Death 7 = Unknown</p>
National Institute on Aging [31]	<p>1 = Recovered, without treatment 2 = Recovered, with treatment 3 = Still present, no treatment 4 = Still present, being treated 5 = Residual effect(s) present – no treatment 6 = Residual effect(s) present – being treated 7 = Participant died</p>
Children’s Hospital Boston, Clinical Research Program [32]	<p>1 = Resolved, no residual effects 2 = Resolved, with sequelae 3 = Continuing 4 = Disability 5 = Death 6 = Unknown at this time</p>
National Institute of Neurological Disorders and Stroke [33]	<p>1 = Resolved without effects 2 = Resolved with effects 3 = Ongoing 4 = Death 5 = Unknown</p>

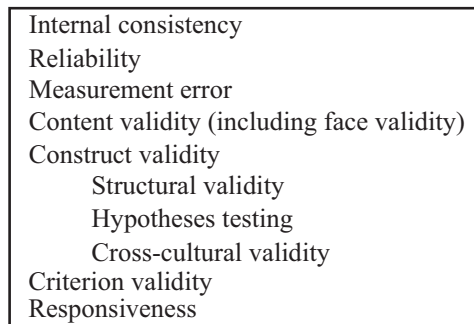


Fig. 1. Quality criteria for a legitimized health instrument's measurement properties.

### Step 3: Assessment of relevant measurement properties

Good measurement properties legitimize a health status questionnaire/instrument [17,27,35]. The quality criteria for a health instrument's measurement properties are outlined in Fig. 1. Only two measurement properties were completely relevant for the validation of these instruments: content validity and hypotheses testing. A portion of reliability was evaluated. The other measurement properties are not relevant or too early in development to assess. Internal consistency and structural validity are not relevant as no total score from these instruments is sought. These instruments have only been developed and validated in English in two Canadian provinces; it is therefore premature to consider cross-cultural validity. Since there is no gold standard for assessing SMT AE, criterion validity cannot be evaluated. Responsiveness and measurement error are not relevant because this study is not looking for change over time.

Content validity assesses the instrument to ensure that the concepts of interest are embodied [35,36]. For this instrument, the development included the following aspects:

*Measurement aim of the questionnaire:* The aim or specific definitions were clearly defined at the start of the study, which was followed up to ensure that each question would allow the terms to be adequately assessed.

*Target population:* Both SMT providers and their patients reviewed and provided feedback during the pre-testing period of the instrument development.

*Concepts:* The overall concept was to measure AEs associated with SMT and this was revisited by the multi-disciplinary team throughout the development of the instruments.

*Item selection and item reduction:* Questions were identified through literature reviews, expert consensus, pilot testing with field practitioners, and discussion with regulatory bodies. Each revision included a thorough review of all instruments to ensure all relevant items were included, while removing redundancies.

*Interpretability of the items:* Pre-testing was used to examine the readability and question comprehension by both the providers and the patients. We also developed 2 provider short instruments so that profession-specific terminology could be accommodated (provider feedback suggested this was important to prevent misinterpretation).

Hypotheses testing (part of construct validity) assesses the instrument's ability to measure the specific question that it was designed to do so [35]. For this instrument, our questions (i.e. hypotheses) and definitions were determined first (*Step 1*), followed by the development of the instruments to address our study questions (*Step 2*). Throughout the development of these instruments there was a consistent ongoing and iterative feedback to ensure that the questions asked were aimed at answering our specific study aim.

Reliability is the extent for which respondents who have not changed are the same when repeated measures are taken under several conditions [27,35]. There are three main components: test-retest, inter-rater, and intra-rater. Of these components the first two are not relevant, in that we expect a change over time and different respondents (both providers and patients) are expected to have different perceptions (the instruments are completed at different points in time). Intra-rater reliability was evaluated on a limited basis during patient and provider pretesting, where the instruments were found to collect the same information that was described during the interviews.

### Pretesting

The penultimate version of the provider instruments was pretested by providers ( $n=12$ ) and patients (approximately  $n=300$ ) in Alberta and British Columbia, Canada. The Health Research Ethics Board at the University of Alberta approved the pretesting of the instruments.

All providers found that the short instrument was quick and easy to use and could be implemented within existing practice procedures. General feedback on the long instrument indicated that the questions were relevant when reporting a moderate, serious, or severe AE.

The penultimate version of the patient instrument was discussed with a small convenience sample of patients ( $n=15$ ) following their visit with a SMT provider. One-on-one interviews were conducted until data saturation was achieved. The interviews were not recorded. A few patients found the instrument too long and some would not be willing to take the extra time to complete it. A common statement heard was 'I would complete the instrument if my provider asked me to. If it was important to him/her, then I would make it important for me to do.' Minor clarifications were requested. All patients stated that the list of potential AEs did not concern them or make them feel any less comfortable with the care that they had just received. Non-English speaking patients were unable to complete the patient comment instrument. The team therefore decided that for Non-English speaking patients, only the provider instruments were to be completed.

### Discussion

This project started with definition of terms to be used consistently throughout measurement and assessment and then developed and validated the measurement instruments to assess AEs after SMT. A limitation of current AE reporting systems includes the lack of ownership by professionals [37]. To try

and engage the SMT community, a multi-disciplinary team of experts in epidemiology, SMT and patient safety research, providers and professional associations/regulators collaborated on the development of our study definitions and instruments. Instrument refinement occurred in an iterative process involving extensive conversation and debate; the process was complete when consensus was reached. Our goal was for each participating profession to feel that the instruments “belonged” to them.

The importance of patients’ perspectives and experience to the patient safety movement was recognized as one of the six aims to the 2001 Institute of Medicine report, *Crossing the Quality Chasm* [38]. While most passive reporting systems are designed for provider reporting only, we have designed a system that provided both patients and clinicians the opportunity to report potential SMT AE. Patient perspective is especially important as health care providers have demonstrated poor reporting of suspected AEs [39]. Additionally, patient reports should come directly to a third party, since patients may be reluctant to report AEs to their providers in fear of being labeled ‘difficult’ [40]. On the basis of patient feedback, we had divided the patient instrument into 2 parts, which allow will reduce recall bias. Another important virtue is the use of standardized terminology and definitions on both the provider and patient instruments [11,41,42]. Similar to Carlesso et al.’s approach, this study used their team of experts and patients to develop the study’s definitions for AE and other related terms.

Surveillance for AE may be passive or active. Passive surveillance systems have been developed for SMT providers, such as the CPIRLS system currently open to all European chiropractors to anonymously report incidents [43,44]. Like other passive surveillance systems (e.g. pharmacovigilance), it is challenged by considerable under-reporting [20,45,46]. Active surveillance systems have shown themselves to improve both the quality and quantity of AE reports, such that they can be evaluated in a meaningful fashion [47].

Both active and passive surveillance systems rest on a foundation of the identification of incidents, or “cases”. Considerable debate has occurred regarding whether or not case reports can be used to infer causation [48,49], including the role of case reports in patient safety. While case reports are the base of the evidence hierarchy when evaluating effectiveness [50], some have proposed an inverted pyramid when evaluating harms, in light of the tremendous amount of information provided by well-reported cases [51]. The majority of harms identified in healthcare first emerged as case reports, which have served to generate hypotheses subsequently evaluated through other study designs [52]. Confounding by indication, or protopathic bias, is a major concern whenever AEs may be associated with the patient’s underlying health condition, rather than due to the intervention. For example, one large case-crossover study recently suggested that vertebrobasilar stroke following SMT reflected patients with cervical dissection-related head and neck pain seeking care from chiropractors, and that the SMT was coincidental and not in the causal pathway of the subsequent strokes [10].

In our study, we prospectively collect SMT exposure data on all patients, whether or not AE occur. We also request outcome

data whether or not an AE occurs, allowing us to compare cases (those who experience AE) to controls (those who do not experience AE). Finally, we have developed an in-depth process to assess moderate, serious, and severe AEs by a multi-disciplinary team using validated approaches for harms assessment. While the instruments described in this paper do not evaluate administrative or other non-clinical incidents, these are included in other parts of the SafetyNet research program.

Our approach combines expert judgment and standardized tools, the gold standards in patient safety [53]. Our research will contribute to knowledge on patient safety and SMT. It will help to gauge the frequency and seriousness of the most common AEs. Most importantly, it will stimulate a dialog on patient safety amongst practitioners of SMT. This in turn will help to develop more advanced study methodologies to assess causal relationships and preventive measures to ensure patient safety. Our goal is to collect high quality data that will make a meaningful contribution to our current understanding of SMT AE.

## Conclusions

The development and validation of instruments to evaluate SMT AEs may benefit SMT research by providing the opportunity for rigorous prospective assessment of potential SMT-related AEs and their risk factors. We have developed profession-specific instruments and engaged members of each profession who can act as champions, promoting patient safety culture for community-based SMT providers. Future efforts with these instruments include putting them into providers’ offices for use on consecutive patients in an effort to assess AE after SMT.

## Funding support

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## Conflict of interest

J.D. Cassidy has been a paid expert in malpractice court actions concerning adverse events after spinal manipulative therapy, and Cassidy has given testimony at public hearings concerning informed consent prior to spinal manipulative therapy.

Others declared that they have no conflict of interest.

## Acknowledgements

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Appendix A.

**DC Short Form**

**Thank you for your support.**

Please complete this form on all consecutive patients throughout your participation, no exceptions (even if the patient decides not to complete their form or is non-English speaking).

**Patient Data (Note - ALL patients are eligible, regardless of age):**

- 1) Age \_\_\_\_\_ months / years (*circle one*)    2) Gender     Male     Female  
 3) Presenting Condition(s):     Preventative/Wellness/No Symptoms     Headache     Neck Pain  
     Thoracic Back Pain     Low Back Pain     Extremity pain     Other, specify \_\_\_\_\_  
 4) Radicular Pain?     Yes     No    5) Please indicate if the primary condition is:     Chronic     Acute  
 6) Any manual therapy within the last week?     Yes     No  
 7) How long has this patient been receiving manual therapy? \_\_\_\_\_ months / years (*circle one*)

**Treatment (please indicate which type of manual therapy and how often applied done for each anatomic location)**

	Cervical Spine	Thoracic Spine	Lumbar Spine	Sacrum / Pelvis	Upper Extremity	Lower Extremity	Other*
# of Manipulations	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+
# of Mobilizations	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+
Mechanical Device	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+
Other Manual Tx	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+
Other Non-Man. Tx	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3+

\*Other (specify) \_\_\_\_\_

**Adverse Event**

Was there any adverse event after the manual therapy treatment?     No     Yes (*complete table below*)

Adverse Event (check all that apply)	Location (if applicable)	Anticipated	Overall Severity Rating
<input type="checkbox"/> Discomfort/Pain		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Stiffness		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Weakness		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Fatigue/Tiredness		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Headache		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Dizziness		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Difficulty with vision		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Sleeping Disturbances		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Irritability / Crying		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Dysarthria		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Nausea/Vomiting		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Numbness/Tingling		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Strains/Sprains		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Gait Disturbances		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Other: _____		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious

**PT Short Form**

**Thank you for your support.**

Please complete this form on all consecutive patients throughout your participation, no exceptions (even if the patient decides not to complete their form or is non-English speaking).

**Patient Data**

1) Age \_\_\_\_\_ months / years (*circle one*)    2) Gender     Male     Female  
 3) Presenting Condition(s):     Preventative/Wellness/No Symptoms     Headache     Neck Pain  
     Thoracic Back Pain     Low Back Pain     Extremity pain     Other, specify \_\_\_\_\_  
 4) Radicular Pain?     Yes     No    5) Please indicate if the primary condition is:     Chronic     Acute  
 6) Any manual therapy within the last week?     Yes     No  
 7) How long has this patient been receiving manual therapy? \_\_\_\_\_ months / years (*circle one*)

**Treatment (as comprehensive as possible, please describe the therapy that you provided for this patient today)**

	Specific Area / Spinal Level	Grade	Direction	More information:
Manual Therapy #1	<input type="checkbox"/> C <input type="checkbox"/> T <input type="checkbox"/> L <input type="checkbox"/> P <input type="checkbox"/> U/E <input type="checkbox"/> L/E	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> Flex <input type="checkbox"/> Ext <input type="checkbox"/> Rot <input type="checkbox"/> Side	
Manual Therapy #2	<input type="checkbox"/> C <input type="checkbox"/> T <input type="checkbox"/> L <input type="checkbox"/> P <input type="checkbox"/> U/E <input type="checkbox"/> L/E	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> Flex <input type="checkbox"/> Ext <input type="checkbox"/> Rot <input type="checkbox"/> Side	
Manual Therapy #3	<input type="checkbox"/> C <input type="checkbox"/> T <input type="checkbox"/> L <input type="checkbox"/> P <input type="checkbox"/> U/E <input type="checkbox"/> L/E	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	<input type="checkbox"/> Flex <input type="checkbox"/> Ext <input type="checkbox"/> Rot <input type="checkbox"/> Side	
Non-manipulation therapies:	<input type="checkbox"/> Exercise(s) <input type="checkbox"/> Stretch(es) <input type="checkbox"/> Acupuncture / Acupressure <input type="checkbox"/> Other, please describe:			

**Adverse Event**  
 Was there any adverse event after the manual therapy treatment?     No     Yes (*complete table below*)

Adverse Event ( <i>check all that apply</i> )	Location ( <i>if applicable</i> )	Anticipated	Overall Severity Rating
<input type="checkbox"/> Discomfort/Pain		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Stiffness		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Weakness		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Fatigue/Tiredness		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Headache		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Dizziness		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Difficulty with vision		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Sleeping Disturbances		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Irritability / Crying		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Dysarthria		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Nausea/Vomiting		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Numbness/Tingling		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Strains/Sprains		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Gait Disturbances		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious
<input type="checkbox"/> Other: _____		<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Serious

Appendix B.

**Provider Long Form**

**Complete ONLY for Moderate, Severe or Serious Adverse Events**

Please consider completing online at:

<https://redcap.med.ualberta.ca/surveys/?s=mx4QVH> or scan this:

**General Adverse Event Narrative**

1) Please describe what happened. (Include date of onset, manual therapy technique/location, treatment schedule, patient's response, tests done to evaluate the symptoms, and all actions taken.)

2) How long after treatment did the adverse event occur? \_\_\_\_\_ Hours OR \_\_\_\_\_ Days

3) In your opinion, what may have contributed to the adverse event?

**Patient Characteristics – Please describe what was known *PRIOR TO* treatment**

4) Reason of patient visit: \_\_\_\_\_

5) What was patient's specific diagnosis for treatment? (Include details such as acute/chronic/recurring, what symptoms they had, and what diagnostic tests were done prior to treatment.)

Please con't on back

**Patient Characteristics con't – Please describe what was known *PRIOR TO* treatment**

6) Has the patient experienced an adverse event to manual therapy in the past?  
 Yes  No  Unknown

If Yes, please specify \_\_\_\_\_

7) Did the patient have any other diagnoses?  Yes  No  Unknown  
If Yes, please specify \_\_\_\_\_

8) Were you aware if the patient had any of the following conditions **prior to treatment**:

<input type="checkbox"/> Acute infection	<input type="checkbox"/> High cholesterol	<input type="checkbox"/> Recent relevant trauma
<input type="checkbox"/> Alcoholism	<input type="checkbox"/> History of cancer	<input type="checkbox"/> Recent upper respiratory infection
<input type="checkbox"/> Arteriosclerosis	<input type="checkbox"/> History of TIA	<input type="checkbox"/> Spinal stenosis
<input type="checkbox"/> Bleeding tendency	<input type="checkbox"/> History of stroke	<input type="checkbox"/> Smoking
<input type="checkbox"/> Connective tissue disorder	<input type="checkbox"/> Hypertension	<input type="checkbox"/> Tuberculosis
<input type="checkbox"/> Degenerative disc disease	<input type="checkbox"/> Migraine	<input type="checkbox"/> Vertigo
<input type="checkbox"/> Diabetes	<input type="checkbox"/> Osteoporosis/Osteopenia	<input type="checkbox"/> Fever
<input type="checkbox"/> Fracture	<input type="checkbox"/> Prior spine surgeries	<input type="checkbox"/> Pregnancy
	<input type="checkbox"/> Radiculopathy	<input type="checkbox"/> Other

9) Please check medication(s) or natural health product(s) the patient was taking **prior to treatment**:

<b>Prescription Medications</b> <input type="checkbox"/> Don't Know	<b>Natural Health Products</b>	<input type="checkbox"/> Don't Know
<input type="checkbox"/> Anticoagulant (warfarin, dicumarol)	<input type="checkbox"/> Garlic	<input type="checkbox"/> Vitamin K
<input type="checkbox"/> Antiplatelet (aspirin)	<input type="checkbox"/> Ginger	<input type="checkbox"/> Other NHP, Specify
<input type="checkbox"/> Oral Contraception	<input type="checkbox"/> Ginkgo	
<input type="checkbox"/> Steroid	<input type="checkbox"/> Omega 3 Fatty Acids	
<input type="checkbox"/> Other, specify _____	<input type="checkbox"/> Vitamin E	

**Outcome (from your perspective/awareness)**

**Patient Impact:**

10) What activities of daily living were affected?

11) Was self-care affected?  Yes  No  Unknown

12) Was the patient hospitalized?  Yes  No  Unknown

13) Describe any residual effect/permanent disability/death:

14) Did the adverse event require treatment?  Yes  No  Unknown

15) Has the adverse event resolved?  Yes  No  Unknown

If Yes, Date of Resolution (dd/mm/yyyy) \_\_\_\_ / \_\_\_\_ / \_\_\_\_

**Provider Impact:**

16) Has this event caused you to make any changes to your practice?  Yes  No

If Yes, describe \_\_\_\_\_

17) Were there factors that could have minimized/prevented this event?  Yes  No

If Yes, describe:

Appendix C.

**Thank you for your support, your feedback is extremely valuable.**

Completion and return of this form means you agree to be part of this study.

If you are consenting on behalf of a son / daughter, the terms 'you' and 'your' should be read as your 'son / daughter'.

- 1) Are you responding for:  Yourself  Son / Daughter
- 2) Why did you come to this appointment?  Preventative/Wellness/No Symptoms  
 Headache  Neck pain  Mid-back pain  Low-back pain  
 Sprain/Strain  Arm / Leg pain  Other, specify \_\_\_\_\_
- 3) How long have you had this/these condition(s)? \_\_\_\_\_ days OR \_\_\_\_\_ weeks  N/A
- 4) How would you rate your pain at this moment?
- No pain  0  1  2  3  4  5  6  7  8  9  10 Worst imaginable pain
- 5) Please indicate any medications that you are taking:  None  
 Aspirin  Birth control pill  Pain Medications  
 Blood thinners (e.g. Warfarin/Coumadin, dicumarol)  Steroid  Other: \_\_\_\_\_
- 6) Please indicate any natural health products that you are taking:  None  Omega-3  
 Garlic  Ginger  Ginkgo  Vitamin E  Vitamin K  Other: \_\_\_\_\_
- 7) Do you have a history of any of the following?  None  Alcoholism  
 Bleeding disorder  Cancer  Connective tissues disorder (e.g. Lupus, scleroderma)  
 Diabetes  High cholesterol  Migraine headache  Osteoporosis (thin bones)  
 Smoking  Spinal surgery  Stroke  TIA (transient ischemic attack)  
 Tuberculosis (TB)  Other, specify: \_\_\_\_\_
- 8) Are you:  Male  Female
- 9) In what year were you born? \_\_\_\_\_
- 10) Today's fees covered by:  Self-pay  Car Accident Coverage  
 WCB  Other Insurance: \_\_\_\_\_

**Please continue with questions on the back.**

	DISCOMFORT/ PAIN	STIFFNESS	WEAKNESS	TIREDFNESS/ FATIGUE	HEADACHE	DIZZINESS	VISION PROBLEMS	PROBLEMS SLEEPING	IRRITABILITY/ CRYING	DIFFICULTY TALKING	NAUSEA/ VOMITING	TINGLING/ NUMBNESS	STRAIN/ SPRAIN	DIFFICULTY WALKING	OTHER:
1) Do you have any of the following? (check all that apply)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
For each symptom you have, please answer the questions below and mark (●) where applicable.															
2) Does it interfere with your usual daily activities (e.g. work, school)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3) How many days have you had it?	_____ days	_____ days	_____ days	_____ days	_____ days	_____ days	_____ days	_____ days	_____ days	_____ days	_____ days	_____ days	_____ days	_____ days	_____ days
4) Does it limit your ability to care for yourself (e.g. bathing, dressing, eating)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Thank you for participating in the study.**  
**Please place this completed form in your provider’s SafetyNET box.**

**\*\*\* Please Return the POST treatment comment form up to one week after your visit.\*\*\***



**Thank you for your support in this study, your feedback is extremely valuable.**

- Completion and return of this form means you agree to be part of this study. Please answer the questions based upon the appointment date identified below.
- You can complete this survey at any time; however, we are most interested in your feedback one week after your visit.
- If you can, please complete this form online at: [www.wchri.ca/safety](http://www.wchri.ca/safety) or scan this QR:

Mark <b>ONLY ONE</b> checkbox on each line	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied
1) How satisfied are you with the information you have been given from your provider?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2) How satisfied are you with the treatment(s) that you received?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3) How satisfied are you with the overall care that you received?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If you are consenting on behalf of a minor, the terms 'you' and 'your' should be read as your 'son / daughter'.

4) Are you responding for:  Yourself  Son / Daughter

5) How would you rate your pain at this moment?

No pain Worst imaginable pain  
 0  1  2  3  4  5  6  7  8  9  10

6) During your appointment, did you receive **manual therapy** (also called manipulation, mobilization or adjustment; defined as 'A hands-on therapy to affect joints in the neck, back or limbs; sometimes hand-held mechanical devices are also used.')

- No, please seal in provided envelope and place in mail
- Yes, please mark all areas where you received a manual therapy:  
 Neck  Back  Arms/Legs  Other: \_\_\_\_\_

**Overall**, What was its effect?  Favorable  Unfavorable  None  Unsure

Did you have any problems/side effects as a result within a week of your treatment?

- Yes, please complete page 2 (on reverse)
- No, please seal in provided envelope and place in mail

	DISCOMFORT/ PAIN	STIFFNESS	WEAKNESS	TIREDFNESS/ FATIGUE	HEADACHE	DIZZINESS	VISION PROBLEMS	PROBLEMS SLEEPING	IRRITABILITY/ CRYING	DIFFICULTY TALKING	NAUSEA/ VOMITING	TINGLING/ NUMBNESS	STRAIN/ SPRAIN	DIFFICULTY WALKING	OTHER:
1) Which side effect(s) did you have? (check all that apply)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
For each side effect you had, please answer the questions below and mark (●) where applicable.															
2) Did you expect this to occur? (Mark (●) for yes)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3) Did it interfere with your usual daily activities (e.g. work, school)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4) Did it limit your ability to care for yourself (e.g. bathing, dressing, eating)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5) Did you need to see a medical doctor because of it?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6) Were you admitted to hospital because of it?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7) How many hours after the therapy did it start?	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____
8) For how many days did it last? (check 'C' if it still continues)	_____ days O C	_____ days O C	_____ days O C	_____ days O C	_____ days O C	_____ days O C	_____ days O C	_____ days O C	_____ days O C	_____ days O C	_____ days O C	_____ days O C	_____ days O C	_____ days O C	_____ days O C
If C, are you currently being treated for it?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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