Improving the Assessment of Safety in Pediatric Chiropractic Manual Therapy

by

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A thesis submitted in partial fulfillment of the requirements for the degree of

Doctor of Philosophy

Medical Sciences - Pediatrics

University of Alberta

Abstract

Introduction

As the cornerstone of high-quality health care, patient safety was first brought to light with the Institute of Medicine's (IOM) *To Err is Human* seminal report in 1999 that outlined the gulf between what is desired to what really exists. This report launched intense research efforts mostly focused on hospital-settings despite the majority of health care occurring in ambulatory settings, including chiropractic offices. Although 14% of US adults and 3.3% of children seek chiropractic care each year, there is a lack of prospective patient safety research focused on this profession. This thesis addresses the gap in patient safety research in ambulatory settings by assessing ways to measure patient safety culture and patient safety performance in such environment, as well as collecting primary data about children seeking care from chiropractors.

Methods

Two distinct methods were used in this thesis. The first was a cross-sectional survey used to assess patient safety culture and barriers/facilitators for participation in an active surveillance reporting system of chiropractors who belong to pediatric organizations. To assess patient safety culture, the AHRQ's *Medical Office Survey on Patient Safety Culture* was adapted for use by spinal manipulation therapy providers, including chiropractors. This portion of the survey measured the attitudes and opinions of respondents to 10 patient safety dimensions, specific patient safety/quality issues, information exchange, and overall perception of patient safety/quality.

The second portion of the cross-sectional survey asked participants about 9-factors identified in the literature as inhibitors to participation in active surveillance reporting systems.

The second method was a pragmatic, superiority, cluster, stratified randomized controlled trial (RCT) to compare the quantity and quality of adverse event (AE) reports after chiropractic manual therapy in children less than 14 years of age using active versus passive surveillance reporting systems. Data were collected from 60 consecutive pediatric patient visits with participating chiropractors who were randomly allocated in a 1:1 ratio. For the active surveillance arm, AE information was collected with three questionnaires (one completed by chiropractors and two completed by patients/caregivers). For the passive surveillance arm, AE information was submitted by the chiropractors using a web-based system called “CPiRLS”. The quantity (by cumulative incidence) of AE reports was the primary analysis. Independent assessment by two content experts was used to evaluate quality of moderate, severe, and serious AEs reports submitted by the chiropractor.

Results

While patient safety attitudes and opinions of responding chiropractors in the first section of the cross-sectional survey were positive, the response rate was only 29.5%. Chiropractors with a pediatric certification were three times more likely to respond but did not differ in their responses from those without this certification on the patient safety dimensions evaluated. One fifth of respondents completed the questions regarding barriers and facilitators to an active surveillance reporting system; ‘time pressure’ and ‘patient concerns’ were identified as the most important barriers and the belief that reporting was necessary as the most important facilitator.

Sixty-nine chiropractors participated in the RCT. Active surveillance had a 8.8% AE reporting rate, while passive surveillance had 0.1%. ($p<0.001$). No regression analyses were conducted because of the small number of reports in the passive surveillance group. In the active surveillance group, 135 AEs were reported by patients/caregivers: 76 (56.3%) were mild; 35

(25.9%) were moderate; and 24 (17.8%) were severe. Quality of AE reports were not evaluated because the five provider-generated AE reports were determined to be of mild severity by the adjudicators and therefore not assessed further.

Conclusion

Research conducted in this thesis has increased the limited body of literature regarding patient safety for pediatric chiropractic care. The cross-sectional survey found responding chiropractors reported a positive patient safety culture, although the low response rate likely introduced selection bias. Key factors affecting providers' willingness to participate in AE reporting systems were identified (i.e., time pressures and concerns about patient responses to such systems), which guided the methods used in the RCT comparing AE reports collected through active versus passive surveillance in pediatric chiropractic care. From the RCT, the frequency of AE reporting was 40-fold increased when using an active surveillance system as opposed to passive surveillance (8.8% vs. 0.1%, $p<0.001$). Recommendations for future research include developing evidence to address identified weaknesses in patient safety dimensions assessed (e.g., if a patient safety dimension, such as 'communication', is found to be a weakness, then interventions that successfully support that dimension can be suggested to the provider or organization as a way to try and improve this area) and more prospective evaluations to explore pediatric AE incidence for specific ages/conditions/treatments. As the inaugural prospective safety study of pediatric chiropractic, AEs were found to be more common than prior retrospective literature suggested, which is important for chiropractors to consider when making pediatric treatment recommendations, as well as to discuss with their patients when seeking informed consent. Further research is needed to identify how to mitigate or prevent moderate and severe pediatric AEs.

Preface

This thesis is an original work by Katherine Ann Pohlman.

The research projects, of which this thesis is a part, received research ethics approval from the University of Alberta Research Ethics Board, Project Name “Pediatric Chiropractic Patient Safety Survey”, No. Pro00043860, January 14, 2014 and “STAIR: Pediatric active surveillance reporting and learning system”, No. Pro00027903, August 8, 2014.

Some of the research conducted for this thesis was informed by an international research group of patient safety and spinal manipulation experts, SafetyNET, which is led by Dr. Sunita Vohra, Professor Tim Caulfield, and Dr. Greg Kawchuk at University of Alberta; Dr. Heather Boon at University of Toronto; and Dr. Maeve O’Beirne at University of Alberta. SafetyNET was funded by the Canadian Institutes of Health Research, Alberta Innovates-Health Solutions, and the Women and Children's Health Research Institute, University of Alberta. Specifically, the cross-sectional survey used in Chapter 3 and the active surveillance data collection forms used in Chapters 5 & 6 were designed by me in close collaboration with the SafetyNET team of experts assisting with content modifications.

Chapter 3 of this thesis has been published as:

> Pohlman KA, Carroll L, Hartling L, Tsuyuki R, Vohra S. Attitudes and opinions of doctors of chiropractic specializing in pediatric care toward patient safety: a cross-sectional survey.J Manipulative Physiol Ther 2016 Sept;39(7):487-493.

I was responsible for the concept development, design, data collection/processing, analysis/interpretation, literature search and manuscript writing. All other authors provided advice and guidance in study development and conduct, as well as critical review of the final paper.

Chapter 4 of this thesis has been published as:

> Pohlman KA, Carroll L, Hartling L, Tsuyuki R, Vohra S. Barriers to implementing a reporting and learning patient safety system: pediatric chiropractic perspective. J Evid Based Complementary Altern Med 2016 Apr;21(2):105-109.

I conceptualize the overall project, designed and managed data collection, analyzed the data, and wrote the manuscript. All other authors provided advice and guidance in study development and conduct, as well as critical review of the final paper.

Chapter 5 of this thesis has been published as:

> Pohlman KA, Carroll L, Tsuyuki RT, Hartling L, Vohra S. Active versus passive adverse event reporting after pediatric chiropractic manual therapy: study protocol for a cluster randomized controlled trial. Trials 2017 Dec 1;18(1):575.

I was responsible for the study conception, conducting the trial and writing the manuscript. All other authors were involved with giving advice to the study concept and critically reviewing the final manuscript.

Acknowledgements

This thesis would not have been possible without the unwavering support and love from my husband, Randy. Thank you for believing in me and knowing what I was capable of achieving before I was even aware of it myself.

To my children, Jacob, Isaiah, Evan, and Tess – Thank you for the constant reminder of what life is all about. Your simple laughter and joy fill me with happiness, which allows me to stay focused on excellence.

To my parents – From day one, you loved, believed in, and supported me. Thank you.

To my family and friends – Thank you for loving me and my family, despite not knowing where I was going to live, when I would be calling or visiting, or why I was still going to school. Your love and friendship mean the world to Randy, our kiddos, and me!

Words are not be available for the mentorship provided by my co-supervisors, Drs. Sunita Vohra and Linda Carroll. Your dedication to my success and constant guidance along my wavy path to this thesis completion was the key to success of both this thesis and my future. Thank you for your encouragement that has helped me to grow as a researcher, an academic, and as a person.

I am grateful for my committee members, Drs. Lisa Hartling and Ross Tsuyuki. Their advice, dedication, and expertise made invaluable contributions to this thesis.

To the entire SafetyNET team of experts – Truly humbling to be 'standing on the shoulder of giants', thank you for this life-changing opportunity to be a part of this project with you.

To the endless mentors in my life – I am one truly blessed individual to have been trained at the Palmer Center for Chiropractic Research with Drs. Long, Goertz, Vining, Hondras, and Lawrence. And then to be an inaugural fellow with the Chiropractic Academy for Research Leadership (CARL) program with Drs. Kawchuk, Hartvigsen, and Adams, as well as my co-fellows who are truly friends and the game-changers of the future.

I would like to acknowledge all of the chiropractors who participated in the studies within this thesis. I appreciate the time they took to share their experience, which has helped our profession understand the care we provide a little bit better.

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List of Abbreviations

AAFP – American Academy of Family Physicians
ACA – American Chiropractic Association
AE – Adverse Events
AEFI – Adverse Events Following Immunizations
AEO – Adverse Event Ontology
AHRQ – Agency for Healthcare Research and Quality
AMA – American Medical Association
ASIPS – Applied Strategies for Improving Patient Safety
CA – California
CAM – Complementary and Alternative Medicine
CCP – Council on Chiropractic Pediatrics
CI – Confidence Interval
CONSORT – Consolidated Standards of Reporting Trials
CPiRLS – Chiropractic Patient Incident Reporting and Learning System
CPSI – Canadian Institute for Patient Safety
CRLS – Chiropractic Reporting and Learning System
CTCAE – Common Terminology Criteria for Adverse Event
DACCP – Diplomate in Pediatrics from the Academy Council of Chiropractic Pediatrics
DC – Doctors of Chiropractic
DICCP – Diplomate in Clinical Chiropractic Pediatrics
DO – Doctor of Osteopathy
e.g. – for example
et al. – and others
FDA – Food and Drug Administration
FL – Florida
GEE – General Estimating Equation
IA – Iowa
ICA – International Chiropractors Association
ICH – International Conference on Harmonisation
ICPA – International Chiropractic Pediatric Association
i.e. –
IHI – Institute for Healthcare Improvement
IOM – Institute of Medicine
KAP – Katherine Ann Pohlman
LPN – Licensed Practical Nurse
LVN – Licensed Vocational Nurse
MD – Medical Doctor
MO – Missouri
NA – Not Applicable
NHS – National Health Service
NP – Nurse Practitioner
NPSF – National Patient Safety Foundation
NRS – Numerical Pain Scale
NY – New York
OAE – Ontology for Adverse Events
PA – Physician Assistant
PIRLS – Patient Incident Reporting and Learning System'
RCT – Randomized Controlled Trial
REDCap – Research Electronic Data Capture
RLS – Reporting and Learning System
RR – Relative Risks
SAQ-A – Safety Attitudes Questionnaire – Ambulatory version
SMT – Spinal Manipulation Therapy
TN – Tennessee
TX – Texas
US – United States
UK – United Kingdom
VBA – Vertebro-Basilar Accident
vs – versus
WA – Washington
WHO – World Health Organization

Chapter 1:
Introduction

1.1 – Overview

The seminal 'To Err Is Human' report released in 1999 by the Institute of Medicine (IOM) raised awareness of medical error and challenged the health care community to improve patient safety [IOM, 2000]. This report was followed by similar reports developed by many other countries with hopes of preventing adverse events in health care systems around the globe [Australia Council, 2000 & Department of Health, 2000; Building a Safer System, 2002]. All of these reports focused on improving a *patient safety culture* and increasing measurement of *patient safety performance*, a focus which in turn was hoped to decrease adverse events and increase overall quality of care.

The focus of this thesis is on the improvement of patient safety assessment for health care providers in ambulatory settings, specifically pediatric chiropractic care. While the IOM report increased the awareness of patient safety, its focus was initially on hospital systems. For ambulatory settings, much less has been studied or reported, perhaps in part because of an assumption that that these environments are safer [Wachter & Gupta, 2017]. Since most health care is delivered in ambulatory settings [Change et al., 2016], more patient safety research is needed in this environment, especially considering the complex treatments available and increasing health care expenditures in these settings. *Patient safety culture* is most commonly assessed with cross-sectional surveys of patient safety attitudes and opinions. Several survey options exist that have had extensive evaluations for their measurement properties when used in hospitals and other settings, such as nursing homes, pharmacies, and medical offices [Patankar et al., 2012; Desmedt et al., 2017]. *Patient safety performance* has been initiated in primary care settings in several countries, including the USA [Philips et al., 2006; Elder et al., 2004; Fernald et al., 2004], England [Kostopoulou et al., 2007; Rubin et al., 2003], Australia [Makeham et al., 2006], and Canada [O'Beirne et al., 2011]. But because these studies all had different data collection methods and definitions for adverse events (AE) were highly variable, most conclusions included a call for a better understanding of the reporting systems use in ambulatory settings. This thesis is specific to an ambulatory setting in chiropractic offices that care for pediatric patients.

Chiropractic is the most commonly sought complementary therapy in the United States [Black et al., 2015] and are becoming more specialized in the care they provide [Garner et al., 2008]. On average, 17% of a general practice chiropractor's patient population are children [Christensen et al., 2015]; however, this increases to 39% for those chiropractors with a pediatric certification [Pohlman et al., 2010]. In the US, a 2012 national survey found that 3.3% of children in the US have received chiropractic or osteopathic manipulative therapy [Black et al., 2015].

In the past two decades, two post-graduate pediatric-focused diplomate programs have been deployed within the chiropractic profession [Hewitt et al., 2016]. These programs were established by chiropractors who had commonly treated pediatric patients within their private practice for several years. The International Chiropractors Association (ICA) specialty Council on Chiropractic Pediatrics (ICA-CCP) started the first post-graduate training program in 1993 [ICA-CCP, accessed 2014] offering a Diplomate in Clinical Chiropractic Pediatrics (DICCP) after all requirements are met. The International Chiropractic Pediatric Association (ICPA) started the second program in 2002 [ICPA, accessed 2014] offering a Diplomate in Pediatrics from the Academy Council of Chiropractic Pediatrics (DACCP). These programs are administered through a chiropractic college's post-graduate department and require between 280-400 hours of training taken over two to three years. Their mission is to train practicing DCs to acquire more advanced skills and competency with the evaluation, diagnosis, and assessment procedures for the pediatric population, as well as to obtain modification to manual therapy skills for this population and clinical conditions with which children commonly present with to a chiropractor. Both post-graduate programs' examinations are self-administered by the respective organizations and are not currently governed by any regulatory body. Competencies expected from graduates of such program have been developed by a content expert Delphi panel [Hewitt et al., 2016] and advances have made to develop an independent examination board to certify doctors of chiropractic who have completed pediatric post-graduate training programs.

As a self-regulated profession, it is the responsibility of the chiropractic profession to ensure that safe and effective care is provided. At the start of this thesis, there was no mechanism to systematically and continuously monitor patient safety for chiropractors providing care to the pediatric population. The need for such monitoring is highlighted by findings from systematic reviews on AEs following spinal manipulation [Vohra et al., 2007; Humphreys 2010]. These reviews identified a lack of high-quality data and because of the high prevalence of pediatric chiropractic care, they called for a prospective population-based surveillance to assess risks of chiropractic care in the pediatric care.

SafetyNET is an international and interdisciplinary team of research leaders and content experts with a goal to develop novel approaches to support a patient safety culture for spinal manipulation therapy providers, including chiropractors [Vohra et al., 2014]. This team had 4 main areas of inquiry that was initiated with the qualitative team who focused on facilitators and barriers to patient safety research in the chiropractic environment [Winterbottom et al., 2015; Rozmovits et al., 2016]. The health law team evaluated risk of litigation when conducting patient safety research [Ries & Fisher, 2013; Renke, 2014; Burningham, Renke, & Caulfield, 2013; Burningham, Rachul, Caulfield, 2013; Du et al., 2017]. Findings from the qualitative and health law team were used to inform the community-based team, which conducted a patient safety culture survey and active surveillance reporting and learning systems for both the chiropractic and physiotherapy professions [Appendix A; Pohlman et al., 2014]. Congruently, the basic science team investigated the potential mechanisms of action for spinal manipulation related AEs [Funabashi et al., 2018; Funabashi et al., 2017; Funabashi et al., 2017; D'Angelo et al., 2016; Howarth et al., 2016; Funabashi et al., 2016; Funabashi et al., 2015]. This thesis is distinct from this team's work, but information from these projects guided studies conducted in this thesis and vice versa.

For this thesis, the content validity of an existing patient safety culture cross-sectional survey was modified and re-assessed in order to measure the *patient safety culture* of chiropractors who are members of pediatric chiropractic organizations. Because of the limited information about the best intervention to collect *patient safety performance* in ambulatory settings in general, and in chiropractic offices in particular, a head-to-head comparison of two commonly used surveillance systems (passive versus active) was conducted.

1.2 – Thesis Organization

Chapter 2 provides a review of the published literature on patient safety culture and performance, measurement options, and brief history and current status of patient safety throughout the world and in ambulatory and chiropractic settings.

Chapter 3 contains my first thesis paper, which is an evaluation of *patient safety culture*. To achieve this, I assessed the patient safety attitudes and opinions of chiropractors who were members of a pediatric chiropractic organizations. This has been published as follows:

> Pohlman KA, Carroll L, Hartling L, Tsuyuki R, Vohra S. Attitudes and opinions of doctors of chiropractic specializing in pediatric care toward patient safety: a cross-sectional survey. J Manipulative Physiol Ther 2016 Sept;39(7):487-493.

Chapters 4, 5, and 6 make up the second section of this thesis, which evaluated methods to collect *patient safety performance*.

Chapter 4 contains my second thesis paper, which described pediatric chiropractors self-reported barriers and facilitators to implementing AE surveillance systems. This second paper has been published as follows:

> Pohlman KA, Carroll L, Hartling L, Tsuyuki R, Vohra S. Barriers to implementing a reporting and learning patient safety system: pediatric chiropractic perspective. J Evid Based Complementary Altern Med 2016 Apr;21(2):105-109.

Chapter 5 contains the published protocol for the cluster randomized controlled trial, which is described in Chapter 6:

> Pohlman KA, Carroll L, Tsuyuki RT, Hartling L, Vohra S. Active versus passive adverse event reporting after pediatric chiropractic manual therapy: study protocol for a cluster randomized controlled trial. Trials 2017 Dec 1;18(1):575.

Chapter 6 provides the cluster randomized controlled trial to compare passive versus active surveillance systems to collect AE reports, as per the protocol seen in Chapter 5. As it is written as a stand-alone paper, there is necessarily some repetition in content with the study protocol in Chapter 5.

Chapter 7 provides an overall summary, conclusion, and implications of this doctoral thesis work. As well as an overall conclusion, which includes a brief summary of the thesis and what it adds to our current knowledge.

This thesis also has 6 appendices:

Appendix A is the pdf of the publication describing the development and validation of the SafetyNET's Survey to Support Quality Improvement. This work was preliminary to the development and conduct of Papers 1 and 2 (found in Chapters 3 and 4).

Appendix B is the pdf of the publication describing the development and content validation for the data collection instruments used in the active surveillance arm of the cluster randomized controlled trial (Paper 3, Chapter 6).

Appendix C contains the ethics approval documentation for conducting the studies in this thesis.

Appendix D provides the SafetyNET's Survey to Support Quality Improvement instrument that was used in the first two studies (described in Chapters 3 & 4), as well as a copy of the data collection instruments used in RCT of the third study (described in Chapters 5 & 6).

Appendix E has extra material for Chapters 5 & 6 (CPiRLS trigger list, AE reports, and full data analysis by symptoms).

Appendix F has copies of the published manuscripts from Chapter 3, 4, and 5.

1.3 – Significance

While patient safety research has made great strides over the past two decades, it is still in the process of evolving and expanding to all areas of health care, including ambulatory settings such as chiropractic offices. Although these environments may treat patients who are less acutely unwell than those seen in inpatient settings, the Agency for Healthcare Research and Quality states: "*It is critical that researchers test the effectiveness of prospective tools and resources in real world circumstances—something hard to do in a fast-paced and busy ambulatory environment"* [Brady et al., 2013, electronic only-page # unavailable]. This thesis addresses the current gap in patient safety assessment with regards to chiropractors who treat the pediatric population.

Chapter 2:
Literature Review

2.1 – Patient Safety Culture – An Overview

Primum non nocere.
(First do no harm.)
– Hippocrates

This section will provide a definition of patient safety culture, explain how *patient safety culture* (attitudes and opinions of patient safety) differs from *patient safety performance* (avoidance of medical error or adverse events (AEs), as well as learning from them when they do occur), and describe existing conceptual patient safety models. It will then provide a brief history of patient safety in developed countries (i.e., United States - US, United Kingdom - UK, Australia, and Canada), with highlights from each country's seminal patient safety report. This section will conclude with an update on the current standing of patient safety.

2.1.1 – Patient Safety Culture: Definition and Models

Like many health care terms, definitions abound for patient safety culture; however, these definitions are typically similar to the one outlined by Singer et al (2009): 'the values shared among organization members about what is important, their beliefs about how things operate in the organization, and the interaction of these with work unit and organizational structures and systems, which together produce behavioral norms in the organization that promote safety' [Singer, et al., 2009, page 400]. To help explain the complexity of a patient safety culture, Patankar et al. created a pyramid-style conceptual model to depict the multi-dimensional layers and dynamic natures involved with patient safety culture [Patankar et al., 2012]. Each layer of the pyramid has unique measurement properties and contributes to the overall stature of a patient safety culture. The foundational layer is *safety values*, which identifies the underlying values and unquestioned assumptions of individual employees and organizations [Patankar et al. 2012]. While it may feel unnecessary or basic to state, it is essential to explicitly state safety in an organization that wants or should include safety in their values. The secondary layer is *safety strategies*, which entails an organization's structures, policies, procedures, practices, and leadership influence. Leadership has a direct influence on safety culture, with best results found when standardized behavioral expectations are known and modeled by all in an organization. *Safety climate*, the tertiary layer, comprises employee attitudes and opinions regarding safety, which has been thought to have the strongest influence on an organization's overall patient

safety culture [Wu et al., 2008]. At the tip of the pyramid is the ultimate goal, *safety performance*, which is avoidance of medical error or AEs, as well as both acting and learning from an error that may occur.

Concurrently, another model has been described by Palmieri et al., with a safety hierarchy model differentiating the often interchanged terms of safety attitudes, safety climate, and safety culture. According to this model, *safety attitudes* refers to the individual or team level, followed by *safety climate* at the unit or department level, followed by *safety culture*, which is the corporate division and organization, and at the top is the safety standards which represent the industry level [Palmieri et al., 2010]. This hierarchy has differences in stability and ease in modification, with the first levels (*safety attitudes* and *safety climates*) being less stable, but more flexible. The top layer (*safety culture*) are stable, but inflexible and resistant to modification [Hoffman & Stetzer, 1996; Wiegmann et al., 2004; Zohar, 2008]. This model does not include patient safety performance, as Palmieri et al. found that despite outcome improvement being the desire, approaches to quantify these outcomes within a patient safety culture framework remained vague and incomplete [Nieva & Sorra, 2003; Zohar, 2008].

In summary, the Institute for Healthcare Improvement (IHI) summarizes the essence of a patient safety culture by stating: ‘in a culture of safety, people are not merely encouraged to work toward change; they take action when it is needed. Inaction in the face of safety problems is taboo, and eventually, the pressure comes from all directions — from peers as well as leaders’ [IHI, 2014a].

2.1.2 – Brief History of Patient Safety in Developed Countries

Throughout the history of health care, there has been fragmented efforts to improve patient safety [Burneet & Vincet, 2007]. During the Crimean War, Florence Nightingale found that more soldiers were dying from infections caused by the health care they were receiving than from battle wounds [Fee & Garofalo, 2010]. However, it was not until 1999-2002 that organized patient safety efforts started in the developed countries of Australia, Canada, UK, and US, where concerted efforts to make their health care systems free from avoidable injury started to be taken [Australia Council, 2000; Building a Safer System, 2002; UK Department of Health, 2000; IOM, 1999]. Shown in Table 2.1 are recommendations or key priority areas written in the seminal reports created by these countries to break the cycle of inaction and silence that surrounded the patient safety issue in health care [IOM, 1999]. The first report released was *To Err is Human*, which was written by the US Institute of Medicine. It had nine recommendations

and laid out a comprehensive strategy to address what they called a 'serious problem in health care to which we are all vulnerable.'

In 2000, both Australia and the UK released their seminal reports, *Safety First* and *An Organization with a Memory*, respectively [Australia Council, 2000 & Department of Health, 2000]. While *Safety First* was Australia's first official report, ongoing efforts had outlined the importance of national leadership and action to improve the quality and safety of health care. Similar to the recommendations in *To Err is Human* report, the *An Organization with a Memory* UK report described a fundamental re-thinking of how their health care system currently did not take advantage of learning from patient AEs and focused on 'bad' doctors versus fixing the system so that human errors were prevented. *A National Integrated Strategy for Improving Patient Safety in Canadian Health Care* was the Canadian report produced in 2002 [Building a Safer System, 2002]. After a national forum in 2001, this document summarized Canada's National Steering Committee with five categories that were similar to the other countries and demonstrated Canada's commitment to patient safety and changing the current culture.

Each of these countries have developed national safety agencies, with objectives and activities reviewed in a 2004 manuscript [Arah & Klazinga, 2004]. Concerns stated from this review were that having multiple safety organizations could have disadvantages as they may be too many, too vague, too narrowly focused, prohibited by litigation, and too optimistic. The review suggested that countries should strive toward a coherent, deeper, focused, evidence-based safety, along with realistic safety initiatives. As countries create patient safety models, the best of those models will include transferability to other countries and research conducted on how the models actually affect safety culture and outcomes [Arah & Klazinga, 2004].

Before the seminal reports were released, other high-risk industries had successes with safety and quality, including nuclear power plants, aviation, and automobile manufacturing. These industries' success relied, in part, on their recognition that diverse experience is needed to produce the best outcome at the lowest cost [Wachter & Gupta, 2017]. Diverse experience isn't the norm within health care in developed countries, which has been hypothesized as one of the reasons for the need to have a specific concerted effort on patient safety within health care worldwide [Wachter & Gupta, 2017]. Other reasons included: 1) no support; 2) siloed professional training; and 3) excessive professional pride [Wachter & Gupta, 2017]. With these reasons explicitly identified, there were high hopes the developed countries' patient safety culture reports with comprehensive recommendations and priority areas documented would lead to drastic change in patient safety culture for the health care industry.

Table 2.1. Categories of patient safety recommendations or priority areas that was initially thought to be addressed by jurisdictions.

United States, 1999 [IOM, 1999]	**Australia,** 2000 [Australia Council, 2000]	**United Kingdom,** 2000 [Department of Health, 2000]	**Canada,** 2002 [Building a Safer System, 2002]
1–Congress should create a Center for Patient Safety within the Agency for Healthcare Research and Quality 2–A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings 3–The development of voluntary reporting efforts should be encouraged 4–Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality 5–Performance standards and expectations for health care organizations should focus greater attention on patient safety 6–Performance standards and expectations for health professionals should focus greater attention on patient safety. 7–The Food and Drug Administration (FDA) should increase attention to the safe use of drugs in both pre- and post-marketing processes 8–Health care organizations and the professionals affiliated with them should make continually improved patient safety a declared and serious aim by establishing patient safety programs with defined executive responsibility. 9–Health care organizations should implement proven medication safety practices.	1–Better using data to identify, learn from and prevent error and system failure 2–Promoting effective approaches to clinical governance and accountability which address both the competence of organisations and individuals 3–Redesigning systems and creating a culture of safety within health care organizations	1–Unified mechanisms for reporting and analysis when things go wrong 2–A more open culture, in which errors or service failures can be reported and discussed 3–Mechanisms for ensuring that, where lessons are identified, the necessary changes are put into practice 4–A much wider appreciation of the value of the system approach in preventing, analyzing and learning from errors	1–Establish a Canadian Patient Safety Institute to facilitate a national integrated strategy for improving PS 2–Improve legal and regulatory processes 3–Improve measurement and evaluation processes 4–Establish educational and professional development programs 5–Improve information and communication processes

2.1.3 – Current Patient Safety Status in Health Care

Although concerted patient safety efforts were made during the past ten years, the desire for increased patient safety culture in health care was not a realization. Specifically, despite focused efforts, one in ten patients had an AE during hospitalization in 2014 [AHRQ, 2014] and one in two surgeries had a medication error and/or adverse drug reaction in 2015 [Nanji et al., 2015]. Globally, it was estimated in 2013 that 42.7 million AEs occur each year from the 421 million hospitalizations [Jha et al., 2013]. Based on that, the US and UK produced follow-up reports to their initial productions that aimed to refocus the efforts [AHRQ, 2014; Illingsworth, 2015].

In 2015, fifteen years after the publication of *To Err is Human*, an expert US panel within the National Patient Safety Foundation (NPSF) was convened to conduct a thorough review of the state of patient safety within the US health care system. Their overall conclusion was that areas within patient safety had improved, such as there was an estimated 1.3 million patient reduction of hospital acquired conditions between 2011-2013 [AHRQ, 2014]. However, the panel emphasized that patient safety was still a major public health issue [NPSF, 2015]. The report gave recommendations to establish a comprehensive approach with a focus on developing a *patient safety culture* versus a focus on *patient safety performance*. Their key recommendation was that leaders in health care organizations need to make a commitment to establishing and sustaining a patient safety culture. Other recommendations included: 1) create centralized and coordinated oversight of patient safety; 2) create a common set of safety metrics that reflect meaningful outcomes; 3) increase funding for research in patient safety and implementation science; 4) address safety across the entire health care continuum; 5) support the health care workforce; 6) partner with patients and families for the safest care; and 7) ensure that the technology is safe and optimized to improve patient safety. The report also concluded that substantially more health care is provided in ambulatory centers (1 billion annual visits) than in hospital settings (35 million annual admissions), thus more focus needs to be done in these environments [NCHS, 2015].

In the same year, The Health Foundation in UK released a follow-up report called *Continuous Improvement of Patient Safety: The Case for Change in the NHS* (National Health Service) [Illingsworth, 2015]. Similar to the US's follow-up report, the UK report found a mixed picture for patient safety changes. For example, people working within the NHS were increasingly more willing to report an incident and feel that action would be taken. However, health care workers

stated that their patient safety culture was a “blame culture” while 41% of patients felt there were not enough nurses, despite their increased feeling of being safe in hospitals [Illingsworth, 2015]. This report suggested three key items to continue their patient safety efforts: 1) make practical improvements, such as front-line health care team members using a checklist for safety improvement when a safety concern is found; 2) involve senior leaders to create an environment for patient safety to flourish; and 3) create systems for effective safety improvements, which includes policies and procedures that are inextricably linked to patient safety.

Both these follow-up reports focused on developing a patient safety culture versus a focus on reducing patient safety errors [NCHS, 2015; Illingsworth, 2015]. They also had a strong focus on the responsibility and ability of leadership to make these changes. Contrary to this was an overview of literature to assess whether improving patient safety culture affect patient outcomes culture [The Health Foundation, 2011]. This overview found that from the 23 research studies, changes in patient outcomes may need to come first, which may lead to a change in culture [The Health Foundation, 2011]. Furthermore, they stated that it may be a reciprocal or two-way relationship between culture and outcomes, as several studies found culture and outcomes improving simultaneously.

Recently, a BMJ manuscript estimated that medical error is the 3rd most common cause of death in the US [Makary & Daniel, 2016]. This manuscript argued that Centers for Disease Control and Prevention’s annual list of the most common causes of death in the US is created from death certifications, which do not capture causes of death. Causes of death can be human and system patient safety factors, such as communication breakdowns, diagnostic errors, poor judgement, and inadequate skills [Makary & Daniel, 2016]. They concluded that the system for measuring national vital statistics need to be modified to better understand the impact medical care has on harms and death rates and should be done with a sound scientific approach, as it is with treating and diagnosing medical conditions [Makary & Daniel, 2016].

2.2 – Process to Measure Patient Safety

This section focuses both on the process through which *patient safety culture* and *patient safety performance* are assessed, as well as specific evaluation to measure these concepts. In essence, although consensus on what survey tool may be best is not known, the measurement of *patient safety culture* has been established with the use of cross-sectional or longitudinal

surveys. *Patient safety performance* is usually evaluated by AE, which is most common collected with two types of surveillance reporting systems: passive and active surveillance.

2.2.1 – Patient Safety Culture

While some studies have attempted to measure *patient safety culture* through observation (i.e., examining communication in surgical or delivery suites) [Berridge et al., 2010; Knight et al., 2014], the most common way to measure *patient safety culture* is through cross-sectional or longitudinal surveys that ask about patient safety attitudes and opinions [Patankar et al., 2012; Wachter & Gupta, 2017]. Several patient safety culture surveys typically use rating scales to measure different dimensions or factors (i.e., teamwork, communication, leadership) and provide snapshots of the sample population. Colla et al. conducted a review of nine *patient safety culture* surveys used in hospital settings and concluded not only that surveys need to be interpreted with caution, but also that more research is needed to establish a link between a *patient safety culture* and patient treatment outcomes [Colla et al., 2005]. Colla et al. also emphasize the importance of established psychometric properties, distribution of safety assessments among all units within an organization, and feedback provided to survey respondents [Colla et al., 2005].

Table 2.2 shows surveys that could be used in ambulatory care settings (these are further discussed in the manuscript in Appendix A). Each of these surveys had been conducted in general medical practices; however, none were conducted with non-medical providers (e.g., chiropractors or physical therapist). Similar to hospital setting surveys, these rating scales measure patient safety dimensions relevant for ambulatory settings. Surprisingly, multi-year surveys of *patient safety culture* have shown not only the large variations in *patient safety culture* occurring between organizations, but also the significant variations within units at the same organization [Campbell et al., 2010], among different providers [Listyowardojo et al., 2012; Bump et al., 2017; Hickner et al., 2016], and caregivers versus administrators [Singer et al., 2003].

Table 2.2. Surveys identified through a scoping literature review to evaluate patient safety attitudes and opinions in ambulatory settings. [Funabashi et al., 2018]

Author, Year	Title	Purpose	Setting, Location	Population Studied (sample size)	Survey Items and Dimensions/Factors
de Wet et al., 2010	The development and psychometric evaluation of a safety climate measure for primary care	To measure perceptions of safety climate among primary care teams outside of North America.	Primary care teams in National Health Service, Scotland	563 primary care team members from 49 general practices	30 items, measuring 5 safety climate factors: 1) Leadership, 2) Teamwork, 3) Communication, 4) Workload, 5) Safety Systems.
Hoffman et al., 2011	The Frankfurt Patient Safety Climate Questionnaire for General Practices (FraSiK): analysis of psychometric properties	To measure patient safety climate in practices with only 1-2 doctors, who are owners with 2-4 other professional employees (small offices).	General practice in Germany	332 health care professionals working in 60 general practices	72 items, measuring 9 dimensions: 1) Teamwork climate, 2) Error management, 3) Safety of clinical processes, 4) Perception of causes of errors, 5) Job satisfaction, 6) Safety of office structure, 7) Receptiveness to health care assistants, 8) Patient safety of medical care. {Adapted from the SAQ-A}
Modak et al., 2007	Measuring safety culture in the ambulatory setting: the Safety Attitudes Questionnaire (SAQ) – Ambulatory Version (SAQ-A)	To measure safety attitudes of outpatient settings.	Academic, urban, outpatient practice in Texas, United States	251 out-patients providers (physicians, nurses, managers, medical assistants and support staff)	62 item survey, measuring 6 factors: 1) Teamwork climate, 2) Safety climate, 3) Perceptions of management, 4) Job satisfaction, 5) Working conditions, 6) Stress recognition.
Sorra et al., 2016	Medical Office Survey on Patient Safety Culture– User Guide	Modification of the *AHRQ Hospital Survey on Patient Safety Culture.* Emphasized safety and quality issues that are known to affect patient safety in medical offices.	Medical Offices in the United States	Pilot tested in 2007 with 200 offices, > 4,100 surveys. First released in 2009, with comparable databases released approximately every 2 years.	51 item survey, measuring 13 dimensions: 1) Teamwork, 2) Work pressure and pace, 3) Staff Training, 4) Office processes and standardization, 5) Communication openness, 6) Patient Care Tracking/Follow-up, 7) Communication about error, 8) Owner/ Leadership support for patient safety, 9) Organizational learning, 10) Overall perceptions of patient safety and quality, 11) List of patient safety and quality issues, 12) Information exchange with other settings, 13) Overall ratings on quality and patient safety.

2.2.2 – Patient Safety Performance

Surveillance reporting systems are the most commonly used strategy to collect, manage, analyze, interpret, and report desired public health information [Rothman & Greenland, 2005]. Alternatives to disease reporting, including advanced surveillance reporting systems, were developed to monitor diseases and other public health concerns in the 1990s [Rothman & Greenland, 2005], and these continue to evolve as technology advances. A diversity of epidemiologic inquiry and public health responsibilities are now monitored through surveillance systems, including acute/chronic diseases, reproductive health, injuries/AEs, disabilities, environmental/occupational health hazards, and health risk behaviors. Within surveillance methodology there is an array of diversity in the procedures used to obtain information.

Using surveillance systems, the outcome measure for patient safety performance is most commonly the identification of an AE (defined below). When the *To Err Is Human* report recommended expanding AE reporting, the American Medical Association and the American Hospital Association raised strong opposition [IOM, 1999; Leape, 2002]. Their concerns were focused around litigation, which brought attention to the conflict between the patient's desire for accountability and a doctor's fear of malpractice liability and loss of reputation. To ease concerns, the *To Err Is Human* report emphasized both voluntary and mandatory (or systematic) AE reporting. The most common patient safety event methods are the voluntary, or *passive surveillance reporting system*; and more rigorous and systematic (often mandatory), but more resource-intensive, *active surveillance reporting system*. Both of these systems are described below in more detail (section 2.2.2.2 and 2.2.2.3).

A reality of any reporting system is that AEs occur one at a time to individual patients, which creates opportunities for either cover-up or transparency through reporting. Providers who choose transparency require protection from blame, legal risk, and public embarrassment [Wachter & Gupta, 2017]. Additionally, reporting systems need to be easy to use and have noticeable improvements made from the submitted reports. When improvements are made, they need to be shared with a vast array of stakeholders, which means that time should be put into tailored reports for each stakeholder population. While most errors do reflect system problems, some can be attributed to provider's malintent or incompetence, in which the relevant regulatory college overseeing the profession need to take appropriate actions [Wachter & Gupta, 2017]. In addition, many terms with heterogeneous definitions exist throughout the patient safety literature, including the definition of AEs, lead to confusion among providers, patients, researchers, and administrators.

2.2.2.1 – Adverse Event (AE) Definitions

A key distinction between the vast array of definitions for AEs explicitly focuses on the potential causation of an adverse outcome as a result of health care treatment versus just the association. Those with only an association may be thought as a more conservative definition and allow for more comprehensive data collection. Commonly accepted definitions from well-recognized health care organizations are outlined in Table 2.3. Inconsistent taxonomy within patient safety remains a challenge to comparing results of studies [Lorincz et al., 2011].

Table 2.3. Definitions of Adverse Event.

Agency for Healthcare Research and Quality (AHRQ) [AHRQ, 2003]	An untoward and usually unanticipated outcome that occurs in association with health care.
Canadian Institute for Patient Safety (CPSI) [Davies, 2003]	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
Common Terminology Criteria for Adverse Event (CTCAE) [Cancer therapy, 2009]	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.
International Conference on Harmonisation (ICH) [Griffin et al., 2009]	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.
Institute for Health Improvement (IHI) [Griffin et al., 2009]	(Harm): Unintended physical injury resulting from or contribute to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death.
Ontology for Adverse Events (OAE) [He et al., 2011] {previously named Adverse Event Ontology (AEO)}	Denotes a pathological bodily process in a patient that occurs after a medical intervention.
US Food and Drug Administration (FDA) [ICH-GCP]	An adverse event is any undesirable experience associated with the use of the medical product in a patient.
World Health Organization (WHO) [WHO, 2005], [WHO, 2010]	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.

2.2.2.2 – Passive Surveillance (Voluntary Reporting)

Passive surveillance reporting system is a mechanism that allows health care workers to report AEs. Currently, passive surveillance systems are either completed on paper or through the web; then routed to an organization's safety officer or a federal regulator. These systems are typically one of three

categories: anonymous, confidential, or open [Wachter & Gupta, 2017]. Anonymous reports have no identifying information from the reporter, while in a confidential system the reporter's identity is known the authorities only. An open reporting system has all people and places publicly available. Although it has a poor track record of use in health care as providers are intimidated to be this transparent and may put patient privacy at risks due to the identifying nature of specific details from the harm report, the open reporting system has the potential to provide detailed reports that can impact change because of the availability to obtain more information from any source related to the AE [Wachter & Gupta, 2017]. Farley et al. described four key components of an effective passive surveillance system found after conducting a survey of 1,600 U.S. hospitals who had been using different categories of passive surveillance systems [Farley et al., 2008]. Characteristics include: 1) organizations' environment supports AE reporting that ensure privacy for those who report; 2) broad range of personnel involved with reporting events, not only nurses; 3) mechanism in place to review reports and develop action plans in a timely manner; and 4) dissemination of report summaries and quality improvement suggestions occurring in a timely fashion. Of these components, Farley only found a minority of the hospitals meeting all criteria. This is despite the fact many hospitals had heavily invested financially into AE reporting systems. With technology advancements, the use of computerized systems have made improvements, including error type and level harm categorization, confidentiality, and increased sophisticated analytics to data mine for trends [Wachter & Gupta, 2017].

Passive surveillance reporting systems are relatively low in cost to administer, but the overall utilization and outcome so far has been disappointing [Wachter & Gupta, 2017]. For an event to become a report, a health care provider (typically a registered nurse in hospitals and pharmacists in pharmacovigilance systems) must perceive the incident as important enough to report over competing priorities [Rowin et al., 2008]. Overall disadvantages of a passive reporting system include that they only capture small fraction of AEs (leading to under-reporting) and typically have little standardization or uniformity on what should be included in the report, with poor quality reports that challenge assessment of causation. Although passive surveillance has limitations, it is the cornerstone of federal pharmacovigilance programs and in hospital settings. For example, despite its limitations, passive surveillance detected a fourfold increase in the number of intussusception cases from what was expected after the introduction of the rotavirus vaccine [Mahajan et al., 2012]. Another success was infection surveillance in hospitals (i.e., those conducting organized surveillance with procedures for reporting infection rates back to practicing surgeons), which decreased nosocomial-infection rates by 26% [Haley et al., 1985]. The future progress of passive surveillance reporting systems will depend on disseminating the lessons and improving the system [Mitchell et al., 2016]. Recommendations include: 1) self-explanatory reporting requiring minimal training; 2) reporting that is meaningful to the reporter; 3) a focus not on number of reports, but rather on system changes; 4) prioritization for what events should be reported and

investigated; and 5) national reporting systems that work with health care provider organizations to reduce preventable harm.

2.2.2.3 – Active Surveillance (Systematic Reporting)

An active surveillance reporting system differs from passive surveillance in that the initiation of an AE report starts with the organization conducting the surveillance via a more systematic data collection process. The systematic approach can include phone-structured interviews, follow-up post-cards, hospital rounds, chart reviews, and/or computer monitoring [Yun et al., 2012]. The desire for a more systematic approach to collect AEs has been a call for action from several major organizations, including the Institute of Medicine and the national surveillance of AEs following immunizations (AEFI). In a narrative review of participant-centered active surveillance of AEFI, active surveillance was found to be a worthwhile approach, especially with e-communication technology capacity increasing [Cashman et al., 2017]. This review discussed nine different active surveillance systems (with some systems using multiple approaches): 1) web questionnaire (may be connected with an email); 2) telephone (may be computer-assisted); 3) diary cards; 4) clinic interviews; 5) medical records; 6) post cards/diary cards; 7) email; 8) text/SMS; and 9) app. The most effective active surveillance method found employed diary cards supplemented with visits and telephone calls, but this was stated to be resource-intensive and studies conducted before technology advances had occurred [Wu et al., 2010]. Cashman et al. concluded in their review that participant-centered active surveillance reporting systems may be an under-utilized opportunity, which could be used for both passive and active surveillance reporting systems. As technology continues to advance, these systems will continue to have more opportunity to assist with research, including patient safety research.

Another clear advantage of active surveillance is the ability to determine numerator (number of AE) and denominator (number of people exposed to the intervention), and thus ability to calculate incidence rates more accurately. Active surveillance also allows for standardized reporting, which helps to ensure more complete, quality reports that can be assessed for potential risk/prognostic factors. Active surveillance reporting systems, which directly survey consumers in a near real time manner, can contribute to public confidence for any health care intervention.

2.3 – Patient Safety Research in Ambulatory Health Care Settings

The advances in hospital research spurred the realization within the medical community that patient safety research should be occurring in all health care settings, not in spite of the vast differences between these settings (i.e., nursing homes, pharmacies, out-patient surgery units), but because of those differences. For most ambulatory care settings, where 2/3 of all health care spending occurs in

the US [Chang et al., 2016], the patient health conditions are typically less severe than those seen in hospitals; patient-provider relationships are longitudinal; organizational structure are different from hospitals in that the physicians are typically the employer or supervisor of the staff (thus staff may be hesitate to identify/report harms as they may fear it could jeopardize their relationship or lead to termination of their job); and extra funds are not available to dedicate personnel to a non-profit-generating activity, such as a patient safety officer [Wachter, 2006].

These differences make up some of the distinct challenges and advantages found when conducting patient safety research in ambulatory settings. Additional challenges include the diverse range of providers in ambulatory care settings, the diverse nature of event types (e.g., diagnostic, medication, and outpatient surgery), and coordination issues because of off-site laboratory/pharmacy services and specialty services [Woods et al., 2007]. On the other hand, the likely advantages of conducting patient safety research in ambulatory settings are that the providers and staff already have an established, ongoing working relationship; patients and personnel have established longitudinal interactions; and patients are typically healthier and may be able to play an active role in their care, including AE reporting. Additionally, a substantive systematic change in an ambulatory office to increase patient safety requires fewer layers of assent than are typically required in hospitals.

In 2011, the American Medical Association (AMA) released a review of research in ambulatory patient safety over the past ten years [Lorincz et al., 2011]. While they found hundreds of studies, because of the vast array of patient safety topics, limited number of ambulatory sites, small sample size, differing taxonomy definitions, and inability to generalize findings, their conclusion was that research in this arena has been critically limited. They encouraged ambulatory patient safety research to be dramatically strengthened with a focus on studies to identify ways that it could be improved upon versus just continuation of the current status.

2.3.1 – Ambulatory Health Care Settings: Patient Safety Culture

As shown in Table 2.2, several patient safety culture surveys have been developed to measure patient safety attitudes and opinions. AHRQ's *Medical Office Survey on Patient Safety Culture* has established a comparative database as a central repository for data, which can be used to gauge current standards and identify areas for improvement. The 2016 comparative database is based on 25,127 providers and staff from 1,528 US medical offices [Sorra et al., 2016], which was collected between November 2013 and November 2015. Most medical offices were owned by a hospital or health system (865) and more than half were from the South Atlantic region (58%). Teamwork and Patient Care Tracking/Follow-up were the two dimensions that had the overall highest average percent positive response (87% and 86%, respectively). Overall dimension for improvement was Work Pressure and Pace (50%). When looked at by primary care specialty, Family Practice/Medicine offices had the highest average positive

percent response for all dimensions and Pediatrics had the highest percent overall positive score on three of the five areas with the fourth as a tie [Famolaro, 2016].

A goal of a patient safety survey is to also assess if changes had been made after an intervention applied. Verbakel et al. conducted a systematic review to assess patient safety interventions that were effective in changing patient safety culture in primary care settings [Verbakel et al., 2016]. They identified only two studies conducted in general practice settings. One of these studies assessed the effect of a two workshop training series for providers, the first on risk management and the second on significant event audit [Wallace et al., 2013]. Twenty practices completed both workshops, leading to an overall improvement in risk management. The second study evaluated the ability to provide safe patient care by implementing an electronic medical record system [McGuire et al., 2012]. In the 18 participating practices, there was an overall improvement in patient safety attitudes and opinion and job satisfaction. Unfortunately, the quality assessment of the systematic review found both included studies of low quality, small sample sizes, and heterogenic interventions, thus no conclusion could be determined aside from the need for more research [Verbakel et al., 2016].

2.3.1.1 – History of the AHRQ Medical Office Survey on Patient Safety Culture

The AHRQ *Medical Office Survey on Patient Safety Culture* is unique in that it was developed from a hospital version and has a comparative database that is updated every 2 years [Sorra et al., 2016]. This survey was first released in 2007 and designed to measure the patient safety culture of providers and staff in medical office settings. This survey was modified from the AHRQ's *Hospital Survey on Patient Safety Culture*, which had been validated and in use since 2004. Both surveys underwent extensive reliability testing and content validation. AHRQ content validation of the medical office survey included [Sorra et al., 2016]:

1) review of published literature and existing surveys;
2) background interviews with medical office providers and staff;
3) identification of key areas of safety culture in the medical office setting;
4) development of draft survey items;
5) cognitive testing of survey items;
6) input from over two dozen researchers & stakeholders; and
7) pilot testing.

Content of the survey includes 38 items that measure ten dimensions of organizational culture that pertain to patient safety: 1) Communication about Error; 2) Communication Openness; 3) Office Processes and Standardizations; 4) Organizational Learning; 5) Overall Perceptions of Patient Safety and Quality; 6) Owner/Managing Partner/Leadership Support for Patient Safety; 7) Patient Care Tracking/Follow-up; 8) Staff Training; 9) Teamwork; 10) Work Pressure and Pace. The survey also queries about problems exchanging information with other settings and about access to care, as well as

questions for respondents to rate their office on five areas of health care quality (i.e., patient-centered, effective, timely, efficient, and equitable) and give a single overall office rating on patient safety and quality.

2.3.2 – Ambulatory Health Care Settings: Patient Safety Performance

Twelve years after the 1999 IOM report, there was no reliable data on how many patients in the US were injured each year in ambulatory settings [Lorincz et al., 2011; Wynia & Classen, 2011]. A study of US hospital discharge estimated that at least 75,000 hospitalizations per year were due to preventable AEs occurring in ambulatory settings [Woods et al., 2007]. These realizations induced the US to adopt five core aims to understand patient safety performance in ambulatory care settings. The aims focused on collecting data on how patients experience harm in ambulatory settings with an emphasis on patient engagement. The aims also advised a focus on linking ambulatory safety directly to improving inpatient environments.

2.3.2.1 – Ambulatory Health Care Settings: Passive Surveillance

Passive surveillance systems in ambulatory care settings have been mostly focused on collecting information on harms related to medications and vaccine safety [Spencer & Campbell, 2014]. In a comprehensive narrative review of tools for primary care patient safety, only one event reporting system was noted for primary care environments. As one of the 'Applied Strategies for Improving Patient Safety' (ASIPS) multi-institutional, practice-based projects funded by AHRQ, the Patient Safety Reporting System was designed to collect, codify, categorize, and analyze data on medical errors occurring in primary care offices and to develop interventions to reduce those errors from reoccurrence [Pace et al, 2003]. This reporting system allowed for voluntary reports to be submitted confidentially, with the option for the reporter to remain anonymous. Reports could be captured by both clinicians and office staff members and could report a medical error or a near miss.

The ASIPS reporting system was rolled out by inviting clinicians from two practice-based research networks, of which 14 practices of 150 clinicians and staff participated [Westfall et al., 2004]. Of the 128 reports, the majority were communication, diagnostic test, or medication errors. From the reports, two learning interventions were designed and implemented for the diagnostic testing and medications errors. In the ASIPS two- and three-year reports, they had worked with 33 practices with a total of 475 clinicians and staff [Fernald et al., 2004; Parnes et al., 2007]. There was a total of 754 reports, of which the ones that were not anonymous allowed for a better understanding of the event and how it could be improved upon. Overall, the series of studies found that a more pervasive patient safety culture is needed to prevent errors, not just a single reporting system.

2.3.2.2 – Ambulatory Health Care Settings: Active Surveillance

Active surveillance in ambulatory settings are scarce. In one such study of 127 general practice and 12,348 patient encounters across France who were asked to report daily on any patient safety incidents on a web-based tool [Michel et al., 2017], an average of one report every two days were found to be associated with a definite possibility for harm. Of these reports, 23% had potential harm to the patient. Most notably, organization of the health care system related to these patient safety reports were three times more frequent than knowledge and skills of the health professional. Specifically, workflow in the general practice office and communication between providers and patients were the most common organizational issue associated with possibility for patient harm. The authors concluded that conducting research of the organizational features in general practices and patient safety incidents remains a major challenge, but one of the most important aspects to increase patient safety in primary care.

2.3.3 – Patient Safety in Ambulatory Health Care Settings for the Pediatric Population

The pediatric population is a vulnerable population who rely on their caregiver to protect them from potential harms. In 2011, the Steering Committee on Quality Improvement and Management and Committee on Hospital Care produced “Principles of Pediatric Patient Safety: Reducing Harm Due to Medical Care” policy statement. In this statement they specified that: “Pediatricians in all venues must have a working knowledge of patient safety language, advocate for best practices that attend to risks that are unique to children, identify and support a culture of safety, and lead efforts to eliminate avoidable harm in any setting in which medical care is rendered to children” [Pediatrics, 2011; page 1199]. It is estimated that 70% of pediatric care occurs in an ambulatory health care setting [Mohr et al., 2005; Neuspiel & Stubbs, 2012] with a paucity of published research on AEs in such environments. One study conducted by the American Academy of Family Physicians (AAFP) reported 17.5% of the errors occurring in a family physician office did so during a visit with a child less than 14 years of age [Dovey et al., 2002]. Given children of younger age’s limited ability to communicate issues of this type, the identification of an AE is a unique challenge for this population. The AAFP study suggest improved chart management and more effective communication among primary care team as error reduction strategies.

Mohr et al. conducted a passive surveillance study using a web-based reporting system with 14 pediatric offices and received 147 reports over a four-month period of time [Mohr et al., 2005]. The study confirmed that medical errors occur in ambulatory settings and that participating providers were satisfied with the data collection web-based system. This study facilitated an opportunity for providers to reflect on patient safety issues and also found providers to need training in error identification and patient safety culture. Further research in pediatric ambulatory settings need to focus on the entire team of providers and involve parent feedback.

2.4 – Patient Safety Research in the Chiropractic Profession

The chiropractic profession is established in more than 90 countries [NBCE, 2015] with 33.6 million or 14% of US adults seeking chiropractic care each year and 57% of adults seeking chiropractic care at least once during their lifetime [Weeks et al., 2015]. Like most ambulatory health care professions, chiropractic patient safety research is still in its infancy, but progress has been made over the last few years. In 2011, an international and interdisciplinary research group was initiated in Canada called SafetyNET whose goal was to develop, pilot, evaluate, and support a patient safety culture for regulated health care professions that provide spinal manipulation therapy (SMT), including chiropractic, physiotherapy, naturopathy, and osteopathy [Vohra et al., 2014]. While all of these professions include SMT as part of their scope of practice, SMT is delivered most commonly by chiropractors. SafetyNET was led by experts in patient safety, SMT, epidemiology, active surveillance, health law, basic science, and qualitative research with four main projects, each with several individual studies. One of the four projects was focused on community-based active surveillance reporting and learning systems. This project began with the development of surveys to assess patient safety culture and then expanded into the implementation of an active surveillance reporting system for US and Canadian chiropractors and physiotherapists [Vohra et al., 2014].

2.4.1 – The Chiropractic Profession: Patient Safety Culture

In 2013, Wangler et al. reported on an anonymous online survey sent to all licensed chiropractors in Switzerland and UK members of The Royal College of Chiropractors, all of whom had access to a passive surveillance AE reporting and learning system [Wangler et al., 2013]. With a 76% response rate, this survey evaluated four clinical scenarios and six safety dimensions (teamwork, work pressure, staff training, process and standardization, communication openness, patient tracking/follow-up). Differences in the four clinical scenarios were evaluated for the Switzerland vs UK members, as well as between female vs male. Overall, both Switzerland and UK male chiropractors would manage potentially risky clinical scenarios with a re-evaluation and change in treatment approach, but female chiropractors were found to be more risk-averse. For the six safety dimensions, all responding chiropractors had a positive outlook, which may suggest the development of a robust patient safety culture.

One outcome of the SafetyNET team study findings was the adaption and implementation of a survey to measure the patient safety attitudes and opinions of SMT providers, specifically chiropractors and physiotherapists (Appendix A). The survey was an adaption of the AHRQ's Medical Office Survey on Patient Safety Culture with the SafetyNET team of investigators ensuring content validity for the modifications made to the survey to allow for best use by SMT providers. The survey has since been distributed to practicing providers within several organizations (including chiropractic organizations in

Newfoundland & Labrador, New Brunswick, Ontario, Alberta; pediatric councils within the American Chiropractic Association and International Chiropractor Association, and physiotherapy association in Alberta) and chiropractic teaching institutions. Currently, results have only been published for the pediatric organizations, which can be found in Chapter 3 and 4 within this thesis.

2.4.2 – The Chiropractic Profession: Patient Safety Performance

Prior to the current research investigation, most of what was initially known regarding the AEs following chiropractic treatment was based on retrospective case reviews, analysis of medico-legal claims data, and clinical trials (which are usually not designed to assess adverse events) [Thiel & Bolton, 2006]. Common AEs related to adult SMT that have been reported from these sources are mostly self-limiting such as radiating musculoskeletal pain, nausea, dizziness, or tiredness [Rubinstein, 2008; Cagnie, 2004]. However, there have also been reports of serious AEs. One such event that has been reported is vertebrobasilar accident (VBA)/stroke, although a case control study found no evidence of excess risk of VBA/stroke associated with chiropractic care compared to primary care (Cassidy et al., 2009). Another serious AE, cauda equina lesions (i.e., nerve injury that may cause loss of bowel or bladder function, lower body sensation or leg paralysis), has also been reported, although its occurrence appears to be extremely rare (1 per 1 million) [Cagnie et al., 2004; Assendelft et al., 1996].

AEs are most often unknown to the practitioner except when the patient reports pain/discomfort during the appointment or has observable signs immediately afterwards [Carlesso et al., 2010]. Therefore, more rigorous research on AEs reported by patients as well as by providers following SMT is fundamental to advance understanding.

2.4.2.1 – Chiropractic Profession: Passive Surveillance

To date, there is only one patient safety surveillance system within the chiropractic profession. Established initially for use in the United Kingdom, the Chiropractic Patient Incident Reporting and Learning System (CPiRLS) was developed to be a confidential web-based passive surveillance system to monitor patient safety incidents. It has an open forum that allows participating chiropractors to both share patient safety incidents and comment on reported incidents in an anonymous and confidential manner. CPiRLS reports have continually been monitored for emerging trends by the CPiRLS Implementation Team, and ‘Safer Practices Notices’ have been produced with additional evidence-based information about these emerging trends in order to enhance the learning opportunities for all CPiRLS participants. As shown in Table 2.4, this system is now available for chiropractors throughout Europe and Australia.

Table 2.4. CPiRLS evolution timeline.

Year	Activity	Countries
2005	The Anglo-European College of Chiropractic and the British Chiropractic Association introduced the 'Chiropractic Reporting and Learning System' (CRLS). This system was adapted from the Anglo-European College of Chiropractic student clinic process to collect patient safety incident data from the British Chiropractic Association members [Thiel & Bolton, 2006].	UK
2007	McTimoney College of Chiropractic launched the 'Patient Incident Reporting and Learning System' (PIRLS).	UK
2009	To facilitate participation of all UK chiropractors, chiropractic colleges, chiropractic educational institutions and professional associations combined their experience to develop the 'Chiropractic Patient Incident Reporting and Learning System' (CPiRLS).	UK
2011	The CPiRLS team members actively addressed the under-utilization of the system by emphasizing the safe, anonymous environment that is supported by patient safety experts.	UK
2012	CPiRLS was opened to chiropractors in the UK (~2700 DCs), Swedish Chiropractic Association members (~300 DCs), and Chiropractic and Osteopathic College of Australia members (~1000 DCs).	UK, Sweden, Australia
2014	CPiRLS is now available Europe-wide with over 6,000 European Chiropractors' Union members having access.	All European countries.

2.4.2.2 – Chiropractic Profession: Active Surveillance

The first large-scale prospective study to record AEs following chiropractic manipulation of the neck was conducted with a sample of UK chiropractors between June 2004 and March 2005 [Thiel et al., 2007]. Data were collected up to seven days after treatment from 19,722 patients and 28,807 visits that had a high-velocity, low-amplitude or instrument-assisted thrust into the cervical spine, of which, no serious AE was reported. More common were reports of minor side effects (as determined by the chiropractor based on operational definitions), suggesting possible neurological impact, including headaches (4 per 100 treatment consultations), numbness/tingling (15 per 1000 treatment consultations), and fainting/dizziness/light-headedness (13 per 1000 treatment consultations).

Another product from the SafetyNET team was the development or deployment of an active surveillance reporting system [Vohra et al., 2014]. The data collection instruments were developed in an iterative process with practicing chiropractors and physiotherapists, study investigators, and patients. This study is currently ongoing in North America, where it is collecting data from 100 participating providers' patient encounters. This study is not limited to the cervical spine and is inclusive of whatever manipulative treatment is provided at the visit. Data are collected up to seven days post treatment, as that is when most AEs are thought to happen [Hurwitz et al., 2004]. Results should yield novel information about risk factors for SMT, which can be used to develop mitigation strategies in order to potentially reduce AEs following SMT.

2.4.3 – Patient Safety in the Chiropractic Profession for the Pediatric Patient

For the pediatric population, no high-quality prospective data exist to evaluate potential adverse events, but two systematic reviews have assessed AEs in the pediatric population following SMT [Humphreys, 2010; Vohra et al., 2007]. Both reviews identified insufficient research on SMT safety within this population. Vohra et al. searched the literature spanning 1946-2004 with defined inclusion criteria: primary investigations of SMT; population of 18 years of age and younger; and reporting an AE. A total of 13,916 articles were considered and the authors identified 13 cases of AEs. There were no restrictions to health care profession or language. Of the 13 cases, two were identified in clinical trials, four from case series, and seven from case reports. There were nine serious AEs (subarachnoidal hemorrhage and death, quadriplegia secondary to spinal cord astrocytoma, progressive neuromuscular deficits, severe occipital and bifrontal headache with vomiting and facial weakness, anterior dislocation of atlas and fracture of odontoid axis at C2, death, acute respiratory decompensation with tracheotomy, neurologic defects at C6 and C7 vertebrae, neck pain and progression to unsteady gait leading to hospitalization to find a delayed diagnosis of congenital occipitalization), one moderate AE (severe headache with a stiff neck), and three minor AEs (acute lumbar pain, midback soreness, and irritability with a loss of consciousness). The serious AEs were identified in eight case reports and one of the case series. In 2010, Humphreys updated Vohra et al.'s review by concluding that there were three new clinical studies (two chiropractic & one osteopathic), one systematic review, and one evidence report. No additional serious AEs were identified in any of these reports. A major limitation to these reviews was under-reporting (to be included in the review, an adverse event had to be published in the peer-reviewed literature). This limitation led the reviews to call for prospectively planned active surveillance so that both numerator (number of AEs) and denominator (patients exposed to SMT) can be known.

Another study performed a three-year retrospective chart audit of pediatric patients at a chiropractic college clinic with 1 in 100 children reporting an AE to their chiropractor at a follow-up visit, of which none were reported as serious [Miller and Benfield, 2008]. A total of 699 patients were included in this study, which represented 5,242 treatment visits. A total of seven minor transient AEs was identified (increased crying, restlessness, sleeping disturbance). Miller and Benfield concluded that pediatric patients may experience minor, self-limiting AEs after chiropractic care, but more prospective investigations are essential for this population as it is not known if AEs in their study were consistently asked about or documented. Additionally, the Miller and Benfield study acknowledged that they relied on parents/caregiver reporting the AE to the provider, which may have been difficult for the parent/caregiver to do.

2.5 – Summary

This literature review provides an understanding of patient safety culture, the disconnect between patient safety culture and patient safety performance (i.e., patient safety culture may be robust, yet harms still occur), and how these constructs can be measured. It also explores the current state of patient safety research for ambulatory settings and specifically the chiropractic profession. Generally, the literature is lacking in the area of patient safety despite the call for actions by many federal governments. Although still evolving, the patient safety research that began in hospital settings provides the groundwork for exploring patient safety in ambulatory health care settings. Because challenges and advantages remain in both hospital and ambulatory care settings, there is a need to better understand how best to collect patient safety research in these differing environments. This thesis addresses this gap in our understanding, as well as collects primary data for a vulnerable population seeking care from an ambulatory care setting, specifically pediatric chiropractic offices.

Chapter 3:
Pediatric chiropractors' attitudes and opinions towards patient safety.

This chapter was published in its entirety (Appendix F) as the following citation:
Pohlman KA, Carroll L, Hartling L, Tsuyuki R, Vohra S. Attitudes and opinions of doctors of chiropractic specializing in pediatric care toward patient safety: a cross-sectional survey. J Manipulative Physiol Ther 2016 Sept;39(7):487-493.

3.1 – Abstract

Objective

To evaluate pediatric chiropractors' attitudes and opinions towards patient safety using a cross-sectional survey.

Methods

The Agency for Healthcare Research & Quality's (AHRQ) Medical Office Survey on Patient Safety Culture was adapted for providers who utilize spinal manipulation therapy and sent out to two US chiropractic organizations' pediatric councils members (n=400) between February and April 2014. Twelve patient safety dimensions were measured, along with questions on patient safety items and quality issues, information exchange, and overall clinic ratings questions. Data analyses included a percent composite average and a non-respondent analysis.

Results

The response rate was 29.5% (n=118). Almost a third of respondents' patients were pediatric ($\leq$ 17 years of age). Chiropractors with a pediatric certification were three times more likely to respond ($p<0.001$), but little qualitative differences in responses were found.

The highest positive composite percentages patient safety dimensions were *Organizational Learning* (both administration and clinical) and *Teamwork* (>90%). *Patient Care Tracking/Follow-up* and *Work Pressure & Pace* were patient safety dimensions that had the lowest positive composite scores (<85%). It also found that there was concern regarding information exchange with insurance/third party payers. Two quality issues identified for improvement were: (i) updating a patient's medication list; and (ii) following-up on critically abnormal results from a lab or imaging test within one day. The survey found that the average Overall Patient Safety Rating score had 83% of respondents rating themselves as 'very good' or 'excellent'.

Conclusions

Compared to 2014 AHRQ physician referent data from medical offices, pediatric chiropractors appear to have a more positive patient safety attitudes and opinions. Future patient safety studies need to prospectively evaluate safety performance with direct feedback from patients and compare results to these self-assessed attitudes and safety, as well as further utilization of this survey to develop a comparable database for spinal manipulation providers.

3.2 – Introduction

Patient safety and quality improvement has been at the top of health care agendas since the Institute of Medicine's (IOM) 1999 report, *To Err is Human* [IOM, 2000]. Reporting and learning systems for medical errors have been implemented as suggested in the IOM report[1] and shown to make some quality improvements in hospital settings [Anderson et al., 2013; DiCuccio, 2015]; however, little has been done for quality improvement in community-based health care offices, where the majority of patient-provider interactions occur [Starfield et al., 2005; O'Beirne et al., 2010].

Currently in the chiropractic profession only one reporting and learning system exists; it was initially deployed in the United Kingdom in 2005, expanded throughout Europe, and has recently been made available in Australia. The 'Chiropractic Patient Incident Reporting and Learning System' (CPiRLS) is an online forum which allows near misses or actual medical errors and incidents/AEs (both clinical and administrative) to be voluntarily reported in an anonymous and confidential manner [Thiel, 2011].

The Agency for Healthcare Quality and Research (AHRQ) responded to the IOM report's recommendation to increase patient safety. One AHRQ initiative was the development of a survey to measure patient safety attitudes and opinions from the perspective of those providing the care [Sorra et al., 2014]. Similar to other patient safety movements, their work started in secondary care (i.e., hospitals) and then expanded into primary care medical offices [Sorra et al., 2014; Nieva & Sorra, 2003]. The goals of the AHRQ medical office survey were to: 1) Raise awareness about patient safety; 2) Assess the current status of patient safety attitudes and opinions; 3) Use for internal patient safety and quality improvement; 4) Evaluate the impact of patient safety and quality improvement initiatives; and 5) Track patient safety attitudes and opinions over time. SafetyNet is a team of patient safety and spinal manipulation therapy experts who adapted this survey for spinal manipulation therapy (SMT) providers and initiated validation with chiropractors and physical therapists [Vohra et al., 2014]. This survey's name was modified to "Survey to Support Quality Improvement" so community-based SMT providers would better understand its content and purpose.[10]

Chiropractic and osteopathic manipulation remains the most popular complementary and alternative medicine (CAM) service sought in the US by the pediatric population [Barnes et al., 2007; Black et al., 2015]. There are several different programs to become a certified pediatric doctor of chiropractic, usually requiring over 300 hours of training to expand upon and deepen the pediatric knowledge base obtained during an accredited chiropractic training program.

Similar to other primary care community-based providers, chiropractors who treat children do not currently have patient safety reporting and/or learning mechanisms established, despite identified gaps in patient safety [Vohra et al., 2007; Todd et al., 2014]. The purpose of this cross-sectional survey is to

evaluate the safety attitudes and opinions of pediatric chiropractors, which is the start of assessing and supporting a patient safety culture for this population.

3.3 – Methods

The SafetyNET's 'Survey to Support Quality Improvement' is a cross-sectional survey to measure patient safety attitudes and opinions, specific patient safety and quality issues, information exchange problems, and overall office ratings on quality and patient safety. This survey was used to evaluate patient safety and quality improvement of responding pediatric chiropractors [Vohra et al., 2014]. The University of Alberta's Research Ethics Board (Pro00043860) reviewed and approved this study. This manuscript was prepared using STROBE Statement for cross-sectional studies [von Elm et al., 2007].

Population

The target population for this survey was pediatric chiropractors; however, it was not limited to only chiropractors with a certification in pediatrics, since all chiropractors are trained to provide care to this population.[16] The ACA-CCP and ICA-CCP (American Chiropractic Association, ACA; International Chiropractors Association, ICA; Councils on Chiropractic Pediatrics, CCP) were identified as our source population as their members all had interest in pediatrics and supported these organizations through membership (n=400). Membership of these organization is based on one's interest in supporting initiatives of these associations and is not dependent on having a pediatric certification. Because the source populations were small enough, all were invited to participate between February and April 2014 and a representative sample size calculation was not conducted.

Survey Design

The SafetyNET's 'Survey to Support Quality Improvement' was developed in four stages: 1) Scoping literature review; 2) Validation and measurement properties consideration of preferred survey; 3) Survey modifications to promote content validity; and 4) Continued content validity testing [Vohra et al., 2014]. The survey has been: piloted with chiropractors in Alberta, Canada; conducted with physiotherapists in Alberta, Canada and chiropractors in Ontario, New Brunswick, and Newfoundland, Canada; has been translated to French and Danish for use among chiropractors in Québec, Canada and Denmark, respectively; and has been and has been modified and conducted at three chiropractic teaching clinics (Anglo-European College of Chiropractic, Canadian Memorial Chiropractic College, and Parker University).

The survey for this study was designed and managed using REDCap electronic data (Vanderbilt University, Nashville, TN) capture tools hosted at the University of Alberta [Harris et al., 2009]. Potential respondents received the survey via email. This email included a letter with information about the study and a direct link to the survey. The email and link were sent 3 times, with at least one week between each mail-out.

The patient safety dimensions measured were: Communication about Error, Communication Openness, Office Processes and Standardization, Organizational Learning (clinical and administrative), Overall Perceptions of Patient Safety and Quality (clinical and administrative), Owner/Managing Partner/Leadership Support for Patient Safety, Patient Care Tracking/Follow-up, Staff Training, Teamwork, and Work Pressure and Pace [Nieva & Sorra, 2003]. Responses were sought on a 5-point rating scale (5 being the best score).

Eight questions were asked directly about specific patient safety items and quality issues: *access to care, charts/records, equipment, medications, and diagnostic tests.* Four questions were asked about information exchange with other settings: *outside labs/imaging center, other physician offices, other health care offices, and insurance/third party payers.* Providers were then asked to rate their office in health care quality areas, on dimensions that affect patient's designed care plan (i.e., *patient centered, timeliness, efficient, equitable)*, and an overall rating for patient safety and quality improvement. The survey concluded with questions about providers practice and patient characteristics, including if the respondent was a certified pediatric doctor of chiropractic.

AHRQ Comparative Database

The 2014 AHRQ Medical Office survey conducted sub-analysis of characteristics, including number of providers, single vs. multi-specialty offices, ownership, geographic regions, and job position (i.e., Physician (MD/DO), Management, PA/NP/Midwife/etc., Nurse (RN/LVN/LPN), Other Clinical Staff or Clinical Support Staff, Admin/Clerical Staff) [Nieva & Sorra, 2003]. For this paper, we compared our results with number of providers in an office and job position (Physician).

Data Analysis

The data were analyzed with Stata13 Software (StataCorp., College Station, TX) and Excel 2013 (Microsoft, Redmond, WA). For comparison with the AHRQ data, a positive percentage composite score was calculated for each item. Negatively worded questions had the disagreeing ratings as the positive responses. The top two or three positive or negative responses were added together and divided by the total responses to obtain the individual percent composite response for each question or dimension.

Bias due to non-response was investigated by comparing gender, location, and pediatric certification status of respondents and the population of those who could have responded (i.e., the ACA-CCP and ICA-CCP membership). These characteristics were available in aggregate fashion for each association. The associations between each characteristic and being a responder were reported as relative risks (RR) and 95% CI. Where statistically significant differences were found between responders and those eligible to respond (i.e., where the confidence interval crossed 1), patient safety study data (responses on each dimension) were stratified on those characteristics to assess whether there were systematic differences in responses. Systematic differences would suggest that non-response may have biased our findings.

3.4 – Results

Response Rate

Of the 400 potential respondents; the response rate was 29.5% (n=118). For the ACA-CCP, the response rate was 42.4% (n=25/58); for the ICA-CCP, the response rate was 26.8% (93/342).

Non-Respondent Analysis

Respondents differed from the eligible population on pediatric certification, but not on gender or location. For ACA-CCP respondents, those who were pediatric-certified were 3.13 (95% CI: 1.44, 6.76) times more likely to have responded to the survey than those who were not certified. For the ICA-CCP respondents, those who were pediatric-certified were 3.23 (95% CI: 1.71, 6.10) more likely to have responded to the survey than those who are not certified. However, there was little qualitative difference in responses to patient safety dimensions between those who were certified pediatric doctors of chiropractic and those who were not. On the teamwork question, pediatric certified and non-certified respondents had scores of 4.6 (95% CI 4.5, 4.7) and 4.8 (95% CI 4.7, 5.0), respectively; and on the Overall Perception – Administration question, scores were 4.3 (95% CI 4.2, 4.5) and 4.6 (95% CI 4.4, 4.8).

Respondent Characteristics

Table 3.1 provides a summary of demographic characteristics for respondents. Certified pediatric doctors of chiropractic were predominantly female (74.7%) with their geographical representation spread uniformly across the US, with 19.1% in other countries. As shown in Table 3.2, respondents' patients were described as mostly female (61%); the pediatric population (newborn to 17 years of age)

represented 31.7% of their practice. Across age groups, the most common reason patients sought care was for low back pain (26%), neck pain (22%), and prevention/wellness (18%).

Survey to Support Quality Improvement Items

In Figure 3.1, the composite scores of the patient safety dimensions are reported and can be compared to the positive composite scores of physicians from the AHRQ 2014 comparative database and medical offices with one provider [AHRQ, 2014]. The composite scores of the current survey were higher (suggesting more positive attitudes toward patient safety) than the AHRQ 2014 physicians and AHRQ medical offices with one provider for almost all dimensions.

Table 3.3 demonstrates information exchange with other settings, as well as the patient safety items and quality issues. Positive responses were high for all information exchange items. One notable exception is respondent concern with information exchange with insurance/third party payers, as only 56% had a positive response to this item. Patient safety items and quality issues identified as not relevant to their practice were: 'updating a patient's medication list' (34%) and 'following up on critically abnormal results from a lab or imaging test within one day' (23%) and 'did not occur commonly' (40% and 22%, respectively).

As also shown in Table 3.3, the overall office self-rating identified pediatric chiropractic offices ratings were slightly better than the AHRQ physicians. From the health care quality areas, *efficient* (i.e., *ensures cost-effective care -avoids waste, overuse, and misuse of services*) was the only area with a significant difference ($p<0.05$). Compared to 64% of AHRQ physician respondents, 83% of the pediatric chiropractors rated themselves at 'very good' or 'excellent'.

Table 3.1. Demographic and background characteristics of respondents (n=75).

Characteristics	n (%)
Gender – Female, n (%)	56 (74.7)
Number of years in practice, mean (SD)	18.75 (8.8)
Hours worked in a typical week, mean (SD)	32.7 (1.7)
Patient visits per week, n (%)	
<50	12 (16.0)
50-99	20 (26.7)
100-149	22 (29.3)
150-199	13 (17.3)
200 +	8 (10.7)
Conferring chiropractic degree	
Palmer College of Chiropractic (IA, FL or CA, USA)	33 (48.5)
Royal Melbourne Institute of Technology University (Melbourne, Victoria)	5 (7.4)
New York Chiropractic College (Seneca Falls, NY)	5 (7.4)
Logan University (St. Louis, MO)	4 (5.9)
University of Western States	4 (5.9)
Other	17 (24.9)
Office geographical location	
US, East	15 (22.0)
US, South	12 (17.7)
US, Midwest	12 (17.7)
US, West	12 (17.7)
Canada	6 (8.8)
Other	7 (10.3)
Professional Organization Membership	
American Chiropractic Association, Council on Chiropractic Pediatrics (ACA-CCP)	15 (18.3)
International Chiropractor Association, Council on Chiropractic Pediatrics (ICA-CCP)	48 (58.5)
International Chiropractic Pediatric Association (ICPA)	16 (22.0)
Pediatric Certification	41 (35)
Likelihood of participant in RLS (reporting and learning system)	
Never	1 (1.2)
Doubtful	10 (11.9)
Possibly	53 (63.1)
Definitely	16 (19.0)

Table 3.2. Patient characteristics as reported by respondents compared to the National Board of Chiropractic Examiners, 2014 Practice Analysis of Chiropractic [Christensen et al., 2015].

Characteristics	Mean % (SD)	NBCE %
Female	61.3 (8.3)	59.0
Patients age		
Newborn to 5	15.9 (15.0)	7.8
6 to 17	15.8 (9.2)	9.6
18 to 30	NA	15.6
18 to 39	27.2 (11.3)	NA
31 to 50	NA	28.5
40 to 64	28.5 (15.3)	NA
51 to 64	NA	22.7
Over 65	13.3 (9.2)	14.7
Reasons patients seeking SMT		
Low back pain	25.9 (13.5)	23.6
Neck pain	22.5 (11.6)	18.7
Preventive/Wellness/No symptom	18.0 (15.8)	8.0
Headaches	12.1 (10.8)	12.0
Thoracic pain	11.2 (5.9)	11.5
Extremity pain	7.9 (5.3)	17.1
Other	11.5 (8.7)	9.1

Figure 3.1. Patient safety dimensions with AHRQ 2014 'Agree/Strongly Agree' referents.

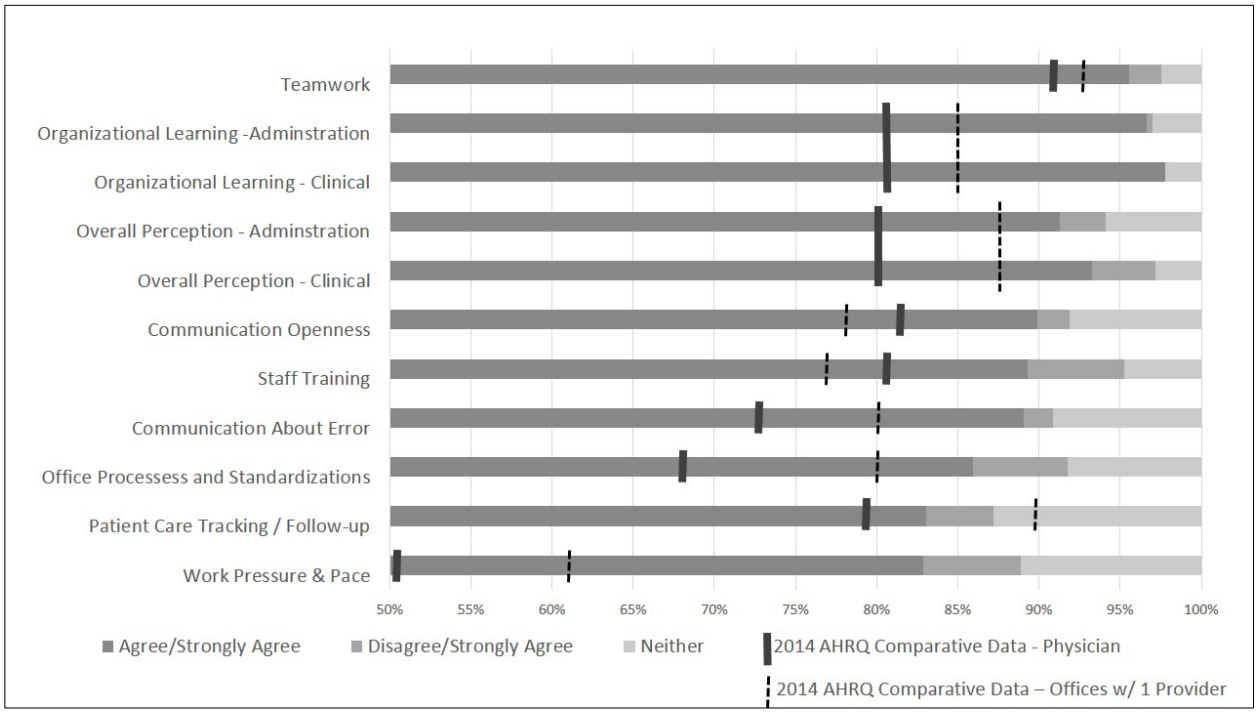


Table 3.3. Information exchange and patient safety items.

Dimension	Pediatric Chiropractor	AHRQ – 2014 Physician
Information Exchange With Other Setting		
Outside labs/imaging centers?	89%	81%
Other physician offices? (AHRQ: Other medical offices/ outside physicians?)	91%	80%
Other health care offices?	92%	NA
Insurance/Third Party Payers?	56%	NA
Other? (i.e., attorneys, billing services, government)	76%	NA
Patient safety items and quality issue.**		
Access to care: Patient was unable to get an appointment within 48 hours for an acute/serious problem.	11%	18%
Patient identification: The wrong chart was used for a patient.	1%	2%
Charts/Records: Patient's chart/record was not available when needed	2%	12%
Charts/Records: Clinical information was filed, scanned, or entered into the wrong patient's chart/record	2%	7%
Equipment: Office equipment was not working properly or was in need of repair or replacement.	2%	8%
Medication: Patient's medication list was not updated during his or her visit. *	40%	28%
Diagnostic Test: Results from a lab or imaging test were not available when needed	6%	24%
Diagnostic Test: Critical abnormal result from a lab or imaging test was not followed up within 1 business day*	22%	6%
Overall Office Self-Rating for Patient Safety and Quality Improvement		
Excellent	33%	28%
Very Good	49%	43%
Good	19%	21%
Fair/Poor	0%	8%

* – Of note, some providers felt these items were not applicable: Medication (34%); Diagnostic Test (23%)

** – The negative composite score is those that responded 'monthly', 'weekly', or 'daily'. The presentation is opposite than what is suggested by AHRQ.

3.5 – Discussion

The awareness of patient safety and quality improvement issues is important for both the safety of patients and the advancement of health care. When a high-risk industry (such as aviation) has a strong and positive patient safety awareness and corresponding positive safety data, they earn the trust from the rest of society [Patankar et al., 2012]. A similar construct could be proposed for health care – a strong, positive patient safety awareness and quality improvement with corresponding positive safety data may provide society with the assurance that undue harm will be minimized in the process of receiving that care [Raeissi et al., 2015; McFadden et al., 2014]. As such, the purpose of this study was to assess the current state of patient safety attitudes and opinions for chiropractors. Although no patient safety reporting system exists within the chiropractic profession in North America, this survey found that attitudes and opinions of chiropractors in these two organizations demonstrate the potential readiness to sustain a reporting system that would make their patient safety and quality improvement initiatives more transparent. Findings were compared to both US medical offices and among chiropractors with and without pediatric certifications. Areas of improvement were discovered and future patient safety endeavors identified [AHRQ, 2014].

Our findings compared to physicians in US medical offices (of all sizes) from the 2014 AHRQ comparative database found chiropractors in this survey having a more positive attitude. When compared to the AHRQ medical offices with only one provider (responses from all personnel within the office, not just the medical physician), high patient safety dimension scores were found in both groups. Differences found between both of these groups (medical physicians and medical offices with one provider) could likely be from the organizational differences between secondary care, where most patient safety research has been conducted, and primary care community-based offices, where most health care occurs [Patankar et al., 2012].

Within the chiropractic profession, there are options to obtain additional training and potential certifications through several post-graduate programs. Whether or not one has a pediatric certification, it is still possible to become a member of several professional organization and councils within associations whose mission include the support of doctors of chiropractic treating the pediatric population. Two of the councils were used as the source population for this survey. When the non-respondent analysis was conducted, it was found that respondents with a pediatric certification were three times more likely to have responded than those without the certification. Further investigation would be needed to explain this difference, but no other difference in response patterns were noted.

A potential area of improvement identified by respondents involved inquiry about medications. This was found to represent an important difference between physician respondents in the AHRQ medical offices

and our survey respondents, as it is not within chiropractor's scope of practice to initiate pharmacotherapy and therefore respondents may not have felt that asking about it falls within their responsibilities. However, whether or not they prescribe medications, updating a medication list is relevant to chiropractors as some medication changes may affect the safety of spinal manipulation therapy (e.g., warfarin). Furthermore, even if spinal manipulation safety is not affected, knowledge of medication changes allows greater awareness of a patient's current health state. For this reason, we recommend chiropractors update a patient's medication list at each visit.

A similar rationale may also explain the reason for the differences with the Diagnosis – Abnormal Results, as chiropractors may not be frequently involved with outside laboratory facilities. When they are involved, it is recommended that procedures be put in place to promptly notify patients regarding the results of any findings, especially critically abnormal results.

There is value in developing a patient safety culture database for spinal manipulation therapy providers, comparable to what AHRQ has developed for medical offices. Such a database would allow more advanced quality improvement initiatives to be developed and their impact measured. We recommend future research initiatives on patient safety include this survey and the development of such a database.

In summary, pediatric chiropractors self-reported positive patient safety attitudes and opinions, which could indicate that this population is well suited to implement a patient safety reporting system. Reporting systems actively evaluate patient safety performance and provide qualitative data on medical errors, both of which can lead to improved patient safety [IOM, 2000; Starfield et al., 2005. As with most health care professions, this survey provided an insight into self-reported patient safety attitudes and opinions; its relationship to patient safety performance of pediatric chiropractic care remains unknown. The implementation of a reporting system would help provide insight into this topic. Future patient safety studies with pediatric chiropractors need to prospectively evaluate safety performance using a reporting system with direct feedback from the patient's perspective.

Limitations

Our target population was chiropractors who treat the pediatric population, with the source population being members of US pediatric councils with an active email address. It is possible that chiropractors who treat children do not belong to either of these organizations and they may have responded systematically different fashion. However, besides the 2014 Survey of Chiropractic Practices finding the gender and pediatric population differences other provider and practice characteristics were comparable in that they had similar years in practice, total number of patient visits, and conferring institution [Christensen et al., 2015].

This study had a risk of selection bias because of the low response rate. In spite of this, our analysis of potential non-response bias found few differences in responses to survey items between groups with higher vs. lower response rates, suggesting that this was not an important source of bias in our findings. A final limitation is the risk for social desirability bias. When asking any sensitive question, such as patient safety and quality improvement items, there are social norms governing some attitudes such that respondents may misrepresent themselves to appear to comply with these norms [Kreuter et al., 2008]. We attempted to decrease this bias by keeping the survey both confidential and anonymous and analyzing the data in an aggregate manner.

3.6 – Conclusion

While patient safety surveys have been developed and utilized in hospitals and more recently in other health care settings (e.g., medical offices, nursing homes, pharmacies), this is the first survey to evaluate patient safety attitudes and opinions from the pediatric chiropractic profession. The survey found respondents to self-report positively across most patient safety dimension, with room for improvement in a few areas, such as medication documentation and abnormal diagnostic lab feedback. Future patient safety studies with pediatric chiropractors need to prospectively evaluate safety performance including direct feedback from the patient's perspective, as well as further utilization of this patient safety survey in other spinal manipulation therapy organizations so that a directly relevant comparative database can be developed and utilized.

Chapter 4:
Barriers to Implementing a Reporting and Learning Patient Safety System: Pediatric Chiropractic Perspective

This chapter was published in its entirety (Appendix F) as the following citation:
Pohlman KA, Carroll L, Hartling L, Tsuyuki R, Vohra S. Barriers to implementing a reporting and learning patient safety system: pediatric chiropractic perspective. J Evid Based Complementary Altern Med 2016 Apr;21(2):105-109.

4.1 – Abstract

A reporting and learning system is a method of monitoring the occurrence of incidents which affect patient safety. This cross-sectional survey asked pediatric chiropractors about factors that may limit their participation in such a system. The list of potential barriers for participation was developed using a systematic approach. All members of the two pediatric councils associated with the US national chiropractic organizations were invited to complete the survey (n=400). The cross-sectional survey was created using an online survey tool (REDCap) and sent directly to member emails address by the respective executive committees. Of the 400 potential respondents, 81 responded (20.3%). The most common limitations to participating were identified as time pressure (96%) and patient concerns (81%). Reporting and learning systems have been utilized to increase safety awareness in many high-risk industries. To be successful, future patient safety studies with pediatric chiropractors need to ensure these barriers are understood and addressed.

4.2 – Introduction

A reporting and learning system is a method of monitoring the occurrence of clinical or administrative incidents which may affect patient safety. It is also a method of developing quality improvement strategies and system changes to address the root cause of an incident. Although, it has been speculated that the implementation of non-punitive reporting and learning systems have increased an open, constructive patient safety environment in hospital settings [Anderson et al., 2013; Verbakel et al., 2013], little has been done to implement these strategies in other settings or professions, especially in community-based health care offices [O'Beirne et al., 2010]. It has been recognized that the majority of patient-provider interactions occur in community-based offices, such as family medical, allied health and complementary and alternative medicine practices [Verbakel et al., 2013; Barnes et al., 2008; Starfield et al., 2005].

In the chiropractic profession, Europe and Australia have a passive reporting and learning system, 'The Chiropractic Patient Incident Reporting and Learning System' (CPiRLS). CPiRLS is an online forum which allows chiropractors to both voluntarily share patient safety incidents and comment on reported incidents in an anonymous and confidential manner [Thiel, 2011; Thiel & Bolton, 2006]. CPiRLS is continuously monitored for emerging trends and 'Safer Practices Notices' are produced with additional evidence-based information about these emerging trends to enhance the learning opportunities for all CPiRLS participants. These learning opportunities are to help support an open, constructive patient safety, which is built around professionalism and trust.

The development of an open constructive patient safety environment can bolster public trust [Patankar et al., 2012]. Chiropractors are in a position to be able to reflect on and recognize patient safety incidents and can help design system changes so that these conditions are reduced or mitigated. However, most providers do not have the knowledge or infrastructure to conduct such evaluations. SafetyNET is a team of international and interdisciplinary research leaders who are taking novel approaches to support a patient safety for spinal manipulation therapy providers, including chiropractors [Vohra et al., 2014]. SafetyNet includes investigation of patient safety amongst chiropractors who treat the pediatric population.

According to a recent US job analysis of the overall chiropractic profession, 17.1% of chiropractic patients are 17 years of age or less; the proportion of pediatric patients increase to 38.7% among chiropractors who have a specialized certification in pediatrics [Christensen et al., 2010; Pohlman et al., 2010]. While CPiRLS does not have age restrictions, limited pediatric data have been reported in that system. Children are at risk for AEs from health care, including spinal manipulation therapy [Vohra et al., 2007; Humphreys, 2010], which highlights the importance of patient safety initiatives for this vulnerable population.

The purpose of this cross-sectional study is to describe factors that may inhibit pediatric chiropractors' participation in a patient safety reporting and learning system. Potential barriers to participation have been identified through research in other health care areas and high-risk industries when implementing reporting and learning system, but to our knowledge, this has not yet been assessed among chiropractors treating a pediatric population [Benn et al., 2009].

4.3 – Methods

The assessment of barriers to participation in a reporting and learning system was one section of the 'Survey to Support Quality Improvement' developed along with several other SafetyNET projects [Vohra et al., 2014]. The original survey also measured: patient safety culture dimensions, patient safety items and quality issues, information exchange with other settings, and overall clinic self-ratings. The University of Alberta's Research Ethics Board reviewed and approved this study (Pro00043860).

Population

All members of the two pediatric councils associated with the US national chiropractic organizations (American Chiropractic Association – ACA and International Chiropractors Association – ICA) were invited via email to complete the survey (n=400). There were two exclusion criteria: 1) if the association did not have an active email address for the member (i.e. the email was returned as undeliverable); 2) if the member was a study investigator. To maintain confidentiality and anonymity, the link to the survey was sent by each organization's executive committee to its own membership.

Study Design

The cross-sectional survey was collected and managed using REDCap electronic data capture tools hosted at the University of Alberta [Harris et al., 2009]. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. Participants accessed the survey from a link sent directly to their email account associated with their council membership. The email had a letter with information about the study and the first page of the survey included instructions for completing the survey. The link was sent three times, with at least one week between each mail-out.

The initial list of potential barriers to reporting and learning system participation came from Benn et al. [Benn et al., 2009], who conducted a mixed method approach to evaluate mechanisms of effective feedback from incident reporting systems in health care and experiences from established reporting

systems in the transport domains and other high-risk industries. This initial list of barriers included: fear of blame; time pressure; resource constraints; the perception that reporting is unnecessary; and a lack of clear definitions as to what constitutes a reportable incident.

Through focus group discussions with spinal manipulation therapy providers and SafetyNET team members (n=15), the following modifications and additions were made to the draft survey: 1) examples of 'resource constraints' (e.g., internet access, computer, etc.) were added; 2) 'the perception that reporting is unnecessary' was changed to 'believe reporting is unnecessary'; and 3) additional potential barriers were identified, specifically: legal implications, regulatory implications, perceived inconvenience for the patients, potential to create negative perception in patients, and an "other, specify" category was added. All factors were rated by respondents on a 3-point scale: *Not at all; Yes, a little, Yes, a lot*.

Data Analysis

The data were analyzed with Stata13 Software (StataCorp. 2013) and Excel 2013. Participant characteristics and reporting and learning system factors were reported using descriptive statistics, specifically percentages. Potential non-response bias was assessed by comparing differences in the gender, location and pediatric certification status of survey respondents and non-responders in each organization's membership. If a difference was found, then each barrier was evaluated for significant differences ($p<0.05$) between comparison (i.e., gender, location, and/or pediatric certification).

4.4 – Results

Of the 400 potential respondents from both organizations; the response rate for this section of the survey was 20.3% (n=81). Table 4.1 provides a summary of demographic characteristics of respondents. Respondents were mostly females (74.7%), 29% treating between 100-149 patients per week, 27% treating between 50-99 patients per week, and work an average of 32.7 hours per week. The respondents had a uniform geographical representation from across the US, with a few in other countries.

Barriers identified by respondents as potential inhibitors to participation in a patient safety reporting and learning system are summarized in Figure 4.1. The largest barrier cited was time pressure (96%) and patient-related concerns (average 80.5%). Most (68%) reported the fear of blame as not being a barrier to reporting. Few endorsed the statement "believe reporting is unnecessary" (12%).

Table 4.1. Demographic and background characteristics of respondents (n=69)*.

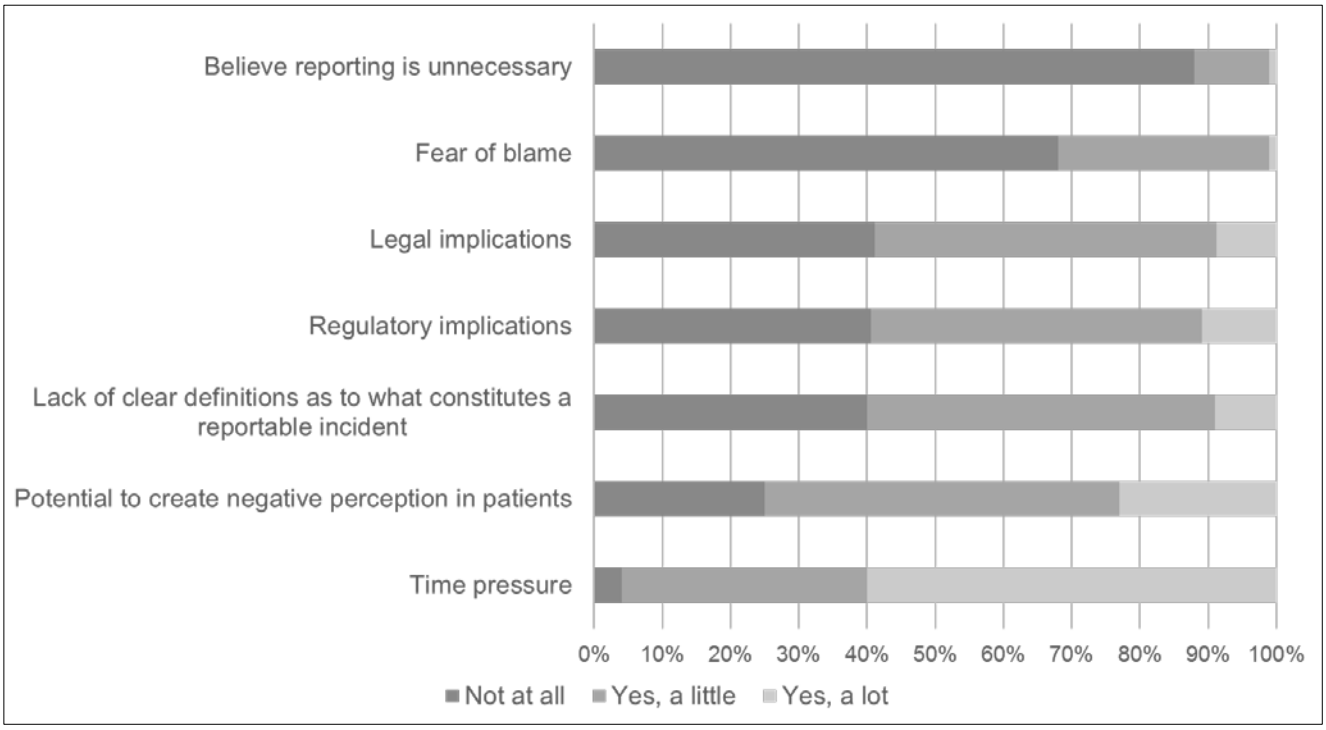
Characteristics	n (%)
Gender – Female, n(%)	56 (74.7)
Number of years in practice, mean (SD)	18.75 (8.8)
Patient visits per week, n (%)	
< 50	12 (16.0)
50-99	20 (26.7)
100-149	22 (29.3)
150-199	13 (17.3)
200 +	8 (10.7)
Conferring chiropractic degree	
Palmer College of Chiropractic	33 (48.5)
RMIT University	5 (7.4)
New York Chiropractic College	5 (7.4)
Logan	4 (5.9)
University of Western States	4 (5.9)
Other (CMCC, LACC, Life, NUHS, NZCC, Parker, Phillip Institute, TCC, UBCC, UQTR, Northwestern)	17 (24.9)
Office geographical location	
USA, East	15 (22.0)
USA, South	12 (17.7)
USA, Midwest	12 (17.7)
USA, West	12 (17.7)
Canada	6 (8.8)
Other International	7 (10.3)
Professional Organization Membership	
American Chiropractic Association (ACA), Council on Chiropractic Pediatrics (CCP)	15 (18.3)
International Chiropractor Association (ICA), Council on Chiropractic Pediatrics (CCP)	48 (58.5)
International Chiropractic Pediatric Association (ICPA)	16 (22.0)
Other (European Pediatric Association)	1 (1.2)
Pediatric Diplomate Certification	41 (59.4)
Interested in participating in pediatric chiropractic research	44 (68.8)

* – This was the final section of the survey, therefore missing data was observed.

Gender, location and pediatric certification status of non-respondents were available in aggregate fashion from each organization. There were no differences between respondents and non-respondents with regards to gender and location of practice, but those with pediatric certification were more likely to respond than those not certified. In the ACA-CCP, those who are pediatric-certified were 3.13 (95% CI: 1.44, 6.76) times more likely to respond to the survey than those who are not certified. In the ICA-CCP, those who are pediatric-certified were 3.23 (95% CI: 1.71, 6.10) times more likely to respond to the survey than those who are not certified.

Responses of pediatric-certified and non-certified participants were very similar. Only one item, 'Lack of clear definitions as to what constitutes a reportable incident' was different between the two groups (p=.003), with those with certification having a slightly higher mean score on that item (mean score of 1.9 vs. 1.4, respectively).

Figure 4.1. Bar graph of the survey factors that may inhibit provider participation in reporting and learning systems (n=81).



4.5 – Discussion

Awareness of potential barriers prior to the development of a pediatric chiropractic reporting and learning system allows for better design and implementation of such systems. Similar to other health care professions, high-risk industry and transport domains, we found that time pressure appears to be the largest barrier to participation in a reporting system [Benn et al., 2009]. This was not unexpected, as time pressure is always a concern as health care providers have many competing demands for their time and "busy-ness" is a socially acceptable excuse for non-participation in research.[16] However, it has been shown that if providers find value in a process and receive timely, usable information from it, they will also find the time to participate [Benn et al., 2009; Cvijovic et al., 2010]. Reassuringly, providers stated that completing the data collection forms only added 30-60 seconds onto each patient visit, which should greatly enhance the feasibility of participation, even in busy offices [Pohlman et al., 2014]. Unlike other organizations, fear of blame and a belief that reporting is unnecessary were not identified as major barriers [Benn et al., 2009]. Absence of these potential barriers should hopefully support future participation in a reporting and learning system.

Concerns about patient perception were another reported barrier to participation. Our team's work in this area suggests this concern is not shared by patients. Patients that have participated in a pilot spinal manipulation therapy reporting system, conducted by our team, reported that instead of developing a negative impression of their provider (as was feared by some respondents), they were pleased that

their provider was willing to participate in a study looking directly at patient safety [Pohlman et al., 2014].

The major limitation of this survey was potential for non-response bias. With only 20% response rate, there may be systematic differences between those who responded and those who did not. More specifically, it is possible that respondents to this survey were those chiropractors who were more or less positive about the importance of such a system. It is unknown how non-respondents may differ with respect to potential barriers that would inhibit their participation in a reporting and learning system. Reassuringly, demographic characteristics of respondents to this survey were similar to those identified in a job analysis we conducted of chiropractors with a pediatric survey conducted in 2009 [Pohlman et al., 2010]. Compared with the National Board of Chiropractic Examiners 2010 chiropractic job analysis, this survey had a higher proportion of females, which was expected for a pediatric-focused provider population [Christensen et al., 2010]. Both of these previous surveys had similar numbers of graduates from Palmer College of Chiropractic (one of the larger chiropractor colleges in the US), had similar number of years in practice, and similar number of patient visits. To increase response rate in future cross-sectional surveys, one may consider using mixed methods (e.g., mail and internet-based), decreasing the length of the survey and increasing awareness/encouraging completion through use of telephone reminders [Sheehan, 2001].

4.6 – Conclusion

Reporting and learning systems have been utilized to facilitate an open constructive patient safety environment in many high-risk industries, including health care. For self-regulated professions, including chiropractic, ensuring patient safety is part of their regulatory mandate. This survey has identified potential barriers to participation in a reporting and learning system for the pediatric chiropractic profession, with the largest barriers identified being time pressure and the potential for patient concerns. Future patient safety studies with chiropractors who treat the pediatric population need to ensure these barriers are understood and addressed to be successful.

Chapter 5:
Active versus passive adverse event reporting after pediatric chiropractic manual therapy: study protocol for a cluster randomized controlled trial

This chapter was published in its entirety (Appendix F) as the following citation:
Pohlman KA, Carroll L, Tsuyuki RT, Hartling L, Vohra S. Active versus passive adverse event reporting after pediatric chiropractic manual therapy: study protocol for a cluster randomized controlled trial. Trials 2017 Dec 1;18(1):575.

5.1 – Abstract

Background

Patient safety performance can be assessed with several systems, including passive and active surveillance. Passive surveillance systems provide opportunity for health care personnel to confidentially and voluntarily report incidents, including adverse events (AEs), occurring in their work environment. Active surveillance systems systematically monitor patient encounters to seek detailed information about AEs that occur in work environments; unlike passive surveillance, active surveillance allows for collection of both numerator (number of AEs) and denominator (number of patients seen) data.

Chiropractic manual therapy is commonly used in both adults and children, yet few studies have been done to evaluate the safety of chiropractic manual therapy for children. In an attempt to evaluate this, this study will compare AE reporting in passive versus active surveillance systems after chiropractic manual therapy in the pediatric population.

Methods/Design

This cluster randomized trial aims to enroll 70 doctors of chiropractic (unit of randomization) to either passive or active surveillance system to report AEs that occur after treatment for 60 consecutive pediatric (13 years of age and younger) patient visits (unit of analysis). A modified enrollment process with a two phase consent procedure will be implemented to maintain provider blinding and minimize drop-outs. The first phase of consent is for the provider to confirm their interest in a trial investigating the safety of chiropractic manual therapy. The second phase ensures that they understand the specific requirements for the group to which they were randomized.

Percentages, incidence estimates, and 95% confidence intervals will be used to describe the count of reported AEs in each group. The primary outcome will be the number and quality of the AE reports in the active versus passive surveillance groups. With 80% power and 5% one-sided significance level,

the sample size was calculated to be 35 providers in each group, which includes an 11% lost to follow-up of chiropractors and 20% of patient visits.

Discussion

This study will be the first direct comparison of AE reporting using passive versus active surveillance. It's also the largest prospective evaluation of AEs reported after chiropractic manual therapy in children, identified as a major gap in the literature.

5.2 – Background

Pediatric Chiropractic Manual Therapy & Patient Safety

Chiropractic manual therapy usually involves the therapeutic application of a force to a pre-determined body structure, which is typically a vertebral or extremity joint. There are numerous manual therapy variations with the velocity, amplitude, loading frequency, choice of lever, location, direction of load, and treatment frequency changing widely amongst the variations [Triano, 2000]. Spinal manipulation therapy (SMT), a type of manual therapy, is regulated for use in many professions (e.g., doctor of osteopathy, medical doctors, and physical therapists), but doctors of chiropractic (DCs) are the most likely to use SMT on a regular basis [Christensen et al., 2010]. According to a 2015 practice analysis of United States DCs, 17.1% of chiropractic patients are 17 years of age or less; this increases to 38.7% among DCs who specialize in pediatrics [Christensen et al., 2010; Pohlman et al., 2010].

AEs after manual therapy, including SMT, have been investigated more thoroughly in the adult patients than in children [Rubinstein, 2008; Cagnie et al., 2004; Assendelft et al., 1996; Cassidy et al., 2008]. Several reviews of AEs in children following manual therapy have identified rare serious AEs, although the studies have been primarily case reports. The main conclusion from these reviews was that there is insufficient primary research on this topic in this population [Todd et al., 2015; Humphreys, 2010; Vohra et al., 2007].

Patient Safety Performance – Surveillance Systems

To measure safety performance, including reporting of AEs, many health care settings have implemented surveillance systems to report and learn from AEs. When established, such systems can provide learning opportunities based on the information gathered [IOM, 2000].

These patient safety surveillance systems vary according to their purpose. Active surveillance systematically collects information from the provider about patient encounters, including AEs, which enhances reporting and demonstrates a health care organization's commitment to patient safety [IOM, 2000]. Although active surveillance can generate higher quality and quantity of reports because both numerator and denominator data are known, the time and resources needed to properly execute an active surveillance reporting system are often limitations to its successful implementation.

Passive surveillance voluntarily collects AE information from the provider and is more commonly utilized throughout health care [Ferranti et al., 2008]. Typically, passive surveillance systems are conducted confidentially and sometimes anonymously, and some have been modified for internet-based fora. These systems can also promote quality improvement by allowing for reporting of AEs,

near misses (an event that could have caused an AE, but did not), and unsafe conditions. Passive surveillance systems are relatively easy to implement and can collect reports from a broad range of topics and individuals [Ferranti et al., 2008]. However, their major limitations include under-reporting (quantity of reports), inadequate information (quality of reports), and limited knowledge of how many patients were exposed (denominator data). Practitioners involved with passive surveillance systems have reported that they commonly forget to write-up their report, are too busy to review others' reports, are not sure who is responsible to write-up a report, or do not report an event because it seemed trivial [Evans et al., 2006].

Study justification

Within the chiropractic profession, active surveillance reporting systems are not used routinely. A passive surveillance system for chiropractic care, called the 'Chiropractic Patient Incident Reporting and Learning System' (CPiRLS), is currently being used in Europe and Australian [Thiel, 2011; Thiel & Bolton, 2011]. Although CPiRLS does not have any age restrictions, to date only limited pediatric data have been reported into the system, despite multiple calls for high quality safety data about pediatric chiropractic manual therapy [Todd et al., 2015; Vohra et al., 2007].

Both active and passive surveillance methods have distinct advantages and limitations. The need for a direct comparison of the ability of active versus passive surveillance to report AEs, and the need to better understand the patient safety performance in the use of chiropractic manual therapies for the pediatric population, led to the development of this cluster randomized clinical trial.

Study aim and hypothesis

Study aim: To compare the quantity and qualify AE reports after chiropractic manual therapy in children 13 years of age or under, using passive versus active surveillance reporting systems. *Hypothesis: DCs randomized to the active surveillance system will report more AEs and will have better quality reporting than those randomized to the passive surveillance system.*

5.3 – Methods

Study Design

The study design is a pragmatic, superiority, cluster randomized clinical trial with a modified enrollment process to maintain participant blinding. DCs in private practice who treat children will be the unit of randomization with random allocation in a 1:1 ratio to active or passive surveillance reporting systems. Cluster randomization was chosen for practical reasons with the unit of analysis being reports from the individual chiropractic patient visits. The University of Alberta's Research Ethics Board reviewed and

approved this study (Pro00027903). The trial has been registered on clinicaltrials.gov (NCT02268331). The study protocol was prepared using the SPIRIT guidelines [Chan et al., 2013] and also the methods section of the CONSORT 2010 checklist for reporting a cluster randomized trial [Campbell et al., 2012].

Recruitment, Randomization, and Enrollment

Licensed DCs in the United States and Canada will be recruited from a variety of venues, including pediatric chiropractic specific events and organizations, social media, and professional newsletters/magazines. Word of mouth and referrals from colleagues and past participants will also be source of referral into the study.

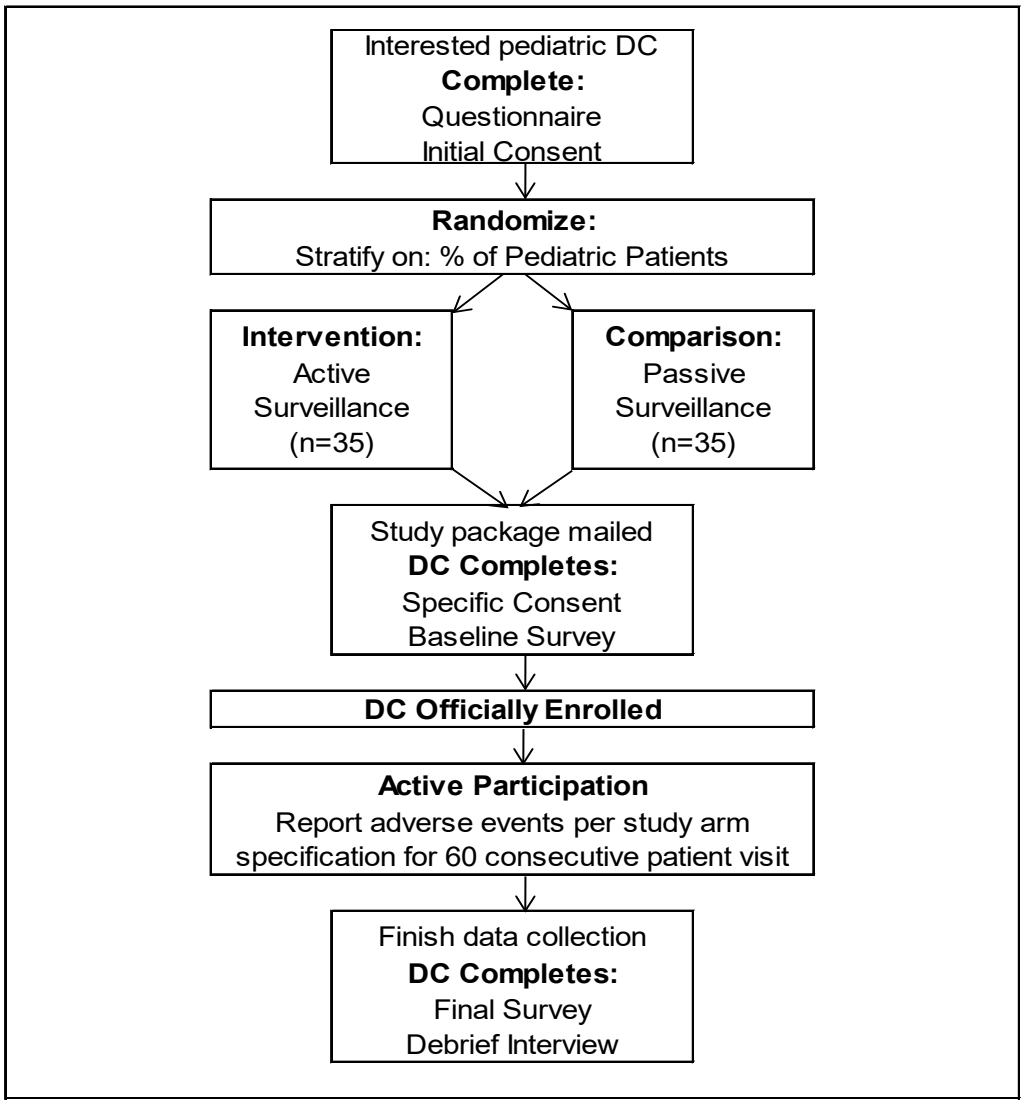
As shown in Figure 5.1, DCs interested in the study will complete a demographic questionnaire and review/sign the initial consent document, which states they are interested in enrolling in a study to report safety information from 60 consecutive pediatric visits. They will then be randomized to passive or active surveillance by the study coordinator (KAP). To promote baseline equivalence, we will stratify by DC's self-reported average proportion of pediatric patients seen (>20% versus $\leq$20%). To maintain allocation concealment, the REDCap (Research Electronic Data Capture) Randomization Module will be utilized with a random variable permuted block size, generated by an independent biostatistician [Harris et al., 2009]. Interested DCs will have study materials sent directly to their offices. This material includes the consent form that gives details on the surveillance system to which they were randomly assigned. DCs are considered enrolled in the study after that consent form is signed and they complete the online baseline survey, which collects additional demographic data and assesses patient safety attitudes [Vogus & Sutcliffe, 2007]. Throughout study participation, to ensure compliance with study methods, regular communications will occur via email or telephone between the study coordinator (KAP) and the DC.

Intervention Arm: Active Surveillance

For 60 consecutive child patient visits, the parents/caregivers will be given an information sheet and asked to complete a pre-treatment form before the child sees the DC. As described in the information sheet and as stated on the top of all data collection forms, consent will be implied if the data collection forms are completed and returned. This ensures patient confidentiality. Patients and providers will each be given a post-treatment form to complete. The patient's post-treatment form is to be completed within one week and returned directly to the investigators using a postage paid envelope. The DC's post-treatment form is to be completed immediately after the patient's visit. A more detailed form documenting AEs will be completed by the provider if a moderate, serious, or severe AE (see definitions in Table 5.1) occurs immediately following treatment or is reported to the DC at a later date. All forms were modified from an ongoing active surveillance study on SMT in Canada [Pohlman et al.,

2014]. The modified forms were reviewed for content validation by a group of experts, which included the original developers, pediatric chiropractic experts, and caregivers of pediatric chiropractic patients.

Figure 5.1. Flow chart of study activities.



Comparison Arm: Passive Surveillance

The passive surveillance system will use the established *Chiropractic Patient Incident Reporting and Learning System* (CPiRLS) [Thiel & Bolton, 2006]. DCs will be asked to report AEs that occur in 60 consecutive pediatric patient visits. In this system, only registered providers can submit, read, or comment on reports. Participating DCs will be given a universal code to protect anonymity and will also be provided with the CPiRLS's "trigger list" (see Appendix E) to advise on what kinds of incidents/AEs should be reported. Reports and comments submitted will be monitored by both the CPiRLS team and the study's investigators.

Table 5.1. Definitions of terminology for study protocol [Pohlman et al., 2014].

Adverse Event	Any unfavorable sign, symptom, or disease temporally associated with the treatment, whether or not caused by the treatment. Specifically, any new symptom or a pre-existing symptom that is worse after treatment.
Seriousness	*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) (for 5 years of age and older); OR urgent or emergency room assessment sought. *Serious*: Results in death OR a life-threatening adverse event OR an adverse event 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.
Causality (i.e., relatedness)	*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. *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.
Preventability	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.
Patient Disposition	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.

Adjudication

In both the active and the passive groups, when a moderate, severe, or serious AE is identified, all information from the report will be reviewed independently by blinded content experts to evaluate the event according to the terminology outlined in Table 5.1 (causality, preventability, and patient disposition). Operational definitions for all terminology were determined through a consensus-based process by the SafetyNET team of manual therapy and patient safety experts [Pohlman et al., 2014; Vohra et al., 2014].

Outcomes

The primary outcome will be the number (the count) and quality (i.e., ability to meaningfully interpret/adjudicate, a binary variable) of the DC's AE(s) reports per patient visit in each group. Quality of AE reports will be assessed by the adjudicators' ability to meaningfully adjudicate the report (section above).

A secondary outcome is the change in patient safety attitudes for participating DCs. This will be measured in both groups using the Safety Organizing Scale [Vogus & Sutcliffe, 2007], which is a 9-item survey with 7 points rating scale (1– 'Not at all'; 7– 'To a very great extent'). This questionnaire is to be completed at two time points: at baseline (the online baseline survey prior to study enrollment) and after AEs data collection is complete for each participating DC. In the active surveillance arm, additional variables to assess AEs and risk/prognostic factors for adverse events include: patient reported AEs, manual therapy treatment description, patient health history, and patient satisfaction [Cherkin et al., 2009].

Minimization of Systematic Error

To reduce potential respondent bias and maximize data integrity, a modified enrollment process will be utilized with a two phased consent process. The first phase has a consent document focused on safety outcomes data collection rather than a comparison of the two different methodologies for collecting such outcomes. This focus is utilized to both blind participants to the comparison under evaluation and minimize drop-outs as one arm (active surveillance) is more time intensive than the other (passive surveillance), but both arms are enhancements to current standard of North America practices. The second phase occurs after randomization with the consent document explaining the exact study procedures of the participant's allocated group without reference to the other group. There will be a debrief interview at the end of a DC's study participation to explain this modified enrollment process and the procedure for both study groups.

Other study personnel who will be blinded in the study include: 1) patients; 2) an independent biostatistician for analysis; and 3) content experts involved in the adjudication process. Because of the major differences in data management, the investigator (KAP) responsible for study coordination cannot be blinded.

Clinical Data Management

All data will be entered and managed using REDCap electronic data capture tools, which is hosted at the University of Alberta [Harris et al., 2009]. REDCap is a secure, web-based application designed to support data capture for research studies.

For the active surveillance group, the data will be verified and validated, and the quality checked by a single study investigator (KAP) who will compare the patient's pre- and post-treatment forms to ensure that inconsistencies are corrected. For audit purposes and to ensure transparency, all changes made will be recorded with the time and date and user ID. The study investigator will discuss any queries with the study team with query resolutions recorded.

Statistical Methods

The count of reported AEs (any severity) in each group will be expressed with percentages and incidence estimates, and their 95% confidence intervals (CIs). The primary analysis will compare the cumulative incidence of AE reports in active versus passive surveillance. Because the outcome is number of events, it is assumed that the data will follow a Poisson distribution. Hence, a Poisson regression with log links will be used in general estimating equation (GEE) analyses with an appropriate sandwich estimator to take into account the DC cluster correlation. Groups will be compared using an intention-to-treat analysis.

Sensitivity analysis, using the same GEE analyses as above, will be conducted for reports that were not adjudicated (because of uninterpretable AEs) and differences in how missing data were handled (i.e., imputing using average incidence, lowest incidence, and highest incidence). The binary variable expressing if the quality of the AE report allowed for meaningful interpretation/adjudication will be evaluated using the McNemar's exact test because of the expected rarity of reports and cluster correlation.

Secondary analysis will address differences in the count of AE reports by patient-only, provider-only, and those reported by both in the active surveillance versus the provider-reports in the passive surveillance. Like the primary analyses, Poisson regression with log links will be used in GEE analyses to account for cluster specific methods. Patient safety attitudes will be measured before and after participation and compared across surveillance groups.

Other planned secondary analysis are designed to identify factors predicting AEs from the data gathered in the active surveillance group. Potential factors for AEs include patient characteristics (e.g., age, presenting condition, sex, health history), provider characteristics (e.g., years in practice, specialty training), and treatment provided (e.g., high-velocity low-amplitude or other). With the AE reports categorized by their severity (i.e., none, mild, moderate, severe, serious), logistic regression analyses will be used to model predictors of AEs. If the number of moderate, severe, and serious AEs is small,

the outcome will be dichotomized as any AE versus no AE. If numbers of moderate, severe and serious events are sufficiently large, multivariable polytomous logistic regression will be used.

Planned exploratory analyses include: 1) sub-group analysis for providers with a specialty pediatric certification and number of reported AEs (i.e., the primary outcome); 2) assessment of the feasibility to implement a surveillance system within chiropractic offices, both descriptive statistics regarding compliance to study protocol and collation of individual provider feedback regarding; and 3) review of debrief interview to gain insight into participating DCs overall thoughts on the study, including barriers to implementation, perceived benefit of participating, and being blinded to intervention. An assessment of bias will be conducted with responding and non-responding patient demographic characteristics for the active surveillance group. All analyses will be conducted using Stata version 13 (StataCorp LP, College Station, TX, USA).

Sample Size

An estimated active surveillance reporting rate of 4.3% and intracluster correlation of ρ=0.13 were based on a pilot study of a similar active surveillance used within the chiropractic profession in Canada [Pohlman et al., 2014; Vohra et al., 2014]. We assumed a passive surveillance reporting rate of 0.53%, based on prior literature [Todd et al., 2015]. A one-sided significance level was utilized as it seems reasonable to believe that passive surveillance will result in under-reporting of AEs [Stockwell et al., 2010]. We calculated that a sample size of 35 providers in each group, with each DC collecting data from 60 pediatric patient visits, and 5% one-sided significance level, would lead to 80% power. This includes an anticipated loss to follow-up of 11% DCs and 20% of patient visits.

5.4 – Discussion

This study will be the largest prospective evaluation of AEs reported after chiropractic manual therapy in the pediatric population, which has been identified as a major gap in the literature [Todd et al., 2015; Humphreys, 2010; Vohra et al., 2007]. This randomized cluster trial assesses the effectiveness of two different surveillance methods to collect observational safety data on a topic that is clinically relevant. To our knowledge, this is the first study to do a direct comparison of active versus passive surveillance reporting of AEs.

The chiropractic profession treats children [Pohlman et al., 2010; Christensen et al., 2015], therefore it has a responsibility to ensure proper safety evaluations. The attitudes and opinions of DCs, who are interested in pediatric treatment, for implementing safety performance systems were evaluated in 2014. The survey identified a robust patient safety climate with time pressure as the barrier of most concern

to participants [Pohlman et al., 2016]. Time pressure is a common barrier for health care provider participation in research, as 'busy-ness' is seen as a socially acceptable excuse for declining 'extra' activities [Cvijovic et al., 2010]. Our study protocol took this concern into consideration. When pilot tested, passive surveillance was found to add 30 seconds per patient visit while active surveillance added only two minutes [Pohlman et al., 2014].

Aside from reports of actual AEs that are collected in this study, each surveillance method also collects additional patient safety information. While not the primary outcome, this study will also clearly describe and report these differences. Such examples from the passive surveillance group includes administrative, incidental patient safety incidents (e.g., use of the wrong clinical file or tripping over office equipment) or 'near misses'/events, which could have caused an AE, but did not. For the active surveillance group, information will be sought not only from the DC, but also directly from the patients; patient provided information can be compared to that information known by the provider. These differences are unique to each surveillance group and should be taken in consideration when an organization is deciding on what method to use to evaluate AE.

Beyond the significance of the study's specific aims, the study procedures also include several notable methodological considerations, such as the attention to outcome measurement and a modified enrollment process to maintain participant blinding. This study started with a content validation of the data collection instruments to ensure they will collect the intended information and that it will be easily understood by the chiropractic pediatric patient's parent/caregiver [Mokkink et al., 2010].

Modified enrollment procedures have been utilized most commonly to avoid biases that occur with non-placebo controlled trials [Adamson et al., 2006]. This study will use a modified enrollment procedure, a two stage consent process, to ensure provider blinding is maintained and drop-outs minimized. To avoid ethical concerns regarding enrolling and randomizing providers without their consent, consent is sought in two stages: first, providers consent to participation in a study on pediatric patient safety and chiropractic manual therapy. The second consent will give full disclosure of their specific study procedures. When participant's complete the study, a debrief interview will unveil the two groups and the purpose for not disclosing this information earlier.

Barriers to study completion

Possible barriers to the study's implementation will be the willingness of DCs to participate in research and their adherence to study procedures. Adherence will be addressed by actively following up on DCs interested in this study's topic, engaging front desk personnel in study processes, and assuring that the study protocol is understood. Despite these precautions, compliance is expected to be challenging,

specifically for chiropractic practices that are assigned to the active surveillance group. Drop-outs have been taken into account in the sample size calculations.

Another concern regarding the study's implementation is the possibility of a low response rate for the active surveillance arm's post-treatment form, to be completed by the patient's caregiver. The pilot study found that DCs who encouraged their patients to complete the data collection instruments had a better response rate [Pohlman et al., 2014; Vohra et al., 2014].

Chapter 6:
Comparison of active vs. passive surveillance adverse event reporting in a pediatric ambulatory chiropractic care setting: a cluster randomized controlled trial

6.1 – Abstract

Introduction

The seminal patient safety report, *To Err is Human,* urged health care providers to monitor adverse events (AEs), which resulted in an uptake of surveillance reporting systems in hospital settings. However, most health care occurs in ambulatory settings. To examine different reporting systems in this setting, this pragmatic, superiority, cluster, stratified randomized controlled trial (RCT) compared the quantity and quality of AE reports after chiropractic manual therapy in children less than 14 years of age, using active versus passive surveillance reporting systems. The hypothesis was that active surveillance system would have more AE reports from patient visits with better quality narrative reports than passive surveillance.

Method

Study data were collected between November 2014 and July 2017 from 60 consecutive pediatric patient visits to participating chiropractors. Chiropractic offices were the unit of randomization with random allocation in a 1:1 ratio to an active or passive surveillance reporting system; unique patients and patient visits were the units of analysis. A modified enrollment process was used to maintain blinding of participating chiropractors to the comparison study arm. Those allocated into the active surveillance arm collected AE information with three questionnaires (two completed by patients/caregivers and one completed by chiropractors) to identify any new or worsening symptoms after treatment. Those allocated into the passive surveillance arm had AE information submitted by the chiropractors using a web-based system called “CPiRLS”. AEs identified by the chiropractor as greater than mild severity were independently assessed by two content experts. To assess quality of a report, those evaluated as moderate, severe, or serious reports by the content experts were assessed with regards to causation, preventability, and patient disposition. The primary outcome was the cumulative incidence of AE reports in active versus passive surveillance.

Results

Of 96 chiropractors who agreed to participate and enrolled in the study, 69 (71.9%) completed data collection and were included in analyses: 34 chiropractors in the active surveillance group with 1,894

patient visits from 1,179 unique patients and 35 chiropractors in the passive surveillance group with 1,992 patient visits from 1,363 unique patients. In the active surveillance group, AEs were reported in 8.8% (n=140, 95% CI 6.72% to 11.18%) of patients/caregivers, compared with 0.1% (n=2, 95% CI 0.02% to 0.53%) in the passive surveillance group ($p<0.001$). Of the 135 AEs reported in the active surveillance group with severity identified, 76 (56.3%) were mild; 35 (25.9%) were moderate; and 24 (17.8%) were severe. Over 90% of moderate or severe AEs were reported by patient/caregiver. The quality of AE reports was not evaluated because the five provider-generated AE reports reviewed by the content experts were determined to be of mild severity and therefore not assessed further.

Conclusion

In this RCT, active surveillance was found to have significantly more AE reports than passive surveillance. Further prospective active surveillance research studies should be conducted with children receiving chiropractic manual therapy to explore modifiable risk factors for moderate and severe AEs, and to further explore how and when to solicit patient safety information, including issues related to proxy reporting in pediatric patient safety research. Until further studies are conducted, this study provides the best available information for chiropractors to consider when making pediatric treatment recommendations as well as to discuss with their patients when seeking informed consent.

6.2 – Introduction

The Institute of Medicine (IOM) urges providers across health care settings to monitor adverse events (AEs) [To error is human, 1999; Patient safety, 2004; Quality chasm, 2006]. Ideally, the information gathered from reported AEs will help identify risks and enhance patient safety by preventing avoidable injury. Thus far, most research on patient safety and collection of AEs has occurred in hospital settings. As most health care is provided in ambulatory settings, there is a need to evaluate which AE reporting systems work best for the providers and patients in those settings [Hoffmann et al., 2011]. Active and passive surveillance AE reporting systems have been evaluated for hospital AE reporting; however, because of the distinct differences in ambulatory care settings, these systems warrant additional evaluation in this environment.

Active surveillance is described by the Food and Drug Administration (FDA) Pharmacovigilance Planning as a mechanism that "seeks to ascertain completely the number of AEs via a continuous pre-organized process" [IOM-CCRIC, 2004]. In other words, active surveillance involves the health care provider or a consumer using a prospective process or systematic approach, which requires events to be reported to either an internal or external entity [To error is human, 1999]. Active surveillance systems provide better detection of AEs since they allow for systematic identification and reporting of such events [To error is human, 1999]. However, active surveillance reporting models are generally more costly and resource-intensive, and may not be as 'real-time' as originally desired [Wachter & Gupta, 2017].

Passive surveillance systems have become a cornerstone system of AE reporting because of their relative ease of implementation, low cost, and ability to capture unexpected events [Wachter & Gupta, 2017]. "Passive" refers to voluntary or spontaneous reporting of events by health professionals or consumers. This approach typically does not provide an accurate numerator (due to likely under-reporting) or denominator (unknown number of patients exposed) and therefore is unable to accurately estimate the incidence of AEs. Under-reporting in passive surveillance results from both patients' failure to report AEs to their health care provider and health care providers' failure to report AEs to the relevant organization. Passive surveillance systems often offer limited-to-no feedback on the assessment and impact (if any) of the AE report to individuals filing reports [Pfeiffer et al., 2010]. Additional barriers to the success of passive surveillance systems include poor quality data that challenge meaningful assessment of AEs and lack of follow-up/outcome data [Hutchinson et al., 2007].

Doctors of chiropractic are licensed, ambulatory care providers who commonly use manual therapy [Christensen, 2015]. On average, children and youth (18 years of age and younger) represent 17% of a general chiropractic practice; this increases to 39% for chiropractors who specialize in children [NBCE 2015; Pohlman et al., 2010]. Children most commonly receive care from chiropractors for

musculoskeletal complaints; some children are seen for other health conditions or for “wellness” [Ndetan et al., 2012; Pohlman et al., 2010]. Although the volume of children seen by chiropractors is high, there is minimal information about the safety of pediatric chiropractic manual therapy. Harms related to pediatric chiropractic care identified in systematic reviews are largely based on retrospective case reports; these reviews have called for further high-quality prospective evaluation on this topic [Vohra et al., 2007; Todd et al., 2014]. This high volume and lack of prospective safety information make pediatric chiropractic offices an ideal ambulatory health care setting to better explore AE reporting systems.

This study is a cluster RCT, which compared the quantity and quality of AE reports after chiropractic manual therapy in children less than 14 years of age, using active versus passive surveillance reporting systems. The study’s hypothesis was that the active surveillance system would identify more AEs and would have better quality narrative reports than the passive surveillance system. In this context, quality is defined as ability to meaningfully adjudicate moderate, severe, or serious reported AEs with regards to causation, preventability, and patient disposition.

6.3 – Methods

Design, Unit of Randomization and Analysis, and Study Definitions

A pragmatic, superiority, cluster, stratified RCT with modified enrollment involving a two-step consent process (described in detail in the next section) was conducted. Cluster randomization was used since chiropractic offices may consist of multiple participating practitioners. Chiropractic offices were the unit of randomization, and unique patients and/or patient visits were the units of analysis. After being enrolled into the study, chiropractic offices were randomly allocated in a 1:1 ratio to active or passive surveillance reporting systems. Randomization was performed using the REDCap (Research Electronic Data Capture) Randomization Module [Harris et al., 2009]. Randomization was stratified based on the chiropractor’s self-reported proportion (<20% or ≥20%) of pediatric patients. If more than one chiropractor in an office participated, stratification was based on the chiropractor who made initial contact with the study coordinator. To maintain allocation concealment, a biostatistician who was not involved in recruitment provided computer-generated random-variable permuted block sizes used in the REDCap Randomization Module.

Study data were collected between November 2014 and July 2017 on 60 consecutive pediatric patient visits with each participating chiropractor. For purposes of this study, the age cut-off to be considered a pediatric patient was less than 14 years, as those 14 years of age or older can consent to medical treatment without parental permission in some jurisdictions where the trial took place [IOM, Ethical

Conduct of Clinical Research Involving Children, 2004]. All pediatric patients were eligible, whether they were new or established patients, being seen for one-time-only or repeated visits. The operational definition for the study's primary outcome, *reported AEs*, was developed by an international multidisciplinary team based on literature review and consensus with multiple stakeholders [Pohlman et al., 2014], which was: any unfavorable sign, symptom or disease temporally associated with the treatment, whether or not caused by the treatment; specifically, any new or pre-existing symptom that is worse after treatment [Pohlman et al., 2014; Pohlman et al., 2017]. Operational definitions for AE severities were also determined by an international multidisciplinary team based on literature review and consensus with multiple stakeholders [Vohra et al., 2014]: *mild* implied the AE required self-care only (no further treatment sought/needed); *moderate* implied temporary limitation of age-appropriate activities of daily living or that care was sought from a medical doctor; *severe* implied limitation in self-care (e.g., bathing, eating, dressing) or need for urgent medical assessment; and *serious* implied inpatient hospitalization, life-threatening event, or death.

Recruitment and Consent

Chiropractic offices in the United States (US) and Canada were recruited for this study through announcements at pediatric chiropractic events and communications through North American pediatric chiropractic organizations, as well as social media, professional newsletters/magazines, and referrals from colleagues or past study participants. A two-step consent procedure was implemented. In the first step, interested chiropractors agreed to participate in a study to evaluate safety of pediatric chiropractic manual therapy by completing AE reports. During the second step, participating chiropractors were randomized and provided with a second consent document that informed them of the detailed procedures for the study arm to which they had been allocated, but did not provide information on the alternative study arm. This consent procedure was implemented as both surveillance methods were additions to usual practice and some providers may have assumed active surveillance would pose too large a burden and not be feasible to implement in their practice. Failure to blind participants about the comparison arm could have influenced participant's perceptions of how difficult their assigned reporting system was to implement. Differential post-randomization withdrawal from either group would have negatively impacted the validity of the data.

Intervention (Active Surveillance) vs Control (Passive Surveillance)

Offices were randomized to either active or passive surveillance to collect AE reports. In the intervention arm (active surveillance), reporting of AEs was conducted through questionnaires completed by the patient/caregiver and chiropractor for each appointment. In the control arm (passive surveillance), the Chiropractic Patient Incident Reporting and Learning System (CPiRLS) web-based

program (https://cpirls.org/) was used by participating chiropractors to report any AEs that occurred in their 60 consecutive pediatric patient visits.

Data Collection

Intervention (Active Surveillance): New or worsening symptoms were considered AEs.

Information on AEs was collected by three questionnaires, two completed by the patient/caregiver (i.e., forms were completed by either the pediatric patient or by the patient's caregiver) and one completed by the chiropractor (also referred to as the provider), with all questionnaires assessing symptoms the patient was currently experiencing. These symptoms were: pain/discomfort, stiffness, weakness, fatigue/tiredness, headache, dizziness, numbness/tingling, irritability/crying, and other. The patient/caregiver completed a pre-treatment questionnaire (Appendix D) immediately prior to the patient being seen, and handed this to his or her chiropractor to review and return to the study team after completing the provider section. Patients/caregivers were also given a post-treatment questionnaire (Appendix D) to complete up to one week following treatment. The post-treatment questionnaire asked patients/caregivers whether a reported symptom was new, better, worse, or unchanged since treatment. To establish pre- and post-treatment symptom severity (mild, moderate, severe, or serious), patients/caregivers were asked a series of questions on symptom-related limitations. The post-treatment questionnaire was sent directly by the patient/caregiver to the study team in a pre-addressed and stamped envelope; it was not reviewed by the chiropractor. Consent was implied from completion and return of these questionnaires.

The provider questionnaire (Appendix D) was completed immediately after treatment. In this questionnaire, the presence or absence of any observed AE was reported, and AEs were rated by the provider as mild, moderate, severe, or serious using the provided study operational definitions [Pohlman et al., 2017]. Any AEs assessed as moderate, severe, or serious by the provider required the provider to complete a longer secondary questionnaire (Appendix D) that captured more detailed information about the event and associated factors. These secondary questionnaires were sent for review by two independent content experts (described below in *Adjudication*).

Control (Passive Surveillance): Any symptom reported was considered an AE.

Information on AEs was submitted from chiropractors participating in the control arm (passive surveillance) through a web-based system called "CPiRLS" (there was no patient involvement in AE reporting in the passive surveillance arm). CPiRLS was established in 2005 for the surveillance of patient safety incidents among the British Chiropractic Association members [Thiel, 2011; Thiel & Bolton, 2006]. Providers with access to this system can anonymously report a suspected AE. Information collected on CPiRLS consists of patient demographics, what happened, explanation of why/how it happened, actions taken by the chiropractor, if the event was avoidable, and any other

information the chiropractor wished to share. All AE reports were reviewed by two independent content experts (described below in *Adjudication*). In addition, for all 60 consecutive pediatric patient study visits, data were collected on whether patients were new or established, had a one-time-only or repeated visits during the study period, reason for visit, patient's date of birth, and appointment date.

Adjudication

As above, providers randomized to the active surveillance group completed a short questionnaire after each of the 60 patient visits and a longer secondary questionnaire if a moderate, severe, or serious AE became known to them; while the passive surveillance group logged into the CPiRLS website to complete an online report if an AE of any severity became known to them during the study period.

For those AE reports sent for adjudication from either group, further independent assessment was done by two blinded content experts: an experienced chiropractor specialized in pediatrics; and an academic pediatric neurologist. The content experts first reviewed the report to evaluate severity of the AE. If their assessment found that an AE was moderate, severe, or serious, then the report was further evaluated for the ability to assess causality/relatedness, preventability, and patient disposition from the material received from the AE report. Operational definitions for all terminology were based on previously published definitions developed by an international multidisciplinary team and have been described in detail elsewhere [Pohlman et al., 2014; Vohra et al., 2014; Pohlman et al., 2017]. If consensus could not be reached by the two independent adjudicators, then the final report would include both assessments.

Sample Size Calculations

The sample size was calculated based on the primary outcome: number of AE reports. For 0.80 power, a 0.05 one-sided significance level, and anticipated 11% loss to follow-up, 35 chiropractors, each collecting data from 60 consecutive pediatric patient visits, were needed in each group. Based on previous research, assumed AE reporting rates were 4.3% for the active surveillance group and 0.5% for the passive surveillance group. [Vohra et al., 2007; Pohlman et al., 2014; Vohra et al., 2014]. The estimated incidence of moderate, severe, or serious SMT-related AE in the active surveillance arm was based on pilot data collected from a similar study in the general population [Pohlman et al., 2014].

Analysis

The characteristics of participating chiropractors and pediatric patients were reported for each arm using descriptive statistics. The primary analysis compared the quantity of AE reports in active versus passive surveillance through cumulative incidence. In the active surveillance group, an AE was identified through any of three different sources. First, an AE was identified when the patient/caregiver-completed post-treatment questionnaire reported a symptom as new or worse. Second, an AE was

identified when the patient/caregiver rated symptoms as more severe on the post-treatment questionnaire than on the pre-treatment questionnaire. Where a symptom was reported on the post-treatment questionnaire, but the severity rating was missing, that symptom was considered worsened (i.e., an AE). Third, any new or worsening symptom reported by the chiropractor immediately post-treatment was identified as an AE. Where a given AE was reported by more than one source, it was counted only once. In the passive surveillance group, any symptom report submitted to CPiRLS was considered an AE.

An intention-to-treat analysis was planned to compare the total number of AEs reported in each arm. This analysis was to implement a Poisson regression with log links to be used in general estimating equation (GEE) analyses and an appropriate sandwich estimator. Additionally, the incidence of AEs per patient visit and incidence of AEs per unique patient were calculated.

For adjudicated reports, quality of AE reports was to be evaluated by the outcome of the adjudication process, that is, the adjudicators' ability to determine causality/relatedness, preventability, and patient disposition based on adequacy of information provided in the AE report versus 'insufficient information'. All analyses were conducted using Stata version 14.2 (StataCorp LP, College Station, TX, USA).

Assessment of Bias due to Non-Participation by Chiropractor

An assessment of participation bias was conducted using a multivariable logistic regression model, built to identify possible bias due to non-participation by chiropractors after random assignment to intervention arms. Candidate explanatory variables for non-participation were: study group (active, passive), chiropractor's self-reported proportion of pediatric patients (<20%, ≥20%), multi-provider vs solo practice setting, how participant was recruited (investigator, conference presentation, referral from colleague, pediatric chiropractic organization), gender (male, female), office geographic location (Canada, US–Northeast, US–South, US–West, US–Midwest), and whether they held a pediatric specialty certification (yes, no). These data were obtained when chiropractors initially consented to participate in the study.

Assessment of Bias due to Patient/Caregiver Non-Response in the Active Surveillance Group

For the intervention group (active surveillance), a multivariable logistic regression model was built to identify possible bias due to patients/caregivers not returning the post-treatment questionnaire. If patients were seen more than once, response status was determined by whether they returned their first visit's post-treatment questionnaire. Candidate explanatory variables were: completion of the pre-treatment questionnaire by mother vs another caregiver; pre-treatment pain intensity on 11-point Numeric Pain Scale (NRS); gender of child; age of child; number of pre-treatment symptoms (none, one, two or more); number of chiropractic visits prior to the study (no prior visits, 1-9, 10 or more prior

visits); medication use at time of visit (no, yes); use of natural health products at time of visit (no, yes); visit covered by self-pay (no, yes); and number of visits during course of the study (1, 2-4, 5 or more).

In addition, in order to assess the possible effect of non-response on the incidence of AEs for unique patients in the active surveillance group, two sensitivity analyses were conducted. The first made a "worst-case scenario" assumption that all non-responders would have reported an AE. The second made a "best-case scenario" assumption in which no non-responders would have reported an AE.

Publication of Protocol, Ethics, and Registration of Trial

A detailed study protocol has been published [Pohlman et al., 2017]. The University of Alberta's Research Ethics Board reviewed and approved this study (Pro00027903). The trial has been registered at ClinicalTrials.gov (NCT02268331).

6.4 – Results

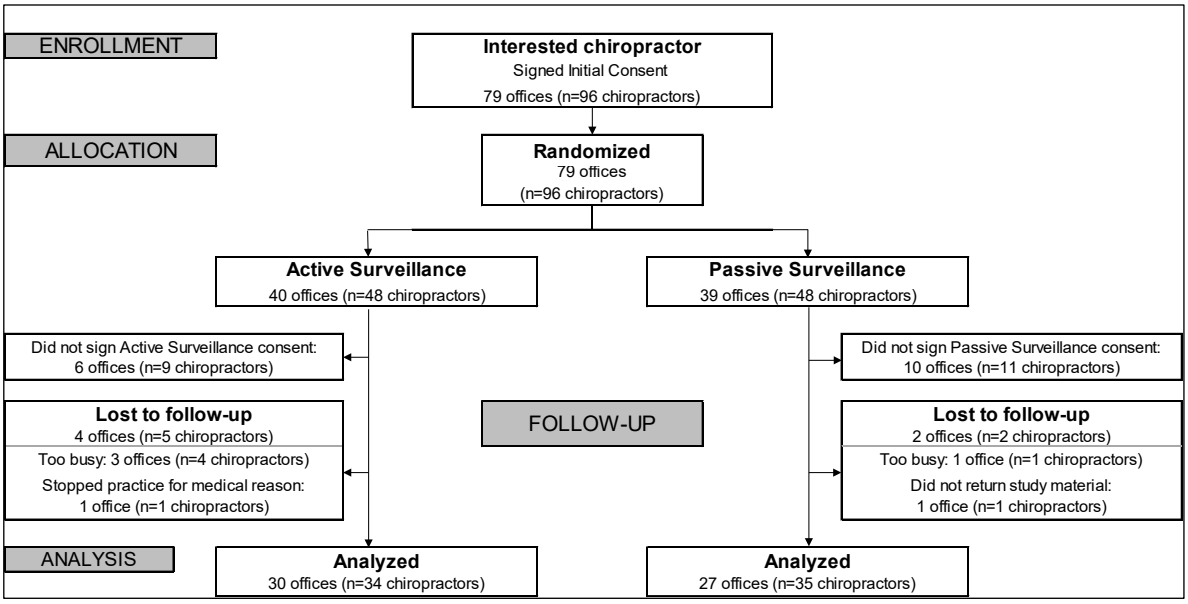
The CONSORT diagram for study participant flow is shown in Figure 6.1. Of the 96 chiropractors in 79 offices who expressed initial interest and signed the first consent document, 69 chiropractors in 57 offices signed the second (specific study-arm) consent document, participated in the study, and provided data that were included in the analysis. There was no evidence of differential post-randomization attrition between the two groups (i.e., randomization to active surveillance was not associated with greater provider attrition). Overall, the units of analysis for the intervention group (active surveillance) was 1,894 patient visits from 1,179 unique patients, whereas the control group (passive surveillance) had 1,992 patient visits from 1,363 unique patients. Participating chiropractors and their patients are described in Table 6.1. The chiropractors in the active surveillance group took a median of 91 days (range 3-626 days) to collect study data on 60 pediatric patients, while the passive surveillance group took a median of 52 days (range 2-555 days). A caregiver (e.g., mother), completed 95.9% of the pre-treatment forms for the pediatric patient.

The incidence of AEs was 8.8% (n=140, 95% CI 6.72% to 11.18%) for the active surveillance group and 0.1% (n=2, 95% CI 0.02% to 0.53%) for the passive surveillance group ($p<0.001$). Of the 1,894 patient visits in the active surveillance group, post-treatment patient-reported questionnaires were returned for 1,056 (55.8%) patient visits. Of the 1,179 unique patients, post-treatment patient-reported questionnaires were returned by 662 (56.1%) patients. As shown in Table 6.2, of the 140 AEs reported in the active surveillance group, 135 had severity ratings questions completed: 76 (56.3%) were mild; 35 (25.9%) were moderate; and 24 (17.8%) were severe. Over 90% of the moderate or severe AEs reported were from patient/caregiver and there was a positive association with pre-existing symptoms ($p<0.001$) (i.e., AEs were more likely to be reported as moderate or severe if these symptoms were pre-

existing, than if they were new). Figure 6.2 displays the severity of AEs by age groups; the highest numbers of moderate and serious AE reports were from children less than one year of age.

Table 6.3 shows the incidence of AEs (i.e., new or worsening symptoms) as reported by providers, patient/caregivers, or both for patient visits and unique patients (as each of these may have had multiple AE reports within them). The most common symptoms were irritability/crying (37.9%, n=53/140) and pain/discomfort (29.3%, n=41/140). All moderate or severe AEs reported by the DC only (n=5) were for irritability/crying. The majority of the moderate or severe AEs identified on the patient/caregiver forms as worsening were irritability/crying (n=15, 37.5%) and pain/discomfort (n=12, 30.0%); however, the moderate or severe AEs reported as a new symptom by the patient/caregiver were: pain/discomfort (n=4, 30.8%), irritability/crying (n=3, 23.1%), and fatigue/tired (n=3, 23.1%).

Figure 6.1. CONSORT flow diagram of participants in this cluster randomized trial.



Providers in the passive surveillance group submitted a total of two AE reports (both worsening of pain/discomfort) on the CPiRLS web-based program. Thus, the incidence of AE reports submitted by chiropractors in the passive surveillance group was two AE reports out of 1,992 patient visits (0.1%) and 1,363 unique patients (0.1%). Because of the small number of reports in the passive surveillance group, no regression analyses were conducted.

All AE reports sent to be reviewed by the content experts can be found in Appendix E. From the active surveillance group, three secondary questionnaires were completed by the treating chiropractor. Each of these reports had an AE (two of which were increased irritability/crying and one was increased pain/discomfort) rated as moderate or severe by the treating chiropractor. Consensus from both content experts was that all three AEs were mild according to the study operational definition based on detailed information within the provider report, therefore not warranting further assessment. In addition,

providers in the active surveillance arm identified another four moderate or severe AEs but failed to complete the secondary questionnaire; these AEs were not assessed by the content experts as the secondary questionnaire was required to initiate their assessment.

Table 6.1. Demographics of participating chiropractors and their pediatric patients.

	Active Surveillance (n=34)	**Passive Surveillance (n=35)**
Chiropractors		
Female, n (%)	27 (79.4%)	23 (76.7%)
Mean years in practice (SD), [range]	11.6 (8.46), [1-32]	11.8 (9.17), [1-39]
Patient Visits / Week, n (%)		
< 50	9 (28.1%)	7 (22.6%)
50-99	7 (21.9%)	10 (32.3%)
100-149	7 (21.9%)	4 (12.9%)
150-199	5 (15.6%)	4 (12.9%)
200+	4 (12.6%)	6 (19.4%)
Highest Non-Chiropractic degree, n (%)		
Bachelor's Degree	29 (90.6%)	24 (77.4%)
Master's Degree	1 (3.1%)	2 (6.5%)
Others (Licensed Massage Therapist)	1 (3.1%)	0
Pediatric specialty certifications*, n (%)		
None	17 (53.1%)	20 (66.7%)
Diplomate/Fellowship	11 (34.4%)	9 (30.0%)
Certification	4 (12.5%)	1 (3.3%)
Patients		
Conditions (by first visits)		
Wellness/Preventative	686 (58.2%)	735 (53.9%)
Musculoskeletal	328 (27.8%)	271 (19.9%)
Neurological/Developmental/Behavioral	48 (4.1%)	75 (5.5%)
Feeding Concerns	48 (4.1%)	69 (5.1%)
Respiratory	116 (9.8%)	27 (2.0%)
Allergy/Asthma/Immunology	26 (2.2%)	30 (2.2%)
Flu/Sickness	8 (0.7%)	11 (0.8%)
Mouth/Teeth/Adenopathy	16 (1.4%)	8 (0.6%)
Colic/Digestive	150 (12.7%)	101 (7.4%)
Otitis Media	52 (4.4%)	44 (3.2%)
Nocturnal Enuresis	8 (0.7%)	15 (1.1%)
Sleep Concerns	24 (2.0%)	21 (1.5%)
Trauma	40 (3.4%)	77 (5.7%)
Miscellaneous	18 (1.5%)	17 (1.3%)
Ages (in years; by first visits)		
0	343 (25.2%)	297 (25.2%)
1	129 (9.5%)	128 (10.9%)
2	115 (8.4%)	87 (7.4%)
3	110 (8.1%)	81 (6.9%)
4	94 (6.9%)	89 (7.6%)
5	79 (5.8%)	74 (6.3%)
6	77 (5.7%)	57 (4.8%)
7	80 (5.9%)	67 (5.7%)
8	65 (4.8%)	66 (5.6%)
9	54 (4.0%)	53 (4.5%)
10	56 (4.1%)	47 (4.0%)
11	46 (3.4%)	39 (3.3%)
12	66 (4.8%)	38 (3.2%)
13	42 (3.1%)	33 (2.8%)

*- Within the chiropractic profession, additional training can be obtained to receive either a diplomate/fellowship (approximately 360 hours) or a certification (approximately 120 hours) in special topics, including pediatrics.

Table 6.2. Number and percentage of new and worsening AE reports from chiropractor, patient/caregiver, and both in the active surveillance group as determined from the post-treatment questionnaire, stratified by severity (n=135*).

	Mild	Moderate	Severe	Serious	Total
Patient/Caregiver Reported Only	36	32	21	0	**89 (65.9%)**
Chiropractor Reported Only	40	3	2	0	**45 (33.3%)**
Both Patient/Caregiver & Chiropractor Reported	0	0	1	0	**1 (0.7%)**
OVERALL TOTAL	**76 (56.3%)**	**35 (25.9%)**	**24 (17.8%)**	**0 (0%)**	**135**

* Missing severity ratings on 5 additional reported AEs reported by patient/caregivers.

Figure 6.2. Number of AE reports by severity and age groups.

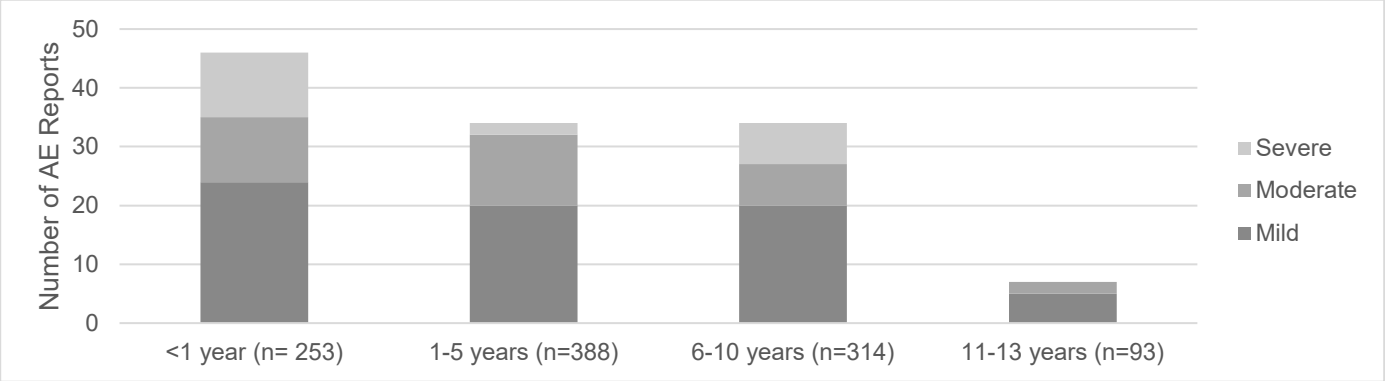


Table 6.3. Incidence and percentages of AEs (i.e., new or worsening symptoms) from chiropractor, patient/caregiver, and both in the active surveillance group, stratified by patient visit and unique patients.

Active Surveillance AE Report – Responders only		**AEs per patient visit (n=1,056 patient visits)**	**AEs per unique patient (n=662 unique patients)**
Patient/Caregiver Reported Only	**Self-Assessed as Worse or New Symptom Only**	6 (0.6%)	6 (0.9%)
	Pre-Post Difference found Worsening Symptom Only	24 (2.3%)	24 (3.6%)
	Symptom Reported by Both Self-Assessment & Pre-Post Difference	2 (0.2%)	2 (0.3%)
Chiropractor Reported Only		33 (3.1%)	25 (3.8%)
Both Patient/Caregiver & Chiropractor Reported		1 (0.1%)	1 (0.2%)
Totals		**65 (6.2%)**	**58 (8.8%)**

From the passive surveillance group, two AE reports (as above, both increased pain/discomfort) were submitted to CPiRLS and sent to the content experts for independent review. Consensus from both content experts was that the two AEs were mild, therefore not warranting further assessment. Because no reported AEs were adjudicated to be moderate, severe, or serious, no further evaluations were conducted. The quality evaluation of the adequacy of reporting in active vs. passive surveillance with regards to causation, preventability, and patient disposition (i.e., comparison of quality of the AE reports) could not be assessed as planned *a priori*.

Table 6.4 reports the findings of the multivariable model describing patient/caregiver response (vs. non-response) to the post-treatment questionnaire. Those factors associated with responding to the questionnaire were: older age of patient ($p=0.003$), less pre-treatment pain ($p=0.004$), and five or more visits during the study ($p<0.001$).

We also conducted sensitivity analyses to evaluate the potential impact of missing data from post-treatment questionnaires that were not returned. Under the assumption that there was an AE experienced by all 517 non-responding unique patients (worst-case scenario), the incidence of AEs would increase to 49.4% (582/1,179; 95% CI: 46.6%, 52.3%). Under the assumption that none of the non-respondents had an AE (best case scenario), the incidence of AEs would decrease to 5.5% (65/1,179; 95% CI: 4.4%, 7.0%). Under both assumptions, active surveillance yielded a statistically significantly incidence of AE reports than passive surveillance ($p<0.001$ for both assumptions).

6.5 – Discussion

While the IOM urges health care providers to monitor for AEs after treatment, there is not yet consensus on how that monitoring should best occur [To error is human, 1999; Patient safety, 2004; Quality chasm, 2006]. In addition, providers and patients, and in the case of children, their parents or caregivers, should know the incidence of AEs in order to make informed decisions about their treatment options and to have their expectations appropriately set [Snyder, 2012]. Better consistency and accuracy in AE monitoring and reporting would provide the foundation for these decisions and expectations, as well as improving patient safety, especially in environments were health care most commonly occurs, i.e., ambulatory settings. In this cluster randomized controlled trial to compare AE reports collected through active versus passive surveillance in pediatric patients receiving care from a chiropractor, a statistically significant difference was found in reported AEs, from 8.8% in the active surveillance group to 0.1% in the passive surveillance group. Active surveillance is feasible in ambulatory care settings; sensitivity analyses confirm our study findings are robust.

Table 6.4. Findings of multivariable logistic model describing characteristics associated with response to the post-treatment questionnaire: Odds ratios (OR) and 95% Confidence Intervals (95% CI). Items in **bold print** were statistically significant (p<0.05).

	Crude OR	95% CI	Adjusted OR	95% CI
Pre-Form completed by, mother	1.00	1.00, 1.00	1.00	1.00, 1.00
Numerical Pain Rating Scale, mean (SD)	**0.92**	**0.88, 0.96**	**0.92**	**0.87, 0.97**
Child Gender, female	1.00	1.00, 1.00	1.00	1.00, 1.00
Child Age, mean (SD)	**1.04**	**1.02, 1.07**	**1.04**	**1.01, 1.07**
Pre-Symptom, none				
1	0.88	0.71, 1.12	1.04	0.80, 1.34
2 or more	**0.73**	**0.59, 0.90**	0.95	0.71, 1.26
Number of Prior Treatment, first visit				
1-9 prior visits	**0.78**	**0.63, 0.96**	0.85	0.67, 1.07
10 or more prior visits	0.95	0.72, 1.26	0.94	0.70, 1.27
Medication Use, none	1.00	1.00, 1.00	1.00	1.00, 1.00
Natural Health Product Use, none	1.00	1.00, 1.00	1.00	1.00, 1.00
Visit fees covered by, self-pay	1.00	1.00, 1.00	1.00	1.00, 1.00
Study Repeat Visit, 1				
2-4 visits	0.99	0.82, 1.21	1.03	0.84, 1.28
5+ visits	**1.69**	**1.26, 2.26**	**1.94**	**1.40, 2.68**

This study has provided the first high quality prospectively gathered safety data on chiropractic manual therapy of children. This is of high relevance, since many chiropractors see children and concern is often expressed about the safety of chiropractic manual for the pediatric population [Vohra S et al., 2007; McClafferty et al., 2017]. This study provides evidence that 8.8% of children may experience an AE (a new or worsening symptom) after chiropractic manual therapy (5.0% mild; 2.3% moderate; 1.6% severe). Our findings are quite different from a three-year retrospective chart audit which concluded that 0.1% of 699 pediatric patients at a chiropractic college report minor transient AEs to their chiropractor at a follow-up visit [Miller and Benfield, 2008]. Chiropractors may not be aware of the occurrence or severity of AE that are reported by patients/caregivers within a week following treatment. Future research should explore modifiable risk factors for moderate and serious AEs occurring after children receive chiropractic manual therapy.

Other observational studies assessing active versus passive surveillance have also demonstrated that active surveillance is more effective in identifying AEs. A 2009 observational study evaluated the safety of a mass vaccination program for H1N1 in China (29,654 children and 65,590 adults) [Wu et al., 2010]; active surveillance yielded 23.4% reports of local or systemic symptoms, while passive surveillance, only 0.2%. Danova et al. also investigated the incidence rates of AEs following immunization and found

active surveillance identified over six times the number of AEs than passive reporting (i.e., 209 vs. 32 AEs per 100,000) [Danova et al., 2017].

Active surveillance has also been successfully implemented to study the safety of complementary therapies in ambulatory health care settings. For example, when an active surveillance system was used to measure AEs in 2.2 million acupuncture treatments, 8.6% of the patients reported at least one adverse effect [Witt et al., 2009]. When active surveillance was implemented for adults receiving cervical spinal manipulation therapy, differences were found between patient- and chiropractor-reported events (680 vs 1 AE per 10,000 treatment consultations) [Thiel et al., 2007]. In this study, chiropractors were requested to report only serious AEs, while patients were asked to report any symptom up to seven days following their treatment consultations; all patient-reported AEs were minor [Thiel et al., 2007].

While this RCT and the other studies described above demonstrate active surveillance's clear superiority to collect AE reports, the implementation of such a reporting system to a large population of ambulatory providers has not been conducted or assessed for feasibility. An obvious barrier to such implementation is potential implications for time and resources. Reassuringly, participating providers in this study found active surveillance to be feasible and did not take up too much time from their practice.

A key to implementation of the active surveillance reporting system found in this and other studies, is patient involvement. Patients (and in the case of children, their parents and/or caregivers) are in the best position to know their own health and report how they are feeling; however, as shown in a 2014 systematic review, effective patient engagement processes in patient safety research are still limited. That review included only six studies, which had a variety of interventions for patient/family engagement and used a variety of methods for collecting patient safety information, making synthesis of findings difficult [Berger et al., 2014]. The authors of the review concluded that the best approach to patient engagement for patient safety research was likely multifaceted, including not only providing patient training or education about the topic and its importance, but also ensuring that the individual with whom information is shared is seen as an ally (versus the doctor to whom a patient often feels subordinate). Another systematic review aimed to identify factors that either support or deter patients from participating in patient safety research [Doherty & Stavropoulou, 2012]. That review concluded that patients' fear of being labelled 'difficult' causes them to be more reluctant to report AE directly to their health care provider. A strength of our study was that AE reports from patients/caregivers went directly to the investigators and not their chiropractor, thus removing this potential fear and potentially contributing to the increased response rate.

Another strength of this study was the modified enrollment process, which was first discussed in 1979 by Zelen, who proposed randomization of participants before obtaining consent, in order to enhance

clinical trial recruitment [Zelen, 1979]. A 2006 systematic review of trials that used post-randomized consent found that the most common intent was to reduce bias by reducing 'resentful demoralization' (i.e., participants in one group being resentful of the other) and avoiding the Hawthorne effect, as one or both groups are commonly not informed that they are taking part in an experiment [Adamson et al., 2006]. The current trial used a modified Zelen approach by obtaining initial consent to be in the trial and then a second consent, in which participants were provided with more detailed procedures for the study arm to which they had been allocated, without disclosing details of the other study arm. At the post data collection debriefing, all providers were told there were two study arms; no participant raised concerns about not knowing about the other arm during these interviews, and some expressed interest in participating in the opposite study arm.

A barrier identified by chiropractors to participating in an AE reporting system was concern that their patients would be hypervigilant to symptoms listed on a data collection form [Pohlman et al., 2014; Pohlman et al., 2016]. Poor outcomes due to negative expectations is a nocebo effect [Kennedy, 1961]. This study tried to minimize patients' focus on negative effects by asking patients their symptom change status (i.e., better, worse, unchanged, or new), as well as seeking balanced information about other aspects of treatment (e.g., satisfaction with care).

Several limitations are important to consider with the interpretation of these studies results. First, this study was not able to compare patient/caregiver and provider AE reports as they were measured at different time points; future research could consider asking both patients and providers to report AE immediately after treatment as well as at a follow-up time point to allow for comparable data. Additionally, not all patients provided adequate information to allow for AE severity to be determined. While missing severity data was modest (n=5) in post-treatment questionnaires received, there were many patients who did not return any post-treatment questionnaires (n=838). Patients who were younger or who had more pre-existing symptoms were most likely not to return post-treatment questionnaires; this is the same population who was more likely to report higher severity AE, suggesting that our findings may under-represent more serious AE. Finally, our study was limited by the use of proxy symptom reporting by parent/caregiver, a common limitation in pediatric health care and research. In the literature, parent/caregiver assessment of child health is contradictory, with both over- and under-estimates reported [Kamper et al., 2016; Upton et al., 2008]. Further research is needed to better understand the effect of proxy reporting of pediatric AE.

6.6 – Conclusion

This cluster RCT compared active versus passive surveillance to collect AE reports following chiropractic manual therapy in children less than 14 years of age. The two systems yielded an

important difference in reported AEs per patient, with incidence of AE reports of 8.8% (n=140, 95% CI 6.72% to 11.18%) in the active surveillance group and 0.1% (n=2, 95% CI 0.02% to 0.53%) in the passive surveillance group. Of these AE reports, 76 (56.3%) events were mild; 35 (25.9%) events were moderate; and 24 events (17.8%) were severe. The most common symptoms reported as AEs after chiropractic treatment were pain/discomfort and irritability/crying: this was true of all degrees of severity (mild, moderate, and severe). The quality of provider AE reports could not be evaluated. No difference in provider attrition between the two study arms was found and the results were robust to both best- and worst-case sensitivity analyses with regards to the superiority of active surveillance in identifying AE. Further research is needed regarding how and when to solicit patient-reported AEs, issues of proxy reporting when studying pediatric AE, and how to prevent and mitigate chiropractic manual therapy associated AEs in children.

Chapter 7:
General Discussion and Conclusions

To improve health care quality overall, it is believed that patient safety culture needs to be enhanced and mitigation strategies developed for modifiable health care risks [McFadden et al., 2014]. It is important to note that these risks can arise from the individual provider, the treatment, or the system in which the providers work. Not all adverse events (AEs) may be error-related (e.g., consequences of a diagnostic procedure or intervention); likewise, not all errors lead to an AE. The assessment of *patient safety culture* and *patient safety performance* (i.e., risk, harms, or AE evaluation) are areas of research that are still evolving as the first step to improve health care quality. The overarching aim of this body of work, which comprised three studies, was to design and conduct an initial patient safety assessment of health care in ambulatory settings, specifically chiropractors who treat the pediatric population. When the planning for this thesis began, little research had been conducted in this pediatric population despite concerns regarding the safety of pediatric manual therapy that is often provided by chiropractors [Vohra et al., 2007; Humphreys, 2010]. Thus, the specific aims of this body of work were to: (i) measure the attitudes and opinions that contribute to patient safety culture; (ii) identify barriers and facilitators for providers participating in patient safety reporting systems; and (iii) compare AE reports from two patient safety reporting systems used to measure patient safety performance.

In the first study, the initial step to evaluate patient safety culture among chiropractors who treat children was to conduct a patient safety attitudes and opinions survey, which found that respondents reported patient safety as a priority. Furthermore, respondents identified aspects that could improve patient safety, including practical measures such as updating patients' medication lists (as a change in medication could indicate a change in health status that a chiropractor should be aware of) and the need to lessen work pressure and pace in the office. The survey also addressed the second study aim by assessing self-perceived barriers to implementing a patient safety reporting system, which was reported in the second study of this thesis. Two predominant barriers were identified: first, time pressure, and second, provider concern that their participation in a patient safety reporting system could create negative perceptions in their patients. Specifically, since data collection forms would list potential AEs that could occur after treatment, providers thought that this might lead patients to believe that chiropractic care was riskier than they believed.

The major limitation to this survey was the low response rate (29.5%). A comparison of responders and non-responders found no differences in responses by gender or location, but chiropractors with a pediatric certification were three times more likely to respond without any other qualitative differences in findings based on this difference. Other systematic differences that weren't measured between responders and non-responders may also have affected the findings. Recent survey studies have

explored the impact of personality traits, such as conscientiousness, on nonresponse and outcome variables [Almlund et al., 2011; Heckman et al., 2006; Cheng et al., 2018]. In considering possible sources of responder bias related to personality, it may be useful here to consider what has been coined “The Big Five Personality Traits” (openness to experience, conscientiousness, extraversion, agreeableness, and neuroticism); a framework developed to classify the broad dimensions of personalities that have been found to affect life outcomes (such as academic aptitude and achievement, and work performance) in a variety of ways [John & Srivastava, 1999]. Individuals with a conscientious personality trait are more likely to complete a survey and need fewer reminders to do so [Almlund et al., 2011; Heckman et al., 2006; Cheng et al., 2018]. It seems likely that respondents to this survey were more conscientious than non-responders. Given that conscientious individuals have a high awareness of the impact their behavior has on those around them, differential response could have led to an overestimate of self-reported patient safety performance and adherence to systems that benefit patient safety [John & Srivastava, 1999]. Interestingly, while respondents did report aspects of patient safety needing improvement, these aspects were related to others’ actions rather than their own (e.g., problems with information exchange with insurance companies).

The third and final study for this thesis was a cluster randomized trial comparing AE reports collected through active and passive surveillance reporting systems in order to assess *patient safety performance* and establish the frequency and severity of AE following pediatric chiropractic manual therapy. The design of this study was informed by the survey conducted for the first two studies, with pre-testing of the active surveillance protocol to ensure that the study would run smoothly in an office-based setting, specifically with regards to time constraints and patient perception [Pohlman et al., 2014]. Active surveillance data collection was pilot tested to ensure minimally burdensome for providers [Pohlman et al., 2014] and was noted by participating providers to be ‘easy’. Patient perception and the nocebo effect was also considered when the active surveillance system was being developed [Pohlman et al., 2014]. As such, the active surveillance data collection forms didn’t ask about AEs, but about symptoms, including improvement, no change, worsening, or new. Additionally, in a pilot study of a similar active surveillance study, it was found that contrary to the provider assumptions (i.e., that patients would worry more about treatment safety if asked about AE), patients said that they were reassured when their providers took part in safety research and thought more highly of them for it [Pohlman et al., 2014].

The final study clearly demonstrated that active surveillance collects more AE reports than passive surveillance by orders of magnitude. It also provided prospective data on the frequency and types of AEs reported after chiropractic treatments for children. Previous pediatric studies were limited to systematic reviews or a retrospective chart review [Vohra et al., 2007; Humphreys 2010, Miller and Benfield, 2008], both of which are at risk for under-reporting. This study identified pediatric AEs may not

be as rare as previously assumed, including moderate and severe AEs. This has implications for both research and practice.

Research Implications

For patient safety performance, further investigations are recommended. There continues to be a need for more high-quality research studies on both the effectiveness and safety of chiropractic manual therapy for the pediatric population. Among these studies, is the need to better explore the difference between ineffective treatments associated with worsening symptoms as the condition develops (which might be misinterpreted as an AE), ineffective treatments which lead to AEs, and effective treatments which, nonetheless, lead to AEs. As in all health interventions, it is important to determine whether the benefit of the treatment outweighs the associated harms. While 3% of children in the US have had chiropractic care, rigorous data regarding the effectiveness of pediatric treatment are limited [Black et al., 2018]. As noted in a recent systematic review, only adolescent low back pain has been shown to have moderate evidence for beneficial treatment outcomes from the use of chiropractic manual therapy [Parnell-Provost et al., 2019]. Given the high frequency of AEs found in the current study (almost 9% of all patients) and limited evidence for effectiveness for the range of conditions seen, more research is urgently needed regarding the use of chiropractic manual therapy in the pediatric population. Given the frequency with which this therapy is used, and the incidence of AE identified, this research is both important and feasible.

Second, it is important to study the measurement properties of instruments used to identify AE severity. The active surveillance data collection instruments used in this study were evaluated for face validity by general chiropractic patients and pediatric chiropractors, but not by parents/caregivers of pediatric chiropractic patients. Further assessment of how best to assess change in symptoms to minimize recall bias and maximize accuracy would be helpful.

The third research recommendation is to investigate the impact of using parents' or caregivers' proxy-reports to identify the presence and severity of AEs in children. As discussed in Chapter 6, proxy-reporting is a widespread limitation throughout pediatric health care and research. In this thesis, 328 pediatric patients in the active surveillance arm had a musculoskeletal condition. Data collected from 700 Danish school children between the ages of 10-14 with musculoskeletal pain explored the agreement of child's pain reported by the parent and child self-report [Kamper et al., 2016]. The Danish study found the agreement to be between 50%-68% and that children identified the pain as more severe than parents [Kamper et al., 2016]; if this under-estimation occurred in our study, caregivers may have under-reported their child's pain (incidence and severity). The Danish study and other studies on parent–child agreement encouraged further research to systematically investigate the impact of the

level of agreement on the outcome [Kamper et al., 2016; Zhou et al., 2008], which is also important to the future studies on pediatric AEs.

A fourth research recommendation relates to the need for patient engagement strategies in patient safety research. This study found patient/caregiver involvement to have a major impact on AE identification and reporting. Strengths of this study included soliciting patient reporting, ensuring it was sent directly to study investigators (not to the treating provider), and linking data with treatment information from the provider. Future research enhancing patient engagement in AE reporting should consider issues related to anonymity and, whenever possible, promote linkage to provider treatment information. This additional information is essential for meaningful adjudication to assess causation, preventability, and patient disposition.

Clinical Implications

One of the most important clinical implications of this body of work is the prospective risk assessment of chiropractic manual therapy for children. Information obtained from this study can now provide a better understanding of the harms that may occur after pediatric chiropractic manual therapy. The active surveillance portion of this study found almost 9% of pediatric patient visits having a reported AE, of which 26% were rated by the patient/caregiver as moderate and 18% as severe (these symptoms were primarily: increased pain/discomfort, increased irritability/crying, and fatigue/tiredness). This increase not only shows that AEs in this population are likely more common and more severe than previously thought, but also provides more information about the nature of these new or worsening symptoms than was previously known. This information needs to be incorporated into health care decision-making and informed consent.

Another related clinical implication is the importance for health care providers to pursue evidence-informed care, including both the benefits and harms for potential care options. Current evidence for manual therapy use to benefit pediatric health conditions is minimal [Parnell-Provost et al., 2019] and the active surveillance portion of this thesis found higher than expected AE reporting following pediatric chiropractic visits. Transparent dialogue about both benefits and risks of treatment options could emphasize the importance of following-up with any symptom change the patient may have after care, so that providers are more aware of how patients feel after treatment.

This study also identified important feasibility information for active and passive surveillance reporting systems to be used in chiropractic offices. While both systems were found to be feasible regarding convenience and ease-of-use, passive surveillance was ineffective at collecting AE reports. Passive surveillance has been the most commonly used AE reporting system, but this study demonstrated that it has clear weaknesses, including lack of direct patient involvement. Specifically, in the active surveillance reporting system, over half of the AE reports were directly from patients. Future passive

surveillance designs might try to include patient feedback, possibly through an online database giving patients a single login to ensure anonymity; however, a major limitation of this approach would be lack of, linkage to provider treatment data. Resources and time may be better spent considering how to adapt active surveillance models to collect population-based AE data from more practicing providers. Electronic data collection, or an app should be evaluated, as it could allow for skip patterns, specific follow-up questions from the pre- to post- data collection forms, as well as the potential to share information between provider and patient (which could be at the discretion or desire of the patient). While confidentiality, anonymity, and risk of litigation remain concerns for patient safety research, technology advancements and research policy developments (such as certificate of confidentiality, https://grants.nih.gov/policy/humansubjects/coc.htm), will allow these different data collection options to become a viable option for the future. Population-based data about exposure and outcome could be a powerful way to advance chiropractic care.

Ensuring patient safety is presumably part of the directive of self-regulating professions whose mandate includes protection of the public. Commitment to an active surveillance reporting system from leadership at multiple levels (relevant professional associations, educational institutes, and regulatory bodies) would be optimal if this system were to be successfully implemented on a larger scale. This commitment would need to include financial support for the necessary resources to develop and maintain the reporting system, evaluate the data, and produce effective translation materials to share the findings with evidence-based solutions. This commitment to patient safety would be an important step forward for current leadership of educational institutions, professional organizations, and regulatory bodies.

In conclusion, we found the respondents' *patient safety culture* attitudes to prioritize patient safety to be similar to other ambulatory care settings; however, this finding had a low response rate, which is a major limitation to the interpretation of results due to probable respondent bias. We also evaluated the *patient safety performance* following pediatric chiropractic treatment and enhanced the current state of the literature by identifying the value of active surveillance, the significance of patient involvement in patient safety research, and the opportunity for more hiqh-quality safety research that was previously thought not to be feasible due to large sample sizes required to study rare events. As the inaugural prospective safety study of chiropractic manual therapy for the pediatric population, this work should serve to fill a gap in the literature, to provide better information that can be used to mitigate AEs, and to encourage enhanced communication between health care providers and patients about potential risks associated with treatment.

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Appendices

Appendix A –

Development of the SafetyNET's Survey to Support Quality Improvement

Funabashi M, Pohlman KA, Mior S, O'Beirne M, Westaway M, DeCarvalho D, Haig B, Wade DJ, Thiel HW, Cassidy JD, Hurwitz E, Kawchuk GN, Vohra S. SafetyNET Community-based patient safety initiatives: Development and application of a Patient Safety and Quality Improvement Survey. J Can Chiropr Assoc. 2018;62(3):130-142.

ISSN 0008-3194 (p)/ISSN 1715-6181 (e)/2018/130–142/$2.00/©JCCA 2018

SafetyNET Community-based patient safety initiatives: development and application of a Patient Safety and Quality Improvement Survey

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The authors have no disclaimers or competing interests to report in the preparation of this manuscript.

Source of Funding:
This study was supported by funding from the Canadian Institutes of Health Research (CIHR # TIR-112758), Alberta Innovates – Health Solutions (AIHS#20111389) and by the generosity of the Stollery Children's Hospital Foundation and supporters of the Lois Hole Hospital for Women through the Women and Children's Health Research Institute through the SafetyNET grant.

Objectives: *To: 1) develop/adapt and validate an instrument to measure patient safety attitudes and opinions of community-based spinal manipulative therapy (SMT) providers; 2) implement the instrument; and 3) compare results among healthcare professions.*

Methods: *A review of the literature and content validation were used for the survey development. Community-based chiropractors and physiotherapists in 4 Canadian provinces were invited.*

Results: *The Agency for Healthcare Research and Quality's (AHRQ) Medical Office Survey on Patient Safety Culture was the preferred instrument. The survey was modified and validated, measuring 14 patient safety dimensions. 276 SMT providers volunteered to respond to the survey. Generally, SMT providers had similar or better patient safety dimension scores compared to the AHRQ 2016 medical offices database.*

Discussion: *We developed the first instrument measuring patient safety attitudes and opinions of community-based SMT providers. This instrument provides understanding of SMT providers' opinions and attitudes on patient safety and identifies potential areas for improvement.*

(JCCA. 2018;62(3):130-142)

KEY WORDS: chiropractic, patient safety, survey, spinal manipulation

Objectifs : *1) Élaborer/adapter et valider un instrument servant à évaluer les attitudes à l'égard de la sécurité du patient et les opinions des praticiens effectuant des manipulations vertébrales (MV); 2) adopter cet instrument; et 3) comparer les résultats obtenus entre les professionnels de la santé.*

Méthodologie : *Pour élaborer le sondage, on a revu la littérature, on a validé le contenu et on a invité des chiropraticiens et des physiothérapeutes de quatre provinces canadiennes à participer.*

Résultats : Le *Medical Office Survey on Patient Safety Culture de l'Agency for Healthcare Research and Quality's (AHRQ) était l'instrument préféré. Le sondage a été modifié et validé et a servi à mesurer 14 aspects de la sécurité du patient. 276 professionnels effectuant des MV ont accepté de répondre au sondage. En règle générale, les cotes obtenues chez les professionnels effectuant des MV pour ce qui des aspects de la sécurité étaient comparables ou meilleurs que celles des professionnels de la santé enregistrés dans la base de données de 2016 de l'AHRQ.*

Discussion : *On a élaboré le premier instrument servant à évaluer les attitudes à l'égard de la sécurité et les opinions des praticiens effectuant des MV dans une collectivité. Cet instrument permet de comprendre les opinions et les attitudes à l'égard de la sécurité du patient des professionnels effectuant des MV et de cerner les aspects qui pourraient être améliorés.*

(JCCA. 2018;62(3):130-142)

MOTS CLÉS : chiropratique, sécurité du patient, sondage, manipulation vertébrale

Introduction

Patient safety is a leading healthcare challenge.[1] In 1999, the U.S. Institute of Medicine's *To Err is Human: Building a Safer Health System*[2] report advised the development and sustainability of an open and constructive patient safety culture. In 2002, the Canadian government's *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*[3] supported and emphasized the need for leadership with this challenge. These reports laid out comprehensive strategies to reduce preventable medical errors, which did not focus on individuals making the error, but rather on how the systems, processes and conditions fail to prevent the error.[4]

One strategy to promote and understand a healthcare organization's existing patient safety culture is by assessing its current attitudes and opinions toward safety.[4] Although several surveys currently exist to assess attitudes

and opinions, most are designed for large, acute care settings rather than community-based health care environments. As the majority of people receive care in community-based settings, further information about community-based health care providers' behaviors, attitudes, and opinions about patient safety is needed.[5]

Spinal manipulative therapy (SMT) is a therapeutic intervention commonly used by chiropractors and physiotherapists and perceived to carry added risks to patients with varying evidence regarding the incidence of associated adverse events (AEs).[6] It is estimated that 4.5 million Canadians and over 50% of Americans receive SMT per year.[7,8] Despite SMT's popularity, few formal patient safety and reporting mechanisms are available[5], increasing the need for specific SMT-related patient safety initiatives. As most SMT is provided in community-based offices/clinics[9], having a patient safety survey specifically for these settings is essential.

SafetyNET is an international and multidisciplinary research team, whose primary goal is to support strategies that promote a patient safety culture among SMT providers.[10] Although AEs following SMT intervention have been described to vary widely in severity and frequency, no robust causal inferences have been made.[6,11,12] Thus, systematic reviews investigating SMT-related AEs have called for more research.[13,14]

To date, only a few patient safety mechanisms, such as reporting and learning systems, exist to systematically monitor and reduce SMT-related harms.[15] With the call for more research and few patient safety measurement options, there is a need to measure and assess current patient safety attitudes and opinions. Therefore, our study aimed to: 1) develop or adapt an assessment tool to measure patient safety attitudes and opinions of community-based SMT providers, specifically chiropractors and physiotherapists; 2) validate this assessment tool; 3) implement this tool with community-based chiropractors and physiotherapists who apply SMT; and 4) compare the resultant scores against other healthcare professions.

Methods

Survey Development

We conducted a literature review with assistance of a health sciences librarian who is expert in scoping reviews to identify available patient safety surveys and their applicability to the SMT setting. Searches were conducted in Google, Google Scholar, and PubMed. Search terms included: 'patient safety survey', 'patient safety culture', and 'patient safety climate'; in conjunction with 'community-based', 'ambulatory', 'medical offices', and 'general practice'. Based on consultation with subject matter experts on our research team, surveys specific for SMT professions were not expected and, therefore, terms related to 'chiropractic', 'physiotherapy', 'manual therapy' or 'spinal manipulative therapy' were not included in the search. In addition to the electronic databases, content experts on the research team were also queried for suggested relevant surveys. All citation abstracts were screened and assessed by the SafetyNET team members to evaluate their relevance to the following criteria: 1) addressed the research question; 2) measurement properties established (i.e., with reported validity and reliability); 3) ease of use (i.e., lack of patient safety jargon, manageable number of sections, each section was not too long); and 4) estimated number of necessary modifications (although this was not a determinant factor).

Relevant surveys (Table 1) were independently assessed by eight SafetyNET multidisciplinary team members with expertise in SMT, epidemiology, patient safety and/or survey development. Feedback was summarized and presented to all 22 expert SafetyNET team members. The preferred survey was identified by consensus and modifications were made to meet our study needs using an iterative consensus-based process.

The final stage involved content validation adhering to the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) checklist.[16] A face-to-face qualitative focus group was conducted to evaluate the relevance and comprehensiveness of the modified survey with a convenience sample of volunteers attending a chiropractic educational conference in Edmonton, Alberta. Then, a feasibility assessment of the survey was conducted by circulating it amongst SMT providers to further evaluate the content and face validity, the functionality and time to complete the survey.

Survey Application

The final survey was created using a standardized Research Electronic Data Capture (REDCap) database. REDCap is a secure, web-based application designed to support data capture for research providing an intuitive

Table 1.
Surveys identified during the literature review that evaluate patient safety attitudes and opinions in ambulatory settings.

Author / Year	Manuscript Title	Purpose	Setting / Location	Population Studied (sample size)	Survey Items and Dimensions / Factors
de Wet *et al.*, 2010 [22]	The development and psychometric evaluation of a safety climate measure for primary care	To measure perceptions of safety climate among primary care teams outside of North America.	Primary care teams in National Health Service, Scotland	563 primary care team members from 49 general practices	30 items, measuring 5 safety climate factors: 1) Leadership, 2) Teamwork, 3) Communication, 4) Workload, 5) Safety Systems.
Hoffman *et al.*, 2011 [21]	The Frankfurt Patient Safety Climate Questionnaire for General Practices (FraSiK): analysis of psychometric properties	To measure patient safety climate in practices with only 1-2 doctors, who are owners with 2-4 other professional employees (small offices).	General practice in Germany	332 healthcare professionals working in 60 general practices	72 items, measuring 9 dimensions: 1) Teamwork climate, 2) Error management, 3) Safety of clinical processes, 4) Perception of causes of errors, 5) Job satisfaction, 6) Safety of office structure, 7) Receptiveness to healthcare assistants, 8) Patient safety of medical care. {Adapted from the SAQ-A}
Modak *et al.*, 2007 [20]	Measuring safety culture in the ambulatory setting: the Safety Attitudes Questionnaire (SAQ)– Ambulatory Version (SAQ-A)	To measure safety attitudes of outpatient settings.	Academic, urban, outpatient practice in Texas, United States	251 outpatients providers (physicians, nurses, managers, medical assistants and support staff)	62 item survey, measuring 6 factors: 1) Teamwork climate, 2) Safety climate, 3) Perceptions of management, 4) Job satisfaction, 5) Working conditions, 6) Stress recognition.
Sorra *et al.*, 2016 [18]	Medical Office Survey on Patient Safety Culture- User Guide	Modification of the *AHRQ Hospital Survey on Patient Safety Culture*. Emphasized safety and quality issues that are known to affect patient safety in medical offices.	Medical Offices in the United States	Pilot tested in 2007 with 200 offices, > 4,100 surveys. First released in 2009, with comparable databases released approximately every 2 years.	51 item survey, measuring 13 dimensions: 1) Teamwork, 2) Work pressure and pace, 3) Staff Training, 4) Office processes and standardization, 5) Communication openness, 6) Patient Care Tracking / Follow-up, 7) Communication about error, 8) Owner / Managing Partner / Leadership support for patient safety, 9) Organizational learning, 10) Overall perceptions of patient safety and quality, 11) List of patient safety and quality issues, 12) Information exchange with other settings, 13) Overall ratings on quality and patient safety.

interface for validated data entry, audit trails for data manipulation, and export procedures.[17] Invitation to participate in survey completion was distributed via email to Canadian community-based chiropractors and physiotherapists from four different Canadian provinces through their respective provincial associations.

Survey Data Analysis

Data on patient safety culture dimensions were analyzed in two ways using Stata13 Software (StataCorp. 2013) and Excel 2013. First, a positive percentage composite score was calculated for each dimension by averaging the percent positive responses on the questions within each dimension. For negatively worded questions, disagreeing was considered a positive response. Second, survey dimensions' scores were calculated based on the mean response to the five-point scale and its 95% confidence interval (CI). Pearson chi-square test was used to compare the scores from SMT providers with the AHRQ medical offices comparative database, with level of significance

at p=0.05. Each dimension required that all questions be answered to be included. Frequencies of responses were calculated for factors inhibiting participation in a reporting and learning system, patient safety items and quality issues, information exchange with other settings, and overall clinic self-ratings.

Comparative Database

The Medical Office Survey on Patient Safety Culture is an expansion of AHRQ's Hospital Survey on Patient Safety Culture to the medical office setting. Its content has been extensively tested for validity and reliability, and it has been in use since 2004.[18] It was designed to measure the culture of patient safety in medical offices from the perspective of providers and staff. The Medical Office Survey on Patient Safety Culture 2016 User Comparative Database has been previously described.[19] Briefly, it consists of data from 1,528 medical offices located across the United States and 25,127 medical office respondents from varied specialties who completed the survey between 2013 and 2015. This comparative database report was developed as a tool for comparison of survey results, internal assessment, and to provide supplemental information to help offices/clinics identify their strengths and areas with potential for improvement.

Results

Survey Development

The literature review identified four commonly used surveys that assessed patient safety attitudes and opinions in community-based settings (Table 1).[18,20–22] The AHRQ Medical Office Survey on Patient Safety Culture was identified as the team's preferred instrument.[18]

Based on feedback from the SafetyNET team, the following modifications were made to the AHRQ medical office survey: 1) the word 'medical' was removed, and, replaced with 'clinical' or 'office'; 2) for 'Organizational Learning' and 'Overall Perceptions of Patient Safety and Quality' each question was asked regarding its clinical and administrative perspective; 3) in the 'Overall Rating' section, *socioeconomic status* was removed from 'Equitable' as the team felt it should not be grouped with the other qualities listed (i.e., gender, race, ethnicity, language) considering SMT is a non-insured service in Canada and access may be affected differently than these other qualities. *Socioeconomic status* was therefore developed into a separate question looking at 'To what degree do the following affect your care plan' with the addition of: 'Insurance coverage'; 'Patient accessibility to the office'; and 'Other (specify)'; and 4) a section on 'Reporting and Learning System Barriers', based on questions adapted from Benn *et al*. (2009)[23] was added. A brief description of the dimensions of the survey as well as the modifications made to the AHRQ medical office survey can be found in Table 2. The full modified survey is available from the authors upon request.

Chiropractors who participated in the focus group (n=24 of 63) stated that the survey was lengthy, but the information obtained would be valuable. They also felt that some questions would be better in different locations to promote response, and that some required additional clarification. Consequently, the following survey items were further modified: 1) the more sensitive section (i.e., List of Patient Safety and Quality Issues) was moved towards the end of the survey; 2) definitions were added to help clarify terminology differences amongst SMT professions (e.g., manual therapy, manipulation, adjustments); 3) modifications were made for each profession, reflecting the language/culture of each responding group (e.g., "office" versus "clinic"); and 4) the title of the survey was changed to 'Survey to Support Quality Improvement', to add clarity for the survey's purpose.

These actions resulted in two versions of the 'Survey to Support Quality Improvement', one for chiropractors and one for physiotherapists. Both surveys have 14 dimensions with seven derived directly from the AHRQ Medical Office Survey on Patient Safety Culture, six from the AHRQ Medical Office Survey with some modified questions, and one dimension unique for this survey added by the SafetyNET team (Table 2).

Survey Application and Comparison

Participant Response

A total of 417 SMT providers volunteered to respond to the survey: 356 chiropractors and 61 physiotherapists. Surveys from 120 chiropractors and 21 physiotherapists were excluded due to missing responses to questions (no complete section). We included 276 surveys, with complete data from 236 chiropractors (85.5%) and 40 physiotherapists (14.5%).

Table 2.

AHRQ's survey dimensions and description, reliability measures, and modifications made for the SafetyNET survey.

Dimensions	Dimension brief description[18]	# of items	AHRQ Cronbach's alpha	SafetyNet modifications
List of Patient Safety and Quality Issues	Issues that can happen in clinical offices that affect patient safety and quality of care.	8	0.86	Removed 'A pharmacy contracted our office to clarify or correct a prescription.'
Information Exchange with Other settings	How often the office had problems exchanging accurate, complete, and timely information with other entities.	4	0.90	Removed 'Pharmacies' and 'Hospitals'. Added 'Other healthcare offices' and 'Insurance / Third Party Payers?'
Teamwork	The extent to which the office has a culture of teamwork, mutual respect, and close working relationships among staff and providers.	4	0.83	No Changes
Work Pressure and Pace	The extent to which there are enough staff and providers to handle the patient load, and the office work pace is not hectic.	4	0.76	No Changes
Staff Training	The extent to which the office gives providers and staff effective on-the-job training, trains them on new processes, and does not assign tasks they have not been trained to perform.	3	0.80	No Changes
Office Processes and Standardization	The extent to which the office is organized, has an effective workflow, has standardized processes for completing tasks, and has good procedures for checking the accuracy of work performed.	4	0.77	No Changes
Communication Openness	The extent to which providers in the office are open to staff ideas about how to improve office processes, and staff are encouraged to express alternative viewpoints and do not find it difficult to voice disagreement.	4	0.81	No Changes
Patient Care Tracking / Follow-up	The extent to which the office reminds patients about appointments, documents how well patients follow treatment plans, follows up with patients who need monitoring, and follows up when reports from an outside provider are not received.	4	0.78	No Changes
Communication About Error	The extent to which providers and staff are: 1) willing to report mistakes they observe and do not feel like their mistakes are held against them, and 2) talk openly about office problems and how to prevent errors from happening.	4	0.75	No Changes
Owner / Managing Partner / Leadership Support for Patient Safety	The extent to which office leadership actively supports quality and patient safety, places a high priority on improving patient care processes, does not overlook mistakes, and makes decisions based on what is best for patients.	4	0.76	No Changes
Organizational Learning	The extent to which the office has a learning culture that facilitates making changes in office processes to improve the quality of patient care and evaluates changes for effectiveness.	6	0.82	Separated each question into administrative / clinical parts.
Overall Perceptions of Patient Safety and Quality	The extent to which the quality of patient care is more important than getting more work done, office processes are good at preventing mistakes, and mistakes do not happen more than they should.	8	0.79	Separated each question into administrative / clinical parts.
Overall Ratings on Quality and Patient Safety	Overall rating of care, systems and clinical processes the office has in place to prevent, catch, and correct problems that have the potential to affect patients.	9	0.87	Separated 'patient's socioeconomic status', 'insurance coverage', 'patient accessibility to the office', and 'other' into individual categories.
Factors inhibiting participation in a reporting and learning system	Not part of AHRQ. {Adapted from Benn *et al*.[24]}	9	NA	Not part of AHRQ. {Adapted from Benn *et al*.[24]}

AHRQ – Agency for Healthcare Research and Quality

Table 3.
Demographic and background characteristics of responding SMT providers. (n=276)

Provider Characteristics	SMT Providers
Gender, Female, n (%)	77 (27.9%)
Years in practice, Mean (range)	19.4 (1-53)
Hours worked in a typical week, Mean (range)	31.6 (4-55)
Average number (range) of personnel working in the clinic	
Other health care provider	3.1 (1-10)
Therapy Assistant	2.7 (1-10)
Other employee/ staff	2.4 (1-6)
Patient visits per week, n (%)	
< 50	45 (16%)
50-99	74 (26.8%)
100-149	44 (15.9%)
150-199	25 (9%)
Highest level of non-physiotherapy / non-chiropractic degree, n (%)	
Bachelor's degree	148 (53.6%)
Master's degree	13 (4.7%)
Academic Doctoral degree	8 (2.9%)
Other	14 (5 %)
Province of practice, n (%)	
Newfoundland and Labrador	31 (11.2%)
New Brunswick	15 (5.4%)
Ontario	190 (68.8%)
Alberta	40 (14.5%)

Table 4.
Providers opinions on factors that may inhibit participation in a reporting and learning system.

Factors inhibiting RLS participation	Not at all	Yes, a little	Yes, a lot
Patient Concerns			
Perceived inconvenience for the patients	22%	51%	27%
Potential to create negative perception in patients	26%	49%	25%
Office Concerns			
Time pressure	11%	42%	46%
Lack of clear definitions as to what constitutes a reportable incident	32%	55%	14%
Resource constraints	65%	28%	7%
Big Picture Concerns			
Regulatory implications	41%	42%	17%
Legal implications	36%	47%	17%
Fear of blame	57%	38%	5%
Believe reporting is unnecessary	65%	32%	3%
RLS – Reporting and Learning System			

Respondent and Patient Characteristics

Table 3 provides a summary of demographic characteristics of respondents. Respondents were predominantly male (72.1%), providing treatment for an average of 31.6 hours per week, and treating less than 100 patients per week.

Patient Safety Culture Dimensions

In Figure 1, composite scores are contrasted with the AHRQ 2016 comparative database. With the exception of Patient Care Tracking/Follow-up scores, all other scores were greater than the AHRQ database. Specifically, Work Pressure and Pace, Office Processes and Standardization, and Overall Perception of Patient Safety – Clinical scored statistically significantly higher than the AHRQ database.

Factors Inhibiting Participation in a Reporting and Learning System

Perceived barriers to participation in a patient safety reporting and learning system are summarized in Table 4. Time pressure was identified as the biggest limitation, with patient concerns (i.e., perceived inconvenience for the patients and potential to create negative perception in patients) being the next most frequently reported limita-

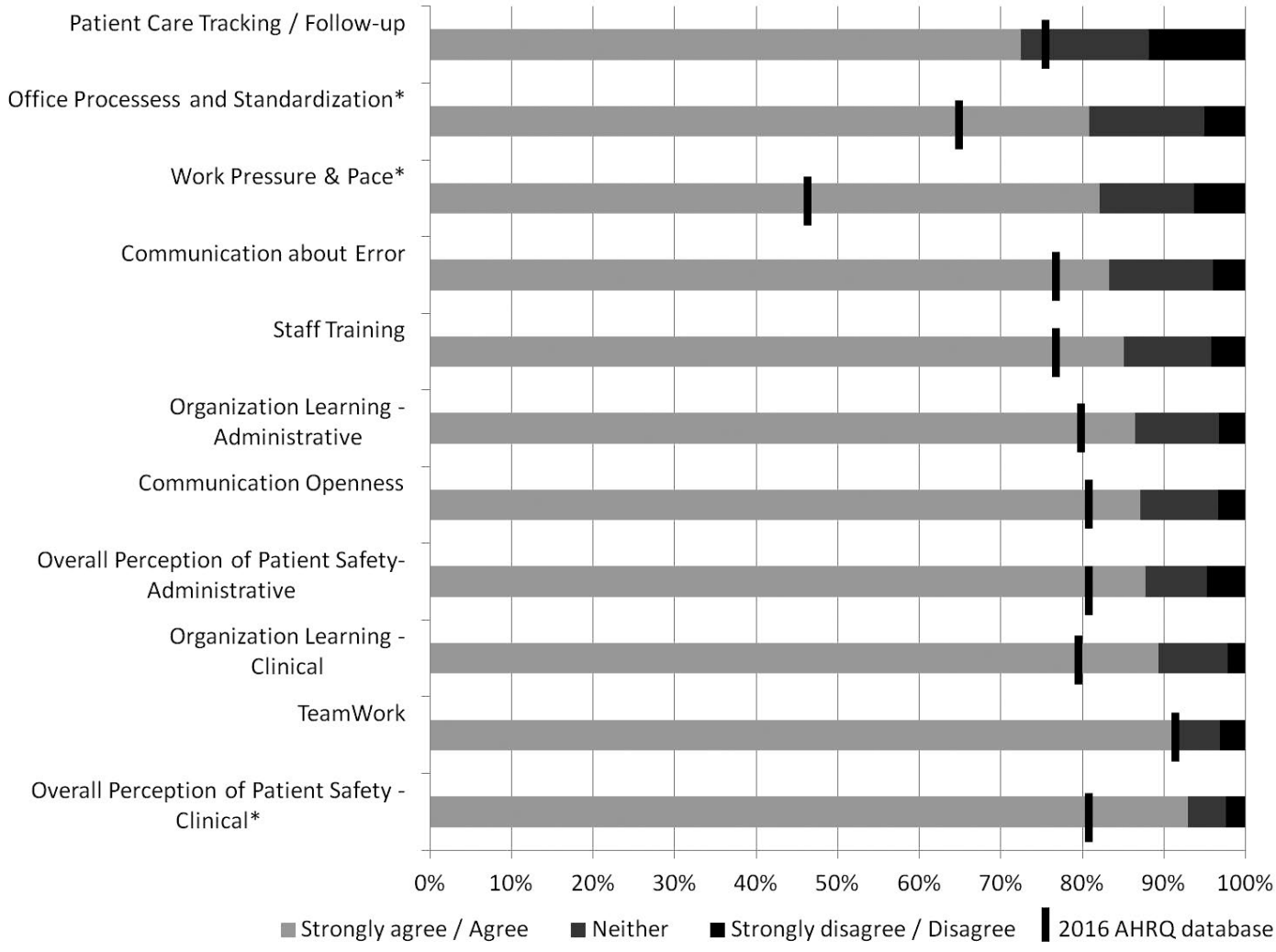

Figure 1.

The positive composite scores from the patient safety dimensions are presented for SMT providers who responded to the survey and the 2016 AHRQ comparative database. Asterisks indicate dimensions that the percentage of positive composite scores for "strongly agree/agree" responses from SMT providers were significantly different than the ones from the 2016 AHRQ medical offices comparative database.

tion. A modest level of concern was reported regarding potential regulatory and legal implications. Most (57%) reported the fear of blame was not a barrier to reporting potential AEs.

Patient Safety Items and Quality Issues/Information Exchange with Other Settings

In comparison to the AHRQ database, SMT providers who responded to the survey had higher scores in most other items (Table 5). The SMT providers scored statistically significantly lower than medical offices in items related to medication list being updated and abnormal lab or imaging test not being followed up within one business day. Scores related to the use of the wrong patient chart, a chart not being available, clinical information filed into the wrong chart, and equipment not working properly were similar to scores in the AHRQ medical office 2016 database (< 5% difference).

Table 5.
Composite-level average percent positive response by number of providers. A desirable outcome corresponds to a high percentage value, which represented less frequency of occurrence.

Dimension	Composite Mean %	AHRQ – 2016
Patient safety items and quality issue		
Access to care: A patient was unable to get an appointment within 48 hours for an acute/serious problem.	89%	90%
Patient identification: The wrong chart/record was used for a patient.	95%	97%
Charts/Records: A patient's chart/record was not available when needed	91%	90%
Charts/Records: Clinical information was filed, scanned, or entered into the wrong patient's chart/record	94%	89%
Equipment: Equipment was not working properly or was in need of repair or replacement	95%	92%
Medication: A patient's medication list was not updated during his or her visit.	56%*	80%
Diagnostics Test: Results from a lab or imaging test were not available when needed	82%*	70%
Diagnostics Test: Critical abnormal result from a lab or imaging test was not followed up within 1 business day	66%*	94%
Difficulty with Information Exchange with Other Setting		
Outside labs / imaging centers	91%	82%
Other physician clinics (AHRQ: Other medical offices / outside physicians)	89%*	77%
Other healthcare clinic	92%	NA
Insurance / Third Party Payers	70%	NA
Other (i.e. Worker's Compensation Board, employers of patients, schools)	76%	NA
AHRQ 2016 – 2016 Agency for Healthcare Research and Quality medical offices comparative database * – Significantly different than 2016 AHRQ database scores		

Respondents described the greatest difficulty in exchanging information with other healthcare clinics. While information exchange with outside labs/imaging centers was comparable, information exchange difficulty with other physician clinics was statistically significantly higher than the AHRQ medical office 2016.

Overall Clinic Self-Ratings

In Table 6, overall clinic self-ratings dimensions for respondents were found to be statistically significantly higher than the AHRQ medical office 2016 database; however, the overall clinic rating was comparable. Items that affect a patient's care plan were found to be equally distributed for items measured. Other items that were described as affecting the patient's specifically designed care plan were: patient's desire to follow care plan, patient's expectations, and patient's level of discomfort.

Discussion

Survey Development

As expected, our literature review did not retrieve a specific instrument developed for SMT providers, but it identified an existing validated survey used for other healthcare professions did meet our criteria. The selected survey tool, AHRQ's *Medical Office Survey on Patient Safety Culture* was adapted and minimally modified for SMT providers, allowing comparison of 14 patient safety dimensions with AHRQ medical office 2016 database.

A previous review of several patient safety surveys, including the AHRQ Medical Office Survey on Patient Safety, concluded that survey results should be interpreted with caution as there was no established link with improved patient outcomes.[24] However, another recent systematic review reported a trend demonstrating a positive relationship between patient safety culture and patient

Table 6.
Providers' perception of overall clinic self-rating.

Dimension	Poor	Fair	Good	Very Good	Excellent
Patient centered	0%	2%	12%	34%*	52%*
AHRQ 2016	0%	7%	27%	36%	30%
Timely	1%	3%	20%	41%*	35%*
AHRQ 2016	7%	13%	31%	35%	15%
Efficient	0%	1%	20%	43%*	36%*
AHRQ 2016	3%	9%	26%	45%	18%
Equitable					
Patient: gender, race, ethnicity, language, etc	0%	0%	5%	34%*	61%*
AHRQ 2016: gender, race, ethnicity, socioeconomic status, language etc.	1%	5%	15%	27%	52%
Overall clinic rating to prevent, catch, and correct problems that have the potential to affect patients	1%	5%	27%	46%	21%
AHRQ 2016	1%	7%	26%	49%	18%
*– Significantly different than 2016 AHRQ database for the same scores					
How do the following dimension affect patient's specifically designed care plan?	**Never**	**Rarely**	**Sometimes**	**Most of the time**	**Always**
Socioeconomic status	22%	22%	40%	10%	5%
Insurance coverage	32%	20%	33%	11%	4%
Patient's accessibility to clinic	26%	28%	34%	9%	3%
Other	9%	9%	55%	18%	9%
AHRQ – Agency for Healthcare Research and Quality AHRQ 2016 – 2016 AHRQ medical offices comparative database					

outcomes in hospital settings but this was not statistically significant.[25] In high-risk industries, an open constructive safety environment was found to lead to high employee safety compliance and better organizational performance.[26] The need to understand patient safety attitudes and opinions through the use of cross-sectional surveys may help researchers, patient safety personnel, and administrators identify areas of strengths and those in need of improvement with an aim to increasing positive patient outcomes and reducing medical error, despite the lack of current evidence for this result.

Survey Application

We present the first study to measure community-based SMT providers' patient safety attitudes and opinions. The patient safety dimension of 'work pressure & pace' scored greater than the AHRQ comparative data base, indicating that respondents often felt rushed and that they may have too many patients for the amount of time available. This was also observed in medical offices regardless of the job position[27], indicating the need for processes and systems to accommodate the busy work-load and to reduce potential staff burnout[27].

Similar to other healthcare professions, this survey found that 'time pressure and lack of clear reportable incident definitions' were the largest concern of SMT providers in participating in a reporting system.[23,28] Time pressure was an expected finding, as healthcare providers often have competing demands for their time and perceive themselves as "too busy" to report incidents[5,28,29], emphasizing the importance of 'ease of use' when developing an evaluation system. Although "busyness" is a socially acceptable excuse for non-participation in incident reporting systems, patient safety is one of the most prominent healthcare challenges and improving health care is a shared responsibility that must include health

care providers, researchers and patients to be successful.[1]

'Lack of a clear definition for reportable incident' has been identified in previous studies among chiropractors and other professionals utilizing SMT.[5,28,30] More specifically, a qualitative study with SMT providers observed that not only was defining AEs following SMT challenging, but also that the perceived difficulty of tracking these events would exceed the benefits of having the reported information.[31] Similar to our survey findings, a systematic review focusing on clinical incident reporting suggested having a standardized definition of an AE, along with clearly described reporting methods, including mechanism, anonymity, accessibility, and ease of input.[32] To address these perceived challenges, the SafetyNET team adapted an AE definition based on the patient safety scientific literature and their content team experts to "*any unfavorable sign, symptom, or disease temporally associated with the treatment, whether or not caused by the treatment*"[33]. Regarding the incident reporting mechanism, the SafetyNET team has also developed and validated profession-specific instruments to track and evaluate potential AEs related to SMT in a systematic yet in a time-efficient manner.[34] Provider feedback from a larger study using these instruments (personal communication) suggest that both providers and patients find these instruments easy and quick to use .[34]

We found that providers perceived that 'potential patient concerns' were an important barrier to participation in a reporting system. Previous studies, however, suggest this concern is not shared by patients.[10,34] Patients who have participated in a SafetyNET's pilot reporting system stated that they were pleased their provider was participating in a study directly assessing patient safety.[34] Additionally, Huerta and colleagues (2016)[35] observed that not only can patients provide unique input on safety and care, but by reporting events related to safety, they are more engaged in their care.

Regarding direct patient safety items, our study found that respondents scored the item 'updating a patient's medication list' lower than medical offices.[19] Although prescribing medications is typically not within the scope of the SMT providers, seeking information about a patient's medication list provides healthcare professionals with important information regarding the patient's current health status.[36,37] Thus, not only do changes in a patient's medication list indicate a change in the patient's health condition[38], but some medications may pose specific risks for SMT treatment, such as increased risk of bleeding[39]. Therefore, adequate pharmacological training and continued professional development to recognize the importance of asking about patient medication use at every visit could potentially increase patient safety within health care providers' clinics/offices.

The development and application of the survey described in this study is an important step towards creating a paradigm-shift in SMT providers regarding patient safety research and initiatives. Understanding the opinions and attitudes of SMT providers towards patient safety and identifying potential areas for improvement can lead to specific strategies and interventions to promote a constructive patient safety culture and support the development of effective systems for continuous learning and quality improvement. Although patient safety strategies and initiatives are currently being developed to promote a safety culture and address specific areas, future investigations are needed to assess the feasibility of these strategies' and their impact on patient outcomes.

Limitations

Survey Development

Results from the pilot study conducted with the developed Survey to Support Quality Improvement suggest that a limitation of this instrument is its length. A lengthy survey is likely to lower the response rate, especially for items positioned at the end of the survey, and may lead to an increased chance for non-response bias.[40]

Survey Application

Given that the results presented in this study include responses from 276 SMT providers, the results from this study should be interpreted with caution as it only reflects the attitudes and opinions of SMT providers who responded to our survey.

Another limitation of our work is the comparator group. Although Canadian SMT providers' patient safety attitudes and opinions were investigated in the current study, an American database from medical offices (from AHRQ) was used for comparison as a Canadian patient safety database is not available. Therefore, potential cul-

tural differences should also be considered as a potential limitation when interpreting our results.

Conclusions

This study identified, adapted, and conducted content validation for the SafetyNET's Survey to Support Quality Improvement to measure the patient safety culture of SMT providers, specifically chiropractors and physiotherapists. The survey measures the perceptions of their attitudes and opinions toward patient safety and quality improvement items and is the first study of its kind conducted in Canada. Generally, SMT providers had similar or better patient safety dimension scores compared to the AHRQ 2016 medical offices database. By understanding SMT providers' opinions and attitudes towards patient safety and identifying areas for improvement, organization-specific strategies can be developed to support a culture of patient safety and promote quality improvement.

Acknowledgements

The work was done as part of a team grant; the authors would like to thank their team members, Dr. Michael D. Hill and Dr. Jerome Yager for their insightful comments and suggestions to improve the work. This study was supported by funding from the Canadian Institutes of Health Research (CIHR # TIR-112758), Alberta References Innovates—Health Solutions (AIHS # 20111389), and the generosity of the Stollery Children's Hospital Foundation and supporters of the Lois Hole Hospital for Women through the Women and Children's Health Research Institute (WCHRI # RES0013182).

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Appendix B –
Development of the Active Surveillance Data Collection Instruments

Pohlman KA, O'Beirne M, Thiel H, Cassidy JD, Mior S, Hurwitz EL, Westaway M, Ishaque S, Yager JY, Vohra S. Development and validation of providers' and patients' measurement instruments to evaluate adverse events after spinal manipulation therapy. Eur J Integrative Medicine: special Patient Safety edition 2014;6(4):451-466.

Available online at www.sciencedirect.com

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European Journal of Integrative Medicine 6 (2014) 451–466

European Journal of INTEGRATIVE MEDICINE

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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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Received 14 September 2013; accepted 3 January 2014

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.

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 Safety 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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http://dx.doi.org/10.1016/j.eujim.2014.01.002

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 subitems; 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 multidisciplinary 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]	**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 ER assessment sought. **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 hours; a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; a congenital anomaly/birth defect.
National Cancer Institute (NCI) Common Toxicity Criteria [24]	**Mild**: Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated. **Moderate**: Minimal, local, or non-invasive intervention (e.g. ice/heat pack, analgesic, anti-inflammatory meds) indicated; limiting age-appropriate activities of daily living (*ADL*). **Severe**: Medically significant, but not immediately life-threatening; hospitalization; disabling; limiting self-care ADL. **Serious**: Results in death; OR a life-threatening adverse event; OR an adverse event that results in inpatient hospitalization or prolongation of existing hospitalization for >24 h; a persistent or signification 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.
International Conference on Harmonisation (ICH) [19]	**Serious**: 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.
WHO International Classification for Patient Safety (ICPS) [20]	**Minor temporary**: 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). **Major temporary**: A temporary injury that exceeds minor temporary or increases length of stay one day or more. Examples: Facial sutures, minor fractures, severe drug reaction. **Minor permanent**: 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. **Major permanent**: 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).
Institute for Healthcare Improvement [22]	**Category E**: Temporary harm to the patient and required intervention. **Category F**: Temporary harm to the patient and required initial or prolonged hospitalization. **Category G**: Permanent patient harm. **Category H**: Intervention required to sustain life. **Category I**: Patient death.
National Health Services (NHS) [26]	**Low**: Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care. **Moderate**: Any patient safety incident that resulted in a moderate increase in treatment e and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care. **Severe**: Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care. **Death**: Any patient safety incident that directly resulted in the death of one or more persons receiving NHS funded care.

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]	**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. **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.
WHO Collaborating Center for International Drug Monitoring [28]	**Certain**: 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. **Probable/likely**: 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). **Possible**: 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. **Unlikely**: 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. **Conditional/unclassified**: 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. **Unassessable/unclassifiable**: A report suggesting an adverse reaction which cannot be judged because information is insufficient or contradictory, and which cannot be supplemented or verified.
European Union Pharmocovigilance [29]	**Category A**: Reports including good reasons and sufficient documentation to assume a causal relationship, in the sense of plausible, conceivable, likely, but not necessarily highly probable. **Category 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. **Category O**: 'Reports where causality is, for one or another reason, not assessable, e.g. because of missing or conflicting data.
Patient disposition	
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) [30] and SafetyNET** [18]	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
National Institute on Aging [31]	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
Children's Hospital Boston, Clinical Research Program [32]	1 = Resolved, no residual effects 2 = Resolved, with sequelae 3 = Continuing 4 = Disability 5 = Death 6 = Unknown at this time
National Institute of Neurological Disorders and Stroke [33]	1 = Resolved without effects 2 = Resolved with effects 3 = Ongoing 4 = Death 5 = Unknown

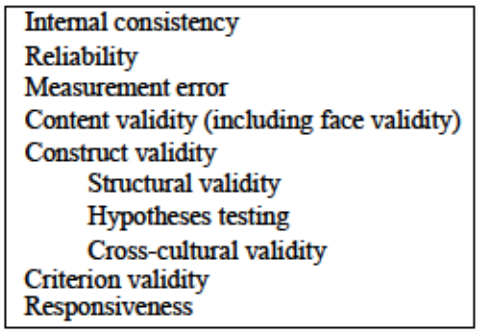

Fig. 1. Quality criteria for a legitimized health instrument's measurement properties.

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

This work was supported by funding from the Canadian Institutes of Health Research, Alberta Innovates – Health Solutions, and the Women and Children's Health Research Institute, University of Alberta.

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

Katherine Pohlman receives an educational fellowship from NCMIC: Sunita Vohra receives salary support as an AIHS Health Scholar.

The work was done as part of a team grant; the authors would like to thank their team members, Greg Kawchuk and Michael Hill, as well as the EPICORE Centre for their insightful comments and suggestion to improve the work.

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	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+
# of Mobilizations	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+
Mechanical Device	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+
Other Manual Tx	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+
Other Non-Man. Tx	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐3+	☐1 ☐2 ☐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
☐ Discomfort/Pain		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Stiffness		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Weakness		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Fatigue/Tiredness		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Headache		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Dizziness		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Difficulty with vision		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Sleeping Disturbances		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Irritability / Crying		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Dysarthria		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Nausea/Vomiting		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Numbness/Tingling		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Strains/Sprains		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Gait Disturbances		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Other: _____		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious

Appointment Date: __ __ / __ __ / 201__ Visit Code

Visit Number:

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	☐C ☐T ☐L ☐P ☐U/E ☐L/E	☐1 ☐2 ☐3 ☐4 ☐5	☐Flex ☐Ext ☐Rot ☐Side	
Manual Therapy #2	☐C ☐T ☐L ☐P ☐U/E ☐L/E	☐1 ☐2 ☐3 ☐4 ☐5	☐Flex ☐Ext ☐Rot ☐Side	
Manual Therapy #3	☐C ☐T ☐L ☐P ☐U/E ☐L/E	☐1 ☐2 ☐3 ☐4 ☐5	☐Flex ☐Ext ☐Rot ☐Side	
Non-manipulation therapies:	☐ Exercise(s) ☐ Stretch(es) ☐ Acupuncture / Acupressure ☐ Other, please describe:			

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
☐ Discomfort/Pain		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Stiffness		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Weakness		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Fatigue/Tiredness		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Headache		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Dizziness		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Difficulty with vision		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Sleeping Disturbances		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Irritability / Crying		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Dysarthria		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Nausea/Vomiting		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Numbness/Tingling		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Strains/Sprains		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Gait Disturbances		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious
☐ Other: _____		☐ Yes ☐ No	☐ Mild ☐ Moderate ☐ Severe ☐ Serious

Appointment Date: __ __ / __ __ / 201__ Visit Code

Visit Number: _____

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

Appointment Date: __ __ / __ __ / 201__ Visit Code

Visit Number:

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:**

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

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

Prescription Medications ☐ Don't Know	**Natural Health Products**	☐ Don't Know
☐ Anticoagulant (warfarin, dicumarol)	☐ Garlic	☐ Vitamin K
☐ Antiplatelet (aspirin)	☐ Ginger	☐ Other NHP, Specify
☐ Oral Contraception	☐ Ginkgo	
☐ Steroid	☐ Omega 3 Fatty Acids	
☐ Other, specify _____	☐ 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
☐ Blood thinners *(e.g. Warfarin/Coumadin, dicumarol)* ☐ Pain Medications
☐ Steroid ☐ Other: _____

6) Please indicate any natural health products that you are taking: ☐ None
☐ Garlic ☐ Ginger ☐ Ginkgo ☐ Omega-3
☐ 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.

Appointment Date: __ __ / __ __ / 201__ Visit Code

Visit Number:

	Discomfort/ Pain	Stiffness	Weakness	Tiredness/ 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)*	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
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)?	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
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)?	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O

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 or scan this QR:

Mark ONLY ONE 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?	☐	☐	☐	☐	☐
2) How satisfied are you with the treatment(s) that you received?	☐	☐	☐	☐	☐
3) How satisfied are you with the overall care that you received?	☐	☐	☐	☐	☐

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 ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Worst imaginable pain

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

Appointment Date: __ __ / __ __ / 201__ Visit Code

Visit Number: _____

Page 2 *(Turn Over To Start)*

	Discomfort/ Pain	Stiffness	Weakness	Tiredness/ 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)*	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
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)	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
3) Did it interfere with your usual daily activities (e.g. work, school)?	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
4) Did it limit your ability to care for yourself (e.g. bathing, dressing, eating)?	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
5) Did you need to see a medical doctor because of it?	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
6) Were you admitted to hospital because of it?	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
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?	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O

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Appendix C –
Ethics Approval Documentation: Survey

Notification of Approval

Date:	January 14, 2014	
Study ID:	Pro00043860	
Principal Investigator:	Katherine Pohlman	
Study Supervisor:	Sunita Vohra	
Study Title:	Pediatric Chiropractic Patient Safety Survey	
Approval Expiry Date:	January 13, 2015	
Sponsor/Funding Agency:	CIHR - Canadian Institutes for Health Research Women and Children's Health Research Institute	CIHR WCHRI

Thank you for submitting the above study to the Research Ethics Board 2. Your application has been reviewed and approved on behalf of the committee.

A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. If you do not renew on or before the renewal expiry date, you will have to re-submit an ethics application.

Approval by the Research Ethics Board does not encompass authorization to access the staff, students, facilities or resources of local institutions for the purposes of the research.

Sincerely,

Stanley Varnhangen, PhD
Chair, Research Ethics Board 2

Note: This correspondence includes an electronic signature (validation and approval via an online system).

Appendix C –
Ethics Approval Documentation: RCT

Approval Form

Date:	August 8, 2014
Study ID:	Pro00027903
Principal Investigator:	Sunita Vohra
Study Title:	STAIR: Pediatric active surveillance reporting and learning system
Approval Expiry Date:	August 7, 2015
Approved Consent Form:	Approval Date — Approved Document
Sponsor/Funding Agency:	Alberta Innovates Health Solutions — AIHS — Canada CIHR - Canadian Institutes for Health Research — CIHR Women and Children's Health Research Institute — WCHRI

RSO-Managed Funding:

	Project ID	Project Title	Speed Code	Other Information
View	RES0009942	CIHR Team in Safety Culture for Spinal Manipulation Therapy: (SAFETYNET: an academic and professional partnership building a culture of safety for Spinal Manipulation Therapy)		

Thank you for submitting the above study to the Health Research Ethics Board - Health Panel. Your application, including revisions received July 22 and August 5, 2014, has been reviewed and approved on behalf of the committee.

A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. If you do not renew on or before the renewal expiry date, you will have to re-submit an ethics application.

Approval by the Health Research Ethics Board does not encompass authorization to access the patients, staff or resources of Alberta Health Services or other local health care institutions for the purposes of the research. Enquiries regarding Alberta Health Services approvals should be directed to (780) 407-6041. Enquiries regarding Covenant Health should be directed to (780) 735-2274.

Sincerely,

Anthony S. Joyce, Ph.D.
Chair, Health Research Ethics Board - Health Panel

Note: This correspondence includes an electronic signature (validation and approval via an online system).

Appendix D –
Study Material: SafetyNET's Survey to Support Quality Improvement

Survey to Support Quality Improvement:

SECTION A: Working in The Clinic

How much do you agree or disagree with the following statements?	Strongly Disagree ▼	Disagree ▼	Neither Agree nor Disagree ▼	Agree ▼	Strongly Agree ▼	Does Not Apply or Don't Know ▼
1. When someone in this clinic gets really busy, others help out	☐1	☐2	☐3	☐4	☐5	☐9
2. In this clinic, there is a good working relationship between all personnel	☐1	☐2	☐3	☐4	☐5	☐9
3. In this clinic, we often feel rushed when taking care of patients	☐1	☐2	☐3	☐4	☐5	☐9
4. This clinic trains necessary personnel when new processes are put into place	☐1	☐2	☐3	☐4	☐5	☐9
5. In this clinic, we treat each other with respect	☐1	☐2	☐3	☐4	☐5	☐9
6. We have too many patients for the number of clinicians / interns in this clinic	☐1	☐2	☐3	☐4	☐5	☐9
7. This clinic makes sure all personnel get the on-the-job training they need	☐1	☐2	☐3	☐4	☐5	☐9
8. This clinic is more disorganized than it should be	☐1	☐2	☐3	☐4	☐5	☐9
9. We have good procedures for checking that work in this clinic was done correctly	☐1	☐2	☐3	☐4	☐5	☐9
10. Some personnel in this clinic are asked to do tasks they haven't been trained to do	☐1	☐2	☐3	☐4	☐5	☐9
11. We have enough personnel to handle our patient load	☐1	☐2	☐3	☐4	☐5	☐9
12. We have problems with workflow in this clinic	☐1	☐2	☐3	☐4	☐5	☐9
13. This clinic emphasizes teamwork in taking care of patients	☐1	☐2	☐3	☐4	☐5	☐9
14. This clinic has too many patients to be able to handle everything effectively	☐1	☐2	☐3	☐4	☐5	☐9
15. Personnel in this clinic follow standardized processes to get tasks done	☐1	☐2	☐3	☐4	☐5	☐9

SECTION B: Information Exchange With Other Settings

How often has your clinic had <u>problems exchanging accurate, complete, and timely information</u> with:

	Problems daily ▼	Problems weekly ▼	Problems monthly ▼	Problems several times in the past 12 months ▼	Problems once or twice in the past 12 months ▼	No problems in the past 12 months ▼	Does Not Apply or Don't Know ▼
1. Outside labs/imaging centers?	☐1	☐2	☐3	☐4	☐5	☐6	☐9
2. Other physician offices?	☐1	☐2	☐3	☐4	☐5	☐6	☐9
3. Other healthcare offices?	☐1	☐2	☐3	☐4	☐5	☐6	☐9
4. Insurance/Third Party Payers?	☐1	☐2	☐3	☐4	☐5	☐6	☐9
5. Other? (Specify): _____	☐1	☐2	☐3	☐4	☐5	☐6	☐9

SECTION C: Communication and Follow-up

How often do the following things happen in your clinic?	Never ▼	Rarely ▼	Some-times ▼	Most of the time ▼	Always ▼	Does Not Apply or Don't Know ▼
1. Clinicians in this clinic are open to ideas from other personnel about how to improve office processes	☐1	☐2	☐3	☐4	☐5	☐9
2. All personnel are encouraged to express alternative viewpoints in this clinic	☐1	☐2	☐3	☐4	☐5	☐9
3. This clinic reminds patients when they need to schedule an appointment for preventive or routine care	☐1	☐2	☐3	☐4	☐5	☐9
4. Some personnel are afraid to ask questions when something does not seem right	☐1	☐2	☐3	☐4	☐5	☐9
5. This clinic documents how well our chronic-care patients follow their treatment plans	☐1	☐2	☐3	☐4	☐5	☐9
6. Our clinic follows up when we do not receive a report we are expecting from an outside provider	☐1	☐2	☐3	☐4	☐5	☐9
7. Personnel feel like their mistakes are held against them	☐1	☐2	☐3	☐4	☐5	☐9
8. All personnel talk openly about clinic problems	☐1	☐2	☐3	☐4	☐5	☐9
9. This clinic follows up with patients who need monitoring	☐1	☐2	☐3	☐4	☐5	☐9
10. It is difficult to voice disagreement in this clinic	☐1	☐2	☐3	☐4	☐5	☐9
11. In this clinic, we discuss ways to prevent errors from happening again	☐1	☐2	☐3	☐4	☐5	☐9
12. All personnel are willing to report mistakes they observe in this clinic	☐1	☐2	☐3	☐4	☐5	☐9

SECTION D: XXX University Clinic Administration

How much do you agree or disagree with the following statements about the XXX University Administration?	Strongly Disagree ▼	Disagree ▼	Neither Agree nor Disagree ▼	Agree ▼	Strongly Agree ▼	Does Not Apply or Don't Know ▼
1. They aren't investing enough resources to improve the quality of care in this clinic	☐1	☐2	☐3	☐4	☐5	☐9
2. They overlook patient care mistakes that happen over and over	☐1	☐2	☐3	☐4	☐5	☐9
3. They place a high priority on improving patient care processes	☐1	☐2	☐3	☐4	☐5	☐9
4. They make decisions too often based on what is best for the clinic rather than what is best for patients	☐1	☐2	☐3	☐4	☐5	☐9

SECTION E: The Clinic

How much do you agree or disagree with the following statements?	Strongly Disagree ▼	Disagree ▼	Neither Agree nor Disagree ▼	Agree ▼	Strongly Agree ▼	Does Not Apply or Don't Know ▼
1. When there is an administrative problem in our clinic, we see if we need to change the way we do things	☐1	☐2	☐3	☐4	☐5	☐9
2. Our clinic processes are good at preventing administrative mistakes that could affect patients	☐1	☐2	☐3	☐4	☐5	☐9
3. Administrative mistakes happen more than they should in this clinic	☐1	☐2	☐3	☐4	☐5	☐9
4. It is just by chance that we don't make more administrative mistakes that affect our patients	☐1	☐2	☐3	☐4	☐5	☐9
5. This clinic is good at changing administrative processes to make sure the same problems don't happen again	☐1	☐2	☐3	☐4	☐5	☐9
6. In this clinic, getting more administrative work done is more important than quality of care	☐1	☐2	☐3	☐4	☐5	☐9
7. After this clinic makes administrative changes to improve the patient care process, we check to see if the changes worked	☐1	☐2	☐3	☐4	☐5	☐9

SECTION F: Overall Ratings

Overall Ratings on Quality

1. Overall, how would you rate your clinic on each of the following areas?

		Poor ▼	Fair ▼	Good ▼	Very good ▼	Excellent ▼
a. Patient centered	Is responsive to individual patient preferences, needs, and values	☐1	☐2	☐3	☐4	☐5
b. Effective	Is based on scientific knowledge	☐1	☐2	☐3	☐4	☐5
c. Timely	Minimizes waits and potentially harmful delays	☐1	☐2	☐3	☐4	☐5
d. Efficient	Ensures cost-effective care (avoids waste, overuse, and misuse of services)	☐1	☐2	☐3	☐4	☐5
e. Equitable	Provides the same quality of care to all individuals regardless of gender, race, ethnicity, language, etc.	☐1	☐2	☐3	☐4	☐5

Overall Rating on Patient Safety

2. Overall, how would you rate the administrative systems and clinical processes your clinic has in place to prevent, catch, and correct problems that have the potential to affect patients?

Poor ▼	Fair ▼	Good ▼	Very good ▼	Excellent ▼
☐1	☐2	☐3	☐4	☐5

SECTION G: List of Patient Safety and Quality Issues

The following items describe things that can happen in clinics that affect patient safety and quality of care. **In your best estimate, how often did the following things happen in your clinic**?

	Daily ▼	Weekly ▼	Monthly ▼	Several times in the past 12 months ▼	Once or twice in the past 12 months ▼	Not in the past 12 months ▼	Does Not Apply or Don't Know ▼
Access to Care							
1. A patient was unable to get an appointment within 48 hours for an acute/serious problem	☐1	☐2	☐3	☐4	☐5	☐6	☐9
Patient Identification							
2. The wrong chart/record was used for a patient	☐1	☐2	☐3	☐4	☐5	☐6	☐9
Charts/Records							
3. A patient's chart/record was not available when needed	☐1	☐2	☐3	☐4	☐5	☐6	☐9
4. Clinical information was filed, scanned, or entered into the wrong patient's chart/record	☐1	☐2	☐3	☐4	☐5	☐6	☐9
Equipment							
5. Equipment was not working properly or was in need of repair or replacement	☐1	☐2	☐3	☐4	☐5	☐6	☐9
Medication							
6. A patient's medication list was not updated during his or her visit	☐1	☐2	☐3	☐4	☐5	☐6	☐9
Diagnostics & Tests							
7. The results from a lab or imaging test were not available when needed	☐1	☐2	☐3	☐4	☐5	☐6	☐9
8. A critical abnormal result from a lab or imaging test was not followed up within 1 business day	☐1	☐2	☐3	☐4	☐5	☐6	☐9

SECTION H: Responder Demographics

The following questions relate to you, which will remain anonymous.

Gender:

☐1 Male

☐2 Female

Highest level of non-chiropractic education attained:

☐1 High school Diploma

☐2 Associate Degree

☐3 Bachelor's Degree

☐4 Master's Degree

☐5 Doctoral Degree

☐6 Other (Specify):_____

Are you interested in participating in safety research? If yes, please send a separate email indicating interest to: {insert email} (this ensures survey responses stay anonymous).

☐1 Yes

☐2 No

SECTION I: Your Comments

Please feel free to write any comments you may have about patient safety or quality of care in your clinic.

Please feel free to write any comments you may have about your experience completing this survey.

THANK YOU FOR COMPLETING THIS SURVEY.

Appendix D –
Study Material: RCT Active Surveillance Data Collection Instruments

PATIENT PRE-TREATMENT FORM
AND PROVIDER FORM

Thank you for your support.
Your feedback is extremely valuable.

Completing this form means you agree to be part of this study. Please give to your chiropractor before your visit starts.

1. This form is being completed for this child by: ○ Mother ○ Father ○ Other, specify: _____

2. Please mark the reason(s) for your child's appointment today:
   ○ Preventative / Wellness / No Symptoms ○ Headache ○ Neck pain ○ Mid-back pain
   ○ Low-back pain ○ Arm / Shoulder / Knee / Leg Pain ○ ADD / ADHD ○ Autism
   ○ Breastfeeding Difficulties ○ Cold ○ Colic ○ Digestive Issues ○ Plagiocephaly
   ○ Torticollis ○ Other, specify: _____

3. How long has your child had this condition? _____ week(s) ○ >1 year ○ N/A

4. How many treatments has your child had for this condition? _____ treatments ○ N/A
   Over what period of time? _____ week(s) ○ >1 year ○ N/A

5. In the past 7 days, how would you rate your child's pain on average?

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

6. Please indicate any medications that your child is taking: ○ None
   ○ Acetaminophen / Ibuprofen ○ Cetirizine (Zyrtec/Reactine) ○ Diflucan ○ Gaviscon
   ○ Omeprazole (Prilosec, Losec) ○ Ranitidine (Zantac) ○ Other: _____

7. Please indicate any vitamins or natural health products that your child is taking: ○ None
   ○ Omega-3 ○ Probiotics ○ Vitamin D ○ Other: _____

8. Does your child have a history of any of the following? ○ None
   ○ Bleeding disorder ○ Cancer ○ Diabetes ○ Other: _____

9. Child is: ○ Male ○ Female ○ Other: _____

10. Child's date of birth? ____Month ____Day 20____ ____

11. Today's fees covered by: ○ N/A ○ Self-pay ○ Car Accident Coverage ○ Other Insurance: _____

Please continue with questions on the back.

First: Does your child have any of the following? (check all that apply)	**Second:** For each item checked, please answer the questions below		
	How long has your child had it?	**Does it interfere with their usual daily activities (e.g. play, school)?**	**Does it limit their ability to care for themselves (e.g. bathing, dressing, eating)?**
○ Discomfort / Pain	_____ week(s) ○ >1 year	○ Yes ○ No	○ Yes ○ No
○ Stiffness	_____ week(s) ○ >1 year	○ Yes ○ No	○ Yes ○ No
○ Weakness	_____ week(s) ○ >1 year	○ Yes ○ No	○ Yes ○ No
○ Fatigue / Tiredness	_____ week(s) ○ >1 year	○ Yes ○ No	○ Yes ○ No
○ Headache	_____ week(s) ○ >1 year	○ Yes ○ No	○ Yes ○ No
○ Dizziness	_____ week(s) ○ >1 year	○ Yes ○ No	○ Yes ○ No
○ Numbness / Tingling	_____ week(s) ○ >1 year	○ Yes ○ No	○ Yes ○ No
○ Problems Sleeping	_____ week(s) ○ >1 year	○ Yes ○ No	○ Yes ○ No
○ Irritability / Crying	_____ week(s) ○ >1 year	○ Yes ○ No	○ Yes ○ No
○ Other: _____ _____	_____ week(s) ○ >1 year	○ Yes ○ No	○ Yes ○ No
○ None of the above			

STOP **Please give the form to the CHIROPRACTOR, who will complete the remainder *below*:**

(1) **Radicular Pain?** ○ Yes ○ No (2) **Please indicate if the main condition is:** ○ Chronic ○ Acute ○ Recurring ○ NA

TREATMENT	**Cervical Spine**	**Thoracic Spine**	**Lumbar Spine**	**Sacrum / Pelvis**	**Upper Extremity**	**Lower Extremity**	**Other ***
# of Manipulations	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+
# of Mobilizations	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+
Mechanical Device	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+
Other Manual Tx*	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+
Other Non-Man. Tx*	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+	○1 ○2 ○3+

***Other**, (specify) _____

POST SYMPTOMS

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

Post Symptoms (check all that apply)	**Pre-Existing:**	**If Yes: Better, Worse, or Unchanged?**	**Anticipated?**	**Overall Severity Rating**
○ Discomfort / Pain	○ Yes ○ No	○B ○W ○U	○ Yes ○ No	○ Mild ○ Moderate ○ Severe ○ Serious
○ Stiffness	○ Yes ○ No	○B ○W ○U	○ Yes ○ No	○ Mild ○ Moderate ○ Severe ○ Serious
○ Weakness	○ Yes ○ No	○B ○W ○U	○ Yes ○ No	○ Mild ○ Moderate ○ Severe ○ Serious
○ Fatigue / Tiredness	○ Yes ○ No	○B ○W ○U	○ Yes ○ No	○ Mild ○ Moderate ○ Severe ○ Serious
○ Headache	○ Yes ○ No	○B ○W ○U	○ Yes ○ No	○ Mild ○ Moderate ○ Severe ○ Serious
○ Dizziness	○ Yes ○ No	○B ○W ○U	○ Yes ○ No	○ Mild ○ Moderate ○ Severe ○ Serious
○ Numbness / Tingling	○ Yes ○ No	○B ○W ○U	○ Yes ○ No	○ Mild ○ Moderate ○ Severe ○ Serious
○ Irritability / Crying	○ Yes ○ No	○B ○W ○U	○ Yes ○ No	○ Mild ○ Moderate ○ Severe ○ Serious
○ Other: _____ _____	○ Yes ○ No	○B ○W ○U	○ Yes ○ No	○ Mild ○ Moderate ○ Severe ○ Serious

Please put completed form in SafetyNET Box.

PATIENT POST-TREATMENT FORM

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 on behalf of this child. 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 the feedback **one week after your child's visit, but before his / her next visit**.

1. Date of completion: _____ _____ / _____ _____ / 201_____ (Month / Day / Year)

2. This form is being completed for this child by: ○ Mother ○ Father ○ Other: _____

Mark only one checkbox on each line	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied
3 How satisfied are you with the information you have been given from your child's chiropractor?	○	○	○	○	○
4 How satisfied are you with the treatment(s) that your child received?	○	○	○	○	○
5 How satisfied are you with the overall care that your child received?	○	○	○	○	○

6. In the past 7 days, how would you rate your child's pain on average?

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

7. During the appointment with the chiropractor, did your child 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**
   - ○ **Yes**, please mark all areas where you received a manual therapy:
     - ○ Neck ○ Back ○ Shoulder/Arms/Knee/Legs ○ Other: _____

8. Since your child's appointment with the chiropractor, what other treatments / therapies has your child had?
   - ○ None
   - ○ Other **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.*')
     please specify: _____
   - ○ New medicine, please specify: _____
   - ○ New natural health products, please specify: _____
   - ○ Other, please specify: _____

9. How would you describe the overall effect of your child's visit with your chiropractor?
   ○ Favorable ○ Unfavorable ○ None ○ Unsure

Please complete page 2 (on reverse)

① **FIRST:** Since the appointment did your child have any of the following? (check all that apply below)	**SECOND:** For each item you checked 'yes' in the first column, please answer the questions								
	② Did you expect this to occur?	③ If symptom was there before treatment, is it now: **N**ew, **B**etter, or **W**orse, **U**nchanged?	④ Did it interfere with your child's usual daily activities?	⑤ Did it limit your child's ability to care for them self?	⑥ Did your child need to see a MD?	⑦ Was your child admitted to hospital	⑧ Started how many hours after treatment:	⑨ How long did it last? (check 'C' if it still continues)	If 'C', is child being treated for it?
Discomfort/Pain ◯ Yes ◯ No	◯ Yes ◯ No	◯B ◯W ◯U ◯N	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	_____ hour(s)	_____ hour(s) ◯ C	◯ Yes ◯ No
Stiffness ◯ Yes ◯ No	◯ Yes ◯ No	◯B ◯W ◯U ◯N	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	_____ hour(s)	_____ ◯ C	◯ Yes ◯ No
Weakness ◯ Yes ◯ No	◯ Yes ◯ No	◯B ◯W ◯U ◯N	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	_____ hour(s)	_____ ◯ C	◯ Yes ◯ No
Tiredness/Fatigue ◯ Yes ◯ No	◯ Yes ◯ No	◯B ◯W ◯U ◯N	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	_____ hour(s)	_____ ◯ C	◯ Yes ◯ No
Headache ◯ Yes ◯ No	◯ Yes ◯ No	◯B ◯W ◯U ◯N	◯ Yes ◯ No	◯Yes ◯No	◯ Yes ◯ No	◯ Yes ◯ No	_____ hour(s)	_____ ◯ C	◯ Yes ◯ No
Dizziness ◯ Yes ◯ No	◯ Yes ◯ No	◯B ◯W ◯U ◯N	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	_____ hour(s)	_____ ◯ C	◯ Yes ◯ No
Numbness/Tingling ◯ Yes ◯ No	◯ Yes ◯ No	◯B ◯W ◯U ◯N	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	_____ hour(s)	_____ ◯ C	◯ Yes ◯ No
Problems Sleeping ◯ Yes ◯ No	◯ Yes ◯ No	◯B ◯W ◯U ◯N	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	_____ hour(s)	_____ ◯ C	◯ Yes ◯ No
Irritability/Crying ◯ Yes ◯ No	◯ Yes ◯ No	◯B ◯W ◯U ◯N	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	_____ hour(s)	_____ ◯ C	◯ Yes ◯ No
Other Condition _____ ◯ No	◯ Yes ◯ No	◯B ◯W ◯U ◯N	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	◯ Yes ◯ No	_____ hour(s)	_____ hour(s) ◯ C	◯ Yes ◯ No

PROVIDER SECONDARY LONGER QUESTIONNAIRE

Complete ONLY for Moderate, Severe or Serious Adverse Events

- Please fax completed forms to: **214-902-2482**
- Completion of this form does not replace your usual communication with your insurance group.

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.)

_____

_____

_____

_____

6. Has the patient experienced an adverse event to manual therapy in the past?

○ Yes ○ No ○ Unknown ○ **If yes**, please specify _____

Please continue with questions on the back.

PATIENT CHARACTERISTICS con't – Please describe what was known *PRIOR TO* treatment

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**?

- ○ Acute infection
- ○ Bleeding tendency
- ○ Connective tissue disorder
- ○ Diabetes
- ○ Fracture
- ○ History of cancer
- ○ History of stroke
- ○ Prior spine surgeries
- ○ Radiculopathy
- ○ Recent relevant trauma
- ○ Recent upper respiratory infection
- ○ Vertigo
- ○ Fever
- ○ Other _____

---

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

Prescription Medications

- ○ Don't Know
- ○ Acetaminophen / Ibuprofen
- ○ Ceririzine (Zyrtec)
- ○ Diflucan
- ○ Gaviscon
- ○ Omerprzole (Prolosec, Losec)
- ○ Ranitidine (Zantac)
- ○ Other, Specify _____

Natural Health Products

- ○ Don't Know
- ○ Omega 3 Fatty Acids
- ○ Probiotics
- ○ Vitamin D
- ○ Other NHP, Specify:

_____

_____

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) ____ ____ / ____ ____ / 201 ____

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 E –
Extra Material: CPiRLS trigger list for the passive surveillance group

CPIRLS

www.cpirls.org

CPiRLS Trigger List

The trigger list below is designed to help you participate in CPiRLS by providing examples of incidents that you might experience and should report. Some incidents may be fairly common while some may be extremely rare. The list is not exhaustive but provides the categories/subcategories of incident that match those examples listed in the online reporting form. These same categories/subcategories can be applied to near misses and potential incidents on the understanding that you are referring to the *avoidance* of the incident or an *identified risk* of a particular incident occurring.

DOCUMENTATION	EXAMINATION/ ASSESSMENT	TREATMENT/ MANAGEMENT	ACCIDENTS/ EQUIPMENT/ INFRASTRUCTURE
Patient record inadequate	Incorrect diagnosis	Patient experienced post-treatment distress/pain	Patient trip/fall
Failure to take notes on a new episode	Investigation undertaken to detriment of patient	Wrong positioning of patient during treatment	Patient unable to contact clinic in an emergency
Failure to document diagnosis / prognosis	Significant pathology missed	Patient experienced significant post treatment effects e.g. neurological problem, disc prolapsed	Equipment malfunction
Patient record misplaced	Case history inadequate, missed secondary condition	Patient experienced negative effects during treatment e.g. fractured rib or clavicle	Failure to use equipment appropriately
Records confused, treated wrong patient	Over-exposure of film	Suggested drugs to patient which had adverse effect	Health and Safety measures inadequate
Treated before referral notes arrived, missed significant finding	Over-exposure of patient	Did not modify treatment plan to take account of patient preferences or health needs	Failure to dispose of sharps and clinical waste appropriately
Failure to gain consent	Failure to request x-ray report	Slow to refer after patient did not respond to treatment	Medical emergency inadequately handled
Breach of confidentiality	X-ray misinterpretation	Did not discontinue treatment when appropriate to do so	Exposure to blood
	Exposure of pregnant patient	Patient discharged without arranging future care	Exposure to harmful substances
	Failure in referral process		

Appendix E –
Extra Material: Adjudicated AE Reports

Active Surveillance – Report #1
Female child born in 2012 came in for visit in March 2016 for a self-paid preventative/wellness visit. The mother stated that the child had a pain rating of 1 on the numerical pain (0-10) rating scale (NRS) and taking several natural health products (Omega-3, Probiotics, Vit D, and a multi-vitamin). No medication or reportable prior history stated, nor any pre-treatment symptoms. Manipulation was applied to 2 segments in the cervical spine, 1 segment in the thoracic spine, 1 segment in the lumbar spine, and 1 segment in the sacrum/pelvis. Immediately after treatment, the chiropractor reported that the child had irritability/crying that was anticipated and severe in nature. Doctor stated that this reaction ('severe screaming before, during, and after the adjustment') happens every time this child is treated. The event was stated as resolved the same day.

ADJUDICATION NOTES –-Seriousness: Mild (Agreement), no further assessment

Active Surveillance – Report #2
During the study period, this 17-18 month old female child was seen by the chiropractor 3 times between February and March of 2016 for a cold. These appointment's fees were covered under insurance. Mother reported that the cold started ~3.5 weeks prior to the first visit. At the first 2 visits, the mother rated the child's pain as 1 on the numerical pain (0-10) rating scale (NRS) and a 0 on the last visit. No reportable health history was noted. The mother did not report any pre-treatment symptoms prior to care on any of the visits. On the 3rd visit, the chiropractor reported applying manipulation to 3+ segments in the cervical spine, 2 segments in the thoracic spine, 2 segments in the lumbar spine, and 1 segment in the sacrum/pelvis. The doctor reported that the patient had pre-existing discomfort/pain and stiffness that was unchanged immediately after care, anticipated, and mild in nature; as well as irritability/crying that was also pre-existing, but worsened, anticipated, and moderate in nature, but resolved within 2 minutes after treatment. The doctor stated the child cried for the same amount of time (2 minutes) on the first 2 appointments, but felt that the intensity was more on the 3rd visit.

ADJUDICATION NOTES –-Seriousness: Mild (Agreement), no further assessment

Active Surveillance – Report #3
This 11 year old female child was seen in February 2016 with neck pain, mid-back pain, low back pain, and digestive issues. Fees for this visit were covered by insurance. Mother stated this was the first visit and she had had these conditions for an unknown period of time. Pain was rated as a 6 on the numerical pain (0-10) rating scale (NRS). Child had no remarkable health history. Mother stated that the patient had 'discomfort/pain' prior to treatment that did not interfere with daily activities or did not limit her ability to care for herself. Doctor stated that the patient's condition was not radicular and was recurring in nature. Treatment consisted of manipulation to 2 segments in the cervical spine, 3 or more to the thoracic spine, 2 segments to the lumbar spine, 1 segment to the sacrum/pelvis, mechanical device utilized on 1 segment in the sacrum/pelvis, and cervico-thoracic electrical muscle stimulation was utilized. Doctor described the patient as having 'discomfort/pain' immediately after care that was pre-existing, unchanged, anticipated, and a moderate severity.

The doctor completed the AE form for this visit and stated it was a 'normal visit' and 'patient had flare up of pain and had moderate discomfort/pain that was unchanged after the adjustment.' The doctor stated a contributing factor was that it was 'pre-existing'. Patient characteristics described were: 1) reason for the visit: 'flare up of neck pain'; 2) specific diagnosis: 'recurring neck pain and headache, x-rays & postural analysis previously completed'; 3) any prior AE to manual therapy in the past was 'unknown'; and 4) doctor noted same medication, health history, and natural health product utilization as described by the patient. Outcome of the event was described as having no effect on daily living and that ice was applied and she felt better. The event was stated as resolved the same day.

ADJUDICATION NOTES –-Seriousness: Mild (Agreement), no further assessment

Passive Surveillance – Report #1

Gentle manual manipulation was reported to be performed on female patient under 16 years of age. Child told her mother later after leaving the appointment that she was sore and that she was afraid to return to the office. Mother also reported that the child had no other signs of distress except soreness the following day and apprehension to return. Chiropractor reported they were unsure of the cause. The child was small for age in both height and weight. No known disease state/condition had been identified. Chiropractor called to follow-up with parent and no other concerns were stated. Chiropractor stated that the child may do better with Activator technique until she is older, but may also never have the same reaction again.

ADJUDICATION NOTES -Seriousness: Mild (Agreement), no further assessment

Passive Surveillance – Report #2

Female patient under 16 years of age stated she was sore after she was adjusted. Chiropractor reported that sometimes after getting adjusted patients experience soreness due to the body shifting and adapting to the adjustment. Icing was recommended for the patient when she got home. The doctor noted that: 'The patient's mother isn't consistent about getting her daughter in for care, so the more adjustments are spaced out, the more soreness may be experienced (just like if you haven't worked out in a long time and then workout).'.

ADJUDICATION NOTES – Seriousness: Mild (Agreement), no further assessment

Appendix E –
Extra Material: Full active surveillance group data analysis by symptoms

Full Analysis Tables of the Active Surveillance Data

Table E.1. Detailed description of patient/caregiver & provider reported worsening symptoms.

	Worsening - Patient/Caregiver Report	**Worsening - Patient/Caregiver Difference**	**Worsening - Patient/Caregiver Both Difference & Self-Report**	**Worsening - Patient/Caregiver Self-Report**	**Worsening - Doctor Provider Report**	**Worsening - Both Patient/Caregiver and Provider Reported**
Pain / Discomfort	15 mild=2 moderate=6 severe=7	11 moderate=4 severe=7	0	4 mild=2 moderate=2	3 mild=3	1 severe=1 (both DC & patient/caregiver, as well as self-report and pre/post difference)
Irritability / Crying	18 mild=3 moderate=10 severe=5	11 moderate=7 severe=4	0	7 mild=3 moderate=3 severe=1	10 mild=6 moderate=2 severe=2	0
Stiffness	8 mild=2 moderate=3 severe=3	5 moderate=2 severe=3	0	3 mild=2 moderate=1	0	0
Fatigue / Tiredness	2 mild=1 moderate=1	0	0	2 mild=1 moderate=1	1 mild=1	0
Headache	1 mild=1	0	0	1 mild=1	1 mild=1	0
Weakness	2 mild=1 severe=1	1 severe=1	0	1 mild=1	0	0
Numbness / Tingling	0	0	0	0	0	0
Dizziness	0	0	0	0	0	0
Other	6 mild=2 severe=4	3 severe=3	0	3 mild=2 severe=1	0	0
Raw Totals	**52** **mild=12** **moderate=20** **severe=20**	**31** **moderate=13** **severe=18**	**0**	**21** mild=12 moderate=7 severe=2	**15** **mild=11** **moderate=2** **severe=2**	**1** **severe=1**
Totals by patient visit	**50**	**27**	**1**	**15**	**12**	**2***
Totals by unique patients	**44**	**26**	**0**	**9**	**9**	**1**

Table E.2. Detailed description of patient/caregiver & provider reported new symptoms.

	New - Patient/Caregiver Report	New - Provider Report	New - Both Patient/Caregiver and Provider Reported
Pain / Discomfort	9 mild=5 moderate=4	13 mild=13	0
Irritability / Crying	8 mild=4 moderate=2 severe=1	17 mild=16 moderate=1	0
Stiffness	1 mild=1	0	0
Fatigue / Tiredness	11 mild=6 moderate=3	0	0
Headache	6 mild=3 moderate=1	0	0
Weakness	1 mild=1	0	0
Numbness / Tingling	0	0	0
Dizziness	0	0	0
Other	6 mild=4 moderate=2	0	0
Raw Totals	**42** mild=24 moderate=12 severe=1	**30** mild=29 moderate=1	**0**
Totals by patient visit	**30**	**24**	**4* (0)**
Totals by unique patients	**21**	**18**	**3 (0)**

Table E.3. Detailed description of patient/caregiver & provider reported symptoms combined.

	Raw Total AEs (worse or new counted *individually* per patient visit)	AEs (worse or new counted once per patient visit)	AEs (worse or new counted once per unique patient)
Pain / Discomfort	**41 mild=23 moderate=10 severe=8**	**30**	**26**
Irritability / Crying	**53 mild=29 moderate=15 severe=8**	**41**	**38**
Stiffness	**9 mild=3 moderate=3 severe=3**	**8**	**8**
Fatigue / Tiredness	**14 mild=8 moderate=4**	**3**	**3**
Headache	**8 mild=5 moderate=1**	**5**	**5**
Weakness	**3 mild=2**	**1**	**1**
Numbness / Tingling	**0**	**0**	**0**
Dizziness	**0**	**0**	**0**
Other	**12 mild=6 moderate=2 severe=4**	**8**	**8**
Raw Totals	**140 mild=76 (54.3%) moderate=35 (25.0%) severe=23 (16.4%)**	**96**	**89**
Totals by patient visit	**66**	**65**	**58**
Totals by unique patients	**46**	**58**	**58**

Appendix F –

pdf of the published manuscripts from Chapter 3

Pohlman KA, Carroll L, Hartling L, Tsuyuki R, Vohra S. Attitudes and opinions of doctors of chiropractic specializing in pediatric care toward patient safety: a cross-sectional survey. J Manipulative Physiol Ther 2016 Sept;39(7):487-493.

Attitudes and Opinions of Doctors of Chiropractic Specializing in Pediatric Care Toward Patient Safety: A Cross-sectional Survey

Katherine A. Pohlman, DC, MS,[a] Linda Carroll, PhD,[b] Lisa Hartling, PhD, MSc,[c] Ross Tsuyuki, PharmD, MSc,[d] and Sunita Vohra, MD, MSc[d]

Abstract

Objective: The purpose of this cross-sectional survey was to evaluate attitudes and opinions of doctors of chiropractic (DCs) specializing in pediatric care toward patient safety.

Methods: The Medical Office Survey on Patient Safety Culture of the Agency for Healthcare Research and Quality was adapted for providers who use spinal manipulation therapy and sent out to 2 US chiropractic organizations' pediatric council members (n = 400) between February and April 2014. The survey measured 12 patient safety dimensions and included questions on patient safety items and quality issues, information exchange, and overall clinic ratings. Data analyses included a percent composite average and a nonrespondent analysis.

Results: The response rate was 29.5% (n = 118). Almost one- third of respondents' patients were pediatric (≤17 years of age). DCs with a pediatric certification were 3 times more likely to respond ($P < .001$), but little qualitative differences were found in responses. The patient safety dimensions with the highest positive composite percentages were *Organizational Learning* (both administration and clinical) and *Teamwork* (>90%). *Patient Care Tracking/ Follow-up* and *Work Pressure and Pace* were patient safety dimensions that had the lowest positive composite scores (<85%). The responses also indicated that there was concern regarding information exchange with insurance/third-party payors. Two quality issues identified for improvement were (1) updating a patient's medication list and (2) following up on critically abnormal results from a laboratory or imaging test within 1 day. The average overall patient safety rating score indicated that 83% of respondents rated themselves as "very good" or "excellent."

Conclusions: Compared with 2014 Agency for Healthcare Research and Quality physician referent data from medical offices, pediatric DCs appear to have more positive patient safety attitudes and opinions. Future patient safety studies need to prospectively evaluate safety performance with direct feedback from patients and compare results with these self-assessed safety attitudes, as well as make further use of this survey to develop a comparable database for spinal manipulation providers. (J Manipulative Physiol Ther 2016;39:487-493)

Key Indexing Terms: *Pediatrics; Patient Safety; Quality Improvement; Chiropractic*

Introduction

Patient safety and quality improvement has been at the top of health care agendas since the 1999 Institute of Medicine (IOM) report, *To Err Is Human*.[1] Reporting and learning systems for medical errors have been implemented as suggested in the IOM report[1] and found to make some quality improvements in hospital settings[2,3]; however, little has been done for quality improvement in community-based health care offices, where the majority of patient-provider interactions occur.[4,5]

Currently in the chiropractic profession, only 1 reporting and learning system exists; it was deployed initially in the United Kingdom in 2005, expanded throughout Europe, and recently has

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Paper submitted December 15, 2015; in revised form June 16, 2016; accepted June 29, 2016.
0161-4754

http://dx.doi.org/10.1016/j.jmpt.2016.06.003

been made available in Australia. The Chiropractic Patient Incident Reporting and Learning System is an online forum that allows near misses or actual medical errors and incidents or adverse events (both clinical and administrative) to be voluntarily reported in an anonymous and confidential manner.[6]

The Agency for Healthcare Quality and Research (AHRQ) responded to the IOM report's recommendation to increase patient safety. One AHRQ initiative was the development of a survey to measure patient safety attitudes and opinions from the perspective of those providing the care.[7] Similar to other patient safety movements, their work started in secondary care (ie, hospitals) and then expanded into primary care medical offices.[7,8] The goals of the AHRQ medical office survey were to (1) raise awareness about patient safety, (2) assess the current status of patient safety attitudes and opinions, (3) use for internal patient safety and quality improvement, (4) evaluate the impact of patient safety and quality improvement initiatives, and (5) track patient safety attitudes and opinions over time. SafetyNET is a team of patient safety and spinal manipulation therapy (SMT) experts who adapted this survey for SMT providers and initiated validation with doctors of chiropractic (DCs) and physical therapists.[9] This survey's name was modified to Survey to Support Quality Improvement so that community-based SMT providers would better understand its content and purpose.[10]

Chiropractic and osteopathic manipulation remains the most popular complementary and alternative medicine service sought in the United States by the pediatric population.[11,12] There are several different programs available to those wishing to become a certified pediatric DC, which usually require more than 300 hours of training to expand on and deepen the pediatric knowledge base obtained during an accredited chiropractic training program.

Similar to other primary care community-based providers, DCs who treat children do not currently have established patient safety reporting or learning mechanisms, despite identified gaps in patient safety.[13,14] The purpose of this cross-sectional survey is to evaluate the safety attitudes and opinions of pediatric DCs, which is the start of assessing and supporting a patient safety culture for this population.

Methods

SafetyNET's Survey to Support Quality Improvement is a cross-sectional survey to measure patient safety attitudes and opinions, specific patient safety and quality issues, information exchange problems, and overall office ratings on quality and patient safety. This survey was used to evaluate patient safety and quality improvement of responding pediatric DCs.[9] The University of Alberta's Research Ethics Board (Pro00043860) reviewed and approved this study. This manuscript was prepared using the STROBE (strengthening the reporting of observational studies in epidemiology) Statement for cross-sectional studies.[15]

Population

The target population for this survey was pediatric DCs; however, it was not limited to only DCs with a certification in pediatrics, because all DCs are trained to provide care to this population.[16] The American Chiropractic Association, Council on Chiropractic Pediatrics (ACA-CCP) and International Chiropractors Association, CCP (ICA-CCP) were identified as our source population because their members all had interest in pediatrics and supported these organizations through membership (n = 400). Membership of these organizations is based on one's interest in supporting initiatives of these associations and is not dependent on having a pediatric certification. Because the source populations were small enough, all were invited to participate between February and April 2014, and a representative sample size calculation was not conducted.

Survey Design

SafetyNET's Survey to Support Quality Improvement was developed in 4 stages: (1) scoping literature review; (2) validation and measurement properties consideration of preferred survey; (3) survey modifications to promote content validity; and (4) continued content validity testing.[9] The survey has been piloted with DCs in Alberta, Canada; conducted with physiotherapists in Alberta, Canada, and DCs in Ontario, New Brunswick, and Newfoundland, Canada; has been translated to French and Danish for use among DCs in Québec, Canada, and Denmark, respectively; and has been modified and conducted at 3 chiropractic teaching clinics (Anglo-European College of Chiropractic, Canadian Memorial Chiropractic College, and Parker University).

The survey for this study was designed and managed using REDCap electronic data capture tools (Vanderbilt University, Nashville, TN) hosted at the University of Alberta.[17] Potential respondents received the survey via email. This email included a letter with information about the study and a direct link to the survey. The email and link were sent 3 times, with at least 1 week between each mailing.

The patient safety dimensions measured were *Communication about Error*, *Communication Openness*, *Office Processes and Standardization*, *Organizational Learning (clinical and administrative)*, *Overall Perceptions of Patient Safety and Quality (clinical and administrative)*, *Owner/Managing Partner/Leadership Support for Patient Safety*, *Patient Care Tracking/Follow-up*, *Staff Training*, *Teamwork*, and *Work Pressure and Pace*.[8] Responses were sought on a 5-point rating scale (5 being the best score).

Eight questions were asked directly about specific patient safety items and quality issues: *access to care, charts/records, equipment, medications,* and *diagnostic tests*. Four questions were asked about information exchange with other settings: *outside labs/imaging center, other physician offices, other health care offices,* and *insurance/third party payors*. Providers were then asked to

rate their office in health care quality areas, on dimensions that affect patients' designed care plans (ie, *patient centered, timeliness, efficient, equitable*), and provide an overall rating for patient safety and quality improvement. The survey concluded with questions about providers' practices and patient characteristics, including if the respondent was a certified pediatric DC.

AHRQ Comparative Database

The 2014 AHRQ medical office survey conducted a subanalysis of characteristics, including number of providers, single vs multispecialty offices, ownership, geographic regions, and job position (ie, physician [MD/DO]; management; physician assistant, nurse practitioner, midwife, etc; nurse [registered nurse, licensed vocational nurse, licensed practical nurse]), other clinical staff or clinical support staff, administration/clerical staff).[18] For this paper, we compared our results with the number of providers in an office and job position (physician).

Data Analysis

The data were analyzed with Stata 13 Software (StataCorp, College Station, TX) and Excel 2013 (Microsoft, Redmond, WA). For comparison with the AHRQ data, a positive percentage composite score was calculated for each item. For negatively worded questions, the disagreement responses were considered the positive responses. The top 2 or 3 positive or negative responses were added together and divided by the total responses to obtain the individual percent composite response for each question or dimension.

Bias as a result of nonresponse was investigated by comparing gender, location, and pediatric certification status of respondents and the population of those who could have responded (ie, the ACA-CCP and ICA-CCP membership). These characteristics were available in aggregate fashion for each association. The associations between each characteristic and being a responder were reported as relative risks and 95% confidence intervals (CIs). Where statistically significant differences were found between responders and those eligible to respond (ie, where the CI crossed 1), patient safety study data (responses on each dimension) were stratified on those characteristics to assess whether there were systematic differences in responses. Systematic differences would suggest that nonresponse might have biased our findings.

Results

Response Rate

Of the 400 potential respondents, the response rate was 29.5% (n = 118). For the ACA-CCP, the response rate was 42.4% (25/58); for the ICA-CCP, the response rate was 26.8% (93/342).

Nonrespondent Analysis

Respondents differed from the eligible population on pediatric certification but not on gender or location. For ACA-CCP respondents, those who were pediatric certified were 3.13 (95% CI, 1.44-6.76) times more likely to have responded to the survey than those who were not certified. For the ICA-CCP respondents, those who were pediatric certified were 3.23 (95% CI, 1.71-6.10) more likely to have responded to the survey than those who are not certified. However, there was little qualitative difference in responses to patient safety dimensions between those who were certified pediatric DCs and those who were not. On the teamwork question, pediatric-certified and noncertified respondents had scores of 4.6 (95% CI, 4.5-4.7) and 4.8 (95% CI, 4.7-5.0), respectively; and on the *Overall Perception—Administration* question, scores were 4.3 (95% CI, 4.2-4.5) and 4.6 (95% CI, 4.4-4.8), respectively.

Respondent Characteristics

Table 1 provides a summary of demographic characteristics for respondents. Certified pediatric DCs were predominantly female (74.7%), with their geographical representation spread uniformly across the United States, and with 19.1% in other countries. As shown in Table 2, respondents' patients were described as mostly female (61%); the pediatric population (newborn to 17 years of age) represented 31.7% of their practice. Across age groups, the most common reason patients sought care was for low back pain (26%), neck pain (22%), and prevention/wellness (18%).

Survey to Support Quality Improvement Items

In Figure 1, the composite scores of the patient safety dimensions are reported and can be compared with the positive composite scores of physicians from the 2014 AHRQ comparative database and medical offices with 1 provider.[18] The composite scores of the current survey were higher (suggesting more positive attitudes toward patient safety) than those of the AHRQ 2014 physicians and AHRQ medical offices with 1 provider for almost all dimensions.

Table 3 demonstrates information exchange with other settings, as well as the patient safety items and quality issues. Positive responses were high for all information exchange items. One notable exception is respondent concern with information exchange with insurance/third-party payors, as only 56% had a positive response to this item. The patient safety items and quality issues identified as *not relevant* to their practice were "updating a patient's medication list" (34%) and "following up on critically abnormal results from a lab or imaging test within 1 day" (23%).

As also shown in Table 3, the overall office self-rating scores showed that ratings from pediatric chiropractic offices were slightly better than those of AHRQ physicians.

Table 1. *Demographic and Background Characteristics of Respondents (n = 75)* [a]

Characteristics	n (%)
Female gender, n (%)	56 (74.7)
Number of years in practice, mean (SD)	18.75 (8.8)
Hours worked in a typical week, mean (SD)	32.7 (1.7)
Patient visits per week, n (%)	
<50	12 (16.0)
50-99	20 (26.7)
100-149	22 (29.3)
150-199	13 (17.3)
200+	8 (10.7)
Conferring chiropractic degree	
Palmer College of Chiropractic (IA, FL, or CA)	33 (48.5)
Royal Melbourne Institute of Technology University (Melbourne, Victoria)	5 (7.4)
New York Chiropractic College (Seneca Falls, NY)	5 (7.4)
Logan University (St. Louis, MO)	4 (5.9)
University of Western States (Portland, OR)	4 (5.9)
Other	17 (24.9)
Office geographical location	
United States, East	15 (22.0)
United States, South	12 (17.7)
United States, Midwest	12 (17.7)
United States, West	12 (17.7)
Canada	6 (8.8)
Other	7 (10.3)
Professional organization membership	
American Chiropractic Association, Council on Chiropractic Pediatrics	15 (18.3)
International Chiropractor Association, Council on Chiropractic Pediatrics	48 (58.5)
International Chiropractic Pediatric Association	16 (22.0)
Pediatric certification	41 (35)
Likelihood of participating in reporting and learning system	
Never	1 (1.2)
Doubtful	10 (11.9)
Possibly	53 (63.1)
Definitely	16 (19.0)

[a] Only 75/118 respondents completed the demographic portion of the survey, the last section.

Table 2. *Patient Characteristics as Reported by Respondents Compared With the National Board of Chiropractic Examiners, 2015 Practice Analysis of Chiropractic*[22]

Characteristics	Mean % (SD)	NBCE %
Female	61.3 (8.3)	59.0
Patient ages		
Newborn to 5	15.9 (15.0)	7.8
6-17	15.8 (9.2)	9.6
18-30	NA	15.6
18-39	27.2 (11.3)	NA
31-50	NA	28.5
40-64	28.5 (15.3)	NA
51-64	NA	22.7
65+	13.3 (9.2)	14.7
Reasons patients seeking SMT		
Low back pain	25.9 (13.5)	23.6
Neck pain	22.5 (11.6)	18.7
Preventive/wellness/no symptom	18.0 (15.8)	8.0
Headaches	12.1 (10.8)	12.0
Thoracic pain	11.2 (5.9)	11.5
Extremity pain	7.9 (5.3)	17.1
Other	11.5 (8.7)	9.1

NA, Not applicable; *NCBE,* National Board of Chiropractic Examiners; *SMT,* spinal manipulation therapy.

From the health care quality areas, *efficient* (ie, *ensures cost-effective care—avoids waste, overuse, and misuse of services*) was the only area with a significant difference ($P < .05$). Compared with 64% of AHRQ physician respondents, 83% of the pediatric DCs rated themselves as "very good" or "excellent."

Discussion

The awareness of patient safety and quality improvement issues is important for both the safety of patients and the advancement of health care. When a high-risk industry (such as aviation) has a strong and positive customer safety awareness and corresponding positive safety data, they earn the trust of the rest of society.[19] A similar construct could be proposed for health care; a strong, positive patient safety awareness and quality improvement with corresponding positive safety data may provide society with the assurance that undue harm will be minimized in the process of receiving that care.[20,21] As such, the purpose of this study was to assess the current state of patient safety attitudes and opinions for DCs. Although no patient safety reporting system exists within the chiropractic profession in North America, this survey found that attitudes and opinions of DCs in these 2 organizations demonstrate the potential readiness to sustain a reporting system that would make their patient safety and quality improvement initiatives more transparent. Findings were compared with both US medical offices and among DCs with and without pediatric certifications. Areas of improvement were discovered and future patient safety endeavors identified.[18]

Our findings revealed that compared with physicians in US medical offices (of all sizes) from the 2014 AHRQ comparative database, DCs in this survey have a more positive attitude. When comparing DCs in this survey with the AHRQ medical offices with only 1 provider (responses from all personnel within the office, not just the medical physician), high patient safety dimension scores were found in both groups. Differences found between both of these groups (medical physicians and medical offices with 1 provider) likely could be from the organizational differences between secondary care, where most patient safety research has been conducted, and primary care community-based offices, where most health care occurs.[19]

Within the chiropractic profession, there are options to obtain additional training and potential certifications through several postgraduate programs. Whether or not one has a pediatric certification, it is still possible to become a member of several professional organizations and

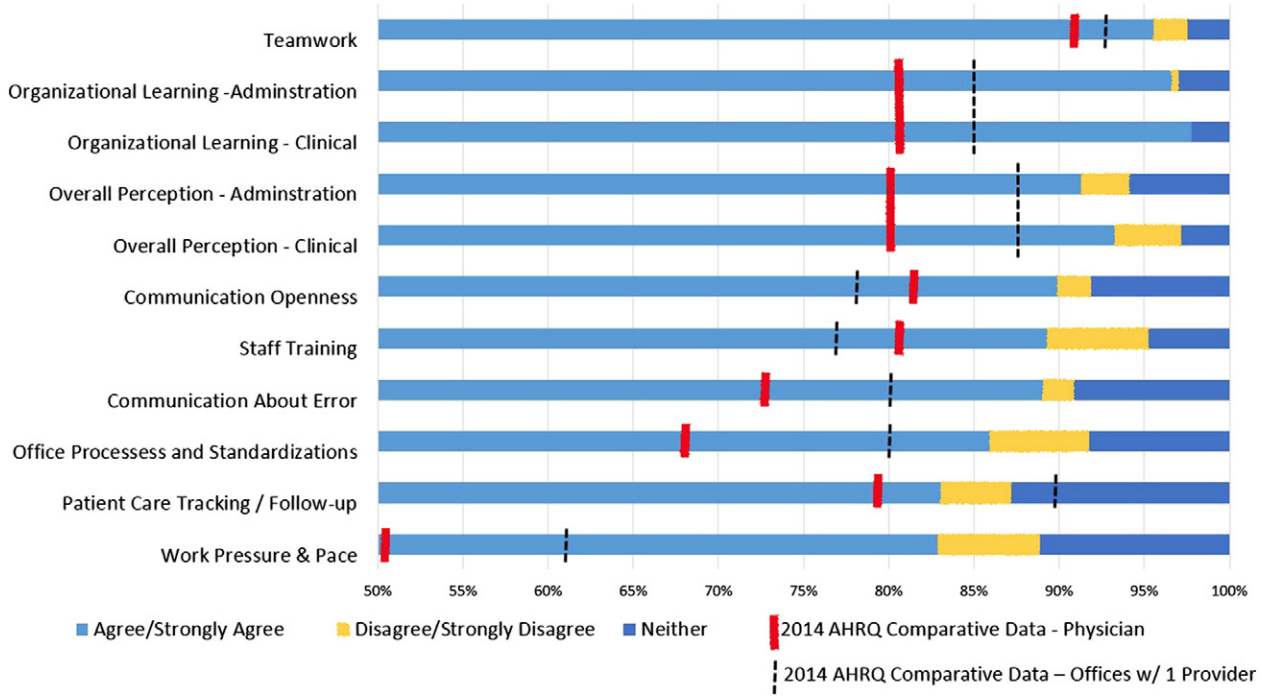

Fig 1. *Patient safety dimensions with 2014 Agency for Healthcare Research and Quality Agree/Strongly Agree referents.*

Table 3. *Information Exchange and Patient Safety Items*

Dimension	Pediatric Chiropractor	2014 AHRQ Physician
Information Exchange With Other Settings		
Outside labs/imaging centers?	89%	81%
Other physician offices? (AHRQ: Other medical offices/outside physicians?)	91%	80%
Other health care offices?	92%	NA
Insurance/third-party payors?	56%	NA
Other? (ie, attorneys, billing services, government)	76%	NA
Patient Safety Items and Quality Issues [a]		
Access to care: Patient was unable to get an appointment within 48 hours for an acute/serious problem.	11%	18%
Patient identification: The wrong chart was used for a patient.	1%	2%
Charts/records: Patient's chart/record was not available when needed.	2%	12%
Charts/records: Clinical information was filed, scanned, or entered into the wrong patient's chart/record.	2%	7%
Equipment: Office equipment was not working properly or was in need of repair or replacement.	2%	8%
Medication: Patient's medication list was not updated during his or her visit. [b]	40%	28%
Diagnostic test: Results from a lab or imaging test were not available when needed.	6%	24%
Diagnostic test: Critical abnormal result from a lab or imaging test was not followed up within 1 business day. [b]	22%	6%
Overall Office Self-Rating for Patient Safety and Quality Improvement		
Excellent	33%	28%
Very good	49%	43%
Good	19%	21%
Fair/poor	0%	8%

AHRQ, Agency for Healthcare Research and Quality.

[a] The negative composite score is those that responded "monthly," "weekly," or "daily." The presentation is the opposite of what is suggested by AHRQ.

[b] Of note, some providers felt these items were not applicable: medication (34%); diagnostic test (23%).

councils within associations whose mission includes the support of DCs treating the pediatric population. Two of the councils were used as the source population for this survey. When the nonrespondent analysis was conducted, it was found that respondents with a pediatric certification were 3 times more likely to have responded than those without the certification. Further investigation would be needed to explain this difference, but no other differences in response patterns were noted.

A potential area of improvement identified by respondents involved inquiry about medications. This was found to represent an important difference between physician

respondents in the AHRQ medical offices and our survey respondents, because it is not within the chiropractic scope of practice to initiate pharmacotherapy, and, therefore, respondents may not have felt that asking about it fell within their responsibilities. However, whether or not they prescribe medications, updating a medication list is relevant to DCs because some medication changes may affect the safety of SMT (eg, warfarin). Furthermore, even if spinal manipulation safety is not affected, knowledge of medication changes allows greater awareness of a patient's current health state. For this reason, we recommend that DCs update a patient's medication list at each visit.

A similar rationale may also explain the reason for the differences with *Diagnosis—Abnormal Results*, because DCs may not often be involved with outside laboratory facilities. When they are involved, it is recommended that procedures be put in place to notify patients promptly regarding the results of any findings, especially critically abnormal results.

There is value in developing a patient safety culture database for SMT providers, comparable to what AHRQ has developed for medical offices. Such a database would allow more advanced quality improvement initiatives to be developed and their impact measured. We recommend that future research initiatives on patient safety include this survey and the development of such a database.

In summary, pediatric DCs self-reported positive patient safety attitudes and opinions, which could indicate that this population is well suited to implement a patient safety reporting system. Reporting systems actively evaluate patient safety performance and provide qualitative data on medical errors, both of which can lead to improved patient safety.[1,4] As with most health care professions, this survey provided an insight into self-reported patient safety attitudes and opinions; its relationship to patient safety performance of pediatric chiropractic care remains unknown. The implementation of a reporting system would help provide insight into this topic. Future patient safety studies with pediatric DCs need to prospectively evaluate safety performance using a reporting system with direct feedback from the patient's perspective.

Limitations

Our target population was DCs who treat the pediatric population, with the source population being members of US pediatric councils with an active email address. It is possible that some DCs who treat children do not belong to either of these organizations, and they may have responded in a systematically different fashion. However, besides the 2014 Survey of Chiropractic Practices finding of gender and pediatric population differences, other provider and practice characteristics were comparable in that they had similar years in practice, total number of patient visits, and conferring institutions.[22]

This study had a risk of selection bias because of the low response rate. In spite of this, our analysis of potential nonresponse bias found few differences in responses to survey items between groups with higher vs lower response rates, suggesting that this was not an important source of bias in our findings. A final limitation is the risk for social desirability bias. When asking any sensitive question, such as in the patient safety and quality improvement items, social norms govern some attitudes such that respondents may misrepresent themselves to appear to comply with these norms.[23] We attempted to decrease this bias by keeping the survey both confidential and anonymous and by analyzing the data in an aggregate manner. Future patient safety studies with pediatric DCs need to prospectively evaluate safety performance, including direct feedback from the patient's perspective, as well as further use of this patient safety survey in other SMT organizations so that a directly relevant comparative database can be developed and used.

Conclusions

Although patient safety surveys have been developed and used in hospitals and more recently in other health care settings (eg, medical offices, nursing homes, pharmacies), this is the first survey to evaluate patient safety attitudes and opinions from the pediatric chiropractic profession. The survey revealed that respondents self-reported positively across most patient safety dimensions, leaving room for improvement in a few areas, such as medication documentation and abnormal diagnostic laboratory feedback.

Funding Sources and Conflicts of Interest

Support and funding was provided by a SafetyNET team grant for the development of the survey. The ACA and ICA's Council on Pediatric Chiropractic Executive Councils supported this research by distributing the survey to their members. This study was also supported by the Women's and Children's Health Research Institute, University of Alberta, and the Canadian Institutes of Health Research. K. A. Pohlman is supported by a NCMIC Educational Fellowship. L. Carroll and S. Vohra receive salary support as an Alberta Innovates–Health Solutions: Health Senior Scholar and Health Scholar, respectively. No other conflicts of interest were reported for this study.

Contributorship Information

Concept development (provided idea for the research): K.A.P., S.V., L.C., R.T., L.H.

Design (planned the methods to generate the results): K.A.P., S.V., L.C.

Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): S.V., L.C.

Data collection/processing (responsible for experiments, patient management, organization, or reporting data): K.A.P.

Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): K.A.P., S.V., L.C., R.T., L.H.

Literature search (performed the literature search): K.A.P.

Writing (responsible for writing a substantive part of the manuscript): K.A.P.

Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): K.A.P., S.V., L.C., R.T., L.H.

Practical Applications

- Doctors of chiropractic specializing in pediatric care self-report positive patient safety attitudes and opinions, making them well suited to implement a patient safety reporting system.
- Compared with the Agency for Healthcare Research and Quality medical office comparative database, most patient safety and quality improvement items were found to be improved or similar.
- Patient safety areas self-identified for improvement were *Patient Care Tracking/Follow-up*, *Medication*, and *Diagnosis*.

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Appendix F –

pdf of the published manuscripts from Chapter 4

Pohlman KA, Carroll L, Hartling L, Tsuyuki R, Vohra S. Barriers to implementing a reporting and learning patient safety system: pediatric chiropractic perspective. J Evid Based Complementary Altern Med 2016 Apr;21(2):105-109.

Journal of Evidence-Based Complementary & Alternative Medicine
2016, Vol. 21(2) 105-109

DOI: 10.1177/2156587215609191
cam.sagepub.com

Barriers to Implementing a Reporting and Learning Patient Safety System: Pediatric Chiropractic Perspective

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Abstract

A reporting and learning system is a method of monitoring the occurrence of incidents that affect patient safety. This cross-sectional survey asked pediatric chiropractors about factors that may limit their participation in such a system. The list of potential barriers for participation was developed using a systematic approach. All members of the 2 pediatric councils associated with US national chiropractic organizations were invited to complete the survey (N = 400). The cross-sectional survey was created using an online survey tool (REDCap) and sent directly to member emails addressed by the respective executive committees. Of the 400 potential respondents, 81 responded (20.3%). The most common limitations to participating were identified as time pressure (96%) and patient concerns (81%). Reporting and learning systems have been utilized to increase safety awareness in many high-risk industries. To be successful, future patient safety studies with pediatric chiropractors need to ensure these barriers are understood and addressed.

Keywords

pediatric, doctor of chiropractic, spinal manipulation, patient safety

Received May 4, 2015. Received revised September 5, 2015. Accepted for publication September 8, 2015.

A reporting and learning system is a method of monitoring the occurrence of clinical or administrative incidents that may affect patient safety. It is also a method of developing quality improvement strategies and system changes to address the root cause of an incident. Although it has been speculated that the implementation of nonpunitive reporting and learning systems have increased an open, constructive patient safety environment in hospital settings,[1,2] little has been done to implement these strategies in other settings or professions, especially in community-based health care offices.[3] It has been recognized that the majority of patient–provider interactions occur in community-based offices, such as family medical, allied health, and complementary and alternative medicine practices.[2,4,5]

In the chiropractic profession, Europe and Australia have a passive reporting and learning system, "The Chiropractic Patient Incident Reporting and Learning System" (CPiRLS). CPiRLS is an online forum that allows chiropractors to both voluntarily share patient safety incidents and comment on reported incidents in an anonymous and confidential manner.[6,7] CPiRLS is continuously monitored for emerging trends, and "Safer Practices Notices" are produced with additional evidence-based information about these emerging trends to enhance the learning opportunities for all CPiRLS participants. These learning opportunities are to help support an open, constructive patient safety, which is built around professionalism and trust.

The development of an open constructive patient safety environment can bolster public trust.[8] Chiropractors are in a position to be able to reflect on and recognize patient safety incidents and can help design system changes so that these conditions are reduced or mitigated. However, most providers do not have the knowledge or infrastructure to conduct such evaluations. SafetyNET is a team of international and interdisciplinary research leaders who are taking novel approaches to support a patient safety for spinal manipulation therapy providers, including chiropractors.[9] SafetyNET includes investigation of patient safety among chiropractors who treat the pediatric population.

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According to a recent US job analysis of the overall chiropractic profession, 17.1% of chiropractic patients are 17 years of age or less; the proportion of pediatric patients increases to 38.7% among chiropractors who have a specialized certification in pediatrics.[10,11] While CPiRLS does not have age restrictions, limited pediatric data have been reported in that system. Children are at risk for adverse events from health care, including spinal manipulation therapy,[12,13] which highlights the importance of patient safety initiatives for this vulnerable population.

The purpose of this cross-sectional study is to describe factors that may inhibit pediatric chiropractors' participation in a patient safety reporting and learning system. Potential barriers to participation have been identified through research in other health care areas and high-risk industries when implementing reporting and learning system, but to our knowledge, this has not yet been assessed among chiropractors treating a pediatric population.[14]

Methods

The assessment of barriers to participation in a reporting and learning system was one section of the "Survey to Support Quality Improvement" developed along with several other SafetyNET projects.[9] The original survey also measured the following: patient safety culture dimensions, patient safety items and quality issues, information exchange with other settings, and overall clinic self-ratings. The University of Alberta's Research Ethics Board reviewed and approved this study.

Population

All members of the 2 pediatric councils associated with the US national chiropractic organizations (American Chiropractic Association [ACA] and International Chiropractors Association [ICA]) were invited via email to complete the survey (N = 400). There were 2 exclusion criteria: (*a*) if the association did not have an active email address for the member (ie, the email was returned as undeliverable); (*b*) if the member was a study investigator. To maintain confidentiality and anonymity, the link to the survey was sent by each organization's executive committee to its own membership.

Study Design

The cross-sectional survey was collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at the University of Alberta.[15] REDCap is a secure, web-based application designed to support data capture for research studies, providing (*a*) an intuitive interface for validated data entry, (*b*) audit trails for tracking data manipulation and export procedures, (*c*) automated export procedures for seamless data downloads to common statistical packages, and (*d*) procedures for importing data from external sources. Participants accessed the survey from a link sent directly to their email account associated with their council membership. The email had a letter with information about the study and the first page of the survey included instructions for completing the survey. The link was sent 3 times, with at least 1 week between each mail-out.

Table 1. Demographic and Background Characteristics of Respondents (n = 69)[a].

Characteristics	n (%) or Mean (SD)
Gender—Female, n (%)	56 (74.7)
Number of years in practice, mean (SD)	18.75 (8.8)
Patient visits per week, n (%)	
<50	12 (16.0)
50-99	20 (26.7)
100-149	22 (29.3)
150-199	13 (17.3)
200+	8 (10.7)
Conferring chiropractic degree	
Palmer College of Chiropractic	33 (48.5)
RMIT University	5 (7.4)
New York Chiropractic College	5 (7.4)
Logan	4 (5.9)
University of Western States	4 (5.9)
Other (CMCC, LACC, Life, NUHS, NZCC, Parker, Phillip Institute, TCC, UBCC, UQTR, Northwestern)	17 (24.9)
Office geographical location	
USA, East	15 (22.0)
USA, South	12 (17.7)
USA, Midwest	12 (17.7)
USA, West	12 (17.7)
Canada	6 (8.8)
Other international	7 (10.3)
Professional organization membership	
American Chiropractic Association (ACA), Council on Chiropractic Pediatrics	15 (18.3)
International Chiropractor Association (ICA), Council on Chiropractic Pediatrics	48 (58.5)
International Chiropractic Pediatric Association (ICPA)	16 (22.0)
Other (European Pediatric Association)	1 (1.2)
Pediatric diplomate certification	41 (59.4)
Interested in participating in pediatric chiropractic research	44 (68.8)

[a]This was the final section of the survey; therefore, missing data were observed.

The initial list of potential barriers to reporting and learning system participation came from Benn et al,[14] who conducted a mixed methods approach to evaluate mechanisms of effective feedback from incident reporting systems in health care and experiences from established reporting systems in the transport domains and other high-risk industries. This initial list of barriers included fear of blame, time pressure, resource constraints, the perception that reporting is unnecessary, and a lack of clear definitions as to what constitutes a reportable incident.

Through focus group discussions with spinal manipulation therapy providers and SafetyNET team members (n = 15), the following modifications and additions were made to the draft survey: (*a*) examples of "resource constraints" (eg, Internet access, computer, etc) were added; (*b*) "the perception that reporting is unnecessary" was changed to "believe reporting is unnecessary"; and (*c*) additional potential barriers were identified, specifically, legal implications, regulatory implications, perceived inconvenience for the patients, potential to create negative perception in patients, and an "other, specify" category was added. All factors were rated by respondents on a 3-point scale: *Not at all*; *Yes, a little*; and *Yes, a lot*.

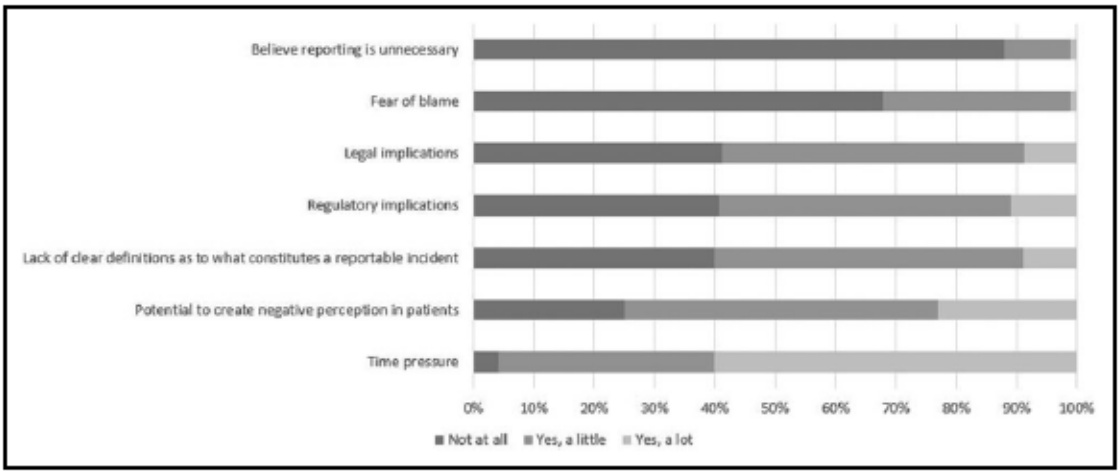

Figure 1. Bar graph of the survey factors that may inhibit provider participation in reporting and learning systems (n = 81).

Data Analysis

The data were analyzed with Stata13 Software (StataCorp) and Excel 2013. Participant characteristics and reporting and learning system factors were reported using descriptive statistics, specifically percentages. Potential nonresponse bias was assessed by comparing differences in the gender, location, and pediatric certification status of survey respondents and nonresponders in each organization's membership. If a difference was found, then each barrier was evaluated for significant differences ($P < .05$) between comparison (ie, gender, location, and/or pediatric certification).

Results

Of the 400 potential respondents from both organizations, the response rate for this section of the survey was 20.3% (n = 81). Table 1 provides a summary of demographic characteristics of respondents. Respondents were mostly females (74.7%), 29% treating between 100 and 149 patients per week, 27% treating between 50 and 99 patients per week, and work an average of 32.7 hours per week. The respondents had a uniform geographical representation from across the United States, with a few in other countries.

Barriers identified by respondents as potential inhibitors to participation in a patient safety reporting and learning system are summarized in Figure 1. The largest barrier cited was time pressure (96%) and patient-related concerns (average 80.5%). Most (68%) reported the fear of blame as not being a barrier to reporting. Few endorsed the statement "believe reporting is unnecessary" (12%).

Gender, location, and pediatric certification status of nonrespondents were available in aggregate fashion from each organization. There were no differences between respondents and nonrespondents with regard to gender and location of practice, but those with pediatric certification were more likely to respond than those not certified. In the ACA-CCP, those who are pediatric-certified were 3.13 (95% confidence interval = 1.44, 6.76) times more likely to respond to the survey than those who are not certified. In the ICA-CCP, those who are pediatric-certified were 3.23 (95% confidence interval = 1.71, 6.10) times more likely to respond to the survey than those who are not certified.

Responses of pediatric-certified and noncertified participants were very similar. Only one item, "Lack of clear definitions as to what constitutes a reportable incident," was different between the 2 groups ($P = .003$), with those with certification having a slightly higher mean score on that item (mean score of 1.9 vs 1.4, respectively).

Discussion

Awareness of potential barriers prior to the development of a pediatric chiropractic reporting and learning system allows for better design and implementation of such systems. Similar to other health care professions, high-risk industry and transport domains, we found that time pressure appears to be the largest barrier to participation in a reporting system.[14] This was not unexpected, as time pressure is always a concern as health care providers have many competing demands for their time and "busy-ness" is a socially acceptable excuse for nonparticipation in research.[16] However, it has been shown that if providers find value in a process and receive timely, usable information from it, they will also find the time to participate.[14,16] Reassuringly, providers stated that completing the data collection forms only added 30 to 60 seconds onto each patient visit, which should greatly enhance the feasibility of participation, even in busy offices.[17] Unlike other organizations, fear of blame and a belief that reporting is unnecessary were not identified as major barriers.[14] Absence of these potential barriers should hopefully support future participation in a reporting and learning system.

Concerns about patient perception were another reported barrier to participation. Our team's work in this area suggests this concern is not shared by patients. Patients that have participated in a pilot spinal manipulation therapy reporting system, conducted by our team, reported that instead of developing a negative impression of their provider (as was feared by some

respondents), they were pleased that their provider was willing to participate in a study looking directly at patient safety.[17]

The major limitation of this survey was potential for nonresponse bias. With only 20% response rate, there may be systematic differences between those who responded and those who did not. More specifically, it is possible that respondents to this survey were those chiropractors who were more or less positive about the importance of such a system. It is unknown how nonrespondents may differ with respect to potential barriers that would inhibit their participation in a reporting and learning system. Reassuringly, demographic characteristics of respondents to this survey were similar to those identified in a job analysis we conducted of chiropractors with a pediatric survey conducted in 2009.[11] Compared with the National Board of Chiropractic Examiners 2010 chiropractic job analysis, this survey had a higher proportion of females, which was expected for a pediatric-focused provider population.[10] Both of these previous surveys had similar numbers of graduates from Palmer College of Chiropractic (one of the larger chiropractor colleges in the United States), had similar number of years in practice, and had similar number of patient visits. To increase response rate in future cross-sectional surveys, one may consider using mixed methods (eg, mail and internet-based), decreasing the length of the survey, and increasing awareness/encouraging completion through use of telephone reminders.[18]

Conclusion

Reporting and learning systems have been utilized to facilitate an open constructive patient safety environment in many high-risk industries, including health care. For self-regulated professions, including chiropractic, ensuring patient safety is part of their regulatory mandate. This survey has identified potential barriers to participation in a reporting and learning system for the pediatric chiropractic profession, with the largest barriers identified being time pressure and the potential for patient concerns. Future patient safety studies with chiropractors who treat the pediatric population need to ensure these barriers are understood and addressed to be successful.

Acknowledgments

This study was done as a part of KAP's PhD research thesis. The authors would like to acknowledge the SafetyNET team grant for its contribution to the development of the survey.

Author Contributions

KAP conceptualized the overall project, designed and managed data collection, analyzed the data, and drafted the first manuscript. LC, LH, RTT, and SV participated in the design of the overall project and manuscript preparation. LC and SV advised on data analysis. LH and RTT are mentors who contributed equally to this work. All authors critically edited drafts of this manuscript and approved the final manuscript.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This study has been supported by the Women's and Children's Health Research Institute, University of Alberta, and the Canadian Institutes of Health Research. Katherine A. Pohlman is supported by an NCMIC Educational Fellowship. Linda Carroll and Sunita Vohra receive salary support as an Alberta Innovates-Health Solutions: Health Senior Scholar and Health Scholar, respectively.

Ethical Approval

The University of Alberta's Research Ethics Board reviewed and approved this study (Pro00043860).

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Appendix F –

pdf of the published manuscripts from Chapter 5

Pohlman KA, Carroll L, Tsuyuki RT, Hartling L, Vohra S. Active versus passive adverse event reporting after pediatric chiropractic manual therapy: study protocol for a cluster randomized controlled trial. Trials 2017 Dec 1;18(1):575.

Pohlman et al. Trials (2017) 18:575
DOI 10.1186/s13063-017-2301-0

Trials

STUDY PROTOCOL Open Access

Active versus passive adverse event reporting after pediatric chiropractic manual therapy: study protocol for a cluster randomized controlled trial

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Abstract

Background: Patient safety performance can be assessed with several systems, including passive and active surveillance. Passive surveillance systems provide opportunity for health care personnel to confidentially and voluntarily report incidents, including adverse events, occurring in their work environment. Active surveillance systems systematically monitor patient encounters to seek detailed information about adverse events that occur in work environments; unlike passive surveillance, active surveillance allows for collection of both numerator (number of adverse events) and denominator (number of patients seen) data.

Chiropractic manual therapy is commonly used in both adults and children, yet few studies have been done to evaluate the safety of chiropractic manual therapy for children. In an attempt to evaluate this, this study will compare adverse event reporting in passive versus active surveillance systems after chiropractic manual therapy in the pediatric population.

Methods/design: This cluster randomized controlled trial aims to enroll 70 physicians of chiropractic (unit of randomization) to either passive or active surveillance system to report adverse events that occur after treatment for 60 consecutive pediatric (13 years of age and younger) patient visits (unit of analysis). A modified enrollment process with a two-phase consent procedure will be implemented to maintain provider blinding and minimize dropouts. The first phase of consent is for the provider to confirm their interest in a trial investigating the safety of chiropractic manual therapy. The second phase ensures that they understand the specific requirements for the group to which they were randomized. Percentages, incidence estimates, and 95% confidence intervals will be used to describe the count of reported adverse events in each group. The primary outcome will be the number and quality of the adverse event reports in the active versus the passive surveillance group. With 80% power and 5% one-sided significance level, the sample size was calculated to be 35 providers in each group, which includes an 11% lost to follow-up of chiropractors and 20% of patient visits.

Discussion: This study will be the first direct comparison of adverse event reporting using passive versus active surveillance. It is also the largest prospective evaluation of adverse events reported after chiropractic manual therapy in children, identified as a major gap in the academic literature.

Trial registration: ClinicalTrials.gov, ID: NCT02268331. Registered on 10 October 2014.

Keywords: Pediatrics, Adverse event, Active surveillance, Passive surveillance

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Background

Pediatric chiropractic manual therapy and patient safety

Chiropractic manual therapy usually involves the therapeutic application of a force to a pre-determined body structure, which is typically a vertebral or extremity joint. There are numerous manual therapy variations with the velocity, amplitude, loading frequency, choice of lever, location, direction of load, and treatment frequency changing widely amongst the variations [1]. Spinal manipulation therapy (SMT), a type of manual therapy, is regulated for use in many professions (e.g., doctor of osteopathy, medical physicians, and physical therapists), but doctors of chiropractic (DCs) are the most likely to use SMT on a regular basis [2]. According to a 2015 practice analysis of United States DCs, 17.1% of chiropractic patients are 17 years of age or less; this increases to 38.7% amongst DCs who specialize in pediatrics [2, 3].

Adverse events after manual therapy, including SMT, have been investigated more thoroughly in adult patients than in children [4–7]. Several reviews of adverse events in children following manual therapy have identified rare serious adverse events, although the studies have been primarily case reports. The main conclusion from these reviews was that there is insufficient primary research on this topic in this population [8–10].

Patient safety performance – surveillance systems

To measure safety performance, including reporting of adverse events, many health care settings have implemented surveillance systems to report and learn from adverse events. When established, such systems can provide learning opportunities based on the information gathered [11].

These patient safety surveillance systems vary according to their purpose. *Active surveillance* systematically collects information from the provider about patient encounters, including adverse events, which enhances reporting and demonstrates a health care organization's commitment to patient safety [11]. Although active surveillance can generate higher quality and quantity of reports because both numerator and denominator data are known, the time and resources needed to properly execute an active surveillance reporting system are often limitations to its successful implementation.

Passive surveillance voluntarily collects adverse event information from the provider and is more commonly utilized throughout health care [12]. Typically, passive surveillance systems are conducted confidentially and sometimes anonymously, and some have been modified for Internet-based fora. These systems can also promote quality improvement by allowing for reporting of adverse events, near misses (an event that could have caused an adverse event, but did not), and unsafe conditions. Passive surveillance systems are relatively easy to implement and can collect reports from a broad range of topics and individuals [12]. However, their major limitations include under-reporting (quantity of reports), inadequate information (quality of reports), and limited knowledge of how many patients were exposed (denominator data). Practitioners involved with passive surveillance systems have reported that they commonly forget to write-up their report, are too busy to review others' reports, are not sure who is responsible to write-up a report, or do not report an event because it seemed trivial [13].

Study justification

Within the chiropractic profession, active surveillance reporting systems are not used routinely. A passive surveillance system for chiropractic care, called the "Chiropractic Patient Incident Reporting and Learning System" (CPiRLS), is currently being used in Europe and Australia [14, 15]. Although CPiRLS does not have any age restrictions, to date only limited pediatric data have been reported into the system, despite multiple calls for high-quality safety data about pediatric chiropractic manual therapy [8, 10].

Both active and passive surveillance methods have distinct advantages and limitations. The need for a direct comparison of the ability of active versus passive surveillance to report adverse events, and the need to better understand the patient safety performance in the use of chiropractic manual therapies for the pediatric population, led to the development of this cluster randomized clinical trial.

Study aim and hypothesis

Study aim: to compare the quantity and qualify adverse event reports after chiropractic manual therapy in children 13 years of age or under, using passive versus active surveillance reporting systems. *Hypothesis: DCs randomized to the active surveillance system will report more adverse events and will have better quality reporting than those randomized to the passive surveillance system.*

Methods

Study design

The study design is a pragmatic, superiority, cluster randomized clinical trial with a modified enrollment process to maintain participant blinding. DCs in private practice who treat children will be the unit of randomization with random allocation in a 1:1 ratio to active or passive surveillance reporting systems. Cluster randomization was chosen for practical reasons with the unit of analysis being reports from the individual chiropractic patient visits. The University of Alberta's Research Ethics Board reviewed and approved this study (Pro00027903). The trial has been registered at ClinicalTrials.gov (NCT02268331). The study

protocol was prepared using the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [16] (see Additional file 1) and also the "Methods" section of the Consolidated Standards of Reporting Trials (CONSORT) 2010 Checklist for reporting a cluster randomized controlled trial [17] (see Additional file 2).

Recruitment, randomization, and enrollment

Licensed DCs in the United States and Canada will be recruited from a variety of venues, including pediatric chiropractic-specific events and organizations, social media, and professional newsletters/magazines. Word of mouth and referrals from colleagues and past participants will also be source of referral into the study.

As shown in Fig. 1, DCs interested in the study will complete a demographic questionnaire and review/sign the initial consent document, which states that they are interested in enrolling in a study to report safety information from 60 consecutive pediatric visits. They will then be randomized to passive or active surveillance by the study coordinator (KAP). To promote baseline equivalence, we will stratify by DC's self-reported average proportion of pediatric patients seen (>20% versus ≤ 20%). To maintain allocation concealment, the REDCap (Research Electronic Data Capture) Randomization Module will be utilized with a random, variable, permuted block size, generated by an independent biostatistician [18]. Interested DCs will have study materials sent directly to their offices. This material includes the Consent Form that gives details on the surveillance system to which they were randomly assigned. DCs are considered enrolled in the study after that Consent Form is signed and they complete the online baseline survey, which collects additional demographic data and assesses patient safety attitudes [19]. Throughout study participation, to ensure compliance with study methods, regular communications will occur via email or telephone between the study coordinator (KAP) and the DC.

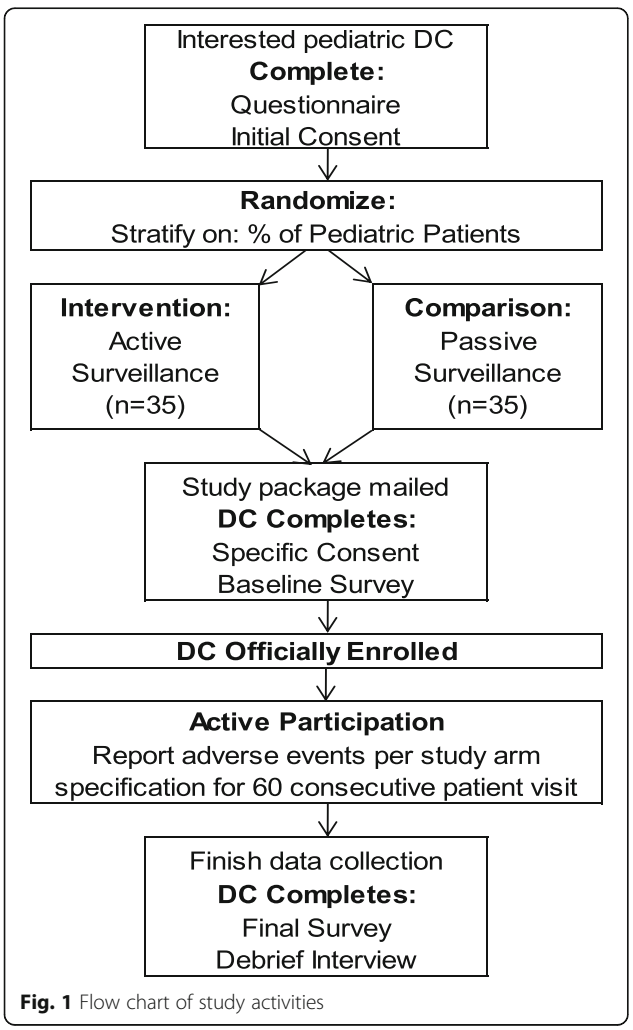

Fig. 1 Flow chart of study activities

Intervention arm: active surveillance

For 60 consecutive child patient visits, the parents/caregivers will be given an Information Sheet and asked to complete a pre-treatment form before the child sees the DC. As described in the Information Sheet and as stated on the top of all data collection forms, consent will be implied if the data collection forms are completed and returned. This ensures patient confidentiality. Patients and providers will each be given a post-treatment form to complete. The patient's post-treatment form is to be completed within 1 week and returned directly to the investigators using a postage-paid envelope. The DC's post-treatment form is to be completed immediately after the patient's visit. A more detailed form documenting adverse events will be completed by the provider if a moderate, serious or severe adverse event (see definitions in Table 1) occurs immediately following treatment or is reported to the DC at a later date. All forms (see Additional file 3) were modified from an ongoing, active surveillance study on SMT in Canada [20]. The modified forms were reviewed for content validation by a group of experts, which included the original developers, pediatric chiropractic experts, and caregivers of pediatric chiropractic patients.

Comparison arm: passive surveillance

The passive surveillance system will use the established *Chiropractic Patient Incident Reporting and Learning System* (CPiRLS) [15]. DCs will be asked to report adverse events that occur in 60 consecutive pediatric patient visits. In this system, only registered providers can submit, read or comment on reports. Participating DCs will be given a universal code to protect anonymity and will also be provided with the CPiRLS's "trigger list" to advise on what kinds of incidents/adverse events should be reported (see Additional file 4). Reports and comments submitted will be

Table 1 Definitions of terminology for study protocol [20]

Adverse event (AE)	Any unfavorable sign, symptom or disease temporally associated with the treatment, whether or not caused by the treatment. Specifically, any new symptom of moderate severity or a pre-existing symptom that is worse after treatment
Seriousness	*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 physician
	Severe: medically significant but not immediately life-threatening; temporarily limits self-care (e.g., bathing, dressing, eating) (for 5 years of age and older); *or* urgent or emergency room assessment sought
	Serious: results in death *or* a life-threatening adverse event *or* an adverse event 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 to conduct normal life functions; a congenital anomaly/birth defect
Causality (i.e., relatedness)	*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
	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
Preventability	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
Patient disposition	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

monitored by both the CPiRLS team and the study's investigators.

Adjudication

In both the active and the passive groups, when a moderate, severe or serious adverse event is identified, all information from the report will be reviewed independently by blinded content experts to evaluate the event according to the terminology outlined in Table 1 (causality, preventability, and patient disposition). Operational definitions for all terminology were determined through a consensus-based process by the SafetyNET team of manual therapy and patient safety experts [20, 21].

Outcomes

The primary outcome will be the number (the count) and quality (i.e., ability to meaningfully interpret/adjudicate, a binary variable) of the DC's adverse event(s) reports per patient visit and per patient in each group. Quality of adverse event reports will be assessed by the adjudicators' ability to meaningfully adjudicate the report (section above).

A secondary outcome is the change in patient safety attitudes for participating DCs. This will be measured in both groups using the Safety Organizing Scale [19], which is a nine-item survey with a 7-point rating scale (1 – "Not at all"; 7 – "To a very great extent"). This questionnaire is to be completed at two time points: at baseline (the online baseline survey prior to study enrollment) and after adverse event data collection is complete for each participating DC. In the active surveillance arm, additional variables to assess adverse events and associated factors for adverse events include: patient-reported adverse events, manual therapy treatment description, patient health history, and patient satisfaction [22].

Minimization of systematic error

To reduce potential respondent bias and maximize data integrity, a modified enrollment process will be utilized with a two-phased consent process. The first phase has a consent document focused on safety outcomes data collection rather than a comparison of the two different methodologies for collecting such outcomes. This focus is utilized to both blind participants to the comparison under evaluation and minimize dropouts as one arm (active surveillance) is more time intensive than the other (passive surveillance), but both arms are enhancements to current standard of North America practices. The second phase occurs after randomization with the consent document explaining the exact study procedures of the participant's allocated group without reference to the other group. There will be a debrief interview at the end of a DC's study participation to explain this

modified enrollment process and the procedure for both study groups.

Other study personnel who will be blinded in the study include: (1) patients, (2) an independent biostatistician for analysis, and (3) content experts involved in the adjudication process. Because of the major differences in data management, the investigator (KAP) responsible for study coordination cannot be blinded.

Clinical data management

All data will be entered and managed using REDCap electronic data capture tools, which is hosted at the University of Alberta [18]. REDCap is a secure, web-based application designed to support data capture for research studies.

For the active surveillance group, the data will be verified and validated, and the quality checked by a single study investigator (KAP) who will compare the patient's pre- and post-treatment forms to ensure that inconsistencies are corrected. For audit purposes and to ensure transparency, all changes made will be recorded with the time and date and user ID. The study investigator will discuss any queries with the study team with query resolutions recorded.

Statistical methods

The count of reported adverse events (any severity) in each group will be expressed with percentages and incidence estimates, and their 95% confidence intervals (CIs). The primary analysis will compare the cumulative incidence of adverse event reports in active versus passive surveillance. Because the outcome is number of events, it is assumed that the data will follow a Poisson distribution. Hence, a Poisson regression with log links will be used in general estimating equation (GEE) analyses with an appropriate sandwich estimator to take into account the DC cluster correlation. Groups will be compared using an intention-to-treat analysis.

Sensitivity analysis, using the same GEE analyses as above, will be conducted for reports that were not adjudicated (because of uninterpretable adverse events) and differences in how missing data were handled (i.e., imputing using average incidence and highest incidence). The binary variable expressing if the quality of the adverse event report allowed for meaningful interpretation/adjudication will be evaluated using the McNemar's exact test because of the expected rarity of reports and cluster correlation.

Secondary analysis will address differences in the count of adverse event reports by patient-only, provider-only, and those reported by the active surveillance versus the provider-reports in the passive surveillance. Like the primary analyses, Poisson regression with log links will be used in GEE analyses to account for cluster-specific methods. Patient safety attitudes will be measured before and after participation and compared across surveillance groups.

Other planned secondary analyses are designed to identify factors associated with adverse events from the data gathered in the active surveillance group. Potential factors for adverse events include patient characteristics (e.g., age, presenting condition, sex, health history), provider characteristics (e.g., years in practice, specialty training), and treatment provided (e.g., high-velocity, low-amplitude or other). With the adverse event reports categorized by their severity (i.e., none, mild, moderate, severe, serious), logistic regression analyses will be used to model factors associated with the adverse events. If the number of moderate, severe, and serious events are small, the outcome will be dichotomized as any adverse event versus no adverse event. If numbers of moderate, severe and serious events are sufficiently large, multivariable polytomous logistic regression will be used.

Planned exploratory analyses include: (1) subgroup analysis for providers with a specialty pediatric certification and number of reported adverse events (i.e., the primary outcome); (2) assessment of the feasibility to implement a surveillance system within chiropractic offices from individual provider feedback; and (3) review of debrief interview to gain insight into participating DCs' overall thoughts on the study, including barriers to implementation, perceived benefit of participating, and being blinded to intervention. An assessment of bias will be conducted with responding and non-responding patient demographic characteristics for the active surveillance group. All analyses will be conducted using Stata version 13 (StataCorp LP, College Station, TX, USA).

Sample size

An estimated active surveillance reporting rate of 4.3% and intracluster correlation of $\rho = 0.13$ were based on a pilot study of a similar active surveillance used within the chiropractic profession in Canada [20, 21]. We assumed a passive surveillance reporting rate of 0.53%, based on prior academic literature [8]. A one-sided significance level was utilized as it seems reasonable to believe that passive surveillance will result in under-reporting of adverse events [23]. We calculated that a sample size of 35 providers in each group, with each DC collecting data from 60 pediatric patient visits, and 5% one-sided significance level, would lead to 80% power. This includes an anticipated loss to follow-up of 11% of DCs and 20% of patient visits.

Discussion

This study will be the largest prospective evaluation of adverse events reported after chiropractic manual therapy in the pediatric population, which has been identified as a major gap in the academic literature [8–10, 24]. This randomized cluster trial assesses the effectiveness

of two different surveillance methods to collect observational safety data on a topic that is clinically relevant. To our knowledge, this is the first study to do a direct comparison of active versus passive surveillance reporting of adverse events.

The chiropractic profession treats children [3, 25]; therefore, it has a responsibility to ensure proper safety evaluations. The attitudes and opinions of DCs, who are interested in pediatric treatment, for implementing safety performance systems were evaluated in 2014. The survey identified a robust patient safety climate with time pressure as the barrier of most concern to participants [26]. Time pressure is a common barrier for health care provider participation in research, as "busy-ness" is seen as a socially acceptable excuse for declining "extra" activities [27]. Our study protocol took this concern into consideration. When pilot tested, passive surveillance was found to add 30 s per patient visit while active surveillance added only 2 min [20].

Aside from reports of actual adverse events that are collected in this study, each surveillance method also collects additional patient safety information. While not the primary outcome, this study will also clearly describe and report these differences. Such examples from the passive surveillance group includes administrative, incidental patient safety incidents (e.g., use of the wrong clinical file or tripping over office equipment) or "near misses"/events, which could have caused an adverse event, but did not. For the active surveillance group, information will be sought not only from the DC, but also directly from the patients; patient-provided information can be compared to that information known by the provider. These differences are unique to each surveillance group and should be taken in consideration when an organization is deciding on what method to use to evaluate adverse event.

Beyond the significance of the study's specific aims, the study procedures also include several notable methodological considerations, such as the attention to outcome measurement and a modified enrollment process to maintain participant blinding. This study started with a content validation of the data collection instruments to ensure that they will collect the intended information and that it will be easily understood by the chiropractic pediatric patient's parent/caregiver [28].

Modified enrollment procedures have been utilized most commonly to avoid biases that occur with non-placebo-controlled trials [29]. This study will use a modified enrollment procedure, a two-stage consent process, to ensure that provider blinding is maintained and dropouts minimized. To avoid ethical concerns regarding enrolling and randomizing providers without their consent, consent is sought in two stages: first, providers consent to participation in a study on pediatric patient safety and chiropractic manual therapy. The second consent will give full disclosure of their specific study procedures. When participant's complete the study, a debrief interview will unveil the two groups and the purpose for not disclosing this information earlier.

Barriers to study completion

Possible barriers to the study's implementation will be the willingness of DCs to participate in research and their adherence to study procedures. Adherence will be addressed by actively following up on DCs interested in this study's topic, engaging front desk personnel in study processes, and assuring that the study protocol is understood. Despite these precautions, compliance is expected to be challenging, specifically for chiropractic practices that are assigned to the active surveillance group. Dropouts have been taken into account in the sample size calculations.

Another concern regarding the study's implementation is the possibility of a low response rate for the active surveillance arm's post-treatment form, to be completed by the patient's caregiver. The pilot study found that DCs who encouraged their patients to complete the data collection instruments had a better response rate [20, 21].

Trial status

This is the first version of the study protocol. Modification or amendments that have an impact on the conduct of the study will be documented and described in further publications. At the time of protocol submission, this trial was in active recruitment.

Additional files

Additional file 1: SPIRIT 2013 Checklist. (PDF 48 kb)
Additional file 2: CONSORT 2010 Checklist. (PDF 137 kb)
Additional file 3: Active Surveillance Study Forms. (PDF 23072 kb)
Additional file 4: Passive Surveillance Trigger List. (PDF 365 kb)

Abbreviations

CPiRLS: Chiropractic Patient Incident Reporting and Learning System; DC: Doctor of chiropractic; GEE: General estimating equation; REDCap: Research Electronic Data Capture; SMT: Spinal manipulation therapy

Acknowledgements

This project was done as part of a team grant, SafetyNET; the authors would like to thank all principal investigators, Drs. Kawchuk, Caulfield, Boon, and O'Beirne, as well as members of Team #3 (M Funabashi,, for their insightful comments and suggestions to improve the project). In addition, the authors would like to acknowledge the ACA and ICA Council on Chiropractic Pediatrics for their support reviewing the protocol and with recruitment of physician. Lastly, the authors acknowledge, Dr. Elise Hewitt, a pediatric chiropractic specialist who supported the study design upon inception, was instrumental in pilot testing and recruitment, and is a leader and mentor within the chiropractic profession.

Funding

This study has been supported by the Women's and Children's Health Research Institute, University of Alberta (RES0013182) and the Canadian Institutes of Health Research (TGSTAIR 112758). L Carroll and S Vohra

received salary support as an Alberta Innovates-Health Solutions: Health Senior Scholar and Health Scholar, respectively.

Availability of data and materials
Not applicable

Authors' contributions
KAP, SV, and LC were responsible for study conception. Trial design was the responsibility of all authors. KAP was responsible for conducting the trial and writing the manuscript with critical review and contributions by SV, LC, RT, and LH. All authors read and approved the final manuscript.

Ethics approval and consent to participate
The University of Alberta's Research Ethics Board reviewed and approved this study (Pro00027903); no other ethical review is necessary as each participant was in private practice. Informed consent will be obtained from all participants.

Consent for publication
Not applicable

Competing interests
The authors declare that they have no competing interests.

Publisher's Note

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Received: 24 October 2016 Accepted: 21 October 2017
Published online: 01 December 2017

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