

EXPLORING PATIENT SAFETY ISSUES IN MASSAGE THERAPY AND
UNDERSTANDING PATIENT SAFETY INCIDENTS (ADVERSE EVENTS)

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By

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ABSTRACT

Background

Despite the presence of over 17,000 massage therapists (MTs) within regulated provincial healthcare systems in Canada, a dearth of information on patient safety persists. The views of massage therapy (MT) experts about patient safety is unknown while classification of adverse events (AEs) is not standardized. The objectives of this study are: 1) To explore MT regulators' views on patient safety in the practice of MT; 2) To explore taxonomies for describing patient safety incidents (PSIs) or AEs in the published literature and compare to international frameworks and 3) To reflect on how the findings of the study aid the patient safety culture of MT in Canada.

Methods

A mixed methods approach included a focus group with 10 members of the College of Massage Therapists of British Columbia. Data was analyzed with thematic analysis. Then a scoping review in ten peer-reviewed electronic databases limited to English as well as bibliographies, citations and key authors was conducted. Inclusion/exclusion criteria were applied to all records independently by two reviewers and data was extracted and charted. Consultation with stakeholders facilitated knowledge transfer.

Results

The results of the focus group investigation show that MT can usefully be characterized as a pantheon built on a foundation of trust, and supported by three pillars: a well-defined role for the massage therapist, clear treatment expectations, and protection of unique patient vulnerability. In the scoping study, the titles of 967 articles were identified and their abstracts reviewed; 67 articles were retrieved and read. 14 of them met the final inclusion criteria and were retained for analysis. Mapping shows lack of uniformity but shared elements of AE classification that conform to international standards. Stakeholders recommended translating this new knowledge widely.

Conclusions

A lack of standardization of operational definitions of the Canadian MT provider and the intervention impedes MT research and a robust patient safety culture. The findings of this study demonstrate the views that massage can hurt and it can harm. Discourse on patient safety is fraught with competing interpretations. There is a need for a Canadian MT specific patient safety framework including standardization in curriculum, education and licensing.

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I also want to thank my family for their never-ending patience, support, and love.

DEDICATION

To the loving memory of my father.

To my mother, who models living a loving life.

To my son, who brings inimitable joy.

And to my tribe, for whom I am so grateful.

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LIST OF ABBREVIATIONS

AE	Adverse event
ARAQ	Adverse Reactions to Acupuncture Questionnaire
CAHC	Complimentary and Alternative Health Care
CAM	Complimentary and Alternative Medicine
CIHC	Complimentary and Integrative Health Care
CIHR	Canadian Institute of Health Research
CMTBC	College of Massage Therapists of British Columbia
CMTO	College of Massage Therapists of Ontario
CPSI	Canadian Patient Safety Institute
CRDCN	Canadian Research Data Centre Network
CRLS	Chiropractic Reporting and Learning System
ESO	European School of Osteopathy
FOMTRAC	Federation of Massage Therapy Regulatory Authorities of Canada
ICD	International Classification of Diseases
ICF	International Classification of Functioning, Disability and Health
ICH	Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICPS	International Classification of Patient Safety
IKT	Integrated Knowledge Translation
IMPS	Information Models for Patient Safety
KT	Knowledge Translation
MIM	Minimal Information Model
MT	Massage Therapy
MTs	Massage Therapists
NRS	Numeric Rating Scale
PSI	Patient Safety Incident
RMT	Registered Massage Therapist
SMT	Spinal Manipulative Therapy
TCM	Traditional Chinese Medicine
WHO	World Health Organization

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CO-AUTHORSHIP STATEMENT

The findings of this study are written as two separate but interrelated manuscripts (Chapters 4 and 5). Both manuscripts are in preparation for submission to peer-reviewed academic journals but have not yet been submitted for review.

Chapter 4

Gowan D, Leis A. Perspectives on Adverse Events in Massage Therapy: Canadian regulators' views on patient safety (unpublished).

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Chapter 5

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CHAPTER 1: INTRODUCTION

Science is not about control. It is about cultivating a perpetual condition of wonder in the face of something that forever grows one step richer and subtler than our latest theory about it. It is about reverence, not mastery.

—Richard Powers

1.1 Introduction

For decades, discussion among members of the Canadian community of massage therapists (MTs), massage therapy (MT) students, regulators, association leaders, and educators has focused on the lack of national standardization of operational definitions for both the massage provider and the intervention. Dialogue about the need for standardization in title, licensing and practice permeates professional discourse formally within MT organizations and informally through social media. At the same time, the numbers of massage therapists practicing in Canada and the number of legislatively authorized regulatory bodies has risen in recent decades. It is the long history of unresolved issues within the field in Canada and the potential ramification on public safety that led to the research conducted here. This study seeks to better understand the important issues regarding patient safety in MT in Canada by eliciting the views of Canadian MT authorities in the field and to investigate what the research literature of massage and other health care professions reveals about how adverse events are identified, defined and classified in the study of patient safety.

The research presented here stems from research consultation and participation of valued stakeholders within the Canadian massage therapy community, of which the author has been a part for thirty years. This approach allows an integrated attempt toward filling some of the knowledge gaps that may bar consensus on standardization of massage provider and intervention to serve future research, practice, policy, and education. A thorough understanding of the current issues in the field regarding title and licensing is needed to foster improved knowledge about safety, which is the topic of this study. These issues are discussed next in this introduction as background to the topic of MT and patient safety in Canada. A brief discussion of patient safety

in the healthcare context follows in order to provide important background information. Two important aspects of the discourse on massage and patient safety are then introduced to provide the foundation on which subsequent chapters build. These two aspects are: current views regarding the nature and extent of patient safety incidents and research issues in the study of safety in massage and manual therapies. The rationale for the study follows in the next section. This chapter concludes with a description of the organizational structure of the dissertation and declaration of the contributions of the primary investigator.

1.1.1 AN INTRODUCTION TO MASSAGE THERAPY IN CANADA

Lack of Standardization of Massage Intervention across Canada

The College of Massage Therapists of Ontario (CMTO), the oldest and largest of the Canadian regulatory authorities defines the scope of practice of massage therapy this way:

The practice of Massage Therapy is the assessment of the soft tissue and joints of the body and the treatment and prevention of physical dysfunction and pain of the soft tissues and joints by manipulation to develop, maintain, rehabilitate or augment physical function, or relieve pain (1).

The CMTO describes the method of treatment to be mainly ‘hands-on’ manipulation of the body with ‘Swedish’ massage being the most common approach but also hydrotherapy, remedial exercise, and client education (1). It must be noted that the term ‘manipulation’ is conceptualized differently by MT authorities compared to its common use in fields such as physiotherapy in Canada. For example, Canadian research from physiotherapy operationalizes manipulation as “a high-velocity, low-amplitude movement of the joint that takes the joint beyond its normal physiologic range” (2). This movement technique is not in the scope of practice of Canadian massage therapists, a point that is made clear in the legislative documents in the regulated provinces.

For example, The Massage Therapists Regulation of the British Columbia *Health Professions Act* states that:

"massage therapy" means the health profession in which a person provides, for the purposes of developing, maintaining, rehabilitating or augmenting physical function,

or relieving pain or promoting health, the services of (a) assessment of soft tissue and joints of the body, and (b) treatment and prevention of physical dysfunction, injury, pain and disorders of soft tissue and joints of the body by manipulation, mobilization and other manual methods. (3)

Included in the limits or conditions imposed on the registrants is that they may not “move a joint of the spine beyond the limits the body can voluntarily achieve using a high velocity, low amplitude thrust” (3). Similarly, the College of Massage Therapists of Newfoundland and Labrador state that:

"massage therapy" means the assessment of the soft tissue and joints of the body and the treatment and prevention of physical dysfunction and pain of the soft tissues and joints by manipulation to develop, maintain, rehabilitate or augment physical function or to relieve pain or to promote health. (4)

The College of Massage Therapists of New Brunswick define the practice with explicit consideration of the need to define the term “manipulation” and state that the practice of massage therapy is:

the assessment of the soft tissues and joints of the body and the treatment and prevention of physical dysfunction and pain of the soft tissues and joints by mobilization to develop, maintain, rehabilitate or augment physical function, or relieve pain, and does not include manipulation or movement of the spine or the joints of the body beyond an individual’s usual physiological range of motion, using a high velocity, low amplitude thrust. (5)

It should be noted also that the term “soft-tissue manipulation” (STM) is commonly used to describe a portion of what massage therapists do (6) much like “spinal manipulation therapy” (SMT) is commonly used to describe a portion of other manual therapy providers work (2). As can be seen, in the four Canadian provinces in which MT is a regulated healthcare profession, massage therapists and the authorities who regulate them use the term manipulation but do not mean “high-velocity/low amplitude” thrusting techniques. Therefore, the terminology of

“manipulation” is used differently across massage and other professions that use manual therapy for patient care.

Other complementary modalities that are not contained within the defined scope but are permitted to be incorporated into assessment and treatment include, for example, aromatherapy and yoga (7). The CMTO also lists modalities that are deemed outside of scope and therefore must not be provided as massage therapy by registrants. Examples include sound therapy, energy healing practices such as non-contact Reiki, and traditional healing practices like Traditional Chinese Medicine (8).

As do other professionals that use manual therapy in patient care, Canadian MTs utilize both “hands-on” passive approaches such as soft-tissue manipulation, range of motion techniques, and joint mobilization along with “hands-off” active strategies like exercises for home care (9). Similarly, MTs use “communication skills such as; empathy, listening, education, positive attitude, and reassurance” (9). Massage MT also often categorized as Complementary and Alternative Medicine (CAM) (10) although the alliance with CAM or with conventional healthcare is controversial and often polarizing (11). Opposing viewpoints on desired identity and the degree of regulation required are rampant in the field. Opinions vary from a desire to be included in mainstream healthcare to a more liberal view of ‘hands-on’ intervention that seeks to provide alternative options from a standard biomedical model.

In Canada, because the practice of MT is not regulated in every province and territory, the role of MTs in healthcare lacks uniform expression. A lack of a standardized operational definition of the intervention of massage therapy across the nation leads to confusion among the public on what constitutes MT. Lack of uniformity also influences the extent to which MTs are included as members of interprofessional teams (12). It also impacts the conduct of research and the collection of data. Information from the research of other professions that use ‘hands-on’ or manual means for patient care and have standardized operational definitions for the provider and the intervention may help to lead research efforts in MT.

Professional associations exclusively representing MTs in unregulated Canadian provinces continue to engage with provincial governments to pursue legislation regulating MT. In addition to varying levels of provincial regulation, uneven provincial competency requirements, and inclusion or exclusion in collaborative practice, the development of a uniform professionalization ethos and culture of inquiry is emerging as an important issue (13, 14). In North America, the professional practice of MT takes place within a complex historical, social, and political context. Although the therapeutic use of massage is based on millennia of experience in the art and science of healing, the identity or archetype of the modern massage therapist exposes conflicted views intraprofessionally as MT seeks to define itself (6, 11, 15, 16). The development of a patient safety culture, with the infrastructure to accurately and uniformly identify, monitor, and learn from harm when it occurs, is an important part of the professional development of any health profession. MT lags behind other healthcare professions in scholarship and research related to patient safety.

Lack of Standardization of Title

In Canada, over 17,000 MTs provide MT as part of provincial healthcare systems under the legislatively derived authority of regulatory Colleges (17, 18). MTs are regulated healthcare providers in the provinces of Ontario, British Columbia, Newfoundland/Labrador, and New Brunswick. Therefore, the title ‘massage therapist’ (MT) or ‘registered massage therapist’ (RMT) are reserved by law for registrants of the regulatory bodies in only these four Canadian provinces. It can be estimated that in addition, approximately ten thousand MTs and RMTs provide MT subject to varying standards as voluntary registrants of member service associations in provinces where the profession is not regulated as a health profession (19, 20). The exact number is difficult to determine as member service organizations and holistic health organizations, but not Colleges, may represent practitioners with varied training and credentials in massage and various methods including, but not exclusive to, MT. Examples of the holistic health practices that are most commonly represented in volunteer membership outside of MT exclusive organizations include reflexology, reiki, Thai massage, and craniosacral therapy (see glossary of practice terms in Appendix H (19)).

Canadian MTs in regulated provinces are supported and bound by uniform competency, training, practice and discipline standards with public safety served through the legislated regulation that defines the intervention and the provider. Provincial *Acts* governing the health professions, including MT, serve the public interest by way of title protection to identify College registrants: specifically, only members of the regulatory College in the Province can call themselves RMTs or MTs. The Federation of Massage Therapy Regulatory Authorities of Canada (FOMTRAC) describes an RMT as a healthcare provider who “helps people by maintaining, rehabilitating, and augmenting physical function, or by relieving pain or promoting health” (21). FOMTRAC states that RMTs do so by “assessing soft-tissue and body joints, and by providing treatment that includes manipulation, mobilization, and other manual methods” (21).

The absence of legal title protection nationally, an important aspect of health care regulatory legislation in Canada, contributes to the variance in whom the title of MT and RMT describes (22). Uniform standards, entry-to-practice competency evaluation, and patient safety complaints and discipline processes also serve the public interest in the provinces where MT has self-regulatory status from the appropriate government Ministry. In unregulated Canadian provinces and territories thousands of practitioners practice under the unprotected title of massage therapist and/or registered massage therapist. Thus, legislated healthcare practice quality and safety support measures are unavailable to a large number of professional MTs and their patients in Canada.

1.1.2 INTRODUCTION TO PATIENT SAFETY IN HEALTHCARE

Patient safety, defined by the World Health Organization’s Working Group on Methods and Measures for Patient Safety, is the reduction of the risk of unnecessary harm associated with healthcare (23). Healthcare-related harm is an important topic in population health and health services research both globally and within Canada (23, 24). The Canadian Patient Safety institute extends the definition of patient safety to include “the use of best practices shown to lead to optimal patient outcomes” as well as “the reduction and mitigation of unsafe acts within the healthcare system” (25). Research aimed at understanding the nature and extent of harm experienced by patients is of necessity predicated by the rigorous definition and classification of adverse events and the development of systems to identify, describe, and track incidents of harm.

This is a burgeoning area of investigation on a global scale (26). The use of simple descriptive taxonomies to collect safety event data was identified as one of the main strategies to advance methods and measures in patient safety research (23).

Healthcare providers, researchers, and policy-makers share the burden of understanding and learning from harmful events in health services delivery. Research evidence to support appropriate identification and mitigation of adverse patient outcomes in all forms of healthcare is needed to support decision making. This information is needed by practitioners, patients, healthcare profession leaders, and politicians.

Harm is defined as “the impairment of structure or function of the body and/or any deleterious effect arising therefrom, including disease, injury, suffering, disability and death” (27). Notably, there is a shift in language and terminology away from the common term “adverse events” to “harmful incidents” to denote an incident that resulted in harm to a patient (27). The terms will be used interchangeably in this dissertation in order to accommodate the use of the term “adverse events” in the bulk of the published medical literature but preference is given to the contemporary World Health Organization (WHO) term “harmful incident or patient safety incident.” (26) This nomenclature is also preferred by the Canadian Patient Safety Institute in the development of patient safety resources and tools (25). The WHO International Classification of Patient Safety (ICPS) Conceptual Framework offers the following definition for the term: “A patient safety incident is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. The use of the word ‘unnecessary’ in this definition recognizes that errors, violation, patient abuse and deliberately unsafe acts occur in healthcare” (28).

The definition of concepts regarding safety and harm data provided in both the Cochrane Handbook for Systematic Reviews of Interventions (29) and the CONSORT extension for reporting harms in randomized controlled trials (30) illuminate important points related to intentionality, causality, and the tonal qualities of outcomes (i.e. beneficial or harmful). Specifically, according to these sources, an adverse event is an unfavourable outcome that comes during or after an intervention but is not necessarily caused by it. The terminology of adverse effect and adverse reaction denotes a definitive causal relationship between the intervention and

the outcome. For example, a side effect is unintended but could be beneficial rather than adverse. Lastly, the term “complication” is suggested for use only with invasive types of interventions such as surgery.

In patient safety research, the study of harm experienced by patients in hospital settings has been well studied and constitutes much of the literature on adverse events. The WHO is now promoting a shift in focus from hospitals and surgeries to include community-based healthcare such as family practices, pharmacy, midwifery, and home care (31). The need to create an improved patient safety culture is seen as a priority goal in developed countries (32).

1.1.3 AN INTRODUCTION TO THE DISCOURSE ON THE NATURE AND EXTENT OF PATIENT SAFETY INCIDENTS

In the broad healthcare sphere, high-profile or “egregious” cases of patient harm such as wrong-site surgery in medicine or death associated with cervical spine manipulation (33) tend to attract media attention even though the frequency of occurrence is thought to be rare (34). As the patient safety gaze turns toward community-based care, the importance of understanding the contribution of less severe but more common harmful incidents to the burden of patient safety becomes more evident. To illustrate, Baker notes that in patient safety research “many patient safety events are rare, but high frequency but lower harm, immediacy or causality incidents may contribute more harm overall than high profile, rare events” (23) (p.12).

As the literature specific to MT safety, especially Canadian MT safety is scant, it is valuable to provide information from other fields that use manual therapy methods as an intervention in order to introduce the prevailing discourse related to the nature and extent of safety incidents and to learn from professions with a broader research base. While the focus of the research project described in this dissertation is not on risk per se but rather how potentially harmful outcomes are described, it is useful to understand how other professions frame issues related to patient safety and adverse events. For example, Gorrel et al. in a recent systematic review of adverse event reporting in spinal manipulative therapy research (SMT), state that “while maintaining a focus on catastrophic events is understandable, quantifying the incidence of non-catastrophic adverse events is also necessary to accurately inform patient choice” (35) (p 1144). Thiel et al.

similarly advocate the value of investigating not just serious but also minor adverse events in SMT of the cervical spine in their prospective study to estimate risks along the spectrum of treatment outcomes (36). They conclude that the risk of serious events is low to very low but minor incidents such as worsening of symptoms and/or onset of some musculoskeletal discomforts such as headache, fainting, and numbness are considerably higher.

In their systematic review of adverse events associated with manual therapy provided by regulated healthcare practitioners in the UK, Carnes et al. conclude that the “risk of major adverse events with manual therapy is low, but around half of manual therapy patients may experience minor to moderate adverse events after treatment. In comparison, the relative risk of adverse events appears greater with drug therapy but less with usual care” (37) (p355). In their systematic review on adverse events associated with the use of cervical manipulation and mobilization for the treatment of neck pain in adults (38) and in another commentary article (39), Carlesso et al. concur with three important points: that mild adverse events are common in manual therapy treatment, that serious events are rare and yet the focus of most discussion, and that there is a lack of standardized definitions and classifications to aid the gathering of this information. These points are echoed by McDowell et al. in their narrative review on the classification of adverse reactions to acupuncture (40).

A study by Paanalahti et al. also describes AEs in a comparative effectiveness trial on manual therapy, defined as treatment including SMT, mobilization, muscle stretching, and massage (41). These authors also found that the occurrence of AEs did not differ between groups when SMT or stretching was excluded but rather that AE were common and transient across the treatment arms. Rajendran et al. conducted a study of post-treatment outcomes in an osteopathic teaching clinic and found that over eighty percent of patients experience mild pain, stiffness, or other symptoms after care but that three-quarters of patients reported feeling better from the treatment at one week post-treatment (42). Numerous studies with various methodologies from case reports to prospective designs of acupuncture risks conclude that serious harm is rare but that mild transient AEs are common (43).

“Every healthcare intervention comes with the risk, great or small, of harmful or adverse effects”: this statement introduces the need to consider adverse effects in the Cochrane Handbook for Systematic Reviews of Interventions (29) (section 14.1.1). In Canada, experts in health profession regulation assert that “[h]ealthcare is ‘risky business,’ a field of practice that demands high levels of knowledge and skills” (44) (p.3). While patient safety and quality improvement is clearly a priority in the delivery of healthcare in Canada and worldwide (45), just ten years ago it was noted that one “may be surprised and even disappointed by the paucity of high quality evidence for many patient safety practices. The field is young” (46) (p2).

1.1.4 INTRODUCTION TO RESEARCH ISSUES IN THE STUDY OF SAFETY IN MASSAGE AND MANUAL THERAPY

Adding to the complexity of studying harmful incidents in professions that use manual therapies is the similarity between manual modalities used by different professional groups. Examples include the insertion of needles and the use of tools to manipulate soft tissue and joints. For example, Brady et al. describe a prospective study conducted to determine the number of adverse events occurring in clinical practice through dry needling of trigger points in physiotherapy (47), while Tsai and Wang describe the adverse consequences of a traditional Chinese gua sha therapy that uses a metal tool for scraping over the tissues of the body in their case report (48).

Of course, modalities may be shared between different healthcare professions such as spinal manipulation in chiropractic, physiotherapy, and osteopathy or therapeutic massage in MT and all the former groups. Numerous healthcare providers utilize massage for patient care in varying degrees including nurses as described by Westman and Blaiswell (49) and chiropractors, naprapaths, osteopaths, physicians and physiotherapists as described by Paanalahti et al. (41) (see glossary of practices in Appendix H). Massage shares “the unbounded and multiprofessional nature” of delivery as well as use by unregistered providers as described regarding SMT by Rozmovitz et al. (33) (p6).

Researchers studying chiropractic, physical therapy, acupuncture, massage therapy, and other ‘hands-on’ fields have attempted to more clearly define the patient safety concerns related to harmful incidents or adverse events using a variety of methodological approaches and study

designs (37, 39, 50-59). Patient safety has been studied via research review of insurance and regulator reports, as has been done in the profession of osteopathy (60, 61). Ijaz et al. examined issues of safety in Traditional Chinese Medicine (TCM) using a critical postcolonial lens (62). In their 2012 investigation of Complementary and Alternative Medicine (CAM) studies, Pilkington and Boshnakova reiterate the necessity for safety or harms data to be gleaned from a wide range of research designs from case reports to meta-analyses in order to capture both common and uncommon events (63).

Carlesso et al. illustrate the need for more study of patient safety in professions that use manual therapy in patient care, stating that “[o]rthopaedic physical therapy is considered safe, based on a lack of reported harms. Most of the research until now has focused on benefits” (39) (p. 445). Cagnie et al. lament the same situation in chiropractic, noting the dearth of patient safety information despite the fact that chiropractic care has been widely used for centuries (64). There is, to date, little consensus about defining, classifying, recording, and reporting these occurrences within and between professions with overlapping scopes of practice (33).

The need for reporting systems, registries, and systematic data collection mechanisms for adverse or harmful incidents has been identified in chiropractic, physiotherapy, massage therapy, and CAM groups (65-68) . Researchers have recently turned a spotlight on safety issues in various forms of health-related services in CAM generally (69, 70) and in specific fields such as homeopathy (71). Issues with regulations to mitigate risk in the provision of health services are apparent not only in the MT literature (22) but in a broad range of complementary fields internationally (62, 72, 73).

Interestingly, most investigations regarding adverse events in manual therapies exclude MTs. Several published studies involve physiotherapists, chiropractors, or osteopaths (56, 60, 61, 74). MT has been omitted explicitly from investigations of harm in clinical practice because MTs lack regulated health provider status in some jurisdictions (57, 75).

The introduction to the dissertation given here presents background information on patient safety, current issues in MT, perspectives on the nature and extent of patient safety incidents, and

research issues in the study of patient safety in massage and manual therapy. The background also includes important commentary and review from key researchers in patient safety in various professions that use manual therapies in patient care. While the epidemiological research in the safety literature from professions that use manual methods for patient care includes research on incidence of adverse events, studies with benefit-risk analyses, and studies on risk factors, these topics are not the focus of this dissertation. The rationale for the study, purpose and objectives of this research are described next.

1.2 Rationale

MT in Canada does not generally receive public funding but policy and practice decisions regarding all healthcare interventions rely on data regarding cost, effectiveness, and safety (76). Among Canadians with extended health care benefits MT is the most used of the insured health services in the paramedical or other health provider category (77). Annual survey data show that 57% of respondents used MT as a health benefit within the reporting year. This proportion exceeds use of physiotherapy (41%), chiropractic (37%), acupuncture (15%) and osteopathy (9%) (77).

MT, studied around the world and in various forms but most typically as ‘hands-on’ soft-tissue manipulation, has been shown to have beneficial health effects for numerous conditions of illness that burden Canadians (78), with potential for health promotion among well populations (79) but there is scant research on harm in the practice of MT. There are few Canadian specific clinical data available in the literature. Yet, national statistics show that increasing numbers of Canadians are accessing the care of MTs, with the latest Canadian data (2016) revealing that 44% of Canadians have visited a massage therapist at least once in their lifetime, up from 35% having used it in 2006 and only 23% in 1997 (80). Lifetime massage use exceeds that of chiropractic (which 42% of Canadians have tried it at least once) and acupuncture (which 22% of Canadians have used) (80).

A recent systematic review of twenty-two surveys studying the twelve-month prevalence of visits to MTs across six countries showed a median of 5.5% of the general population of the USA, UK, Canada, Australia, Singapore, and South Korea (81). This proportion exceeded visits

to medical herbalists, acupuncturists, osteopaths, and homeopaths but is less than chiropractic visits globally (median of 7.5%) (81).

MTs are increasingly working with people with complex conditions (and therefore potentially greater risk of poor health status) such as cancer patients (82), older adults with declining physical and cognitive health (83), and children (84). MTs are primary healthcare providers in that physician oversight is not required. MTs work in a variety of clinical settings but often in solo practice with sole responsibility for assessment and treatment. Musculoskeletal complaints such as back, neck, and shoulder pain, with or without underlying conditions such as arthritis, are conditions commonly treated by MTs in Canada (85).

Possible negative consequences associated with exposure to massage have been assumed to include potential physical, financial, or emotional/psychological harm that could result from incompetent or unethical practice (22). Epidemiological data on risk in MT is sparse. It appears that only one paper in the peer-reviewed literature base has examined liability claims involving massage and this 1998 American study reports on data spanning only three years in the mid-1990s from one insurance company (86). Studdert et al. state that 1.8 claims per 1000 were made involving MTs (86). Johnson describes a small number of physiotherapy-treatment injury claims attributed to massage as the treatment modality (87). Both systematic and narrative reviews of case reports of harm in MT can be found in the literature and will be discussed in detail in a later chapter.

As massage therapy research is a nascent field, many knowledge gaps exist. A small number of studies have investigated patient expectations regarding treatment outcomes of interventions including massage (88-91). In general, patients tend to view massage favourably. Boulanger examined both treatment outcome and therapist role expectations and found positive expectations not only for clinical results but also for interpersonal and educational processes as part of the therapeutic encounter (88). None of these studies included Canadian MTs and their patients. Patient safety issues in massage therapy are understudied.

Due to disparate knowledge, facility, and practice around patient safety, it is important to make internationally developed and accepted terminology, definitions, and information models

meaningful for Canadian MT. This is clearly an important step for the development of data collection methods based on a classification schema (taxonomy) informed by research evidence and will be useful for future epidemiological study.

1.3 Research Purpose and Objectives

The overall aim of this dissertation is to deepen the understanding of patient safety incidents (adverse events) in healthcare offered by members of the profession of MT in order to advance the reporting, monitoring, and prevention of harmful incidents in MT in Canada and other jurisdictions where MT is used as a health care intervention.

The specific objectives set to achieve this purpose are as follows:

1. To explore massage therapy (MT) regulators' views on patient safety and adverse events (AEs) in the practice of MT (**Paper 1**)
- 2A. To explore taxonomies for understanding, evaluating, or reporting patient safety incidents (adverse events) in existing published literature on massage and manual therapies (**Paper 2**).
- 2B. To compare available massage and manual therapy patient safety incident taxonomies with an internationally developed framework in order to summarize and collate the results (**Paper 2**).
3. To reflect on and discuss how the findings of the dissertation aid the patient safety culture of the profession of MT in Canada, including knowledge translation and transfer.

1.4 Organizational Structure of the Dissertation

In this dissertation, which consists of seven chapters and uses a manuscript- style format, two chapters are written as interrelated but separate manuscripts (Chapters 4 and 5). Each of the manuscripts have been formatted for coherence and consistency of style across the dissertation. In the following section, an overview of the remaining chapters of the dissertation in service of meeting the research purpose and objectives is given. The contents of each chapter is described as it relates to the broad context of the dissertation as a whole. In order to provide the connection to the dissertation, a brief introduction is included at the beginning of each manuscript and the

contribution of each manuscript to the dissertation objectives are given in the concluding chapter of the dissertation.

Chapter 1, the present chapter, provides an introduction to the study on patient safety issues and adverse events in massage therapy. This chapter introduces MT in Canada, patient safety in healthcare, the discourse on adverse events, and research issues in massage and manual therapies. This chapter also identifies the study rationale and the purpose and objectives of the research.

Chapter 2, *Context for the Thesis*, provides first an overview of important models and frameworks that inform this research. Specifically, international recognized and consensus based conceptual frameworks and models of patient safety are described. Knowledge of these frameworks and models is built on in the dissertation research in order to meet the research purpose and objective. Subsequent chapters will describe how the dissertation research builds on what is currently known and recommended. Next in this chapter, common nomenclature in the literature on patient safety is introduced with definitions provided. This will provide clarity and uniformity of language throughout the dissertation and serve as a basis for the dissertation research objectives. Then selected research from the literature will be reviewed to describe key studies that seek to advance the identification, definition, and classification of AEs in massage and other manual therapies; explore the opinions and views of stakeholders on patient safety; and investigate the development of recording and reporting tools and learning systems using taxonomies.

Chapter 3, entitled *Trainee Background and Review of Research Methods*, describes the dissertation research's mixed methods approach with a brief outline of the research trainee's background as it relates to the positionality of the researcher in the investigation. The study design and methods used are also described in this chapter. The overarching approach of integrative knowledge translation undertaken in this research is introduced here and referenced for building on in subsequent chapters in the dissertation. The three components of the research: the focus group investigation, scoping study, and stakeholder consultation are outlined in this chapter.

Chapter 4, *Perspectives on Adverse Events in Massage Therapy: Canadian Regulators' Views on Patient Safety* addresses the dissertation research's first research objective by examining MT regulators' views on patient safety and AEs in the practice of MT. Through the study's findings a model representing patient safety in Canadian MT was developed and is illustrated as a pantheon of safety in which the foundation constitutes issues of trust, the supporting pillars contain issues of the health provider role, protecting patient vulnerability, and treatment expectations, and where the roof of safe massage offers public protection. These results appear in the dissertation as an unpublished manuscript in preparation for submission to a peer-reviewed journal (Paper 1).

Chapter 5, entitled *Patient Safety Incident (Adverse Event) Definitions and Taxonomies in Massage and Manual Therapies Research: A Scoping Study*, addresses the dissertation research's second research objective by scoping the literature for taxonomies for understanding, evaluating, or reporting patient safety incidents (adverse events) and then comparing current knowledge and practices in the research with internationally accepted frameworks and models. Building on the views shared by experts in the community of MT in Canada in the focus group investigation described in the previous chapter this manuscript synthesizes the current discourse, knowledge, and practices in patient safety and adverse events in massage and other manual therapies.

Descriptive analysis maps the included studies by variables such as study method, provider and intervention definition, and country of origin. Qualitative thematic analysis revealed three main themes: the challenge of meaning in concepts such as hurt, harm, and healing; that standardization in definition and classification is lacking; agreement on essential elements of patient outcomes such as level of discomfort and impairment of function as well as how to measure and record the impact show the basis for a common approach in research and practice. This chapter is prepared as a second unpublished manuscript in preparation for submission to a peer-reviewed journal (Paper 2).

Chapter 6, *Knowledge Translation and Stakeholder Consultation*, addresses the dissertation research's third objective by reflecting how the findings of the dissertation aid the patient safety culture of the profession of MT in Canada. This chapter focuses on the integrated knowledge

transfer approach with consultation and participation of key stakeholders in the MT community. Highlights of participants input and feedback are discussed and include responses ranging from surprise that harm from MT can occur at all to impassioned concern that it too often does. Further feedback reiterated that trust in all professional relationships in the field (not only between patient and practitioner but also in relationships with researchers, regulators, and other healthcare providers. Final stakeholder consultation helped shape draft messages for future action on the knowledge created in this dissertation research.

Chapter 7, *Discussion*, summarizes and discusses the key findings of the dissertation research. Integrated data analysis reveals three main highlights: consideration of both procedural and post-treatment hurt are necessary and harm does occur; discourse on patient safety in massage and other manual therapies is fraught with competing interpretations; there is consensus that simple taxonomies to identify, define, and classify adverse events are valuable and needed and should conform to international standards. Recommendations for research, policy, and practice based on the research findings are given.

References: Chapter 1

1. College of Massage Therapists of Ontario. About the profession [Internet]. [cited 2017 May 3]. Available from: <http://www.cmtto.com/about-the-profession/>.
2. Carlesso LC, Macdermid JC, Santaguida PL, Thabane L, Giulekas K, Larocque L, et al. Beliefs and practice patterns in spinal manipulation and spinal motion palpation reported by Canadian manipulative physiotherapists. *Physiother Can.* 2013;65(2):167-75.
3. College of Massage Therapists of British Columbia. Massage Therapy Regulation [Internet]. [cited 2017 June 21, 2017]. Available from: http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/280_2008.
4. College of Massage Therapists of Newfoundland and Labrador. [Internet]. [cited 2017 June 21, 2017]. Available from: <http://www.assembly.nl.ca/Legislation/sr/statutes/m01-2.htm>.
5. The College of Massage Therapists of New Brunswick. [Internet]. [cited 2017 June 21, 2017]. Available from: <http://www.cmtnb.ca/wp-content/uploads/2015/03/Chap-49.pdf>.
6. Kennedy AB, Cambron JA, Sharpe PA, Travillian RS, Saunders RP. Clarifying definitions for the massage therapy profession: the results of the best practices symposium. 2016-06-10; 9(3):[12 p.]. Available from: <http://www.ijtmb.org/index.php/ijtmb/article/view/312>.
7. College of Massage Therapists of Ontario. Complementary modalities [Internet]. [cited 2017 May 3]. Available from: <http://www.cmtto.com/about-the-profession/policies/policies/practice/complementary-modalities/>.
8. College of Massage Therapists of Ontario. Modalities considered outside scope [Internet]. [cited 2017 May 3]. Available from: <http://www.cmtto.com/about-the-profession/policies/policies/practice/modalities-considered-outside-scope/>.
9. Hidalgo B. Evidence based orthopaedic manual therapy for patients with nonspecific low back pain: an integrative approach. *J Back Musculoskel Rehab.* 2016;29(2):231-9. PubMed PMID: 115136309.
10. Esmail N. Complementary and alternative medicine use in Canada: trends in use and public attitudes 1997-2006. Vancouver, British Columbia: The Fraser Institute, 2007 Contract No.: 87.
11. Benjamin P. The emergence of the massage therapy profession in North America: a history in archetypes. Toronto: Curties-Overzet Publications, Inc.; 2015.
12. Fournier C, Reeves S. Professional status and interprofessional collaboration: a view of massage therapy. *J Interprof Care.* 2012;26(1):71-2.
13. Baskwill A. A guiding framework to understand relationships within the profession of massage therapy. *J Bodywork Movement Therap.* 2015;In Press, Corrected Proof, Available online 17 December 2015.
14. Kania-Richmond A, Menard MB, Barberree B, Mohring M. "Dancing on the edge of research" – What is needed to build and sustain research capacity within the massage therapy profession? A formative evaluation. *J Bodywork Movement Therap* [Internet]. 2016:[1-10 pp.]. Available from: <http://www.sciencedirect.com/science/article/pii/S1360859216301115>.
15. Walkley S. When the body leads the mind: perspectives on massage therapy in the United States. In: Oths KS, Hinojosa SZ, editors. *Healing by hand: manual medicine and bonesetting in global perspective.* Walnut Creek, CA: AltaMira Press; 2004. p. 23-42.
16. Fortune LD, Gillespie E. The influence of practice standards on massage therapists' work experience: a phenomenological pilot study. *Int J Ther Massage Bodywork* [Internet]. 2010 2010-08-18; 3(3):[7 p.]. Available from: <http://www.ijtmb.org/index.php/ijtmb/article/view/73>.
17. College of Massage Therapists of Ontario. 2015 Annual report: enhancing accountability. CMTO Annual Report [Internet]. 2015. Available from: <http://www.cmtto.com/key-publications/annual-report/>.

18. College of Massage Therapists of British Columbia. CMTBC 2015 Annual report. Available from: <http://www.cmtbc.ca/sites/default/files/CMTBC-Annual-Report-2015.pdf>.
19. Natural Health Practitioners of Canada. About us [Internet]. [cited 2017 May 3, 2017]. Available from: <https://www.nhpcanada.org/about-us/index.html>.
20. Canadian Massage Therapy Alliance. Members of the CMTA [Internet]. [cited 2017 May 3]. Available from: <http://www.crmta.ca/?page=7>.
21. Federation of Massage Therapy Regulatory Authorities of Canada. What's an RMT? [Internet]. [cited 2017 May 5]. Available from: <http://www.fomtrac.ca/whats-an-rmt/>.
22. Gowan-Moody D, Baskwill A. Report on policy issues concerning the regulation of massage therapy in Canada. The Federation of Massage Therapy Regulatory Authorities of Canada (FOMTRAC), 2006 May. Report No.
23. Baker GR. Report of the working group on methods and measures for patient safety. World Health Organization, 2007.
24. Baker GR, Norton P. Patient safety and healthcare error in the Canadian healthcare system. Ottawa, Canada: Health Canada. 2002;1:167.
25. Institute CPS. Available from: <http://www.patientsafetyinstitute.ca/en/Topic/Pages/Patient-Safety-Incident.aspx>.
26. World Health Organization. WHO Patient Safety - programme areas [internet]. Available from: <http://www.who.int/patientsafety/about/programmes/en/>.
27. Runciman W, Hibbert P, Thomson R, Van Der Schaaf T, Sherman H, Lewalle P. Towards an international classification for patient safety: key concepts and terms. Qual Assur Health Care. 2009 February 1, 2009;21(1):18-26.
28. World Health Organization. More than words. Final technical report conceptual framework for the International Classification for Patient Safety. 2009.
29. Higgins JPT GSe, editor. Cochrane handbook for systematic reviews of interventions Version 5.1.0. Available from www.handbook.cochrane.org.2011.
30. Ioannidis JA, Evans SW, Gøtzsche PC, et al. Better reporting of harms in randomized trials: an extension of the consort statement. Ann Intern Med. 2004;141(10):781-8.
31. Cresswell KM, Panesar SS, Salvilla SA, Carson-Stevens A, Larizgoitia I, Donaldson LJ, et al. Global research priorities to better understand the burden of iatrogenic harm in primary care: an international Delphi exercise. PLoS Med. 2013;10(11):6.
32. World Health Organization. Patient safety research: a guide for developing training programmes. 2012.
33. Rozmovits L, Mior S, Boon H. Exploring approaches to patient safety: the case of spinal manipulation therapy. BMC Complement Altern Med. (2016) 16:164;16(164).
34. Brown C, Hofer T, Johal A, Thomson R, Nicholl J, Franklin B, et al. An epistemology of patient safety research: a framework for study design and interpretation. Part 1. Conceptualising and developing interventions. Qual Saf Health Care. 2008;17(3):158-62.
35. Gorrell LM, Engel RM, Brown B, Lystad RP. The reporting of adverse events following spinal manipulation in randomized clinical trials—a systematic review. The spine journal : official journal of the North American Spine Society. 2016.
36. Thiel HW, Bolton JE, Docherty S, Portlock JC. Safety of chiropractic manipulation of the cervical spine: a prospective national survey. Spine. 2007;32(21):2375-8. PubMed PMID: 17906581.
37. Carnes D, Mars TS, Mullinger B, Froud R, Underwood M. Adverse events and manual therapy: a systematic review. ManTher. 2010 Aug;15(4):355-63. PubMed PMID: 20097115. Epub 2010/01/26. eng.
38. Carlesso LC, Gross AR, Santaguida PL, Burnie S, Voth S, Sadi J. Adverse events associated with the use of cervical manipulation and mobilization for the treatment of neck pain in adults: a systematic review. ManTher. 2010 Oct;15(5):434-44. PubMed PMID: 20227325. English.

39. Carlesso LC, MacDermid JC, Santaguida LP. Standardization of adverse event terminology and reporting in orthopaedic physical therapy: Application to the cervical spine. *J Orthop Sports Phys Ther.* 2010 //;40(8):455-63.
40. McDowell J, Johnson G, Bradnam L. Towards a neurophysiological mechanisms-based classification of adverse reactions to acupuncture. *Phys Ther Rev.* 2011;16(2):118-25.
41. Paanalahti K, Holm LW, Nordin M, Asker M, Lyander J, Skillgate E. Adverse events after manual therapy among patients seeking care for neck and/or back pain: A randomized controlled trial. *BMC Musculoskelet Disord.* 2014 12 Mar;15 (1) (no pagination)(77). PubMed PMID: 2014288695.
42. Rajendran D, Bright P, Mullinger B, Froud R. Reporting patterns and predictors of common minor adverse events following osteopathic treatment: Lessons learned from a prospective, patient-administered questionnaire feasibility study in a UK teaching clinic. *Eur J Integr Med.* 2015 01 Dec;7(6):634-44. PubMed PMID: 20151056297.
43. Chung KF, Yeung WF, Kwok CW, Yu YM. Risk factors associated with adverse events of acupuncture: a prospective study. *Acupunct Med.* 2014 01 Dec;32(6):455-62. PubMed PMID: 25271149.
44. L B. Underlying philosophies and trends affecting professional regulation. Vancouver, British Columbia: College of Registered Nurses of British Columbia, 2012 Pub. No. 783.
45. Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, et al. The Canadian adverse events study: the incidence of adverse events among hospital patients in Canada. *CMAJ.* 2004 May 25, 2004;170(11):1678-86.
46. Shojania KG, Duncan BW, McDonald KM, Wachter RM, Markowitz AJ. Making health care safer: a critical analysis of patient safety practices. Evidence report/technology assessment (Summary) [Internet]. 2001; (43):[i-x, 1-668 pp.]. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK26998/>.
47. Brady S, McEvoy J, Dommerholt J, Doody C. Adverse events following trigger point dry needling: a prospective survey of chartered physiotherapists. *J Man Manip Ther.* 2014 Aug;22(3):134-40. PubMed PMID: 25125935. Pubmed Central PMCID: PMC4101552. Epub 2014/08/16. eng.
48. Tsai K-K, Wang C-H. Acute epiglottitis following traditional Chinese gua sha therapy. *CMAJ.* 2014 May 13, 2014;186(8):E298.
49. Westman K, Blaiswell C. Many benefits, little risk: the use of massage in nursing practice. *AJN.* 2016.
50. Anders J, March J, Perez A. Safety of cervical manipulation: Are adverse events preventable and are manipulations being performed appropriately? [D.P.T.]. Ann Arbor: University of Nevada, Las Vegas; 2011.
51. Oliphant D. Safety of Spinal Manipulation in the Treatment of Lumbar Disk Herniations: A Systematic Review and Risk Assessment. *J Manipulative Physiol Ther.* 2004 3//;27(3):197-210.
52. Cherkin DC, Sherman KJ, Deyo RA, Shekelle PG. A review of the evidence for the effectiveness, safety, and cost of acupuncture, massage therapy, and spinal manipulation for back pain. *Ann Intern Med.* 2003 Jun 3;138(11):898-906. PubMed PMID: 12779300. Epub 2003/06/05. eng.
53. McDowell J, GM J, L H. Adverse reactions to acupuncture: policy recommendations based on practitioner opinion in New Zealand. *NZ J Physiother.* 2013;41(3):94-101.
54. Vincent C. The safety of acupuncture: acupuncture is safe in the hands of competent practitioners. *BMJ.* 2001;323:467-8.
55. Yamashita H, Tsukayama H. Safety of acupuncture practice in Japan: patient reactions, therapist negligence and error reduction strategies. Evidence-based complementary and alternative medicine : eCAM [Internet]. 2008 Dec 2586322; 5(4):[391-8 pp.]. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/18955234>.
56. Rajendran D, Bright P, Bettles S, Carnes D, Mullinger B. What puts the adverse in 'adverse events'? Patients' perceptions of post-treatment experiences in osteopathy--a qualitative study using focus groups. *ManTher.* 2012 Aug;17(4):305-11. PubMed PMID: 22425134.

57. Carnes D, Mullinger B, Underwood M. Defining adverse events in manual therapies: a modified Delphi consensus study. *ManTher*. 2010 Feb;15(1):2-6. PubMed PMID: 19443262.
58. Cambron J. A, Dexheimer J., Coe P., Swenson R. Side-effects of massage therapy: a cross-sectional study of 100 clients. *J Altern Complement Med*. 2007;13(8):793-96.
59. Long AF, Esmonde L, Connolly S. A typology of negative responses: a case study of shiatsu. *ComplementTher Med*. 2009 6//;17(3):168-75.
60. Leach J, Fiske A, Mullinger B, Ives R, Mandy A. Complaints and claims against osteopaths: a baseline study of the frequency of complaints 2004–2008 and a qualitative exploration of patients' complaints 2011 [Nov 1, 2016]. Available from: http://www.osteopathy.org.uk/uploads/complaints_and_claims_against_osteopaths_2004-2008_public.pdf
61. Carnes D. What can osteopaths learn from concerns and complaints raised against them? A review of insurance and regulator reports. *Int J Osteopath Med*.
62. Ijaz N, Boon H, Muzzin L, Welsh S. State risk discourse and the regulatory preservation of traditional medicine knowledge: the case of acupuncture in Ontario, Canada. *Soc Sci Med*. 2016;170:97-105.
63. Pilkington K, Boshnakova A. Complementary medicine and safety: A systematic investigation of design and reporting of systematic reviews. *ComplementTher Med*. 2012 February;20(1-2):73-82. PubMed PMID: 2012072279.
64. Cagnie B, Vinck E, Beernaert A, Cambier D. How common are side effects of spinal manipulation and can these side effects be predicted? *ManTher*. 2004 8//;9(3):151-6.
65. Biley FC. Primum non nocere: thoughts on the need to develop an 'adverse events' register for complementary and alternative therapies. *Complement Ther Nurs Midwifery*. 2002 5//;8(2):57-61.
66. Cunningham JE, Benhamu J, Hawkes D. The need for a chiropractic adverse events reporting system in Australia. *Med J Aust* 2014; ;200(4).
67. Dryden ME, RMT, Trish, Sumpton BSN, Bryn, Shipwright B, RMT, Stacey, Kahn P, EdM, LMT, Janet, Reece R, BSN, Barbara. Massage therapy and Canadians' health care needs 2020: proceedings of a national research priority setting summit. *Int J Ther Massage Bodywork [Internet]*. 2014; 7(1). Available from: <http://www.ijtmb.org/index.php/ijtmb/article/view/228>.
68. Pohlman KA, O'Beirne M, Thiel H, Cassidy JD, Mior S, Hurwitz EL, et al. Development and validation of providers' and patients' measurement instruments to evaluate adverse events after spinal manipulation therapy. *Eur J Integrat Med*. 2014 8//;6(4):451-66.
69. Boon H, MacPherson H, Robinson N. Recent research shows maturity in addressing safety issues associated with CAM therapies. *Eur J Integrat Med*. 2014 8//;6(4):401-3.
70. White A, Boon H, Alraek T, Lewith G, Liu J-P, Norheim A-J, et al. Reducing the risk of complementary and alternative medicine (CAM): challenges and priorities. *Eur J Integrat Med*. 2014 8//;6(4):404-8.
71. Posadzki P, Alotaibi A, Ernst E. Adverse effects of homeopathy: a systematic review of published case reports and case series. *Int J Clin Pract*. 2012;66(12):1178-88.
72. Wahlberg A. A quackery with a difference—new medical pluralism and the problem of 'dangerous practitioners' in the United Kingdom. *Soc Sci Med*. 2007 12//;65(11):2307-16.
73. Angell M, Kassirer JP. Alternative medicine — the risks of untested and unregulated remedies. *The New England journal of medicine*. 1998;339(12):839-41. PubMed PMID: 9738094.
74. Carlesso LC, Cairney J, Dolovich L, Hoogenes J. Defining adverse events in manual therapy: an exploratory qualitative analysis of the patient perspective. *ManTher*. 2011 Oct;16(5):440-6. PubMed PMID: 21377403.
75. Batavia M. Contraindications for therapeutic massage: do sources agree? *J Bodyw Mov Ther*. 2004 1//;8(1):48-57.

76. Herman PM, Poindexter BL, Witt CM, Eisenberg DM. Are complementary therapies and integrative care cost-effective? A systematic review of economic evaluations. *BMJ Open*. 2012;2(5):e001046.
77. nd. THE Sanofi Canada healthcare survey 2015 [April 2, 2016]. Available from: <http://www.sanofi.ca/l/ca/en/layout.jsp?cnt=65B67ABD-BEF6-487B-8FC1-5D06FF8568ED>.
78. Moyer C, Rounds J, JW H. A meta-analysis of massage therapy research. *Psychol Bull*. 2004;130(1):3-18.
79. Hawk C. Potential role of complementary and alternative health care providers in chronic disease prevention and health promotion: An analysis of National Health Interview Survey data. *Prev Med*. 2012;54:18-22.
80. Esmail N. Complementary and alternative medicine; use and public attitudes 1997, 2006, 2016. . Vancouver, Canada: Fraser Institute, 2017.
81. Harris PE, Cooper KL, Relton C, Thomas KJ. Prevalence of visits to massage therapists by the general population: A systematic review. *Complement Ther Clin Pract*. 2014 2//;20(1):16-20.
82. Collinge W, MacDonald G, Walton T. Massage in supportive cancer care. *Seminars in oncology nursing*. 2012 2//;28(1):45-54.
83. Munk N, Zanjani F. Relationship between massage therapy usage and health outcomes in older adults. *J Bodyw Mov Ther*. 2011 4//;15(2):177-85.
84. Beider S, Moyer C. Randomized controlled trials of pediatric massage: a review. *Evidence-based complementary and alternative medicine : eCAM*. 2007;4:23-34.
85. Bronfort G, Haas M, Evans R, Leininger B, Triano J. Effectiveness of manual therapies: the UK evidence report. *Chiropr ManTherap*. 2010;18(1):3.
86. Studdert D, Eisenberg D, Miller F, Curto D, Kaptchuk T, Brennan T. Medical malpractice implications of alternative medicine. *JAMA*. 1998;280:1610-5.
87. Johnson GM, Skinner MA, Stephen RE. Lessons to be learned: a retrospective analysis of physiotherapy injury claims. *J Ortho Sports Phys Ther*. 2012;42(8):698-704. PubMed PMID: 22711215.
88. Boulanger C, Karen T, Jennifer L, Lowe D, John B. The development and validation of the client expectations of massage scale. *Int J Ther Massage Bodywork*. 2012;5(3):3-15.
89. Kalauokalani D, Cherkin DC, Sherman KJ, Koepsell TD, Deyo RA. Lessons from a trial of acupuncture and massage for low back pain: patient expectations and treatment effects. *Spine*. 2001;26(13):1418-24.
90. Jones S, Lange J, Turner J, Cherkin D, Ritenbaugh C, Hsu C, et al. Development and validation of the EXPECT questionnaire: assessing patient expectations of outcomes of complementary and alternative medicine treatments for chronic pain. *J Altern Complement Med [Internet]*. 2016; 22(11).
91. Moyer C, Rounds J. The attitudes toward massage (ATOM) scale: Reliability, validity, and associated findings. *J Bodywork Movement Therap*. 2009;13:22-33.

CHAPTER 2: CONTEXT FOR THE THESIS

Medicine is a social institution. It comprises a set of beliefs and practices which only become possible when held and carried out by members of an organized society, among whom a high degree of the division of labour and specialization of the social function has come into being.

—W.H.R. Rivers, *Massage in Melanesia*

2.1 Introduction

The study of the relevance, meaningfulness, and utility of internationally-developed patient safety definitions, classification schemas, and reporting models within the Canadian MT context relies on an understanding of the topic within the broader healthcare realm. This chapter first describes the recent iterative developments in identifying, defining, and classifying patient safety incidents at the global level as initiated and conducted by the World Health Organization (WHO) World Alliance for Patient Safety in order to provide context for the thesis. Next, a brief glossary of the important nomenclature and definition of terms is provided.

Then, selected literature is presented and summarized to review relevant themes and concepts from studies that relate to the topic of patient safety in MT. First, studies that profess specifically to study massage therapy safety are summarized and examined. As MT research is a nascent field generally, much can be learned from the research from other health professions. Therefore, studies from several professions that use ‘hands-on’ manual methods for patient treatment are reviewed in order to set a context for the identification of both developments and gaps in knowledge in regard to how patient safety is talked about in the community of patients, practitioners or clinicians, and scholars.

Last, a summary of the present chapter concludes a description of the context for the thesis that highlights the aspects that will be built upon in subsequent study chapters. Specifically, what is known from international frameworks and models that were developed by consensus among the broader healthcare domain will serve as a standard against which the dissertation research study findings will be compared in forthcoming chapters. Also, the gaps in knowledge identified as important to the context for the thesis guides the development of the study and will be described in the chapters to follow. Mapping the methodologies and methods within this present chapter serves the development of the study methodological approach and methods that is the focus of the next chapter.

2.2 Information Models for Patient Safety (IMPS)

The WHO defines an information model for patient safety (IMPS) as consisting of:

a systematic representation of a knowledge domain, describing their essential constitutive concepts and the relationship between them. The model can thus be understood in terms of essential data categories and their relationships. It can have several functionalities, including the reporting of patient safety incidents, documenting injuries and complications, conducting investigations, etc. (1).

In 2012, a working group of the WHO stated that “the lack of universal concepts and definitions to name and report patient safety incidents” remained a significant challenge within patient safety research (2) (p2). The historical timeline of developments to address this challenge on an international scale began with the creation of The Patient Safety Programme of the WHO in 2004 (3), the creation of the “Draft Guidelines for Reporting and Learning Systems” published in 2005 (4), and with the “Conceptual Framework for the International Classification for Patient Safety (ICPS)” in 2009 (5).

2.2.1 MINIMUM INFORMATION MODEL (MIM) FOR PATIENT SAFETY INCIDENTS

In a follow-up 2013 report, the WHO outlined the development of a Minimal Information Model (MIM) for reporting patient safety incidents that “aimed to facilitate comparison, sharing and global learning from the occurrence and actions around patient safety incidents” (6) (p3). The minimal information model refers to “a minimal common architecture for the core concepts considered to be essential for information and comparison purposes of patient safety incident

reports, while additional concepts can be included and customized based on every context. As a consequence, incident reports would expectedly be more homogenously structured and amenable to national and international aggregation and comparison” (7) (p4).

The working template of the MIM is intended as a “prototype, or a pilot version, which requires extensive testing and evaluation for its fit for purpose, feasibility, acceptability and effectiveness” (7) (p13). The prototypical MIM consists of specific data categories, the definition of the category, the rationale for inclusion of the category, and a value set or range of permitted values for each category from the International Classification of Diseases (ICD) and the International Classification of Functioning, Disability and Health (ICF). Box 1 sets out the agreed upon frame for “patient outcome” data within the model of reporting.

<p>Patient Outcomes Definition: the impact upon a patient which is wholly or partially attributable to an incident. Rationale: to describe the consequence of an incident for the patient in detail. Value set: Already existing international classifications codes, such as ICD and ICF codes.</p>

Figure 2.1 WHO MIM Elements of Patient Outcomes (7)

2.2.2 CONCEPTUAL FRAMEWORK FOR THE INTERNATIONAL CLASSIFICATION FOR PATIENT SAFETY (ICPS)

The Conceptual Framework for the ICPS was published in detail in a 2009 WHO Final Technical Report (5) and is described by Sherman in the *International Journal for Quality in Health Care* (8). The conceptual framework itself is “a comprehensive Information Model for understanding the epistemology of patient safety incidents” (9).

The conceptual framework consists of ten high level classes (*patient characteristic*, for example) and forty-eight key concepts (such as *patient*) for organizing patient safety information. The

purpose of the framework was to help identify patient safety issues and to create uniform data organization for tracking and comparison. The technical report also includes an extensive Annex that provides diagrammatic representation of the concepts by class (for example, *incident type*). Continuing the example, there are thirteen sub-classes that relate to the class *incident type*, such as *clinical process*, *medical device*, or *provider behavior* and each of these sub-classes in turn has a diagrammatic representation to describe the pertinent options. The sub-class *clinical process*, for example, may relate to *assessment/diagnosis* or *treatment/intervention* or *screening/prevention*. As a result, there are approximately 600 concepts represented in the conceptual framework of the ICPS (8). Importantly, the two classes of *incident type* and *patient outcomes* are intended as clinically meaningful categories for incident identification and retrieval (5, 8). In the ICPS framework, the classes of *patient characteristics*, *incident characteristics*, *contributing factors/hazards*, and *organizational outcomes* all serve to establish context for the incident. The remaining four classes in the framework (*detection*, *mitigating factors*, *ameliorating actions*, and *actions taken to reduce risk*) guide information gathering for learning about prevention and system-related issues (8).

The class *patient outcome* and the sub-classes of *type of harm*, *social and/or economic impact*, and *degree of harm*, as described in the conceptual model, will define the scope of investigation for this research. Type of harm is sub-divided into three categories: “pathophysiology,” “injury,” and “other.” The ICPS Conceptual Framework directs that both types of harm and social and/or economic impact can be recorded in accordance with the International Classification of Diseases (ICD), International Classification of Primary Care 2nd Ed., International Classification of External Causes of Injury, and the International Classification of Functioning, Disability and Health. Box 2 depicts the sub-class and operational definitions for degree of harm outlined in the ICPS.

Degree of Harm:

None – patient outcome is not symptomatic or no symptoms detected and no treatment is required.

Mild – symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention.

Moderate –requiring intervention or causing permanent or long term harm or loss of function.

Severe –requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function

Death – on balance of probabilities, death was caused or brought forward in the short term by the incident.

Figure 2.2 WHO Degree of Harm Classification Elements (5)

2.3 Definitions and Nomenclature

Key Concepts and Preferred Terms of the WHO ICPS (10)

Patient Safety: the reduction of **risk** of unnecessary **harm** associated with **healthcare** to an acceptable minimum.

An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment.

Risk: the probability that an incident will occur.

Harm: impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes **disease, injury, suffering, disability** and **death**. Degree of harm: the severity and duration of harm, and any treatment implications, that result from an incident.

Disease: a physiological or psychological dysfunction.

Injury: damage to tissues caused by an agent or event.

Suffering: the experience of anything subjectively unpleasant.

Disability: any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with past or present harm.

Healthcare: services received by individuals or communities to promote, maintain, monitor or restore **health**. Healthcare includes self-care.

Health: the state of complete physical, mental and social well-being and not merely the absence of **disease** or infirmity

Patient safety incident: an **event** or **circumstance** which could have resulted, or did result, in unnecessary **harm** to a **patient**.

Event: something that happens to or involves a **patient**.

Circumstance: a situation or factor that may influence an **event**, **agent** or person(s).

Harmful incident (adverse event): an incident which resulted in **harm** to a patient.

Adverse reaction: unexpected harm resulting from a justified action where the correct process was followed for the context in which the event occurred.

Preventable: accepted by the community as avoidable in the particular set of circumstances.

2.4 An Overview of Selected Literature

This section contains a brief integrative review of the scholarly literature in the area of patient safety and adverse events research in order to summarize important themes and concepts from related studies. The main goal of the review is to provide a better understanding of what can be learned from existing literature about the identification, definition, and classification of patient safety incidents or adverse events. In Canada, MTs often work collaboratively or in parallel practice with other health professions that have a longer history of research such as physiotherapy, chiropractic, and acupuncture. The overview of selected literature aims to provide context for the dissertation by highlighting the prevailing discourse with respect to patient safety and adverse events, the methods of investigation used and the results of the existing research. The conclusions drawn to date and suggestions for future research also is rich ground upon which to build MT specific research by learning from other professions. Several studies in the published literature pertaining to providers and interventions using manual or ‘hands-on’ means, while excluding MT, provide useful information in the study of harmful incidents, although the applicability to the profession of MT is not yet known.

2.4.1 STUDIES PURPORTING TO EXPLORE SAFETY AND RISK OF HARM FROM MASSAGE

Six studies available in the literature refer specifically to massage and massage therapy. Five are review studies and one is original research. These studies are summarized in the table below with respect to the concepts explored, research methods used, strengths and gaps in knowledge evident from each study. The studies are described in detail in text that follows in order to provide context for the dissertation research.

Table 2.1 Studies Referring Specifically to Massage Therapy

Author & Date	Concepts Explored	Methods Used	Strengths	Gaps Exposed
Ernst, 2003	Patient Safety in massage; published cases of adverse events	Systematic review of case reports	Scope fits within Canadian context	Only serious cases reported, no Canadian cases identified; wide range of provider and intervention
Grant, 2003	Published reports of injuries attributed to massage intervention	Literature review	Strict exclusion narrows provider and intervention definition	Scope not a good fit for Canadian context with exclusion of lay persons and MT for pain.
Corbin, 2005	Massage therapy safety for pts with cancer	Literature review	Notes risk of indirect and direct harm	Training recommendations reflect American criteria for provider and intervention definitions.
Posadski & Ernst, 2013	Patient safety in massage therapy	Update case report systematic review	Scope fits within Canadian context	Provider and intervention definitions broad and inclusive
Yin et al, 2014	Entitled “Adverse Events of Massage Therapy”; safety of massage therapy for pain conditions	Literature review	No language restrictions	Provider and intervention descriptions include chiropractic and spinal manipulation - outside scope of MT in Canada
Cambron et al, 2007	Side-effects of massage therapy	Cross-sectional survey of patients	Provider and intervention well defined and operationalized	American student massage therapists

Description of Massage Specific Review Studies

The first systematic review of massage-related harmful incidents to appear in Medline was authored by Edzard Ernst (2003), a German-born, British physician and researcher with hands-on MT training. The review was titled “The Safety of Massage Therapy” (11). Ernst performed an all-language search of Medline, Embase, The Cochrane Library, and AMED. All articles reporting adverse events related to any type of MT excluding injury due to ice or oil were included. Studies involving cardiac, prostate or carotid sinus massage were excluded. For the purposes of his investigation, Ernst defines massage as “the systematic manipulation of soft tissues of the body for pain reduction or other therapeutic purposes,” including palpation (11) (p 1101).

Twenty reports (sixteen case reports and four case series) provided original data of harmful incidents related to massage. Patients included adults of both sexes, including the elderly, as well as children and infants. Some patients were healthy individuals; the health characteristics of other patients included pregnancy and lactation, diabetes with peripheral neuropathy, Hashimoto’s Disease, aortafemoral bypass, anti-coagulant therapy, exostosis, and venous stents.

The type of massage provided included traditional manual healing approaches such as Urut (Malaysian massage), Shiatsu, Traditional Chinese massage, as well as self-massage using massage tools and devices, Rolfing, massage with feet and weight walking on back, deep tissue with and without elbow pressure, and Swedish massage. The providers of the treatment resulting in harm are described with various labels including traditional healer, relative, Shiatsu therapist, alternative therapist, TCM practitioner, Rolfer, and trained massage therapist. In some of the cases the provider description was not given, while in others the injury or harm occurred as a result of self-administered massage.

The massage treatment provided was applied to the following areas of the body: the abdomen, legs or feet, neck, back, arms and hands, testes, and breasts. Conditions noted as treatment indications included pregnancy; back, neck, arm, abdominal, or leg pain; peripheral vascular disease; hydrocele; and mastitis. The adverse outcomes included ruptured uterus, pulmonary embolism, thyrotoxicosis, weakness, ulceration and infection, arterial stenosis, hematoma, pain,

pseudoaneurysm, stent displacement, renal embolism, retinal embolism, hemiparesis, abscess, colon rupture, and posterior interosseous syndrome.

Keith Eric Grant, an American massage therapist, educator and researcher, also published a literature review in 2003, titled “Massage Safety: Injuries Reported in Medline Relating to the Practice of Therapeutic Massage—1965–2003” (12). For this paper, a PubMed search was conducted to determine the number and nature of massage-related injuries: this was done to present the exiting PubMed case abstracts within one document, making the information more accessible. Cases describing massage as a medical procedure (such as cardiac massage) or cases where massage was used to treat injury or pain were not included in the document.

Eleven search hits met Grant’s inclusion criteria. All but three had been included in the Ernst 2003 review. Unique to Grant’s review was an evaluation of a Spanish language abstract of a case series where one of the cases involves massage treatment and extracranial vertebral artery dissection. Grant also found a Russian language abstract related to massage and hearing loss and an abstract describing myositis ossificans and massage. He excluded papers related to Traditional Chinese Medicine massage and Shiatsu machines as well as a case where a wife walking on her husband’s back preceded the injury.

Lisa Corbin, an American medical doctor, conducted a review of the literature regarding the safety of MT for patients with cancer. The title of the article was “Safety and Efficacy of Massage Therapy for Patients With Cancer” (13). The stated goal of the paper, described as an academic topic review, was to facilitate discussion about MT use between doctors and patients with cancer in order to improve relationships and treatment compliance. Corbin argued that due to conflicting information available about massage for patients with cancer, there was a need to provide clarity to physicians and patients.

Databases searched up to January 2005 were MEDLINE (including the CDSR), CINAHL, and the databases and websites of American MT organizations and cancer organizations. English-language articles containing original research, case reports, letters, and reviews on “massage

therapy” and “neoplasm” were included. Articles not related to MT and cancer or focusing on reflexology, prostate massage, and animal studies were excluded.

Corbin synthesized the data extracted from the articles into the following subsections: research findings on the physiological effects of massage, rationale for including massage in cancer care, safety of MT, and benefits of MT for patients with cancer. However, only the portion of the academic topic review specifically addressing the safety of MT is described here. Corbin included information from the Ernst 2003 review in her synthesis as well as a discussion of responses known to occur in healthy populations including bruising, swelling of tissues, and increased pain post-treatment. She also discussed the potential for indirect harm should the massage therapist offer advice on herbs and other alternative cancer treatments to their patient. The cases synthesized by Corbin in her paper also include several of the clinical case reports described by Ernst (2003) (11) and Grant (2003) (12). Corbin’s synthesis paper does not include cases unique to Ernst’s or Grant’s reviews. The implications of physician recommending MT for cancer patients was discussed with conclusion that therapists must have adequate training and education for safety.

Posadski and Ernst (2013), in an effort to update the Ernst 2003 review, conducted a search of the literature for additional reports of adverse events associated with massage and published their results in a paper titled “The Safety of Massage Therapy: An Update of a Systematic Review” (14). MEDLINE, EMBASE, AMED, and The Cochrane Library databases were searched for published articles in all languages. Reports on cardiac, prostatic, or carotid sinus massage were excluded, as were reports related to ice or massage oil, including aromatherapy oil. Studies that were neither case reports nor case series were also excluded. Eighteen primary reports (seventeen case reports and one case series) were included in the review. One of the case reports described two separate adverse events related to the self-massage use of a Shiatsu massage machine and the case series described the use of a mechanical massage bed with 41 adverse events occurring in a study of 238 users.

The provider characteristics include the above mentioned self-massage incidents but also include descriptive labels of professional masseur, lay masseur, non-medically qualified person, two

MTs at once, Shiatsu therapist, TCM practitioner, physiotherapist, massage at a beauty salon, massage therapist, massage at a massage clinic, chair massage, massage provided with the use of an electric massage device, and unknown. The patients involved in the case reports appear to be adult males and females including the elderly, but in some cases demographic data is not given.

The description of the type of massage listed in the updated review include: massage, massage therapy, Tuina (Chinese massage), friction massage, forceful massage, vigorous massage, stress relieving facial massage, traditional massage, Shiatsu, and massage with infrared heat combined. The paper described massage as being applied to the whole body, neck, face, abdomen, legs, shoulders, and/or elbow; in some cases the site is not mentioned. The individuals sought massage for stress relief, post-partum care, migraine, pain stiffness, tennis elbow, and lumbar disc herniation, as well as for nonmedical reasons. At times the indication was not provided in the report. Harmful incidents included cervical lymphocele, arterial dissection, deep vein thrombosis and pulmonary embolism, bladder rupture, stroke, cerebellar infarction, ataxia, rhabdomyolysis, cervical cord injury, haemorrhage due to cyst rupture, myopathy, severe headache, paraesthesia, paraplegia, nerve palsy, haematuria, and chylothorax.

Yin et al. (2014) published “Adverse Events of Massage Therapy in Pain-Related Conditions: A Systematic Review” in the journal *Evidenced-Based Complementary and Alternative Medicine* (15). The authors of this paper cite Traditional Chinese Medicine institutions in China and Austria as their affiliations. Insufficient knowledge of safety is stated as the rationale for the study. The authors state that massage is commonly used in Eastern medicine for pain-related conditions and note a trend of increased use of massage for this purpose in Western medicine.

Although these authors reference American massage publications and define massage as touch or manipulation of soft tissues of the body, they nonetheless use the terms massage, manual therapy, Tuina, and chiropractic combined with terms related to safety and adverse events in their search strategy. They conducted a literature search of original case reports limited to 2003-2013 without language restrictions. Articles involving study designs other than case reports (such as clinical trials and reviews), conference proceedings, and studies about prostate, cardiac, or

carotid sinus massage were excluded, as were studies about adverse events related to massage with ice or essential oils.

Forty studies met their inclusion criteria. Data related to the author, country of occurrence, patient characteristics, clinician type, manual therapy, adverse event, and outcome were extracted. The studies included 7 case series reporting 95 adverse events and 33 articles describing 43 case reports. Yin et al. found that 60% of the events occurred in China and 30% in Europe. Three studies reported on cases that occurred in the USA and one in Australia.

Among the adverse events reported in the case reports and case series, Yin et al. found a total of 153 adverse signs and symptoms among the 138 cases of adverse events. The authors declare disc herniation as the most common adverse event reported (25 cases representing 16% of the total AEs), with soft tissue trauma as the second most common injury (17 cases representing 11% of the total). There are 13 cases each of neurological and spinal cord damage, 10 cases of arterial damage, and 9 bone fractures. The remaining injuries, such as dislocation, hematoma, and pain, each account for less than 5% of the adverse events.

It is interesting to note that of the 7 case series, 5 list the provider as not mentioned in the original report. The remaining two case series are listed as chiropractic studies. The manual therapy applied prior to the 95 adverse events in the case series papers is described as manipulation in five of the seven case series studies, with one specifically described as neck massage and the other describing a tendon regulating or rotation method.

According to the tables describing the published case reports, 28 out of 43 cases list the provider or clinician type as not mentioned or unknown. Other provider types listed in the tables include chiropractor, unregistered practitioner, spouse, general medical provider, massage therapist, massage doctor, and physiotherapist. The types of therapy listed these tables include manipulation, rotation, joint mobilization, neck massage, and MT.

Yin et al. note that lack of detail, missing information, and poor reporting in the original reports is a problem and that better reporting is required. They note that in 70% of the cases the provider

of the therapy is neither a massage therapist nor a chiropractor but is unknown, unregistered, not mentioned, or another type of health care provider. They discuss the importance of considering the training of the provider in relation to the occurrence of adverse events when making statements about the risk of adverse events occurring. They suggest safe practice guidelines and adequate regulation are needed to reduce AEs associated with these types of therapies.

An Original Report on Side-effects in Massage Therapy

Cambron et al. conducted a cross-sectional survey of 100 new and returning clients at a student MT clinic within an American health sciences university (16). In a telephone survey, individuals who had received MT at the clinic were contacted two to three days following treatment and asked if they experienced any unpleasant reactions or additional discomfort. If they answered yes, they were then asked about the type of reaction, the level and timing of discomfort, and its influence on daily living activities. They also asked about the occurrence of any positive but unexpected reactions to the massage treatment that seemed unrelated to the reason they had gone for treatment. In addition, the 91 completed questionnaires also included demographic questions and details about the treatment, such as area of body treated and type of massage applied. Twelve negative effects were reported by MT clients: the most commonly reported response was increased discomfort or soreness at a range of 3-7 out of 10 on a numeric pain intensity scale (10% of the respondents), followed by one report each of bruising, tiredness/fatigue, and headache. Of the respondents who described a negative response, the majority said that it started less than 12 hours after the treatment and lasted 36 hours or less and did not interfere with daily living activities.

This study's information about the risk of experiencing minor negative responses to MT treatment can be used to facilitate informed consent regarding the risks and benefits of MT. Using a pain intensity scale to collect information about the responses of increased discomfort or soreness was an important contribution of this study. However, no additional information was collected on the report of tiredness and fatigue and using a scale measure would have provided helpful information. Similarly, no additional information about the type, intensity, and duration of the headache report was given nor was there additional information collected about the extent of the bruising that occurred and whether there was pain or discomfort associated with the

bruising. This study therefore suffers from the lack of a standardized or uniform reporting template that would capture appropriate additional details about patient safety incidents following MT. An additional limitation, as pointed out by the study authors, is that the MT was provided by students in the clinic; the incidence of negative responses to MT care in general practice remains unknown.

2.4.2 STUDIES EXPLORING THE VIEWS OF STAKEHOLDERS AND INCIDENT IDENTIFICATION, DEFINITION, AND CLASSIFICATION

Six studies in the literature including research from other fields that use manual methods for patient care provide context regarding the way other professions are exploring patient safety issues and investigating adverse event definition and classification. These studies are summarized in the table below and discussed in detail in the text that follows. Learning how other professions are conducting patient safety related research provides context for the dissertation research.

Table 2.2 Summary of Selected Research on Views and Identification of Adverse Events

Author & Date	Concepts Explored	Research Methods	Emergent Themes	Gaps Exposed
Rosmovitz et al, 2016	Exploring patient safety culture; tracking adverse events	Interviews to solicit views of providers of spinal manipulation therapy (SMT)	Defining viewed as challenging; Disagreement and conflict re provider status	Intervention well operationalized; issues of lack of standardization across provider groups
Marchand, 201	Use of terminology	Literature review	Common terminology but lack of classification description	Classification parameters are often overlooked
Carnes, 2010	Meaning and definition of adverse events	Mixed methods: focus group and modified Delphi survey	Pragmatic definition and taxonomy of mild, moderate, and major adverse events	Consensus was not reached on all signs and symptoms; context is considered crucial
Carlesso et al, 2011	Patients' perspective on defining and classifying adverse events	Patient interviews	Functional impact, duration, and level of discomfort determine classification of mild, moderate, or major	Defining and categorizing is challenging
Rajendran et al, 2012	Patients' perspectives	Patient focus groups	Themes compiled regarding how patients determine if an outcome is negative or not	Variability within views of patients; interpretations of outcomes not straightforward
Carlesso et al, 2013	Patients perceptions of what is adverse	Survey	Standardization of definitions and classifications offers a more patient-centred approach	'major' events are the most easily identified by patients;

Rozmovits et al. explored the views of Canadian healthcare professionals who use spinal manipulation therapy (SMT) in patient care regarding the patient safety culture and the collection and tracking of adverse events (17). Qualitative data was gathered from interviews with practitioners and professional leaders in chiropractic, naturopathy, medicine, and physiotherapy in Ontario and Alberta. These researchers asked professional leaders and practitioners questions about their perceptions on safety issues. They found that “simply defining reportable adverse events” was seen as a challenge by their participants and believed to be a barrier to instituting a useful reporting system.

Participants felt that transient mild outcomes such as increased musculoskeletal discomfort were so common as to be both expected and not useful to track. With respect to more global issues of patient safety, these authors noted the emergence of the themes of disagreement and conflict about issues of safety, mostly regarding who is best and safest at performing SMT. There were also conflicting beliefs about the nature and proper scope of practice and about conflict with commercial or business interests conflating safety issues. How these findings may align with or diverge from practitioners and leaders in the MT field is not yet known.

Marchand conducted a literature review to investigate the use of safety terminology in pediatric spinal manipulation research and to determine if the terms used in the literature on this topic were in accordance with international patient safety reporting guidelines (18). The international framework chosen was the standards of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The ICH template was then adapted to be relevant to chiropractic practice rather than the drug therapy that it was developed for.

One database, PubMed, was searched using the phrases ‘spinal manipulation pediatric, chiropractic safety pediatric, and manual therapy safety pediatric’ without language restrictions. It was found that of the nine studies included in the review all but one used common terminology of adverse events, adverse effects, negative side effects, and complications but few described a method of classification and most failed to use language consistent with the ICH framework for reporting patient safety incidents (18). Marchand suggests that the WHO’s website patient safety

pages guided the focus of this research toward the ICH. There is no discussion in the paper about the ICPS or the MIM which arguably may be more appropriate than adapting a narrower drug AE guideline. Marchand's perspective offers a valuable synthesis of the literature although the population (pediatric patients) is narrow and the intervention is very specific to SMT. It is not known how Marchand's work relates to the practice of MT and the broader population.

Carnes et al. recognized the need for agreed upon definitions, descriptions, and a useful taxonomy of adverse events in order to further research on the incidence of adverse events from manual therapy (19). These authors state that "quality data are sparse, with scientific debate about incidence of adverse events foundering on differences in opinion as to what constitutes a therapy-related adverse event" (19) (p. 1). Using mixed methods, these authors aimed to understand the meaning of adverse events related to manual therapy in order to define adverse events specific to manual therapy intervention (19). A focus group in the United Kingdom consisting of a chiropractor, a physiotherapist, an osteopath, and a GP explored issues that the participants felt were relevant in studying AE in manual therapy, and generated content for a questionnaire to be used in a Delphi survey in the second phase of this study (19).

The participants decided that a classification system ordering adverse events from "not adverse," "minor," "moderate," and "major" would be helpful. They also developed constructs in polar pairs that they believed would provide meaning to AE. Examples of constructs included mild/severe, acceptable/unacceptable, expected/unexpected, function remains intact/function impaired, distressing/not distressing, and others. Carnes et al. invited a total of fifty interdisciplinary researchers and practitioners to participate in a three-round Delphi survey: subjects were approached because they published in the field, were part of the researchers' networks, or were recommended by an existing study subject (snowball sampling). Twenty-five individuals participated. Each successive round aimed to generate consensus on the taxonomy and the constructs (descriptors). Participants also were asked to classify a list of thirty-six potential AEs gleaned from the literature into the categories of minor, moderate, major, and not adverse and to judge where duration and severity of signs and symptoms fit in the taxonomy.

Carnes et al. concluded that “classifying adverse events was difficult without context or detail.” They state that rather than a short and succinct definition of manual-therapy related AE, their study findings provided a “layered pragmatic definition” as follows:

‘Major’ adverse events are medium to long term, moderate to severe and unacceptable, they normally require further treatment and are serious and distressing; ‘Moderate’ adverse events are as ‘major’ adverse events but only moderate in severity; and ‘Mild’ and ‘not adverse’ adverse events are short term and mild, non-serious, the patient’s function remains intact, and they are transient/reversible; no treatment alterations are required because the consequences are short term and contained.

A number of signs and symptoms presented to the Delphi participants did not receive consensus regarding classification of “major or moderate” and “minor or not adverse.” These include symptoms such as reduced range of movement, short term loss of movement, pins and needles, numbness, fainting, psychological distress, anxiety, panic attack, dizziness, muscle ache, increased pain on movement, palpitations, skin rash, depression, migraine, altered sensation, joint pain, and radiating pain. Therefore, the study offers no further clarity on classifying these potential responses. As well, the authors’ decision to group “major or moderate” and “minor or not adverse” does not provide clarity about whether less serious responses (such as headache, muscle tenderness, short term stiffness, short term soreness, and short term increase in pain) are to be considered adverse or not. Lastly, as the authors chose to exclude MTs from participation, this study gives no further insight into the degree of consensus MTs and MT researchers would reach regarding the definitions and classifications that these researchers found.

Carlesso et al. used an exploratory descriptive qualitative study to measure the adverse events that can result from manual therapy techniques, as told from the perspective of the patients of chiropractors, physiotherapists and osteopaths in Ontario (20). Five practitioners in three clinics (osteopathy, chiropractic, and physiotherapy) invited their patients to participate in this study. Patients were eligible if they were receiving manual therapy that the researchers defined as joint mobilization or manipulation, excluding soft tissue manipulation or mobilization. Thirteen patients agreed to one-on-one interviews in which they were asked questions about their “hands-on” treatment, whether or not they had ever experienced a negative reaction to the “hands-on” treatment they received, and what would cause concern significant enough to stop treatment. Thematic content analysis was used to code the available data from four patients per clinic.

Carlesso et al. illustrate their findings in a model demonstrating how the participants defined AE related to their “hands-on” treatment. The main themes of post-treatment responses, beliefs, and expectations were set into a relational depiction of antecedents (body awareness, chronicity, education about possible responses), sequelae (functional impact and severity of post-treatment symptoms, timing and duration of post-treatment symptoms, and ruling out alternative causes for the response), and universal elements (trust and expectations of treatment, experience with treatment, weighing benefits and risk) that together defined the central concept of adverse event.

Participants were asked to ascribe the adjectives “mild, moderate, major, or not adverse” with regard to the intensity and duration of symptoms, including loss of function. Participants were also asked whether alternate explanations for their post-treatment symptoms were likely. Patients only considered a post-treatment response to be adverse if they reasoned that no other explanation was possible. Post-treatment events were considered by patients to not be adverse if they were still able to function, they felt sore but not painful, and the duration was short term. Patients defined a potential AE as mild if their function was intact and if pain was .5 to 2 on a 10 point numeric rating scale (NRS) and lasted from hours up to two days. An AE was defined as moderate if their function needed to be modified, pain rated 1-2 on the NRS and lasted 1-5 days. Patients defined an AE as major if their function was impaired, if pain was greater than 3 points on the NRS, if it included stroke or major neurological symptoms, and lasted longer than 2 days.

This study provides an important view of the patients’ perspective on adverse events in chiropractic, physiotherapy, and osteopathic care. Although none of the research participants in this study had experienced a moderate or severe adverse event, the authors argued that there is a need to explore what symptoms patients do (or do not) consider adverse. These authors also pointed out that it would enrich our understanding of the patients’ perspective to adverse events if study samples included those who have sustained injury and not just the sample of volunteers who likely represent a selection bias to this type of study. These authors did not include MTs, and therefore, this study does not provide information about MT patients’ views about adverse events.

Rajendran et al. conducted a study using focus groups to investigate the views of nineteen participants about adverse events following musculoskeletal treatment (21). Most of the participants were osteopathic patients in the teaching clinic of the European School of Osteopathy (ESO), but a few participants were students and staff from the ESO. Participants were asked how they would decide whether a post-treatment experience was negative or not and what would prompt a complaint. Data collected were analyzed thematically to devise a conceptual model. Four main themes emerged from analysis. The patient-practitioner encounter was considered important and consisted of the following factors: trust, communication, vulnerability, and respect. Another theme was the environment, and in this case, the specifics of the teaching clinic. A third theme was labeled “treatment after-effects” and included experiences such as increased pain, changes in functioning, unexpected emotional responses, and tiredness.

Some participants suggested that experiencing pain after treatment indicated the high quality of treatment – “a no pain, no gain” attitude. Participants also discussed their attribution of cause and acceptability of pain in numerous ways, including how severe their condition was and their ability to cope. The final main theme was expectations of the osteopathic encounter and included both experience and comfort with treatment and expectations of benefit. Participants considered any after-effects that negatively impacted their function the most unacceptable, as well as those that were unexpected.

These authors concluded that multiple factors from within these four main themes influence osteopathic patients’ perceptions of what they consider to be adverse post-treatment effects. Further analysis led the authors to conclude that rather than isolated negative or positive signs and symptoms, osteopathic patients view post-treatment experiences as part of the global osteopathic experience. The conceptual model generated from the findings describes patients’ interpretation of “positive” or “negative” and is given the acronym EPOC. Patient interpretations are said to be influenced by patient expectations (E), their personal investment (P), the osteopathic encounter (O), and any clinical change experienced (C). These authors note that osteopathic patients’ interpretation of post-treatment experiences is not straightforward, especially in relation to mild-moderate post-treatment experiences.

The authors suggest their EPOC conceptual model may be useful to all manual therapists. They further suggest that their model can be used by the practitioner to “enhance positive perceptions of post-treatment experiences and modulate what is perceived as adverse.” Certainly, patient education about post-treatment expectations and self-management is important to MTs as well. Whether MT patients interpret their experiences in relation to the EPOC model is unknown.

Another study by Carlesso et al. used a cross-sectional survey method to investigate the perceptions of patients receiving orthopedic manual physiotherapy in nineteen physiotherapy clinics across Canada: patients were asked about the identification and occurrence of adverse treatment related responses (22). A secondary objective of this study was to predict what patient characteristics are associated with the identification of an adverse response to treatment. Four hundred and twenty-five patients were invited by their physiotherapists and three hundred and twenty-four completed the survey.

Participants were asked questions about potential responses to manual treatment from a physiotherapist and to select those responses that they would consider to be an adverse response and why. They were also asked to categorize potential symptoms as not adverse, mild, moderate, or major and to indicate their agreement regarding statements of contextual factors related to determining whether a response is adverse. For example, patients were asked if their interpretation of the adverse response would be different if they were forewarned by their physiotherapist, or whether the extent they trust their physiotherapist would affect their response. Carlesso et al. asked participants to indicate how they reasoned whether an adverse event was or was not likely related to the manual therapy.

Participants listed more than twenty symptoms after manual therapy such as increased soreness, increased pain, bruising, loss of movement, anxiety, stroke and others, but they maintained that many symptoms such as increased soreness or increased stiffness and bruising were not considered adverse. Participants categorized responses lasting only minutes to hours and not impacting function as not adverse; those lasting up to two days but not impacting function as mild; responses lasting up to a week and requiring modified activity were considered moderate; and those lasting longer than a week and requiring help and/or medical care were categorized as

major. The time between the treatment and onset of the negative response was the factor that gave participants the most confidence in attributing the cause of an AE to the “hands-on” treatment.

Carlesso et al. conclude that standardizing definition and categorization would reflect a more patient-centred approach. Further, they suggest dichotomizing adverse events categories into “major” and “all others”. It is only the “major” category the patients easily identify. However, patients who responded “neither agree nor disagree” were grouped with the “disagree” responses when classifying an event as adverse or not. Those that chose “neither agree nor disagree” could have just as justifiably been included in the “agree” responses, thereby potentially changing the findings. As well, the participants of this study were patients of orthopedic manual physiotherapists only; therefore, the utility of the framework for MT in Canada is not known.

2.4.3 DEVELOPMENT OF RECORDING AND REPORTING TOOLS AND LEARNING SYSTEMS USING TAXONOMIES

Five studies in the literature describe research focused on using taxonomies to develop learning systems and/or tools for recording and reporting patient safety incidents or adverse events. These studies are summarized in the table below to highlight the concepts explored and the products that emerged from the research. The studies are described in detail in the text that follows in order to provide context for the dissertation research that builds on what is known and not known from the existing research from other fields on understanding patient safety and learning from and about adverse events.

Table 2.3 Summary of Research on Recording, Reporting, and Learning Systems

Author & Date	Concepts Explored	Emergent Products
Pohlman et al, 2014	Patient safety reporting and learning systems	Reporting system for spinal manipulation providers as part of ‘SafetyNet’
Thiel & Bolton, 2006	Incident reporting format for chiropractic profession	Chiropractic Reporting and Learning System
McDowell et al, 2011	Provider opinions on adverse reactions to acupuncture	Adverse event questionnaire and development of a reporting template
Leach et al, 2011	Incident reporting format for osteopathic profession	Coding and classification of complaints by type
Long	Systematic classification of potentially adverse Shiatsu outcomes	Typology of harm identification and levels

In their research on developing and validating standardized measurement instruments for operationally defined patient safety terms, Pohlman et al. also identified the need for a better way to identify, report, and assess AEs (23). The intervention of interest in this study was spinal manipulative therapy (SMT) and the research was intended to inform the development of a novel and formal reporting and learning system in North America for SMT providers. This research is part of a program of research projects under the “SafetyNet” initiative which seeks to foster research about improving the safety culture in SMT. Definitions from the ICH and the National Cancer Institute’s taxonomy for severity of patient outcomes in adverse events in medical care were adapted for this study to describe SMT AEs. The study by Pohlman et al. adds value to the literature in its broad inclusion of providers but because the focus is SMT, the utility of these authors’ perspectives to the field of MT is not known.

In their 2006 pilot study, Thiel and Bolton (24) designed and tested a reporting format for patient safety incidents (PSIs) in chiropractic-practice collected data, aided by the participation of members of the British Chiropractic Association and final-year students at a teaching institution. These authors developed a tool to support the creation of the Chiropractic Reporting and Learning System (CRLS). The reporting forms were designed to capture the “when, where, what, why, and how” of any incident that occurred, and to provide a taxonomy to grade the severity of

harm to the patient related to the PSI. The grading system designated low harm as incidents which required only extra observation or minor treatment; moderate harm as incidents which required several outpatient medical visits or hospital admission; and severe harm as incidents which required prolonged hospitalization with permanent disability. Death would be graded when the incident directly resulted in death. Lastly, a near-miss incident was graded as such when a potential harm was discovered but ultimately prevented. These authors state that the forms they developed aimed to constitute a minimally necessary data set for reportable information.

Data was collected over a four-month period in the field and in the teaching clinic. A very poor response rate from the field practitioners (8 completed forms) was noted. In the teaching clinic, sixty-three students reported on 225 PSIs, with sixty-four percent of the PSIs graded as having no harm to the patient and thirty-five percent graded as low harm. One percent of the PSIs were graded as moderate and fifty-four percent as near misses. This study adds value to the literature by highlighting the use of a minimum data set. The relevance for reporting and learning system for MT in the Canadian context is not known.

McDowell et al. investigated the opinions of New Zealand acupuncture providers on adverse reactions to acupuncture (25). Acupuncture practitioners' interpretation of related concepts and associated terminology was explored with the use of the Adverse Reactions to Acupuncture Questionnaire (ARAQ) developed by the researchers from a review of the literature. Twelve female acupuncturists (eleven physiotherapists and one general practitioner) answered questionnaires on two separate occasions in order to evaluate their agreement on semantic meaning and synonymy of important terms in patient safety, such as adverse event, side effect, and complication. The questionnaires also measured their preferences for the definition of important terms, allocation of severity of incidents, and their thoughts on issues of reporting. While agreement on responses from time two answers to time one answers varied, these authors conclude that "agreement on what constitutes an adverse reaction" will strengthen systems which record incidents and report about safety. In 2013, McDowell et al. used the questionnaire they developed to survey 319 New Zealand physiotherapy and general medical practitioner acupuncturists. Although only moderate (48%) consensus was achieved for a proposed

definition, the study results were used to inform the subsequent development of a reporting template that was adopted by an acupuncture organization in New Zealand. The meaningfulness of these definitions and taxonomies for MT in the Canadian context is not known.

A large project on patient safety in osteopathy was funded by the General Osteopathic Council, which is the statutory regulator in the UK. The results of this research are available as a final report by Leach et al. published in 2011 under the auspices of the Consortium for Delivering Osteopathic Research (26). The aim of this large project was threefold: to facilitate the coding and classification of complaints by type of complaint made to the regulators or insurers in order to investigate the number and nature of complaints made; to quantitatively analyse data collected with the new classification system; and to collect and analyse qualitative data via interviews with selected individuals about the complaints and the circumstances that lead to a complaint being made. For coding purposes, the classification system was organized according to the type of complaint. For example, complaints were classified into categories such as clinical care or conduct and communication. Within the clinical care category, a sub-category of adverse event was created and is selected when “treatment caused injury or pain, or more pain or other health effects.”

The researchers describe the methodology of their study as Action Research, which focuses on improving a service or practice within a profession. One of the methods used was the narrative interview of key informants including regulators, professional association leaders, and indemnity insurance representatives. In order to facilitate monitoring and learning, the authors recommend more discussion to further the creation of a national standard for recording key data items. While the expressed aim was to understand the nature of complaints rather than to explore adverse events per se, the findings of this study help to explain current practices in other professions that use manual therapy for patient care.

Long et al. conducted a prospective cohort study of Shiatsu practices in the United Kingdom, Spain, and Austria with the aim of developing a typology for classifying negative responses and applying the typology to determine the prevalence of negative responses (27). The authors describe Shiatsu as a “Japanese body-based life-energy therapy” and whole system therapeutic

approach that addresses the mind and body. Therefore, according to these researchers, Shiatsu could be expected to elicit both positive and negative responses, including both physical and emotional responses. They then introduce the concept of the “healing response” to the topic of understanding possible reactions to manual therapy. The authors then discuss a philosophy they consider to be shared among CAM therapies, namely, that the exacerbation of a patient’s symptoms may be considered not only a normal short term response but a good sign that the therapy is appropriate. They state that “the researcher, in establishing evidence on safety, needs to be able to differentiate a ‘true’ healing response (the natural response of the body to treatment) from a genuine adverse ‘effect’ and adverse ‘event’.”

Eighty-five Shiatsu practitioners recruited 948 patients to answer questions related to their experiences of Shiatsu treatment and their responses to treatment. Self-administered questionnaires were completed at baseline, four to six days after the Shiatsu treatment, three months after treatment, and finally at six months. Six hundred and thirty-three individuals completed all four questionnaires. Analysis of the participants’ responses consisted of organizing the responses according to “types” of response. Data was analyzed by the lead researcher who was also a Shiatsu practitioner and reviewed by the study’s advisory group. A five-fold typology of response type was developed by these researchers. Type 1 responses are responses considered as being independent of the treatment. An example given is coming down with the flu. Type 2 responses are considered as transitional effects and related to the healing response. They are, according to these researchers, transitional because they are characterized by patients as an initially negative response that then becomes positive. Examples given include increased tension and pain followed by total resolution a few days later or a burst of crying followed by relieving peace and calm. Type 3 responses are also called transitional effects by these researchers but with the distinction that the response is not specifically labeled as negative and then positive by the patient but rather by the practitioner, who knows that it relates to the healing nature of the treatment. Examples given include exhaustion, intensification of symptoms, and emotionality. Type 4 responses are considered undesirable but do not pose a risk to the patients’ safety, although they are distressing and impede the patients’ normal daily activities. The examples given include feeling depressed and having enhanced negative feelings. Type 5 responses are

potentially adverse events or effects, and pose a potential risk to the patient's safety. An example given by a participant is back pain, which would be categorized as severe.

This study offers an interesting view on potential treatment responses and the classification of "adverse" and "not adverse" effects. The authors' typology provides a novel articulation of what they describe as a healing response to treatment, which they declare is consistent with traditional treatment theory in a practice such as Shiatsu. Contemporary MT scholarship and research lacks published practice-related theory. It is difficult, therefore, to compare practice theories and thus the typology proposed by Long et al. may or may not be relevant for MT.

2.5 Summary of Context for the Thesis

As can be seen from the introduction, background, and related literature, there are levels of investigation that can inform the study of patient safety in MT in Canada. Adverse events research in manual therapies can be grouped into three categories: studies where the research focus is on epidemiological data, specifically, counting and understanding the patterns of adverse patient responses; studies that explore and problematize the identification, definition, and/or classification of AEs; and studies that focus on the topic of the reporting and/or learning systems for collecting adverse event data. While there is scant original research available that is specific to MT adverse events, much can be learned from the current literature reviewed here. The question of what constitutes an adverse event in manual therapy (including massage, acupuncture, joint mobilization, and spinal manipulation from both healthcare providers and unregulated practitioners) remains the main area of debate. The main contributions of the research to date is the development of operational definitions, classification systems, and reporting and learning systems; however, the lack of uniformity remains a substantive barrier to understanding. Reviewing the literature and summarizing the important themes and concepts from studies related to the current investigation informs the need for MT specific research on patient safety and adverse events.

To date, insufficient information about the nature and extent of harmful incidents in MT in the Canadian healthcare context is available. In provinces where MT is regulated, injury complaints related to MT are reported to the regulatory bodies and described publically in grey literature

such as annual reports, but with insufficient detail and without uniform standards of reporting. To foster quality care, it is important that patient safety incidents in the context of Canadian MT are better understood. This chapter provides an overview of the context in which the was developed and subsequent chapters build on the specific parameters outlined in this chapter where knowledge gaps are identified.

References: Chapter 2

1. World Health Organization. Reporting patient safety incidents [Internet]. [cited 2015 February 2, 2015]. Available from: http://www.who.int/patientsafety/implementation/information_model/en/.
2. World Health Organization. Information model for patient safety incident reporting systems: expert review meeting summary report. University of Tokyo, 2012 Contract No.: WHO/HIS/SDS/2014.6.
3. World Health Organization. Patient safety: About us [Internet]. [January 2, 2015]. Available from: <http://www.who.int/patientsafety/about/en/>.
4. World Health Organization. Draft guidelines for adverse event reporting and learning systems: from information to action. Geneva, Switzerland: World Health Organization, 2005.
5. World Health Organization. More than words. Final technical report conceptual framework for the International Classification for Patient Safety. 2009.
6. World Health Organization Patient Safety & Quality of Care Working Group. WHO-EU: advancing reporting and learning systems. Brussels: 2013.
7. World Health Organization. Working paper: preliminary version of minimal information model for patient safety. 2014 Contract No.: WHO/HIS/SDS/2014.7.
8. Sherman H, Castro G, Fletcher M, Hatlie M, Hibbert P, Jakob R, et al. Towards an international classification for patient safety: the conceptual framework. Qual Assur Health Care. 2009 February 1, 2009;21(1):2-8.
9. World Health Organization. Patient safety: The Conceptual Framework for the International Classification for Patient Safety (ICPS) [Internet]. [cited 2015 February 2]. Available from: <http://www.who.int/patientsafety/implementation/taxonomy/ICPS-report/en/>.
10. Runciman W, Hibbert P, Thomson R, Van Der Schaaf T, Sherman H, Lewalle P. Towards an international classification for patient safety: key concepts and terms. Qual Assur Health Care. 2009 February 1, 2009;21(1):18-26.
11. Ernst E. The safety of massage therapy. Rheumatology. 2003;42:1101-6.
12. Grant KE. Massage safety: injuries reported in Medline relating to the practice of therapeutic massage-1965-2003. J Bodyw Mov Ther. 2003;7(4):207-12.
13. Corbin L. Safety and efficacy of massage therapy for patients with cancer. Cancer Control. 2005;12(3):158-64.
14. Posadzki P, Ernst E. The safety of massage therapy: an update of a systematic review. Focus Alternat Complement Therap. 2013;18(1):27-32.
15. Yin P GN, Wu J, Litscher G, Xu S. Adverse events of massage therapy in pain-related conditions: a systematic review. Evidence-Based Complement Alternat Med. 2014.
16. Cambron J. A, Dexheimer J., Coe P., Swenson R. Side-effects of massage therapy: a cross-sectional study of 100 clients. J Altern Complement Med. 2007;13(8):793-96.
17. Rozmovits L, Mior S, Boon H. Exploring approaches to patient safety: the case of spinal manipulation therapy. BMC Complement Alternat Med. (2016) 16:164;16(164).
18. Marchand AM. A literature review of pediatric spinal manipulation and chiropractic manipulative therapy: evaluation of consistent use of safety terminology. J Manipulative Physiological Therapeut. 2015;38(9):692-8. PubMed PMID: 22951268.
19. Carnes D, Mullinger B, Underwood M. Defining adverse events in manual therapies: a modified Delphi consensus study. ManTher. 2010 Feb;15(1):2-6. PubMed PMID: 19443262.
20. Carlesso LC, Cairney J, Dolovich L, Hoogenes J. Defining adverse events in manual therapy: an exploratory qualitative analysis of the patient perspective. ManTher. 2011 Oct;16(5):440-6. PubMed PMID: 21377403.

21. Rajendran D, Bright P, Bettles S, Carnes D, Mullinger B. What puts the adverse in 'adverse events'? Patients' perceptions of post-treatment experiences in osteopathy--a qualitative study using focus groups. *ManTher*. 2012 Aug;17(4):305-11. PubMed PMID: 22425134.
22. Carlesso LC, MacDermid JC, Santaguida PL, Thabane L. A survey of patient's perceptions of what is "adverse" in manual physiotherapy and predicting who is likely to say so. *J Clin Epidemiol*. 2013 Oct;66(10):1184-91. PubMed PMID: 23856189. Epub 2013/07/17. eng.
23. Pohlman KA, O'Beirne M, Thiel H, Cassidy JD, Mior S, Hurwitz EL, et al. Development and validation of providers' and patients' measurement instruments to evaluate adverse events after spinal manipulation therapy. *Eur J Integrat Med*. 2014 8//;6(4):451-66.
24. Thiel H, Bolton J. The reporting of patient safety incidents—first experiences with the chiropractic reporting and learning system (CRLS): a pilot study. *Clin Chiropract*. 2006;9(3):139-49.
25. McDowell JM, Johnson G, Hale L. Measuring practitioner opinion on adverse reactions to acupuncture. *Australian J Acupunct Chinese Med*. 2011;6(2):28.
26. Leach J, Fiske A, Mullinger B, Ives R, Mandy A. Complaints and claims against osteopaths: a baseline study of the frequency of complaints 2004–2008 and a qualitative exploration of patients' complaints 2011 [Nov 1, 2016]. Available from: http://www.osteopathy.org.uk/uploads/complaints_and_claims_against_osteopaths_2004-2008_public.pdf
27. Long AF, Esmonde L, Connolly S. A typology of negative responses: a case study of shiatsu. *ComplementTher Med*. 2009 6//;17(3):168-75.

CHAPTER 3: TRAINEE BACKGROUND AND REVIEW OF RESEARCH METHODS

The role of the academic is to make everything less simple.

—Mary Beard

3.1 Introduction

This research comprised a mixed methods approach and was consistent with an integrated knowledge translation approach to knowledge creation and action that is presented and discussed in detail in Chapter 6 of the dissertation. The present chapter describes the study design, methods, data collection and analysis that was informed by the integrated knowledge translation that occurred with participation and consultation of the community of Canadian massage therapy (MT) stakeholders. Further, an important consideration in this research is the position of the researcher, who is a member of the community of Canadian massage therapists, researchers, educators, and leaders. The detailed background of the research trainee that follows in this chapter serves to build a platform on which the research undertaken rests.

The mixed methods approach is said to be well-suited to engaging in an integrative process whereby more than one method is used and more than one data set is produced in order to more fully understand a phenomena of interest (1). Subsequent chapters in the dissertation will describe how the methods and data sets were informed first by consultations in the field (Chapter 6) and how the method and data set from one stage of the research (a focus group investigation and views obtained are described in Chapter 4) inform the development of the next stage (a scoping study is described in Chapter 5) and then how knowledge creation and action in consultation with key stakeholders offers strategies for future dissemination and use of the knowledge created in this dissertation research (Chapter 6).

Each method employed in this study serves the goal of this research: to deepen the understanding of patient safety incidents (adverse events) in the profession of MT. The specific objectives set to achieve this purpose were: 1) to explore MT regulators' views on patient safety and adverse events (AEs) in the practice of MT; 2) to explore taxonomies for understanding, evaluating, or

reporting patient safety incidents (adverse events) in existing literature on massage and manual therapies, with a comparison to internationally developed frameworks and models; and 3) to reflect on how the findings of the dissertation aid the patient safety culture of the profession of MT in Canada, including knowledge translation and transfer.

3.2 Clinical, Educational, and Leadership Experience of the Research Trainee

To aid in the perceptual understanding of the dissertation's content and aims, and the orientation and potential bias therein, it is helpful to know the position of the researcher. I will briefly describe my professional involvement in the field of MT as a practitioner, educator, and leader. I am greatly interested in views on what constitutes harmful incidents in the provision of MT in Canada. I see a need in my field to better understand the culture of patient safety and to identify the best means to record incident data in order to learn and improve. I hope to contribute to this knowledge as I continue my training as a researcher, particularly as a health services researcher in Population Health.

When I attended a MT college training program in the late 1980s in Ontario, there was little published research evidence about benefits or harms in applying therapeutic massage as healthcare. I recall MT instructors teaching about a “healing crisis” that could and would commonly occur as we worked to facilitate the health and well-being of our clients. Anecdotes of symptoms getting worse before they got better, emotional responses like crying or grief, or new symptoms “uncovered” through treatment were commonly shared with us as students. At the same time, I recall the curriculum being influenced by an Eastern European medically-based tradition of care that stressed the serious responsibility inherent in intervening in someone's health. *Primum non nocere* was an enculturated idea embedded in the belief that healthcare in all forms, including “hands-on” manual therapy, is not without risk of harm.

I also learned during my University undergraduate training in Psychology that scholarship is essential to the growth and refinement of professions, as members of the profession help shape traditions, forge new paradigms, and develop cultures, norms and values. After completing my BA (Honours), it was an honour to be asked to co-author a report for the Federation of Massage Therapy Regulatory Authorities of Canada (FOMTRAC) on regulatory issues in MT in Canada.

This report was published on the websites of The College of Massage Therapists of Ontario (CMTO) and the College of Massage Therapists of British Columbia (CMTBC) and has been cited and used across Canada by various stakeholders, mainly provincial Associations seeking compiled information and recommendations from the report (2).

MT in Canada enjoys robust provincial and national organization for the support of MTs even though uneven regulatory status across the provinces is a barrier to fully cohesive collaboration. Early to mid-2000s, The Canadian Massage Therapist Alliance (CMTA) supported the formation of the Canadian Massage Therapy Research Network. The purpose of the network was to support research literacy and capacity among Canadian MTs. I served on the leadership committee for several years and then acting as co-chair until the Network dissolved due to lack of available funding. This opportunity led to further involvement with research generally and it was especially the mentorship I received through the Canadian Interdisciplinary Network of Complementary and Alternative Medicine Research (INCAM) that encouraged me to apply to graduate school.

Provincially, I have served on the Board of Directors of the Massage Therapist Association of Saskatchewan (MTAS) as both Director of Education and most recently as the Research Chair. The creation and development of this position speaks to the exponential growth of a culture of interest in and desire for research evidence. In my capacity as the Research Chair I have organized and facilitated journal clubs and research symposium to foster continued growth of a culture of inquiry. During an invitational National Massage Therapy Research Priority Setting Summit convened in Toronto, Ontario I was part of identifying and prioritizing the need for a national adverse events database. Opportunity to serve on the American Massage Therapy Foundation's Best Practices Committee, various of their conference and scientific review committees further aided in my understanding of the international context of MT practice and research. It was an honour to co-author a white paper entitled *Steps Toward Massage Therapy Guidelines: A First Report to the Profession* (3) that represents early collaborative work that laid a foundation and direction to this dissertation research.

After three decades of involvement in the field of MT, I am now aware that its development as a professional practice in North America was also influenced by a less medical and more holistic or esoteric tradition of “mind, body, and spirit” health beliefs and practices. Likewise, my own involvement in research, education, and practice suggests that contemporary practice is in a state of flux. There have been advancements in these areas, including scholarship and policy-making, and I am grateful for the many opportunities I have had to learn and grow within the profession of MT. I am pleased to have contributed to some of the developments in the field and to have benefitted from the efforts and work of others, especially in the field of MT and integrative medicine research.

The culture of evidence-based practice in healthcare generally, and MT specifically, is also driving the need to develop a culture of safety in MT based on research evidence of benefit and harm. Although research literacy and capacity are generally low, massage therapists’ perceptions of research and evidence-based practice (defined as decision-making based on information from clinical experience, patients input, and from available research findings) are favourable (4). Critically evaluating available evidence from research, from practice experience and from each patient’s unique presentation should inform decisions made about patient care. Optimal clinical results for both effective and safe intervention requires healthcare professionals to use clinical reasoning skills. Clinical reasoning refers to “the cognitive processes, or thinking used in the evaluation and management of a patient” (5). Clinical reasoning is understudied in MT (6) but has been the topic of research for quite some time in other professions that use manual therapy as a patient management approach (5, 7).

My training as an epidemiologist makes me certain that the clarification of terminology and the creation of uniformity in data collection methods (informed by the knowledge and experience of those in the field) is the first step in better understanding the risk of harm in MT. My education in population health science allows me to clearly see that those with a stake in the health of the Canadian population need information on both the effectiveness and the safety of health-related practices.

Clear procedures and transparency in the research process are necessary steps taken within this program of research to ensure rigour and manage bias. Specifically, maintaining research logs throughout the project, audio-recording the focus group, supervisory review of the transcripts and frequent research meetings to discuss data collection and analysis were conducted.

Communicating and presenting progress regularly to research advisors, as well as meeting with skilled and experienced librarians, co-authors and stakeholders were additional processes undertaken. Further, I did advance work to build skills by practicing with other researchers with excellent skills in interviewing and moderating. Checking data interpretations made alongside my experienced researcher supervisor has aided both my skill development and the rigour of the study.

3.3 Research Methods

As can be seen from the introduction, background and literature review, several studies have been conducted to investigate important patient safety issues in professions that use manual therapies in patient care. Many studies use methods such as surveys to collect data from patients or practitioners, and some use methods such as focus groups or interviews. There is scant research available in the manual therapy research literature that mixes methods to deepen the understanding of patient safety.

Mixed methods research has been described as a third paradigm alongside natural inquiry and experimental-type methodologies (8). Within this approach, it is possible to use nomothetically derived knowledge (that pertaining to the general) and apply it to idiographic concerns (that which relates to specific phenomena in context) (9). The mixed methods approach is evident in this research as it entailed exploring patient safety issues to better understand the meaning for the participants and stakeholders and then applying that knowledge to an investigation of current practices in patient safety to uncover trends. As patient safety is a complex issue, and massage therapy is a complex intervention, mixed methods as an approach allowed for the connection of data gathered from different paradigmatic approaches to provide greater clarity in answering the research questions.

A mixed methods approach was chosen for this research in order to address that gap and to “maximize” the interpretations of data collected, a quality of mixed methods research heralded by Onwuegbuzie and Leech (2006) (10). This is particularly salient to deepen the understanding of patient safety in MT, a complex phenomenon about which little is known. It is expected that a mixed research approach will improve the analytic power of the study (11) and better handle the great complexity of human phenomena (11, 12). This underscores a key objective in my own research work, which is to better understand the complexity of adverse events in MT by using divergent approaches to describe the phenomenon.

Mixing research methods allows for the addition of multiple perspectives (13). A commonly cited benefit of mixed methods research is that it allows for “complementary strengths and non-overlapping weaknesses” (13) (p 127) which results in improved understanding (14).

Mixed methods research provides a rigorous means for exploring principles and values, current practices and gaps in knowledge from more than one data source (15). Mining knowledge from different communities or sources of knowledge allows for a robust investigation of a research question. A mixed methods research approach is appropriate in uncovering important details and trends in complex topics particularly when one method only may fail to fully capture and preserve valuable information for analysis in solving a problem (15).

A sequential mixed methods design was used to explore patient safety issues in massage and manual therapies. The focus of the mixed methods design in this research was the integration and synthesis of ideas generated from different research methods (13). The research design and analysis are driven by a contemporary view of mixed methods research whereby a more broad and exploratory approach in relation to a phenomenon of interest is combined with analysis of additional data for the description, comparison, and understanding of relationships (10).

The practice of MT has long been considered both an art and a science and thus it seems especially appropriate to employ mixed research in order to confer, as Sandelowski (2000) phrases it, an enhancement to the “artfulness” of research design (11). In this study, methods are mixed for the broad purpose of breadth and depth of understanding (13). The study design and methods are encapsulated within a integrated knowledge translation approach described later in

this dissertation (Chapter 6). Chapter 6 describes the integrative approach in which stakeholder consultation began with development of the research questions, input and resources for the study methods used, recruitment of participants and participation of stakeholders, as well as the knowledge translation activities in stakeholder consultations and future dissemination. In this following section, the study methods and design will be described separately from the integrated knowledge activities described later in the dissertation.

3.4 Research Methods and Design

As shown in Figure 3.1 below, this research has three main components. The first part, concerning the first article within this dissertation, is a qualitative interpretive design using a focus group method. The goal of the focus group was to explore the views of MT regulators, including therapists and public members, about patient safety in MT in order to ascertain what issues are considered salient to the experts in this field. The data was collected with audio recordings and discussion notes taken by the student researcher moderating the focus group, with questions generated from discussion between the student researcher and supervisor (who is the second author of the article). Through descriptive analysis of the data, themes emerged: these themes informed the research questions for the second and third phases of the project.

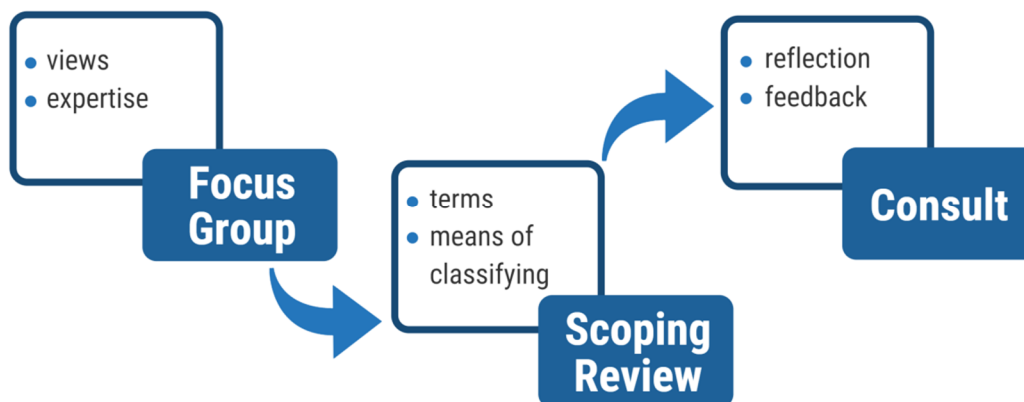


Figure 3.1 Study Design

The second part, which concerns the second article within this dissertation, is a scoping review design, conducted in accordance with the staged tradition of Arksey and O'Malley (16), as depicted in Figure 3.2 below.

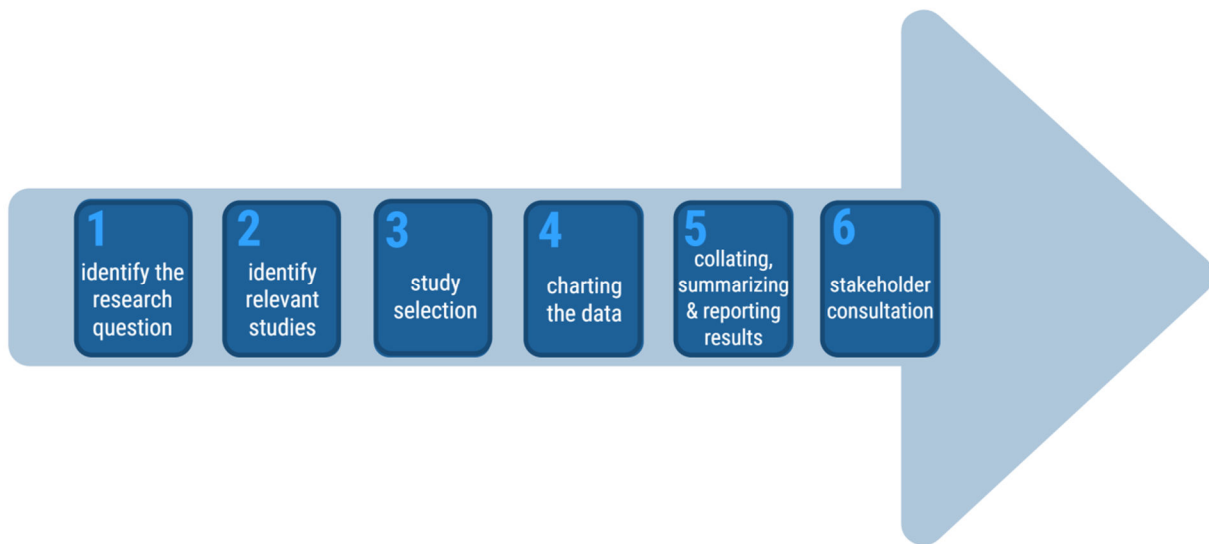


Figure 3.2 Stages of the Scoping Review

The third part is a final stakeholder consultation exercise. The main findings and interpretations of the study were presented to a stakeholder group that included MTs, researchers, educators, industry media representatives and Association leadership in order to solicit their feedback and ideas for knowledge transfer. Future plans include the preparation of an article for a professional magazine regarding stakeholder feedback in order to further knowledge transfer.

3.4.1 STUDY COMPONENT DETAILS

3.4.1.1 Study Component One: Focus Group Settings, Participants, and Procedures

Ethics approval was obtained for the focus group investigation from the BEH REB at the University of Saskatchewan. To obtain a sample of expert individuals who would be able to contribute meaningfully about patient safety issues, up to 12 CMTBC board and staff members were nominated, based on their perceived ability to answer questions related to safety, for invitation to participate by the CMTBC Registrar. Focus group participants were recruited by the

Registrar, who was provided with a letter of invitation (see Appendix A) to email to the selected individuals. Inclusion criteria included: currently serving on the Board of the CMTBC or as staff in an area of inquiry, discipline, patient relations, or compliance. The focus group discussion took place in Vancouver at the location of the CMTBC 2014 Annual General Meeting and Education Day during the lunch hour in a meeting room set aside for the purpose.

On arrival at the focus group, participants were reminded of the study purpose and provided with a written consent form (Appendix A). I served as the moderator of the focus group, managed the group process, and took notes. Questions were informed by a topic guide based on the literature review and my own experience in the field. The dialogue was audio recorded and transcribed by me. A qualitative interpretive approach was used in data analysis with thematic analysis to identify themes and sub-themes. A simple audit trail and study log of process and analysis decisions was created and consensus on emergent themes was achieved with my supervisor Dr. Leis.

3.4.1.2 Study Component Two: Scoping Review Stages, Settings, Participants, and Procedures Stage 1. Identifying the Research Question

In this scoping review we asked: what is the current knowledge and practice of defining and classifying patient safety incidents (adverse events) in massage and manual therapies in the literature regarding patient outcomes as characterized by the WHO minimum information model regarding type of harm, degree of harm, and social and/or economic impact?

Stage 2. Identifying Relevant Studies

With the aid of a health sciences librarian, the electronic databases MEDLINE, MEDLINE IN-PROCESS, EMBASE, CINAHL, SCOPUS, PEDRO, AMED, and ProQuest Theses & Dissertations were searched. The detailed search strategy used for each database is found in Appendix E of this document. A manual search of the bibliographies of key articles was conducted to identify unique items not found in the database search. Additional Web of Science and Google Scholar searches were conducted for key authors and citations.

Stage 3. Study Selection

INCLUSION AND EXCLUSION CRITERIA. To be included in the full-text review, the title and/or abstract must indicate that the article contained research or published reports (including original research, reviews, theses, policy reports, and commentaries, or editorials) involving professions and/or practices that include manual therapy techniques in patient management. Interventions referenced in the title and/or abstract could include commonly used “hands-on” manual treatment such as spinal manipulation or joint mobilization as well as soft-tissue mobilization or manipulation including the use of mechanical tools such as needles, cups, and scrapers or other non-electrophysiological instruments. The paper must be published in English. In addition to the criteria stated above, the article must also pertain to one of the following topics:

1. Study of the means of defining, classifying, characterizing, recording (collecting), or reporting data on patient safety incidents (adverse events) or
2. Study of consensus building to determine definition, classification, recording, or reporting on patient safety incidents (adverse events) or
3. Study of stakeholder (patients, practitioners, policy-makers, regulators) views of patient safety terminology and classification of patient safety incidents (adverse events) or
4. Study of a tool or instrument to define and evaluate the elements and parameters of patient safety incidents or
5. Reported on a methodology for the classification of patient safety incidents.

SCREENING. A protocol for capturing data that meets the standards for literature searches, screening citations, and reviewing full-text articles for systematic reviews was rigorously followed with adaptation for the scoping methodology. The tools include four Excel workbooks: 1) a primary workbook for systematic reviews that contains data sheets for storing and organizing information from each database searched; data sheets to organize information from non-database sources such as author, bibliography, conference, and hand searches; tables for displaying data from the search; data sheets for titles and abstracts; sheets for full-text reviewed citations; sheets for compiling exclusions reasons; a sheet for compiling Cohen’s kappa from two or more reviewers; and a flow diagram tool for the PRISMA model; 2) a workbook for screening titles and abstracts; 3) a workbook for reviewing full-text articles; and 4) a workbook for calculating Cohen’s kappa.

Additional tools include numerous detailed handouts including how to use each workbook, documents with guidance on naming conventions, output styles for data management software, guides for various data management tools such as Endnote, and templates and reporting tools such as a search strategy documentation and PRISMA flow chart template. These tools are available from the University of Texas School of Public Health Library and are licensed under the Creative Commons (17).

AGREEMENT. The lead author served as the first reviewer, while a Registered Massage Therapist and PhD student with a Master of Science degree from McMaster University in Health Research Methodology served as the second reviewer. The Excel workbook designed to calculate Cohen's Kappa for screener inter-rater reliability was used prior to screening all abstracts and titles found in the database searches: this was done to determine whether both reviewers agreed on use of the criteria for deciding which studies to include in the full-text review. The workbook included a random integer generator that allowed a random selection of 66 to 120 citations from all titles and abstracts in the scoping study, a range required to detect a statistically significant kappa at 90% power (18). The calculation used was:

$$\kappa = \frac{\text{Pr}(a) - \text{Pr}(e)}{1 - \text{Pr}(e)}$$

Stage 4. Charting the Data

Information that helped answer the scoping review's research question was extracted from the included studies and charted in a spreadsheet. One reviewer (DGM) performed the charting task. The other reviewer (AB) made modifications and edits. Discussion was held until consensus was reached to resolve any disagreement. Information from the discussions was captured in the study log. Charting included extracted data on patient safety terminology used in each study's title, abstract or text; any *a priori* definition of terms used; the means used to determine patient outcome as regards harm severity, degree and impact; and the taxonomy, classification, or framework offered by the included study.

Stage 5. Collating, Summarizing and Reporting the Results

Descriptive analysis (such as characteristics of the studies included) and thematic analysis were both used to synthesize and organize the data. Figures, tables, and excerpts from the included studies were then used to communicate the findings. The lead author (DGM) determined the themes that best represented the extracted data and then team members reviewed the emergent themes and provided feedback; the analysis proceeded iteratively until consensus was reached.

Stage 6. Stakeholder Consultation

Consultation with stakeholders is considered to be an integral part of scoping study methodology (16, 19, 20) and can be used to support knowledge translation (21). Knowledge translation is defined by the Canadian Institutes of Health Research as “a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically-sound application of knowledge to improve the health of Canadians, provide more effective health services and products and strengthen the health care system” (22).

3.4.1.3 Study Component Three: Stakeholder Setting, Participants, and Procedures

The participants in the stakeholder consultation exercise regarding the study results were drawn from the attendees of an oral presentation of the scoping review at the 9th Canadian Interdisciplinary Network for Complementary and Alternative Medicine Research (INCAM) Symposium in Toronto, Ontario and attendees of a meeting of the Massage Therapy Special Interest Group (MT-SIG) held in conjunction with the symposium. INCAM is the Canadian chapter of the International Society for Complementary Medicine Research. The INCAM Research Symposia, from its inaugural event in 2004, biennially attracts national and international researchers, clinicians, educators, and leaders in integrative healthcare and has been hosted in Ontario, Alberta and British Columbia. The MT-SIG is comprised of individuals interested in MT research. INCAM has several special interest groups on various topics such as osteopathy, naturopathy, and MT and the organization states that “SIGs are meant to be a collaborative space where IN-CAM members with a similar interest in a topic area can come together and work on a research-related project or activity” (23). Other stakeholders were consulted at various points in the project and a detailed description of the integrative knowledge translation that took place as part of this study is discussed in detail in Chapter 6.

The stakeholder consultation process spanned activities from Western to Eastern Canada and from the beginning to the end of the project. At all points, stakeholder views were incorporated into the study design. The specific exercise described here pertains to the solicitation of stakeholder feedback on the results of the scoping review study presented by the lead author (DGM) to attendees of the oral research presentation session at the INCAM Research Symposium. Attendees were informed that extra time had been granted to the presenter in order to facilitate discussion and feedback if the attendees were willing to serve as consultants and offer their feedback on the project and the study findings.

A workshop for the Massage Therapy Special Interest Group (MT-SIG) was the next setting for the stakeholder consultation exercise. At the beginning of the 1.5-hour meeting, the lead author (DGM) informed the participants of the purpose and objective of the stakeholder consultation and asked for their participation and were provided with an overview of the scoping review's main findings. The scoping review's purpose—to explore current knowledge and practices in identifying, defining, and classifying adverse events in massage and manual therapy research literature—was also shared with the workshop participants. Participant feedback on the research findings and their views on knowledge transfer needs were solicited. Questions framing the stakeholder consultation are provided in the Appendix C. Participants were also invited to contact the researchers by email with any additional feedback, views, and opinions. Written notes were taken by one of the researchers (AL) during the SIG meeting; additional feedback from the oral research presentation attendees was collected from team members (AB and AL) by the lead author (DGM). The results of the stakeholder consultation were collated from the notes and comments describing the views of the stakeholders and their suggestions for knowledge translation.

The participants of the stakeholder consultation exercise were the attendees of an oral presentation of the scoping review presented at the 9th Canadian Interdisciplinary Network for Complementary and Alternative Medicine Research (INCAM) in Toronto, Ontario; INCAM is the Canadian Chapter of the International Society for Complementary Medicine Research (ISCMR). Attendees from a meeting of the Massage Therapy Special Interest Group (MT-SIG) (approximately 20 individuals) also participated in the stakeholder consultation exercise.

The study findings (results of the scoping study, which was informed by the focus group investigation), were presented to attendees of the oral research presentation session of the 9th IN-CAM Research Symposium. At the beginning of the 1.5-hour meeting of the IN-CAM Massage Therapy Special Interest Group (MT-SIG), participants were informed of the purpose and objective of the stakeholder consultation and asked for their participation and given a summary of the scoping review's main findings. The purpose of the scoping review—to explore current knowledge and practices in identifying, defining and classifying adverse events in massage and manual therapy research literature—was shared with the workshop participants. Participant feedback on the research findings and their views on knowledge transfer needs was solicited.

Detailed description of the data collection, analysis, and results of the research project are described in Chapter 4 (Paper 1) and Chapter 5 (Paper 2). Paper 1 describes and analyzes the data gathered from the focus group, while Paper 2 focuses on the conclusions of the scoping review. The results of the project are integrated in Chapter 7, where recommendations for next steps are offered.

References: Chapter 3

1. Moran-Ellis J, Alexander VD, Cronin A, Dickinson M, Fielding J, Slaney J, et al. Triangulation and integration: processes, claims and implications. *Qual Res.* 2006;6(1):45-59.
2. Gowan-Moody D, Baskwill A. Report on policy issues concerning the regulation of massage therapy in Canada. The Federation of Massage Therapy Regulatory Authorities of Canada (FOMTRAC), 2006 May. Report No.
3. Grant KE, Balletto J, Gowan-Moody DM, Healy D, Kincaid D, Lowe W, et al. Steps toward massage therapy guidelines: a first report to the profession. *Int J Ther Massage Bodywork.* 2008;1(1):19-36.
4. Gowan-Moody DM, Leis AM, Abonyi S, Epstein M, Premkumar K. Research utilization and evidence-based practice among Saskatchewan massage therapists. *J Complement Integr Med [Internet].* 2013; 10(1):[1-10 pp.].
5. Jones MA. Clinical reasoning in manual therapy. *Phys Ther.* 1992;72:875-.
6. LeMoon K. Clinical reasoning in massage therapy. *Int J Therap Massage Bodywork.* 2008;1(1).
7. Jones M, Grimmer KA, Edwards I, Higgs J, Trede F. Challenges in applying best evidence to physiotherapy practice: Part 2—health and clinical reasoning models to facilitate evidence-based practice. *Internet J Allied Health Sci Pract.* 2006;4(4):9.
8. Creswell JW. *Research design: qualitative, quantitative, and mixed methods approaches.* 2nd ed. Thousand Oaks: Sage 2003.
9. DePoy E, Gitlin L. *Introduction to research: understanding and applying multiple strategies.* 3rd ed. St. Louis: Mosby; 2005.
10. Onwuegbuzie A, Leech N. Linking research questions to mixed methods data analysis procedures. *Qual Rep.* 2006;11(3):474-98.
11. Sandelowski M. Combining qualitative and quantitative sampling, data collection, and analysis techniques in mixed-method studies. *Res Nurs Health.* 2000;23:246-55.
12. Morgan DL. Practical strategies for combining qualitative and quantitative methods: applications to health research. *Qual Health Res.* 1998;8(3):362-76.
13. Johnson R, Onwuegbuzie A, Turner L. Toward a definition of mixed methods research. *J Mix Methods Res.* 2007;1(2):112-33.
14. Plano Clark V, Creswell J, O'Neil Green D, Shope R. Mixing quantitative and qualitative approaches: an introduction to emergent mixed methods research. In: Nagy Hesse-Biber S, Leavy P, editors. *Handbook of emergent methods.* New York: The Guilford Press; 2008. p. 363-87.
15. Classen S, Lopez ED, Winter S, Awadzi KD, Ferree N, Garvan CW. Population-based health promotion perspective for older driver safety: conceptual framework to intervention plan. *Clin Interv Aging.* 2007;2(4):677.
16. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *Int J Soc Res Methodol.* 2005;8(1):19-32. Pubmed Central PMCID: PubMed PMID: 16677313.
17. VonVille HM. Excel workbooks for systematic reviews 2016 [March 1 2016]. Available from: http://libguides.sph.uth.tmc.edu/excel_SR_workbook.
18. Vonville HM. Excel workbook to calculate Cohen's kappa for screener inter-rater reliability [Internet]. University of Texas School of Public Health Library; 2015. Available from: http://libguides.sph.uth.tmc.edu/excel_SR_workbook.
19. Colquhoun HL, Levac D, O'Brien KK, Straus S, Tricco AC, Perrier L, et al. Scoping reviews: time for clarity in definition, methods, and reporting. *J Clin Epidemiol.* 2014 12//;67(12):1291-4.
20. Levac D, Colquhoun HL, O'Brien KK. Scoping studies: advancing the methodology. *Implement Sci [Internet].* 2010; 6(69). Available from: <http://www.implementationscience.com/content/5/1/69>.

21. Grimshaw JM, Eccles MP, Lavis JN, Hill SJ, Squires JE. Knowledge translation of research findings. *Implement Sci.* 2012;7(1):50.
22. Canadian Institute of Health Research. Knowledge Translation [Internet]. [January 29 2017]. Available from: <http://www.cihr-irsc.gc.ca/e/29418.html>.
23. Interdisciplinary Network of Complementary and Alternative Medicine Research. INCAM Research Network Special Interest Groups. Available from: <http://www.incamresearch.ca/content/special-interest-groups-sig>.

CHAPTER 4: PERSPECTIVES ON ADVERSE EVENTS IN MASSAGE THERAPY: CANADIAN REGULATORS' VIEW ON PATIENT SAFETY

Prepared as: Gowan D, Leis A. Perspectives on adverse events in massage therapy: Canadian regulators' views on patient safety (unpublished).

This paper addresses the dissertation's first research objective of exploring massage therapy (MT) regulators' views on patient safety and adverse events (AEs) in the practice of MT. A model was developed, illustrated as a pantheon of safety, where the roof of safe massage offers public protection, supported by the supporting pillars of a health provider role, protection of patient vulnerability, and an understanding of treatment expectations, resting on a foundation of trust in professional relationships.

4.1 Abstract

Introduction

Patients who want to try massage therapy may be advised that “it can't hurt”. Epidemiology data on which to base safety recommendations is sparse. While both use and evidence of the benefits of massage therapy (MT) is growing, the issue of safety has been understudied. Other professions that utilize manual therapy in patient treatment have sought the opinions of stakeholders including patients and practitioners on issues related to patient safety. Little is known about authorities' views on patient safety within the field of MT. The objective of this study was to 1) To explore massage therapy (MT) regulators' views on patient safety and adverse events (AEs) in the practice of MT

Methods

Ten College of Massage Therapists of British Columbia (CMTBC) Board and staff participated in a focus group to share their views on the nature of AEs in MT. Participants responded to

questions about the elements of patient safety, the role of the College and the role of the Registered Massage Therapist (RMT) in promoting safe care. Thematic analysis was used to describe themes from the data.

Results

Participants' shared the view that massage can hurt and it can harm. Main themes emerged from the data analysis. An important finding was that regulators perceive that public trust in the RMT and the College's legislative authority dually serve to mitigate risk of harm. Other themes included the importance of clear role definition of the RMT as healthcare professional, delineation of treatment expectations by both the therapist and the patient, and the fiduciary responsibility of the therapist to safeguard the vulnerability of the patient.

Conclusion

MT regulator participants view the role of the therapist as a healthcare provider entrusted to deliver safe and effective care. Patient expectations of trust are seen as critical especially when treatment might be painful. There is a need to more fully understand the views and opinions of important stakeholders, including regulators, practitioners and patients of MT. The results of this study will be useful to inform further investigation to aid MT practice, education and policy.

4.2 Introduction

Massage therapy (MT) is defined by one Canadian regulatory authority as the health profession in which a person provides, for the purposes of developing, maintaining, rehabilitating or augmenting physical function, or relieving pain or promoting health, the services of assessment of soft tissue and joints of the body and treatment and prevention of physical dysfunction, injury, pain and disorders of soft tissue and joints of the body by manipulation, mobilization and other manual methods (1). The professional practice of MT takes place within a complex historical, social, and political context in Canada. Issues of varying levels of provincial regulation, uneven provincial competency requirements, inclusion or exclusion in collaborative practice, and the development of a uniform professionalization ethos are emerging as important issues, yet the role of MTs in healthcare lacks uniform expression in Canada.

MTs are regulated health care providers in only four jurisdictions in Canada: British Columbia, Ontario, Newfoundland/Labrador, and New Brunswick. In unregulated provinces, professional associations representing MTs continue to engage with provincial governments to pursue legislation to regulate MT. The burden to provide evidence that the practice of MT poses risk to the public that would be mitigated by regulation continues to be a barrier to securing legislation for regulation in jurisdictions such as Saskatchewan (2).

Because the context in which this research takes place is crucial to understanding the methods and results of this study, the issues in regulation of MT in Canada are briefly discussed. British Columbia is a Canadian province in which MTs are regulated and therefore massage therapist is a protected title with a clear scope of practice. The regulators are therefore reasonably granted the authority to offer imprimatur about this subject.

The College of Massage Therapists of British Columbia (CMTBC) reports receiving 30 complaints from members of the public, other RMTs, or other healthcare providers against RMTs in 2015 (3). An additional 15 investigations of members were initiated by the CMTBC's inquiry committee. Of the 30 complaints against RMTs in BC in 2015, four are categorized as patient injury/painful treatment allegations. The total number of registrants in 2015 was 3, 944.

The College of Massage Therapists of Ontario (CMTO) is the oldest of the MT regulatory bodies in Canada. Concerns about conduct, including safety issues, are recorded by the College as either formal complaints received by the College's office or "Registrar's reports," in which an investigation of possible misconduct or incompetence is initiated by the Registrar. The latest data available shows record of 97 new complaints and reports in 2015, two of which are categorized as "treatment causing injury" (4). The total number of registrants in 2015, including inactive members, was 13, 114.

MT has been shown to have beneficial health effects for numerous conditions of illness that burden Canadians (5). National statistics show that increasing numbers of Canadians are accessing the care of MTs with the latest data (2006) revealing that thirty-five percent of Canadians have had MT at least once in their lifetime (6). MTs are increasingly working with

people with complex conditions such as cancer (7), with older adults with declining physical and cognitive health (8), and with children (9).

Studies in British Columbia (10), Saskatchewan (11), and Ontario (12) have focused on Canadian massage therapists' views on important issues that shape the profession and practice, but none have focused on patient safety. The expectations of American MT clients has been explored, although expectations of negative outcomes was not (13). The views of Canadian patients on identifying patient safety incidents in manual therapy (excluding MT) have been explored in research (14, 15). In the United Kingdom, researchers have solicited the views of osteopathic patients regarding how and when an outcome is felt to be adverse (16), as have regulated manual therapy providers and regulators in the UK (17, 18).

Safety in MT is understudied. There is little information on what constitutes an adverse event in MT from the perspective of important stakeholders including MTs, other health care providers, insurers, regulators, educators, and patients. Without information on stakeholders' perceptions of what constitutes an adverse event in MT, there can be no framework from which to inform stakeholders' decision-making. This knowledge of important stakeholders' constructed accounts of what "adverse event" means in MT is absent from the current literature.

Those with a stake in the health of the Canadian population need information on both the effectiveness and safety of health-related practices. While the perspective of the patient is a critical one, this research project will have a scope limited to the views of regulators. In the literature there are several classification schemas including complex frameworks and taxonomies in hospital and primary care (19, 20). Qualitative investigations have resulted in several descriptive adverse events schemas from disciplines such as osteopathy (16, 17) and physiotherapy (15), as well as simple but elegant typologies from complementary and alternative medicine (21). None have included MT as the practice of interest.

Purpose and Objectives

This qualitative research study is part of the larger mixed methods PhD thesis that this dissertation addresses. The sum of the research aims to make internationally accepted adverse

event definitions and terminology applicable and meaningful within the Canadian MT context. This article focuses on which issues Canadian regulators of MT think are important for an understanding of patient safety. The objective of this paper is to explore MT regulators' views on patient safety and adverse events (AEs) in the practice of MT.

4.3 Methods

A qualitative research approach provides an opportunity for a rigorous exploration of the topic with the systematic collection of rich and deep data (22). Bradley et al. (2007) highlight the value of qualitative data analysis in developing taxonomy, themes, and theory for health services research (23). In studying MT, the value of qualitative research is recognized and celebrated as a good match for the challenge of investigating complex healing systems (24, 25). While MT research is still young, there are a number of recent, novel and important qualitative studies that have served to increase the knowledge base about and for the profession with participants from the USA, Canada and the UK (26, 27). There are also numerous recent qualitative studies about the profession specific to the Canadian MT context (10, 28-32).

Focus groups are a common method of collecting data in academic research across healthcare professions (33). Of particular salience in this study, focus groups are particularly useful for “generating information on collective views, and the meanings that lie behind those views” specifically in relation to the groups experiences, norms, and processes (33). With respect to patient safety, focus groups have been used in professions such as nursing (34) and for studying safety culture in health care organizations (35). Smith, Sullivan, and Baxter (2009) used focus groups to explore the attributes of the MT encounter that were most valued by repeat users in New Zealand (36). In the study reported on here, a qualitative interpretive design using a focus group method was used with the goal of exploring the views of MT regulators, including therapists, public members, and staff, about patient safety in MT in order to ascertain the issues important to these experts in the field.

Settings and Participants

Ethics approval was obtained for the focus group investigation from the BEH REB at the University of Saskatchewan. To obtain a sample of expert individuals who would be able to

contribute meaningfully about patient safety issues, up to 12 CMTBC board and staff members were nominated for invitation to participate by the CMTBC Registrar. Focus group participants were recruited by the Registrar, who was provided with a letter of invitation (see Appendix A) to email to the selected individuals. Inclusion criteria included: currently serving on the Board of the CMTBC or as staff in an area of inquiry, discipline, patient relations, or compliance. The focus group discussion took place in Vancouver at the location of the CMTBC Annual General Meeting and Education Day during the lunch hour in a meeting room set aside for the purpose.

Procedures

On arrival at the focus group, participants were reminded of the study purpose and provided written consent (Appendix A). The first author (DGM) served as the moderator of the focus group, managed the group process and took notes. Questions were guided by a topic guide (see Appendix B) based on the literature review as well as the first author's experience in the field. The dialogue was audio recorded and transcribed by the first author. A qualitative interpretive approach was used in data analysis with thematic analysis to identify themes and sub-themes. A simple audit trail and study log of process and analysis decisions was created and consensus on emergent themes was achieved through meeting discussion between the authors.

Data Collection and Analysis

The data were collected with audio recordings and discussion notes taken by the first author who moderated the focus group with questions generated from discussion between the authors. The transcript data was analyzed using an inductive thematic coding process to generate key themes. First, the transcripts were "open" coded and then organized into themes to develop a framework for the coding. As Strauss and Corbin (1990) state, coding is the "analytic processes through which data are fractured, conceptualized, and integrated" (37). While themes are the "recurrent unifying concepts" (23). In turn, this analysis is helpful in health services research in particular for "uncovering links among concepts and behaviors" in the study of complex phenomenon by organizing important insights (23) Through qualitative interpretive analysis of the data, themes emerged that were followed in the research question of the second and again in the third and final phase of the project.

4.4 Results

Figure 4.1 depicts the characteristics of the research participants' views of patient safety in MT, which include the important issues of trust, role and treatment expectations, and vulnerability. These characteristics have been modeled as a pantheon. The form and function of the pantheon of safety—the foundation, the pillars, and the roof—were defined by analyzing the focus group participants' responses and discussions. MT regulators' views of issues in patient safety in MT therefore relate to four major categories of issues or themes of concern. Each component part of the architecture (the roof, pillars, and foundation) are illustrated with focus group excerpts.

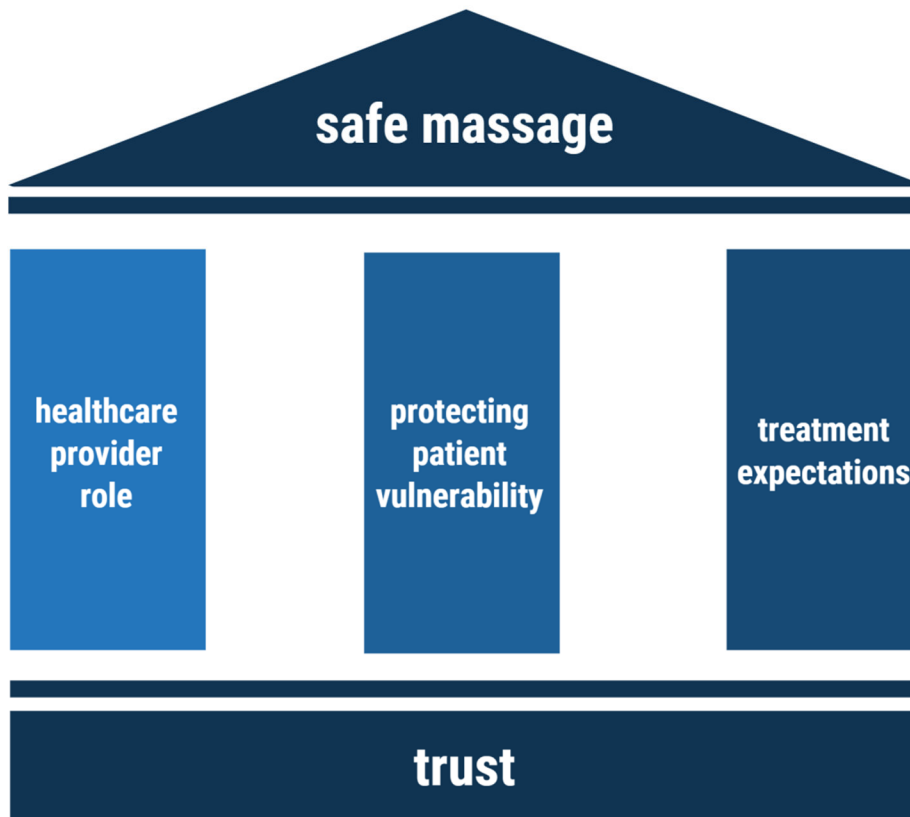


Figure 4.1 Pantheon of Patient Safety in Massage Therapy

The Foundation of Trust

The focus group discussion revealed a belief that the stable ground on which the framework of safe massage rests is essential to mitigate the risk of harm to the public. Participants felt that safety in massage is built on a foundation of trust—the trust that the public has in the massage therapist to both safeguard and promote patients' health and the trust that the public has that there is a system of accountability available in the event of a patient safety incident. The system of accountability is the legislatively derived authority of a self-regulating healthcare profession.

Participants talked about the components necessary to form this foundation of trust, which, they felt, in turn, grounded all the other issues of safety. The following quote from one of the participants illustrates the overarching theme of ensuring patient safety:

The phrase that keeps coming up for me is violation of trust. So, people not being informed about what a MT can or is supposed to do. It comes back to this—I trust that I am in safe hands, that is, a skilled practitioner that can have certain outcomes and treat within a certain scope of practice, and so when that person either practices outside that scope of practice or provides a treatment that gives me something that is different than what those outcomes should be then that is when the patient's trust in the profession has been violated. That is the negative outcome—I placed my trust in this healthcare professional.

Pillar One: The Healthcare Provider Role

The healthcare provider role was an important issue for participants and emerged as a main theme in the focus group. It is characterized as the first pillar resting on the foundation of trust which supports safe MT. Participants felt that uneven provincial legislation across the country (most provinces or jurisdictions are unregulated) coloured the public perception of MTs, even in provinces where the practice is regulated. The following quote illustrates this view:

The perception of massage therapy held by the public varies. If a patient understands how we use the history that they give us, they may choose to disclose more than they do otherwise. Some patients do not appreciate that it is extremely important for an RMT to hear a full history [because ...] they don't perceive the massage therapist in the role of healthcare professional. If they are used to receiving massage from another jurisdiction they may have a different expectation.

Minimum education requirements, mandatory continuing competency requirements, scope of practice adherence, and necessary informed consent were issues that participants thought were important elements in the construction of a solid role for the massage therapist as “healthcare

provider.” For example, one participant stated, “a great deal of our educational system deals with how to appropriately treat a person who comes with certain pathologies ... the simplest mis-approach to that patient could be very harmful.” It was also stated that as regulators there is a “commitment to continuing competency for quality assurance” and a responsibility to correct for “registrants going out of the boundaries of what they are allowed to do.” It was also shared that with regard to treatment approaches, there should be no surprises for the patient; that the “onus [is] on the therapist to negotiate consent for a shared treatment plan.”

Pillar Two: Patient Vulnerability

The focus group discussions suggest a second pillar formed by the theme of protecting patient vulnerability. Participants acknowledged and respected MT patients’ unique vulnerability. One participant described it this way when asked to talk about what is important in patient safety in MT: “I think [of] the inherent vulnerability of our patients ... we often practice with patients disrobed ... they are literally shedding layers.”

Additionally, research participants expressed views that Registered Massage Therapists (RMTs) are experts at managing the unique needs of patients within the therapeutic context. They felt that in a MT treatment intervention, caring physical touch must be provided alongside safeguarding the physical and emotional well-being of the patient. For example, it was stated that:

With respect to touch, it is not just the physicality of it, but also the amount of time that we spend in physical contact with our clients is very unique out there in the healthcare professions. So there might be other providers out there that briefly physically make contact with their patients but we are spending a good proportion of our time in physical contact, which I think touches on the vulnerability part as well.

The elements of patient vulnerability were expanded upon in the discussion this way:

... an adverse event could be many things: it could be dislodging a clot, it could be breaking a bone, it could be dislocating a joint—in the physical aspect. It could be bruising, breaking a blood vessel, a nerve being impinged due to positioning, just like in other professions like surgery. And then there is the emotional or mental aspect that could be an adverse event—you could bring up a whole well of things that this person didn’t even know was there because of that connection, or bring up something from their history like a physical abuse that the patient didn’t disclose. To me, what constitutes an adverse event is that which is a danger to the public along those two confines [the physical and the emotional].

Pillar Three: Treatment Expectations

The next theme that emerged from the focus group discussions centred on treatment expectations. Discussion revealed participants' consideration of the patient's, the therapist's, and the regulator's relative points of view. The theme of treatment expectations is the third pillar necessary to support safe MT.

The need to understand the viewpoints of a diverse patient population was apparent in the focus group discussion and is shown in the following statement:

It is important to be clear that there is a spectrum of possibility after treatment, but [it is also important to] be clear that that is not a goal or intention of the treatment in order for that technique to be effective. Sometimes patients seem to have an ideal like 'Yeah go ahead and hurt me' because that is the right thing to do—that is what is going to produce a productive treatment. It is important to let them know that yes, this is a possibility, but not necessarily what I am going for as a practitioner.

At times, the research participants' discussions revealed conflicting points of view. One participant stated that "A lot of members of the public don't know that MTs can do harm. I came for massage and I didn't expect to have this pain several hours later." In contrast, a different participant suggested that "most of the people I know that go [to massage therapy] know that it is going to benefit them, but that it can hurt too."

Informed consent was considered relevant to treatment expectations and patient safety. Speaking from their position as a regulatory authority, one participant explained that "It [informed consent] allows us to make sure that the patient is at least aware of possible consequences, whether that is immediate or 24 hours later. We describe it in our bylaws as potentially painful treatment, making sure that [the] patient is made aware that there may be repercussions to having massage."

Another view expressed was that "there is that public perception, on one hand, that I shouldn't have had a bruise and the RMT knowledge, on the other hand, that says well certain people do have a tendency to bruise and with this particular technique bruising is a common side effect, and it doesn't mean that the RMT wasn't competent or practicing safely: this is a normal course or part of treatment."

The following example illustrates the therapist’s perspective: “they are coming to me for a specific condition that I am building a treatment plan around: that is patient safety.”

A Roof Over the Pantheon of Patient Safety

The responses of the focus group participants lead to the idea of a roof sheltering the frame of patient safety in MT. The roof both protects that which is within the frame by reducing the risk of damage from negative influences on public safety and contributes to the integrity of the profession, the governing organization, and the professional members in its registry. It does so by defining the boundary of the framework.

Participants responded affirmatively to the question of “can it hurt and can it harm?” One participant said, “very basically ... we have the potential to cause harm with our hands.” They also expressed the opinion that risk is mitigated in specific ways. For example, one participant said, “as regulators we hear about the more dramatic adverse events and [the fact] that we don’t hear a great deal speaks well of the membership.” However, the speaker did acknowledge that “We do have occasional complaints. How we deal with those is—there is an acknowledgement that there is a certain amount of pain that will come with therapeutic touch.”

Participants viewed preparation for practice as essential for mitigating the risk of harm. Minimum competency standards to which RMTs are held are thought to be essential to safety. As one participant stated, “If not trained or not properly trained, in my professional opinion, it is more likely that you could cause harm to someone if you don’t understand what you are doing.”

Summary of Results

Patient safety in MT can usefully be characterized as a pantheon built on a foundation of trust, and supported by three pillars: a well-defined role for the massage therapist, clear treatment expectations, and protection of patient vulnerability. The structure and its component parts serve to reduce the potential risks inherent in the delivery of healthcare. It also forms and binds the integrity of the profession, its members, and its governing organizations.

4.5 Discussion

The main finding of the qualitative study with the focus group was the importance participants placed on a two-fold conceptualization of trust: the public's trust in massage therapists' capacity to promote their health and the public's trust that a system of accountability safeguards their welfare. The regulators were confident that RMTs have demonstrated the capacity to support the well-being of their patients and that the legislatively derived authority of the College promotes public safety.

Similarly, participants in a New Zealand study also thought trust was an important variable in determining what they valued about the MT encounter (38, 39). In a telephone-based focus group investigation with MT users, Smith et al. (2009a, 2009b) report that trust in the therapist was invaluable in continuing to obtain MT health services. Smith et al. (2009b) explored users' views about why they would discontinue care: in contrast to the views expressed by the Canadian regulators in this study, being hurt or harmed did not come up in expressed views about MT in the New Zealand study.

Canadian regulators expressed the expectation of protecting and safeguarding the patients' vulnerability and the harm inherent in any violations of that trust. In a study by Leach et al. about osteopathic practice, the research participants felt that patient vulnerability was exacerbated by the state of undress required in osteopathic assessment and treatment (18). Further, they thought possible patient discomfort and unease in being at least partially undressed may act as a barrier to communication. Unease was thought to inhibit both listening and interpretation in the context of the therapy applied, especially if the level of undress was unexpected by the patient. These findings compliment the regulators' views in the dissertation's focus group investigation, although they are unique in their expression compared to our findings. The notion that vulnerability necessitates extreme care and attention to patients' well-being was also strongly expressed by the MT regulators.

In a pilot study which used the methodology of phenomenology, Fortune and Gillespie explored the experiences of American MTs impacted by a new culture of professionalization, including increased regulation and pressure to adhere to concomitant practice standards (40). While the

study did not pertain to safety *per se*, the results regarding the role of the massage therapist as they are subject to the context of their work environments are relevant to the findings of the focus group. Fortune and Gillespie found that while licensing offered some relief from the discomfort associated with the poorly defined role and identity of American MTs, participants were also discomfited by having to conform to authority-derived standards of practice when individuality in the craft is prized. In contrast, the Canadian regulators were confident in the positive impact of practice standards on practice quality, patient safety, and practitioner accountability.

In their study of spinal manipulation therapy, Rozmovits et al. describe their findings as “a matrix of complex, competing narratives that simultaneously informed and clouded the safety culture” (41). The authors detailed the chiropractic community members’ views and found that considerable discord regarding philosophy of practice may jeopardize both patient safety and the profession’s image. Our findings regarding the regulators’ views were similar with respect to their concerns about adherence to standards of practice and confusion among the public about the appropriate role of MTs in healthcare.

The research participants in this study shared their views on the importance of enforceable practice standards in promoting safety among registrants and in mitigating risk from receiving incompetent care. An effort to compare the findings from our focus group with what is known from the literature on patient safety necessitates looking closely at the available research on massage-related harm, most of which is comprised of clinical case reports and systematic reviews of clinical case reports. The regulators’ views that rigorous standards in education and practice mitigate risk is consistent with the findings from an early (2003) systematic review of the safety of massage in which the author, Edzard Ernst, declares that “the majority of adverse effects were associated with exotic types of manual massage or massage delivered by laymen, while MTs were rarely implicated” (42). Similarly, in an updated systematic review, Posadzki and Ernst (2013) concluded that while new cases of serious massage-related harm had occurred, “in the majority of instances, however, AEs were not inflicted by professionally qualified massage therapists” (43).

Posadzki and Ernst (2013) report on eighteen primary cases published from December 2001 to May 2012. They show that massage has resulted in significant physical harm, including damage to vascular structures, nervous system tissues, organs, and muscle (43). The earlier review published by Ernst (2003) included a search of published articles from January 1995 to December 2001 and reported on sixteen case reports and four case series (42). Ernst (2003) concludes that massage is not entirely risk free, but the incidence of serious adverse events is suspected to be low. Another review published in the same year describes the cases in the literature and draws similar conclusions (44). Under-reporting of adverse effects is considered likely (42). Thus, research evidence supports the regulators' views that harm can result from "hands-on" intervention such as massage.

However, when reading the adverse event clinical case report literature, it is often difficult to determine the qualifications of the individual providing massage that reportedly resulted in harm: this makes it difficult to compare the findings of the focus group study with what is already known. For example, take Chakrapani et al.'s report of an incident resulting in bilateral carotid and bilateral vertebral artery dissection, described as a "spa stress-relieving facial and facial massage" delivered by a "facial massage therapist" (45). It is challenging to make sense of the provider's qualifications and whether the actions performed by the therapist would fall within the practice standards common to MT or not. The lack of detail is not unique to this case (43).

In the literature, there are several case studies that describe massage-related traditional healing practices that resulted in harm. The fact that these practices would not meet contemporary practice standards in Canada (46-48) supports the regulators' view that adherence to scope of practice is critical for safety. Similarly, research describing harm involving massage delivered by un- or under-trained providers supports the regulators' views on the importance of all three pillars of safety: protecting the vulnerability of the patient, understanding treatment expectations, and the role of the massage therapist as healthcare provider. For example, when describing an acute cervical cord injury, Lee et al. explicitly state that "the patient's massage was performed by a lay masseuse in a nonclinical setting. The massage was for relaxation and easing of stress and not for medical purposes; therefore, it is different from professional massage therapy" (49). In another published report in the same journal, Jabr describes the clinical case of a 53-year-old

woman who suffered a massive pulmonary emboli after receiving a vigorous leg massage from a non-massage therapist at a beauty salon (50).

While there is little massage-therapy-specific research to compare the findings of the focus group to, acupuncture researchers state that research results in this practice “show that acupuncture is relatively safe in standard practice, regardless of schools or modes of practice ... In non-standard practice, on the other hand, many serious adverse events have been reported” (51). Adams et al. (2011) reach similar conclusions regarding pediatric acupuncture, suggesting that substandard care is implicated in serious AEs and the risk is reduced with the appropriate training of practitioners (52).

Interestingly, most investigations of harm in manual therapies exclude MT. At times, MT is explicitly omitted from investigations of potential harm in clinical practice, often because of its lack of regulated health provider status (17, 53). It is also implicitly omitted by studies which only include physiotherapists, chiropractors, or osteopaths (15, 16).

There is little known about other health care providers’ views on safety issues in MT. Although outdated, one study suggests that many physicians support MT as likely to be helpful and unlikely to be harmful (54-56), with high physician referral rates relative to other therapies considered to be complementary or alternative medicine (57). In contrast to the regulators’ views that MT can hurt and can harm, Verhoef and Page (1998) found that only 12% of the 161 respondents thought that MT could cause physical or emotional harm to patients (56). Respondents reportedly offered “being too aggressive” and “practicing beyond their area of expertise” as possibilities of how harm could come about (56). These findings are consistent with the expert views of the regulators in this study, who shared these concerns.

Possible risk to the public associated with exposure to massage has been assumed to include potential physical, financial, and emotional/psychological harm resulting from incompetent or unethical practice (2). The participants in this study spoke only of physical and emotional risks, which suggests that the focus of concern is impact on health status only.

As other professions utilizing manual therapy in patient treatment have sought the opinions of stakeholders, including patients and practitioners, on issues related to patient safety, the views of MT regulators fill a gap in current patient safety research. The results of this study will inform the development of future research on patient safety in MT. Exploring regulators' views and opinions on the acceptability, attribution, and interpretation of the whole range of actual and potential adverse events associated with MT has provided the first insight into important perspectives in the Canadian context. It is expected that the results of this research will usefully inform MT practice, education, and policy, with respect to both the monitoring and prevention of adverse events.

Conclusion

MT regulator participants view the therapist's role as that of a healthcare provider entrusted to deliver safe and effective care. Patient expectations of trust and therapists' responsibility to uphold that trust are seen as critical, especially when treatment might be painful. MT patients are thought to be uniquely vulnerable due to the nature of the therapeutic encounter: extended personalized time, a state of undress, and physical touch all serve to exacerbate risks to well-being if not safeguarded by a professional massage therapist who is bound to adhere to practice standards enforceable by a legislatively-defined authority.

Understanding patient safety in MT in the Canadian context is aided by study in a regulated environment, as the mechanism for protection of the public is in place. The knowledge and experiences shared by the research participants demonstrate a commitment to patient safety in MT. The voices and views of other experts are needed to deepen the understanding of patient safety in MT.

In the next chapter, the results of a scoping study serve to investigate perspectives on patient safety from published peer-reviewed literature. In particular, the study explores the current practices used to identify, define, and classify patient outcomes that are, or may be, considered adverse and compares them to universally developed frameworks and models. These models can be viewed as representing the product of a collective striving for clarity in understanding and

representing the phenomenon of adverse events in healthcare. The scoping study seeks to make current practices meaningful for MT as part of healthcare.

References: Chapter 4

1. British Columbia Health Profession Regulation [March 23 2016]. Available from: <http://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/professional-regulation>.
2. Gowan-Moody D, Baskwill A. Report on policy issues concerning the regulation of massage therapy in Canada. The Federation of Massage Therapy Regulatory Authorities of Canada (FOMTRAC), 2006 May. Report No.
3. College of Massage Therapists of British Columbia. CMTBC 2015 Annual report. Available from: <http://www.cmtbc.ca/sites/default/files/CMTBC-Annual-Report-2015.pdf>.
4. College of Massage Therapists of Ontario. 2015 Annual report: enhancing accountability. CMTO Annual Report [Internet]. 2015. Available from: <http://www.cmtbc.ca/sites/default/files/CMTBC-Annual-Report-2015.pdf>.
5. Moyer C, Rounds J, JW H. A meta-analysis of massage therapy research. *Psychol Bull.* 2004;130(1):3-18.
6. Esmail N. Complementary and alternative medicine use in Canada: trends in use and public attitudes 1997-2006. Vancouver, British Columbia: The Fraser Institute, 2007 Contract No.: 87.
7. Collinge W, MacDonald G, Walton T. Massage in supportive cancer care. *Seminars in oncology nursing.* 2012 2//;28(1):45-54.
8. Munk N, Zanjani F. Relationship between massage therapy usage and health outcomes in older adults. *J Bodyw Mov Ther.* 2011 4//;15(2):177-85.
9. Beider S, Moyer C. Randomized controlled trials of pediatric massage: a review. *Evidence-based complementary and alternative medicine : eCAM.* 2007;4:23-34.
10. Shroff FM, Sahota IS. How can massage therapy move forward? Registered massage therapists touch on key points shaping their profession in British Columbia, Canada. *Home Health Care Manag Pract.* 2012;24(4):182-92.
11. Gowan-Moody DM, Leis AM, Abonyi S, Epstein M, Premkumar K. Research utilization and evidence-based practice among Saskatchewan massage therapists. *J Complement Integr Med [Internet].* 2013; 10(1):[1-10 pp.].
12. Baskwill AJ, Dore K. Exploring the awareness of research among registered massage therapists in Ontario. *J Complement Integrat Med.* 2016;13(1):41-9.
13. Boulanger C, Karen T, Jennifer L, Lowe D, John B. The development and validation of the client expectations of massage scale. *Int J Ther Massage Bodywork.* 2012;5(3):3-15.
14. Carlesso LC, MacDermid JC, Santaguida PL, Thabane L. A survey of patient's perceptions of what is "adverse" in manual physiotherapy and predicting who is likely to say so. *J Clin Epidemiol.* 2013 Oct;66(10):1184-91. PubMed PMID: 23856189. Epub 2013/07/17. eng.
15. Carlesso LC, Cairney J, Dolovich L, Hoogenes J. Defining adverse events in manual therapy: an exploratory qualitative analysis of the patient perspective. *ManTher.* 2011 Oct;16(5):440-6. PubMed PMID: 21377403.
16. Rajendran D, Bright P, Bettles S, Carnes D, Mullinger B. What puts the adverse in 'adverse events'? Patients' perceptions of post-treatment experiences in osteopathy--a qualitative study using focus groups. *ManTher.* 2012 Aug;17(4):305-11. PubMed PMID: 22425134.
17. Carnes D, Mullinger B, Underwood M. Defining adverse events in manual therapies: a modified Delphi consensus study. *ManTher.* 2010 Feb;15(1):2-6. PubMed PMID: 19443262.
18. Leach J, Fiske A, Mullinger B, Ives R, Mandy A. Complaints and claims against osteopaths: a baseline study of the frequency of complaints 2004–2008 and a qualitative exploration of patients' complaints 2011 [Nov 1, 2016]. Available from:

http://www.osteopathy.org.uk/uploads/complaints_and_claims_against_osteopaths_2004-2008_public.pdf

19. Buetow S, Kiata L, Liew T, Kenealy T, Dovey S, Elwyn G. Patient error: a preliminary taxonomy. *Ann Fam Med*. 2009 May 1, 2009;7(3):223-31.
20. Chang A, Schyve PM, Croteau RJ, O'Leary DS, Loeb JM. The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events. *Qual Assur Health Care*. 2005 April 1, 2005;17(2):95-105.
21. Long AF, Esmonde L, Connolly S. A typology of negative responses: a case study of shiatsu. *Complement Ther Med*. 2009 6//;17(3):168-75.
22. Denzin NK. *Interpretive Interactionism*. Newbury Park, CA: Sage; 1989.
23. Bradley EH, Curry LA, Devers KJ. Qualitative data analysis for health services research: developing taxonomy, themes, and theory. *Health Serv Res*. 2007;42(4):1758-72.
24. Porcino AJ, Verhoef M. The use of mixed methods for therapeutic massage research. *Int J Therapeut Massage Bodywork*. 2010;3(1):15-25.
25. Menard MB. *Methodological issues in the design and conduct of massage therapy research*. *Massage Therapy: The Evidence for Practice* London, UK: Mosby/Elsevier. 2002.
26. Kennedy AB, Cambron JA, Sharpe PA, Travillian RS, Saunders RP. Process for massage therapy practice and essential assessment. *J Bodywork Movement Therap*. 2016 7//;20(3):484-96.
27. Kennedy AB, Cambron JA, Sharpe PA, Travillian RS, Saunders RP. Clarifying definitions for the massage therapy profession: the results of the best practices symposium. *Int J Ther Massage Bodywork [Internet]*. 2016; 9(3):[15 p.].
28. Fournier C, Reeves S. Professional status and interprofessional collaboration: a view of massage therapy. *J Interprof Care*. 2012;26(1):71-2.
29. Finch P. A qualitative investigation into why the motivation of massage therapy students changes over the course of their professional education. *Int J Ther Massage Bodywork*. 2009;2(1):3.
30. Finch P, Baskwill A. A qualitative investigation into the usefulness and impact of the performance intervention zone system used in the diagnostic assessment of internationally educated massage therapists. *J Bodywork Movement Therap*. 2011;15(2):226-30.
31. Shroff F, Sahota I. The perspectives of educators, regulators and funders of massage therapy on the state of the profession in British Columbia, Canada. *Chiropract Man Therap [Internet]*. 2013; 21(2). Available from: <http://www.chiromt.com/content/21/1/2>.
32. Kania-Richmond A, Menard MB, Barberree B, Mohring M. "Dancing on the edge of research" – What is needed to build and sustain research capacity within the massage therapy profession? A formative evaluation. *J Bodywork Movement Therap [Internet]*. 2016:[1-10 pp.]. Available from: <http://www.sciencedirect.com/science/article/pii/S1360859216301115>.
33. Gill P, Stewart K, Treasure E, Chadwick B. Methods of data collection in qualitative research: interviews and focus groups. *Br Dent J*. 2008 03/22/print;204(6):291-5.
34. Berland A, GK N, Gundersen D. Patient safety and job-related stress: a focus group study. *Intensive Crit Care Nurs*. 2008;24(2):90-7.
35. Kirk S, Parker D, Claridge T, Esmail A, Marshall M. Patient safety culture in primary care: developing a theoretical framework for practical use. *Qual Safe Health Care*. 2007;16(4):313-20.
36. Smith JM, Sullivan SJ, Baxter GD. The culture of massage therapy: valued elements and the role of comfort, contact, connection and caring. *Complement Therap Med*. 2009;17(4):181-9.
37. Strauss A, Corbin J. *Basics of qualitative research*: Newbury Park, CA: Sage; 1990.
38. Smith J, Sullivan S, Baxter D. The culture of massage therapy: Valued elements and the role of comfort, contact, connection and caring. *Complementary therapies in medicine*. 2009;17:181-9.
39. Smith J, Sullivan S, Baxter D. Massage therapy services for healthcare: A telephone focus group study of drivers for clients' continued use of services. *Complement Therap Med*. 2009;17:281-91.

40. Fortune LD, Gillespie E. The influence of practice standards on massage therapists' work experience: a phenomenological pilot study. *Int J Ther Massage Bodywork* [Internet]. 2010 2010-08-18; 3(3):[7 p.]. Available from: <http://www.ijtmb.org/index.php/ijtmb/article/view/73>.
41. Rozmovits L, Mior S, Boon H. Exploring approaches to patient safety: the case of spinal manipulation therapy. *BMC Complement Altern Med*. (2016) 16:164;16(164).
42. Ernst E. The safety of massage therapy. *Rheumatology*. 2003;42:1101-6.
43. Posadzki P, Ernst E. The safety of massage therapy: an update of a systematic review. *Focus Alternat Complement Therap*. 2013;18(1):27-32.
44. Grant KE. Massage safety: injuries reported in Medline relating to the practice of therapeutic massage-1965-2003. *J Bodyw Mov Ther*. 2003;7(4):207-12.
45. Chakrapani AL, Zink W, Zimmerman R, Riina H, Benitez R. Bilateral carotid and bilateral vertebral artery dissection following facial massage. *Angiology*. 2009;59(6):761-4.
46. Li Z, Huan Z, Byard RW. Bruising caused by traditional Chinese massage therapy (ba sha) complicating the assessment of a case of fatal child abuse. *J Forensic Leg Med*. 2015;36:49-51.
47. Sahathevan R, Tan HJ, Abdullah S, Shahizon AM, Hamidon BB, Raymond AA. Spinal cord compression following traditional confinement massage. *The Medical journal of Malaysia*. 2011 Dec;66(5):495-6. PubMed PMID: 22390109. Epub 2012/03/07. eng.
48. Lai M-Y, Yang S-P, Chao Y, Lee P-C, Lee S-D. Fever with acute renal failure due to body massage-induced rhabdomyolysis. *Nephrol Dialysis Transplant*. 2006 January 1, 2006;21(1):233-4.
49. Lee T-H, Chiu J-W, Chan R-C. Cervical cord injury after massage. *Am J Phys Med Rehabil*. 2011;90(10):856-9.
50. Jabr FI. Massive Pulmonary Emboli after Legs Massage. *Am J Phys Med Rehabil*. 2007; 86(8): 691.
51. Vincent C. Safety of acupuncture. *BMJ*. 2002 2002/01/19/;324(7330):170+. English.
52. Adams D, Cheng F, Jou H, Aung S, Yasui Y, Vohra S. The safety of pediatric acupuncture: A systematic review. *Pediatrics*. 2011 December;128(6):e1575-e87. PubMed PMID: 2011679566.
53. Batavia M. Contraindications for therapeutic massage: do sources agree? *J Bodyw Mov Ther*. 2004 1//;8(1):48-57.
54. Astin JA, Marie A, Pelletier K, Hansen E, Haskell WL. A review of the incorporation of complementary and alternative medicine by mainstream physicians. *Arch Intern Med*. 1998; 158(21):2303-10.
55. Crock RD, Jarjoura D, Polen A, Rutecki GW. Confronting the communication gap between conventional and alternative medicine: A survey of physicians' attitudes. *Altern Ther Health Med*. 1999 Mar 1999;5(2):61-6. PubMed PMID: 204814441; 10069090. English.
56. Verhoef M, Page S. Physicians' perspectives on massage therapy. *Can Fam Physician*. 1998;44:1018 - 20.
57. Ezzo J. What can be learned from Cochrane systematic reviews of massage that can guide future research? *J Altern Complement Med*. 2007;13(2):291-5.

CHAPTER 5: PATIENT SAFETY INCIDENT (ADVERSE EVENT) DEFINITIONS AND TAXONOMIES IN MASSAGE AND MANUAL THERAPIES RESEARCH: A SCOPING STUDY

Prepared as: Gowan D, Baskwill A, Leis A. Patient safety incident (adverse event) definitions and taxonomies in massage and manual therapies research: a scoping study (unpublished).

This paper addresses the dissertation's second research objective of exploring taxonomies for understanding, evaluating, or reporting patient safety incidents (adverse events). Building on the focus group investigation described in the previous chapter, in which MT regulators shared their views on patient safety issues, the published literature on massage and other manual therapies was scoped to compare available taxonomies with known international frameworks.

5.1 Abstract

Introduction

Potentially harmful patient outcomes, varying from minor to serious incidents, are known to occur in massage and other manual therapies interventions. There is, however, a common complaint that uniformity and consensus regarding what constitutes an adverse event is lacking in patient safety literature. A scoping review was conducted to explore definitions and taxonomies used to operationalize potentially harmful outcomes across disciplines that use 'hands-on' manual therapy with comparison to internationally developed patient safety frameworks and models. The aim of the scoping review was to gain a better understanding of the current practices in identifying, defining, and classifying adverse events in research from a variety of non-pharmacological and non-surgical healthcare providers research in order to inform future development in the field of massage therapy research.

Methods

Based on the methodology of Arksey and O'Malley, a six stage scoping review was conducted. Eight electronic databases were searched. Inclusion and exclusion criteria were applied for screening then data was extracted and charted to collate and synthesize material ending in a stakeholder consultation to support knowledge translation.

Results

A total of 967 records were identified. Fourteen studies were relevant to this study objectives and were included in the final sample. Reporting of mild, minor and transient adverse events is common in the manual therapy research from massage therapy, acupuncture, chiropractic, physiotherapy, osteopathy and naprapathy. The duration, intensity and impact on function are the common elements used in taxonomies. Numeric rating scales are common means to describe patient outcomes in the study of potential harm.

Conclusion

There is a lack of uniform definition and taxonomy to describe adverse patient outcomes such as worsening pain in patient safety research. The scoping review has provided a useful characterization of where consensus exists.

5.2 Introduction

The need for uniform and useful reporting systems, registries, and systematic data collection mechanisms for adverse or harmful incidents in healthcare has been identified worldwide (1, 2). Building on the Conceptual Framework for the World Health Organization (WHO) International Classification of Patient Safety (ICPS), the WHO has proposed a core template to address the scarcity of universally applicable standards (3) and to redress “ambiguities of terminologies and definitions” with a minimal information model (MIM) for patient safety incident reporting (4).

The ICPS Conceptual Framework and the MIM are intended to facilitate the clinically meaningful and recognizable means for identifying patient safety incidents and learning from them. Along with incident type, patient outcome is the data category considered to be the clinically meaningful element of patient safety incident reporting, and as such, patient outcomes

will be the main concept of interest in this study. The model represents the data categories, definitions, attributes, and value sets felt to be critical in understanding patient safety incidents (PSIs). The use of existing international classification coding, such as the International Classification of Diseases (ICD) and International Classification of Functioning, Disability and Health (ICF) codes, is suggested in the MIM. Preferred terms and clearly agreed upon definitions are offered in the ICPS and MIM regarding the key concepts of harm, disease, injury, suffering, disability, and degree of harm.

Patient outcomes, defined by the WHO as “the impact upon a patient which is wholly or partially attributable to an incident” (3), are fraught with differences in interpretation in patient safety research and in practice. This is especially true of non-pharmacological health care interventions such as the application of manual therapy treatment because ontological and epistemological differences exist regarding what constitutes a good or bad outcome. The purpose of this study was to map the current practices in identifying, defining, and classifying patient outcomes as adverse within the research of professions that use ‘hands-on’ manual therapy care to gain a better understanding of similarities and differences in approaches.

The focus of the scoping review is on the current practices in documenting and discussing adverse patient outcomes. Research from other professions that commonly use ‘hands-on’ manual therapy as part of health intervention provide a useful body of literature to study because harmful or potentially harmful patient outcomes in manual therapy may be of a similar nature even though the scope of the interventions differs. As an example, manual therapy patients may experience new or increased soreness or pain or exacerbated impairment of range of motion (5). How researchers, practitioners, patients and policy-makers describe, discuss, and define these and similar outcomes is the main point of inquiry of the scoping review.

For example, Rozmovits et al. suggest that a clear understanding of spinal manipulative therapy patient safety is confounded by a “complexity of competing narratives” (6). Researching acupuncture regulation in Canada, Ijaz et al. argue that, especially in indigenous knowledge systems of traditional medicine, epistemology shapes the determination of what constitutes harm (7). Anecdotally, intra- and interprofessional controversy abounds regarding whether treatment

sequelae such as increased pain or tissue bruising are normal responses to treatment or should be considered harmful patient outcomes in massage and other manual therapies. A map of the language and terminology that is currently being used in the research from professions that use manual therapy in patient care is needed.

The Canadian Patient Safety Institute (CPSI) has adopted the terminology of the WHO (8). The CPSI defines a patient safety incident as “an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient” with the term “harmful incident” suggested to replace the term “preventable adverse event” (9). Also, the recognition and definition of the term “adverse event” is considered a necessary knowledge competency in the CPSI Competencies Framework (10). A comparison of the language used in research in massage and other manual therapies to national and international frameworks and models is needed to identify gaps in knowledge.

Although massage has a long history as a health and healing practice, the profession of MT has a very young research tradition, with intra-professional research literacy and capacity only starting to grow in recent years (11). Because MT research is so new, much can be learned from the research tradition and research products of other professionals that use manual methods in routine patient care (e.g. massage, mobilization), seek common outcomes (e.g. decrease pain/improved mobility), and treat similar conditions (e.g. back pain, neck pain). Although treatment approaches (for example spinal manipulation thrusting techniques) vary according to the scope of practice of different manual therapy professions (and spinal manipulation is not in the scope of practice of massage therapists in Canada) the purpose of the scoping review is to explore the discourse about patient safety in peer-reviewed literature, the language that is used to describe events, and the implications and recommendations that can be drawn from current massage and other manual therapies research to inform future research.

There has not been a synthesis of patient safety measures and methods with a focus on manual therapy care despite the WHO’s stated interest in community based care (12), the increased focus on patient safety research in many of the professions using “hands-on” manual therapy as the main means of patient care (13-16), and the development of internationally accepted strategies

such as the use of simple taxonomies for advancing patient safety research (2) . A comparison of taxonomies derived from or used in research across disciplines that use “hands-on” manual therapy has not been examined. Of interest in this study is how patient safety incidents are defined and classified in research on “hands-on” therapies, including soft-tissue manipulation or massage of the skin, muscles and connective tissue; mobilization or manipulation of the joints and spine; and various forms of physical perturbation of the human body by needles or other instruments. A scoping review was completed to explore the operationalization and taxonomic description of adverse events or PSIs in existing massage and manual therapy research. Our goal is to delineate and deepen the understanding of patient safety issues while advancing the reporting, monitoring, and prevention of harmful incidents. The results of this scoping review will be used to explore the applicability and meaningfulness of internationally accepted adverse event terms and taxonomies for the Canadian MT profession.

Purpose and Objectives

The focus of this article is the mapping of current knowledge and practices in identifying, defining, and classifying patient safety incidents (adverse events) in massage and manual therapies documented in peer-reviewed research literature. The objectives of the scoping study are: 1) to explore taxonomies for understanding, evaluating, or reporting harmful patient safety incidents (adverse events) in existing published literature for massage and manual therapies; 2) to compare available massage and manual therapy patient safety incident taxonomies with an internationally developed framework and the minimal information model’s patient outcome domain in order to summarize and collate the results; and 3) to inform stakeholders of the project and disseminate key findings in order to solicit feedback and opinions for knowledge transfer.

5.2.1 METHODS

A scoping review or scoping study “is a form of knowledge synthesis that addresses an exploratory research question aimed at mapping key concepts, types of evidence, and gaps in research related to a defined area or field by systematically searching, selecting, and synthesizing existing knowledge” (17). In the tradition of Arksey and O’Malley (2005), the goal is to rigorously collect and summarize existing research evidence to facilitate its effective use. This scoping study is comprised of six stages. The sixth stage which is the stakeholder consultation

exercise is discussed in detail in another chapter of this dissertation. Figure 5.1 depicts the flow of the scoping process.

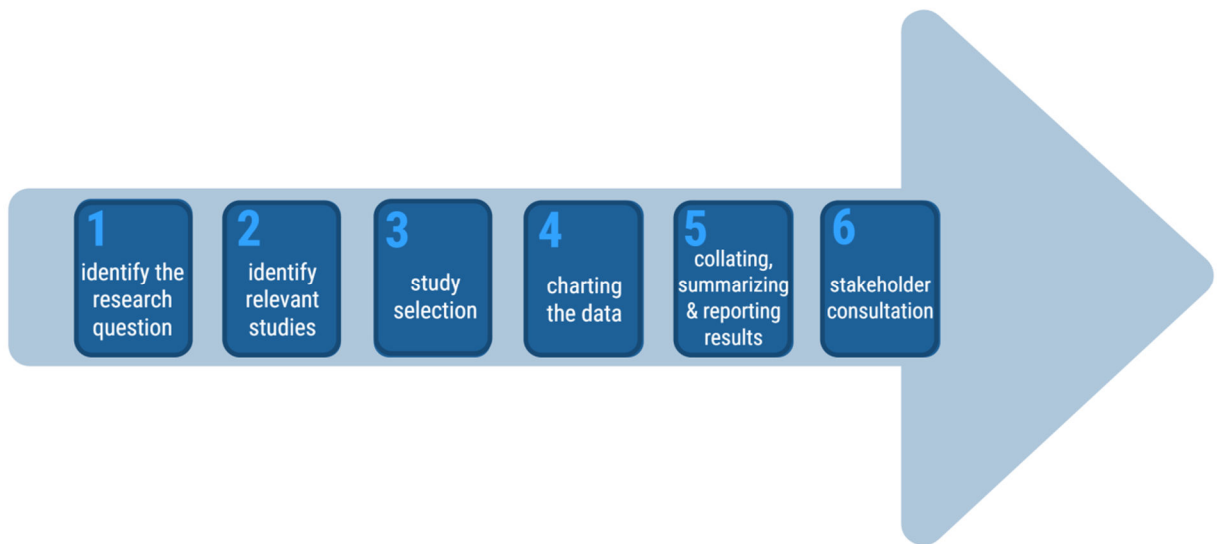


Figure 5.1 Scoping Review Process

Stage 1. Identifying the Research Question

In this scoping review we asked: what is the current knowledge and practice of defining and classifying patient safety incidents (adverse events) in massage and manual therapies in the literature regarding patient outcomes as characterized by the WHO minimum information model regarding type of harm, degree of harm, and social and/or economic impact?

Stage 2. Identifying Relevant Studies

With the aid of a health sciences librarian, the electronic databases MEDLINE, MEDLINE IN-PROCESS, EMBASE, CINAHL, SCOPUS, PEDRO, AMED, and ProQuest Theses & Dissertations were searched. The detailed search strategy used for each database is found in Appendix E of this document. A hand search of the bibliographies of key articles was conducted

to identify unique items not found in the database search. Additional Web of Science and Google Scholar searches were conducted for key authors and citations.

Stage 3. Study Selection

INCLUSION AND EXCLUSION CRITERIA. To be included in the full-text review, the title and/or abstract must indicate that the article contained research or published reports (including original research, reviews, theses, policy reports, commentaries, or editorials) involving professions and/or practices that include manual therapy techniques in patient management. Interventions referenced in the title and/or abstract could include commonly used “hands-on” manual treatment such as spinal manipulation or joint mobilization as well as soft-tissue mobilization or manipulation including the use of mechanical tools such as needles, cups, and scrapers or other non-electrophysiological instruments. The paper must be published in English. As well as the criteria stated above, the article must also pertain to one of the following topics:

1. study of the means of defining, classifying, characterizing, recording (collecting), or reporting data on patient safety incidents (adverse events) or
2. study of consensus building to determine definition, classification, recording, or reporting on patient safety incidents (adverse events) or
3. study of stakeholder (patients, practitioners, policy-makers, regulators) views of patient safety terminology and classification of patient safety incidents (adverse events) or
4. study of a tool or instrument to define and evaluate the elements and parameters of patient safety incidents or
5. reported on a methodology for the classification of patient safety incidents.

SCREENING. A protocol for capturing data that meets the standards for literature searches, screening citations, and reviewing full-text articles for systematic reviews was rigorously followed with adaptation for the scoping methodology. The tools include four Excel workbooks: 1) a primary workbook for systematic reviews that contains data sheets for storing and organizing information from each database searched; data sheets to organize information from non-database sources such as author, bibliography, conference and hand searches; tables for displaying data from the search; data sheets for titles and abstracts; sheets for full-text reviewed citations; sheets for compiling exclusions reasons; a sheet for compiling Cohen’s kappa from two

or more reviewers; and a flow diagram tool for the PRISMA model; 2) a workbook for screening titles and abstracts; 3) a workbook for reviewing full-text articles; and 4) a workbook for calculating Cohen's kappa.

Additional tools include numerous detailed handouts including how to use each workbook, documents with guidance on naming conventions, output styles for data management software, guides for various data management tools such as Endnote, and templates and reporting tools such as a search strategy documentation and PRISMA flow chart template. These tools are available from the University of Texas School of Public Health Library and are licensed under the Creative Commons (18).

AGREEMENT. The lead author served as the first reviewer, while a Registered Massage Therapist and PhD student with a Master of Science degree from McMaster University in Health Research Methodology served as the second reviewer. The Excel workbook designed to calculate Cohen's Kappa for screener inter-rater reliability was used prior to screening all abstracts and titles found in the database searches in order to determine that both reviewers agreed on use of the criteria for deciding which studies to include in the full-text review. The workbook included a random integer generator that allowed a random selection of 66 to 120 citations from all titles and abstracts in the scoping study, a range required to detect a statistically significant kappa at 90% power (19). The calculation used was:

$$\kappa = \frac{\text{Pr}(a) - \text{Pr}(e)}{1 - \text{Pr}(e)}$$

Stage 4. Charting the Data

Information that helped answer the research question of the scoping review was extracted from the included studies and charted in a spreadsheet. One reviewer (DGM) performed the charting task. The other reviewer (AB) made modifications and edits. Discussion was held until consensus was reached to resolve any disagreement. Information from the discussions was captured in the study log. Charting included extracted data on patient safety terminology used in each study's title, abstract or text; any *a priori* definition of terms used; the means used to

determine patient outcome as regards harm severity, degree and impact; and the taxonomy, classification, or framework offered by the included study.

Stage 5. Collating, Summarizing and Reporting the Results

Descriptive analysis (such as characteristics of the studies included) and thematic analysis were both used to synthesis and organize the data. Figures, tables, and excerpts from the included studies were then used to communicate the findings. The lead author (DGM) determined the themes that best represented the extracted data and then team members reviewed the emergent themes and provided feedback. The analysis proceeded iteratively until consensus was reached.

Stage 6. Stakeholder Consultation

Stakeholder consultation was considered essential for knowledge translation in this project. The results of valuable stakeholder consultation exercises are beyond the scope of this article and are instead described elsewhere in an unpublished dissertation.

5.3 Results

The main findings on the current knowledge and practices surrounding the definition and classification of patient safety incidents in massage and manual therapies illustrate the research tradition and present culture of patient safety among professions that use manual therapies, including MT. The main findings describe the results of the literature search, the mapping of studies showing the present state and nature of the research, and the themes exemplifying what is known and being done in research.

Relevant Studies Identified

As shown in the figure below, the titles of 967 articles were identified and their abstracts reviewed; 67 articles were retrieved and read. 14 of them met the final inclusion criteria and were retained for analysis.

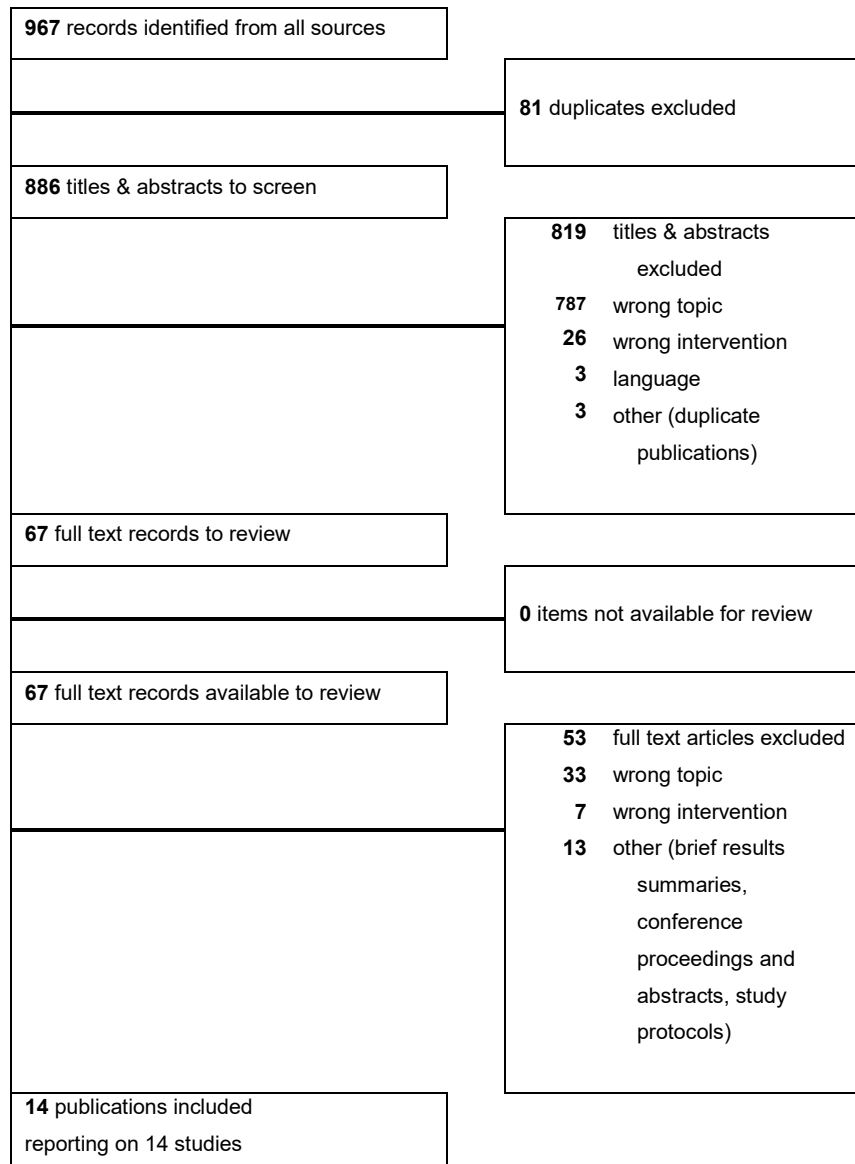


Figure 5.2 Flowchart of the Screening and Eligibility Evaluation Phases

Screening

Any discrepancies in applying the inclusion/exclusion criteria were resolved by discussion and consensus. Reports excluded as “wrong topic” lacked detailed reference to the means of defining, classifying, characterizing, recording (collecting), or reporting data on patient safety incident (adverse event) patient outcomes. Reports excluded as “wrong intervention” described non-”hands-on” therapies such as exercise, natural health products, descriptions of surgical interventions, or electrophysiological instruments and devices. Studies that investigated traditional healing modalities such as moxibustion along with acupuncture or that included

energy-based modalities such as Shiatsu were excluded from the final analysis. Publications in languages other than English and duplicate publications such as trials and study protocols were excluded.

During the full-text review process, the study team decided to only include those reports containing primary data in the scoping study, whether it was data on views on adverse events or data on the type, frequency, and severity of adverse events experienced in a study population. Thus, commentaries and letters to the editor (including brief results and summaries) were excluded.

Published reports that provided specific details regarding the definition of the concept (adverse event), a detailed taxonomic representation of patient safety incidents in “hands-on” manual therapy; or taxonomic means of categorizing the adverse patient outcomes in terms of type, degree of harm, and patient impact were selected for inclusion in the final scoping review results. Included studies described the patient safety incident related terminology used in sufficient detail, as well as the means used to designate or determine type, degree, and impact. As per the WHO ICPS Conceptual Framework (20), the type of harm could be pathophysiological, injury, or other; the degree of harm could range from none to death, and the impact would relate to functioning, disability, and health.

To be included in the final analysis the reports had to describe how the degree and level of impact was determined. For example, reports that only described incidents as being designated as mild patient outcomes with no description of how “mild” was defined were not included. To be included the studies must have operationalized the parameters in some way. A list of included studies is included in Appendix D.

5.3.1 RESULTS OF DESCRIPTIVE ANALYSIS

In Table 1 an overview of the included studies’ characteristics is given. Half of the studies focused on gathering the views of stakeholders and half focused on collecting specific PSI data (adverse events) with consideration of classification details.

Table 5.1 Characteristics of Included Studies (n=14)

Author and Date	Country	Study Design & Methods	Study Aim Related to Safety Taxonomy	Professions Involved
Carlesso LC, MacDermid JC, Santaguida PL, Thabane L; 2013	Canada	Cross-sectional survey of patients.	To describe the patient perspective regarding the identification and occurrence of adverse responses related to manual therapy.	Outpatient orthopedic. Manual physiotherapy.
Carnes D, Mullinger B, Underwood M.; 2010	UK	Modified Delphi survey of practitioners.	To seek an expert consensus definition of adverse events in relation to manual therapy by exploring understanding and meaning using a modified Delphi technique.	Statutory regulated manual therapy professions (chiropractic, osteopathy, and physiotherapy).
Senstad O, Leboeuf-Yde C, Borchgrevink C; 1997	Norway	Prospective clinic-based survey.	To study the type, frequency, and characteristics of unpleasant side effects after spinal manipulative therapy.	Chiropractic.
Carlesso LC, Cairney J, Dolovich L, Hoogenes J; 2011	Canada	Qualitative descriptive: semi-structured interviews with patients.	To describe how patients define adverse events associated with manual therapy techniques.	Physiotherapy. Chiropractic. Osteopathy.
Eriksen K, Rochester RP, Hurwitz EL; 2011	USA	A prospective, multicenter, (practice-based) cohort study.	To describe both symptomatic reactions and clinical outcomes following a short term of chiropractic care.	Chiropractic.
Paanalahti K, Holm LW, Nordin M, Asker M, Lyander J, Skillgate E; 2014	Sweden	RCT.	To describe the occurrence and severity of adverse events after manual therapy for patients seeking care for neck and/or back pain.	Manual therapists (chiropractors, naprapaths, osteopaths, physicians and physiotherapists).
Pohlman K, O'Beirne M, Thiel H, Cassidy JD, Mior S, Hurwitz E, et al.; 2014	Canada	Tool development: iterative consensus among expert panel.	To describe the development and validation of provider and patient measurement instruments to identify potential spinal manipulation therapy adverse events in provider offices.	Spinal manipulation therapy by chiropractors and physiotherapists.
Rajendran D, Bright P, Bettles S, Carnes D, Mullinger B; 2012	UK	Qualitative: focus group discussions.	To investigate how osteopathic patients view post-treatment experiences and what meaning they ascribe to them.	Osteopathy.
Rubinstein SM, et al.; 2007	Netherlands	Prospective multicenter observational cohort study.	To describe both positive clinical outcomes and adverse events following the first 3 treatments in a large cohort presenting with neck pain to 79 chiropractors.	Chiropractic.
Walker BF, Hebert JJ, Stomski NJ, Clarke BR, Bowden RS, Losco B; 2013	Australia	Blinded parallel-group randomized controlled trial.	To establish the frequency and severity of adverse effects from short-term usual chiropractic treatment of the spine when compared with a sham treatment group.	Chiropractic.
McDowell JM, Johnson G, Hale L; 2011	New Zealand	Survey for tool development.	To survey acupuncture practitioners' opinions regarding adverse reactions to acupuncture (ARA) terminology; testing a custom-designed Adverse Reactions to Acupuncture questionnaire (ARAQ).	Acupuncture (physiotherapists and GPs).
McDowell JM, Johnson GM, Hale L; 2013	New Zealand	Survey.	To identify whether practitioners had a preferred definition for an adverse reaction to acupuncture and interpreted key words pertaining to the concept in the same way; also asked which signs and symptoms were considered to be adverse reactions.	NZ physiotherapy and general medical practitioner acupuncturists.

Author and Date	Country	Study Design & Methods	Study Aim Related to Safety Taxonomy	Professions Involved
Thiel H, Bolton J; 2006	UK	A pilot study of adverse event monitoring using a form to collect data from practitioners.	To design and test a reporting format for patient safety incidents (PSIs).	Chiropractic.
Cambron, 2007	USA	A cross-sectional study of client responses.	To determine the amount and type of negative side effects and positive (unexpected) effects experienced after a massage session.	Massage therapy.

As shown in Figure 5.3 half of the studies used survey methods (questionnaires) to elicit patient safety-related data from either patients or practitioners, two of the fourteen studies were qualitative in methodological focus, two were cohort studies, two were randomized controlled trials, and one was consensus-based instrument development.

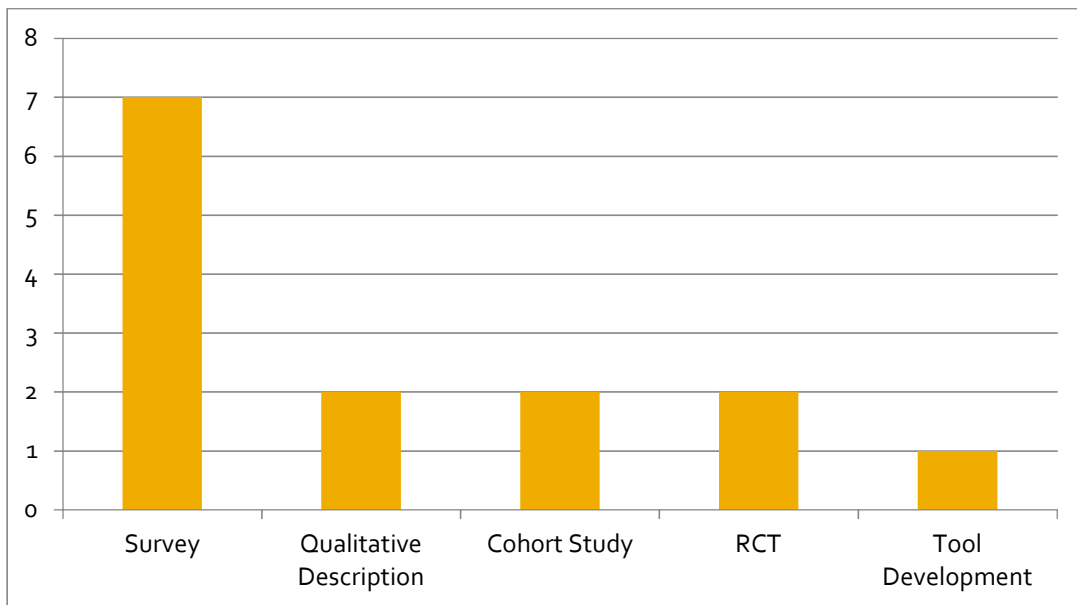


Figure 5.3 Number of Studies by Type of Study Design

Figure 5.4 shows the distribution of countries of origin of the research on patient safety in manual therapies.

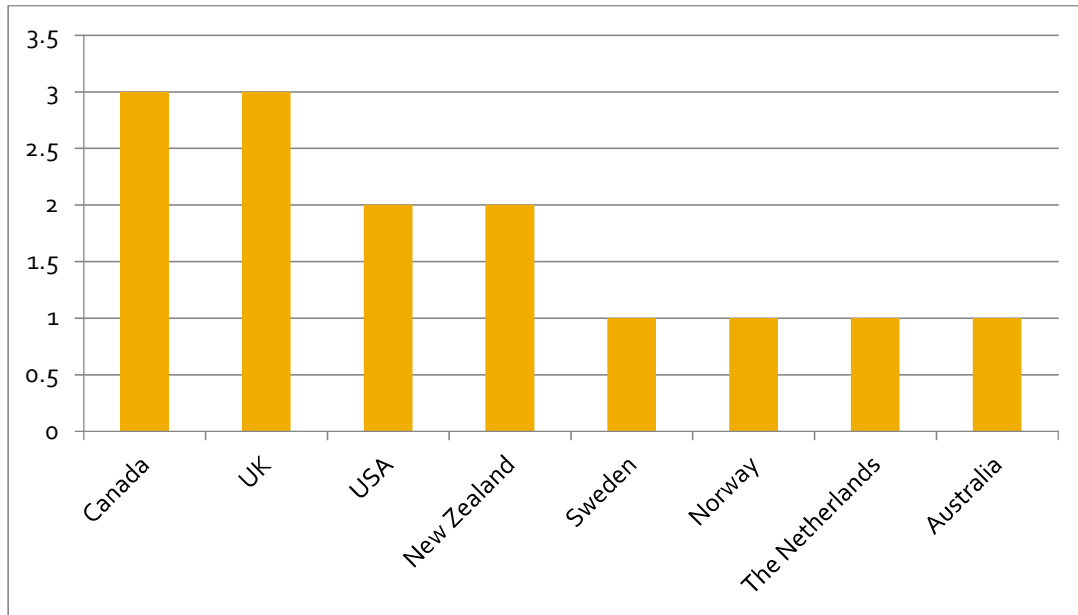


Figure 5.4 Number of Studies by Country of Origin (n=14)

One of the included studies involved students in a MT clinic as the therapy providers, two studied professionals delivering acupuncture, one study involved the work of naprapaths, and one study each involved osteopathic and physiotherapy professionals. The remainder of the studies involved the practices of chiropractic, physiotherapy, and osteopathy inclusively. Figure 5.5 shows the distribution of provider groups.

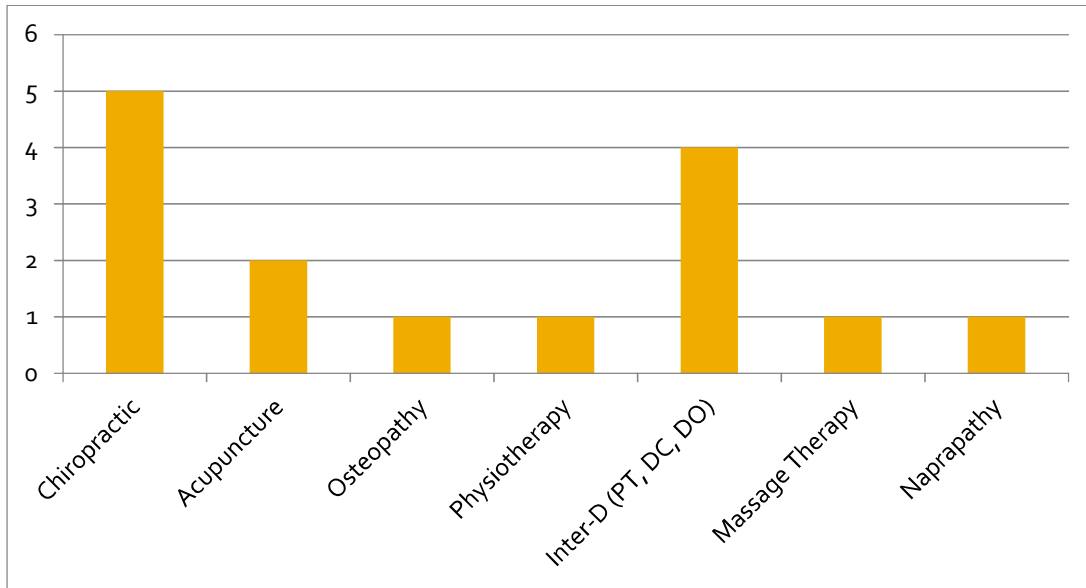


Figure 5.5 Number of Studies by Provider Group

Table 2 provides an overview of the terminology, definitions, means of assessment, and developed taxonomy in the relevant literature (included studies) that addresses the objective of the scoping review.

As shown in Table 5.2, of the 14 studies included in the final analysis, half did not provide an *a priori* definition of the patient safety terminology used in the study. “Adverse event” is the most common terminology used in the studies included in this scoping review, with 6 of the 14 studies utilizing this term. The word “adverse” was used in the title, abstract, or introduction in all but one paper (Cambron, 2007). Only one paper (Thiel and Bolton, 2006) use the term “patient safety incidents” in the title or abstract.

With respect to the means of determining type, degree, and impact for the purposes of categorization, classification, and taxonomy of PSIs, half of the studies used simple numeric rating scales (NRS) (Carnes, 2010; Senstad, 1997; Erikson, 2011; Paanalahti 2014; Rubinstein, 2007; Walker, 2013; Cambron, 2007).

With respect to determining a taxonomy, half of the studies offered a developed taxonomy to aid in answering the research question of this scoping review. All considered duration, severity, or intensity of symptoms and impact on function as critical elements in studying PSIs.

Table 5.2 Terms, Definitions, Assessment, and Taxonomies in the Included Studies (n=14)

Author & Date	Patient Safety Terminology & Definitions Used	Means of Assessment Type, Degree, Impact	PSI Taxonomy, Classification, or Framework
Carlesso et al., 2013	Adverse responses; post-treatment symptoms; no definition provided.	Adverse responses categorized by duration of symptoms and impact on function.	Major: > 1 wk; unable, help required. Moderate: 2-7 days; activities modified. Mild: up to 2 days; normal. Not adverse: mins. to hours; normal
Carnes et al., 2010	Adverse events—no <i>a priori</i> definition provided.	Degree to which the event is distressing on a 1-6 point scale.	Major: medium to long term, mod. to severe and unacceptable, normally require further treatment, and are serious and distressing. Moderate: mod. in severity. Mild and Not Adverse: short term and mild, non-serious, function remains intact, transient/reversible; no treatment alterations required.
Senstad et al.; 1997	Side effects, negative clinical outcomes, normal reactions, adverse reactions, unpleasant reactions—no <i>a priori</i> definition provided.	Severity assessed by 0-4 scale—minor to unbearable discomfort; type; onset (latency) and duration; severity and activities of daily living impact.	No taxonomy offered beyond the method to assess severity, latency, and function impact.
Carlesso et al.; 2011	Adverse event: defined as impacted by antecedent (e.g. injury state), sequelae (e.g. functional impact), and universal elements (e.g. expectations).	Qualitative description of patients' experience with "hands-on" treatment.	A framework of four aspects central to patients' determination if a response is an AE or not. They are: functional impact; post-treatment pain/symptom; timing and duration; and ruling out alternative causes.
Eriksen et al., 2011	Symptomatic reactions (SR); complications; side effects. SR is defined as a new complaint not present at baseline or a worsening of the presenting complaint by >30% on an 11-point NRS occurring <24 hrs after procedure. Serious AE: events resulting in death, life-threatening situations, need for admittance to a hospital, or temporary or permanent disability.	Intense SR is ≥ 8 on the 11-point NRS. SRs were categorized according to their 1) presence (yes or no), 2) start time and severity (\leq within 24 hours and NRS >1), and 3) severity alone (>7).	No taxonomy offered beyond the method to assess severity, latency, and function impact.
Paanalahti et al., 2014	Adverse event— no <i>a priori</i> definition provided.	Categorized on the duration and/or severity of an event occurring within 24 hrs post tx, # of hours event lasted (duration), and 11 point (NRS) from 0–10 (0 = had not bothered them at all and 10 = had bothered them in the worst possible way).	Categorized in to five levels: 1) Short minor (NRS ≤ 3 and < 24 hours of duration), 2) Long minor (NRS ≤ 3 and ≥ 24 hours of duration), 3) Short moderate (NRS > 3 and < 24 hours of duration), 4) Long moderate (NRS > 3 and ≥ 24 hours of duration) and 5) Serious adverse event (loss of bowel/bladder function, stroke, fracture or hospitalized).
Pohlman et al., 2014	Adverse event: any unfavorable sign, symptom, or disease temporally associated with the treatment, whether caused by the treatment.	Questionnaire development for patients and practitioners (DCs and PTs).	Mild: Asymptomatic or mild symptoms, self-care only (e.g. ice/heat, over-the-counter analgesic). Moderate: Limiting age-appropriate ADLs (e.g. work, school) OR sought care from MD. Severe: Medically significant but not immediately life-threatening; temporarily limits self-care (e.g. bathing, dressing, eating) OR urgent or emergency room 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 hr.: a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.

Author & Date	Patient Safety Terminology & Definitions Used	Means of Assessment Type, Degree, Impact	PSI Taxonomy, Classification, or Framework
Rajendran et al., 2012	Adverse events— no <i>a priori</i> definition provided.	Qualitative analysis of focus group research found patient concerns with pain due to treatment. Loss of function regarded as most important concern especially if impacts ADLs; effects that were unexpected in nature or intensity were more likely to be considered unacceptable.	A conceptual model of meaning with four interrelated components (expectations, personal investment, osteopathic encounter, clinical change) under an overarching construct, the “global osteopathic experience”, plus sub-themes.
Rubinstein et al., 2007	Adverse event: defined as either a new related complaint or a worsening of the presenting or existing complaint by >30% compared to baseline based upon an 11-point numerical rating scale.	NRS score. Intense adverse events were defined ≥ 8 . Participants were asked about musculoskeletal pain (worsening), non-msk. (tiredness, fatigue, other), and psychological (depression, confusion, fear).	No taxonomy offered beyond the method to assess severity, latency, and function impact.
Walker et al., 2013	Adverse effects— no <i>a priori</i> definition provided.	“Did you experience any new unwelcome symptoms or an increase of your presenting symptoms during the first 48 hours (2 d) after treatment?”: Intensity (11-point NRS), onset (5 categorical responses ranging from < 10 min to > 24 hr), and duration (5 categorical responses ranging from < 1 hr to > 2 d).	No taxonomy offered beyond the method to assess severity, latency, and function impact.
MacDowell et al.; 2011	Adverse reaction to acupuncture (ARA): any adverse effects possibly related to acupuncture making treatment necessary or severely interfering with the patient’s wellbeing.	Participants (PT and GP acupuncturists) categorized a list of sequelae as known side effect, adverse reaction, complication, or malpractice using VAS, ranking tasks and word categorisation tasks.	A taxonomy was not offered as part of this study.
McDowell et al.; 2013	Adverse reaction: any adverse effects possibly related to acupuncture making treatment necessary or severely interfering with the patient’s wellbeing.	A VAS was used to assess the synonymy of key terms ratings of symptoms as an adverse reaction.	Only three sequelae were able to be categorized as an “adverse reaction” (vomiting, convulsion, and seizure); other terms lacked consensus across the key categories of “malpractice,” “side effect,” “complication,” and “adverse reaction.”
Thiel H and Bolton J; 2006	Patient safety incidents (PSIs): any unintended or unexpected incident(s) that did lead to harm to the patient or had the potential to cause harm but was prevented (near miss).	Following design of a reporting format, chiropractors and/or final year clinical students responded by completing a form.	Grade— low harm: incident required extra observation or minor tx (additional therapy or short term medication); mod. harm: moderate increase in additional tx (requires hospital care, surgery, prolonged care); significant harm; severe harm: permanent disability; death.
Cambron et al., 2007	Side effects, unpleasant reactions.	Questions regarding the type of negative side effect, the level of discomfort, the timing of when the discomfort began and ended, and how much the discomfort affected the client’s ADLs. Level of discomfort measured by self-report on a 0-10 scale.	No taxonomy offered beyond the method to assess severity, latency, and function impact.

5.3.2 RESULTS OF QUALITATIVE THEMATIC ANALYSIS

In order to derive themes that best represent the extracted data, the data from the studies were coded and grouped according to similar conceptualizations, noted highlights and gaps, and consistency with the WHO conceptual framework and model. Three themes and sub-themes emerged in answer to the following two research questions: A) What is the current practice in identifying, defining, and classifying patient safety incidents (AEs) in massage and manual therapies in the literature?; and B) Are available taxonomies of patient outcomes consistent with the WHO ICPS?. Table 3. depicts the resulting themes derived from this analysis.

Table 5.3 Emergent Themes of Included Studies

Theme	Theme 1. Conceptualizing Harm	Theme 2. Uniformity and Non-Uniformity	Theme 3. Convergence
Sub-Theme	Hurt versus harm, harm versus healing, and pain versus suffering.	Knowledge, though incomplete, aligns with WHO ICPS and MIM.	Major/serious and everything else.
Study Excerpts and Key Examples	<p>“It is likely that common and benign reactions that also follow a distinct pattern can be considered ‘normal’” (Senstad, 1997).</p> <p>“reported symptoms may not be considered ‘adverse’ in clinical practice (i.e., tiredness, lower back soreness) but could represent change or healing” (Erikson, 2011).</p> <p>“It is possible that soreness in muscles should not be considered an adverse event but rather a normal reaction due to the treatment, as far as the reaction is mild and transient” (Paanalaihti, 2014).</p> <p>“a client may accept the risk of one form of negative side-effect (i.e., muscle soreness) but not another” (Cambron, 2007).</p>	<p>“A key finding was that patients defined mild, moderate and major AE by pain/symptom severity, functional impact, duration and by ruling out of alternative causes” (Carlesso, 2011).</p> <p>“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” (Pohlman, 2014).</p> <p>“A coherent and standardized approach to reporting clinical incidents is necessary to ensure that certain key points about the event are captured each time. This can be achieved by defining a ‘minimum data set’ for reportable information” (Thiel and Bolton, 2006).</p>	<p>“Adopting a patient-centered approach would suggest that adverse responses may be grouped into two categories: major and all others” (Carlesso, 2013).</p> <p>“There is disparity between the way in which patients perceive these mild to moderate post-treatment experiences and clinical definitions of adverse events” (Rajendran, 2012).</p> <p>“This term [intense] must not be confused with serious adverse events, which refer to events resulting in death, life-threatening situations, the need for admittance to a hospital, or temporary or permanent disability” (Rubinstein, 2007).</p> <p>“Severity and seriousness must also be considered in context; a migraine following acupuncture, for example, may be a severe response but not necessarily a serious response” (McDowell, 2011).</p>

Theme 1: Conceptualizing Harm

The first theme is conceptualizing harm and judging or assessing patient outcomes in accordance with challenging the concepts of hurt versus harm, harm versus healing, and pain versus suffering. Included studies inquired, with varying degrees of detail, about whether a patient outcome constitutes a positive event, an adverse event, or something else. In particular, the studies' queries regarding the difference between hurt (additional or increased pain) and harm (additional damage or disability) reveal a similar conceptualization of patient safety incidents, although it is not explicitly stated this way. In a similar vein, the studies also explored whether increased pain or painful changes in status or function could be evidence of healing rather than harm. Finally, included studies reflected the idea that increased pain or dysfunction may not always be equated with suffering as long as the patient accepts and adapts to things getting worse before they get better.

Theme 2: Uniformity and Non-Uniformity

The second theme is uniformity and non-uniformity, that is, the extent studies conformed to international standards in defining and classifying adverse events. Knowledge gained from the studies' research is presented in an incomplete manner. Studies either fail to provide a definition or a detailed taxonomy. Specifically, while still meeting the other inclusion criteria, half of the studies did not provide an *a priori* definition of the patient safety terminology used and half did not offer a detailed taxonomy.

While uniformity of definition is lacking, the elements considered important by the WHO International Classification of Patient Safety (ICPS) minimum information model are uniformly represented in the literature. All considered duration, severity or intensity of symptoms, and impact on function as critical elements. However, the term most commonly used in the included studies to describe the concept is "adverse event" with the word "adverse" used in the title, abstract, or introduction in all but one paper.

Theme 3: Convergence

The final theme is one of convergence of approaches in means, methods, and measures of identifying and classifying patient safety incidents. Although the included studies investigate

patient safety in manual therapy from different approaches, they do display common strategies in the means of assessing outcomes, for example, the use of numeric rating scales. Most saliently, there was common agreement in admitting the challenges and ambiguity of classifying all but serious adverse events. This convergence of views could be said to constitute a sub-theme of “Major/serious and everything else.” Specifically, there was common judgment in the included studies about what constitutes the most serious cases of adverse events, that is, events that are life-threatening and require emergency medical care. There was also common agreement that mild/moderate AEs are common occurrences in routine manual therapy practice across the professions included in the studies.

5.4 Discussion

This scoping review led to four key findings and three main themes that best represent the current knowledge and practice in identifying, defining and classifying adverse events in research about patient safety involving healthcare by practitioners who use manual or ‘hands-on’ methods. The first key finding was that the term “adverse event” is the most commonly used term in patient safety research in the manual therapies included in this review. The second findings was that, symptoms’ duration, severity, intensity, and impact on function are the common elements used in the creation of taxonomies to describe patient outcomes in the study of potential harm and thus are consistent with the WHO International Patient Safety Framework and the Minimum Information Model for reporting on patient safety incidents. A third key result was that numeric rating scales are useful means of describing and classifying levels of severity, intensity, and impact on function for negative as well as positive patient outcomes. The fourth key finding was that there is a lack of uniform definition and taxonomy to describe adverse patient outcomes in patient safety research in professions that provide manual therapy in regular patient management. The emergent themes constituted conceptualizations of harm, level of uniformity, and convergence or commonality.

Research on the definition and classification of PSIs, side effects, and adverse events in manual therapy comes from many different countries, indicating there is a global interest in patient safety culture. Comparing the terminology and definition of terms in the included study to the WHO MIMS model illuminates the international variance in adopting a common nomenclature.

While the WHO model terminology prioritizes the use of “patient safety incident” over “adverse event,” and this language has been adopted by the Canadian Patient Safety Institute (CPSI) (9), few manual therapy researchers are following suit. None of the studies included the use of International Classification codes for description or recording. All the studies reviewed here did, however, prioritize the elements of duration, severity, intensity, and impact on function when ascertaining harmful outcomes from manual therapies: this is consistent with the WHO framework. As yet, there is no agreed upon standard of grading the elements across, or even within, the professions under study.

It appears that the topic of patient safety in manual therapy is garnering increasing attention within the last fifteen years, as attested by the recency of the fourteen studies uncovered in our scoping review. These studies use various methodologies and research designs (including both qualitative and quantitative research) geared towards answering important questions about harmful patient outcomes, especially as it relates to type, severity, and impact. The use of simple numeric rating scales as a means of describing and classifying severity and impact appears commonly in the literature and would seem appropriate for future research, education, and practice.

Articles describing patient safety research about adverse event definition and classification came from several professions that commonly utilize “hands-on” manual therapy as a healthcare intervention: these included physiotherapy, osteopathy, chiropractic, acupuncture, and MT as well as professional practices not common in Canada, such as naprapathy. While not the focus of the scoping review, the studies make clear that mild, minor, and transient worsening of pain is considered common across all professions that use “hands-on” manual therapy in routine patient care. For the study purpose, manual therapy was operationalized as a set of healthcare interventions in which contact between a practitioner and the patient or client includes mechanical stimulation of the body such as spinal manipulation or joint mobilization and/or soft-tissue mobilization or manipulation using the hands or non-electrophysiological tools including needles that penetrate the dermis. Few of the studies uncovered in the review operationalized either the intervention or outcome of interest.

Descriptions of manual therapy providers within the current literature are typically exclusive of MTs (21, 22). It is within the timeframe of the publication of most of the included studies that the profession of MT in Canada officially adopted evidence-based practice in the regulated provinces (23). In Canada, even in an unregulated province, attitudes toward evidence-based practice are positive (24), but the tradition of research, professionalization, and regulation as health care providers in Canada is shorter in MT than other manual therapy fields. This may contribute to the lack of inclusion of the group. Several of the studies explicitly evaluated the practice of spinal manipulation, which is outside the scope of practice of MTs in Canada.

The research reviewed here supports the claim that the concept of adverse events within the patient safety literature lacks uniform definition (25). This is evident in the variance in the definitions and taxonomies offered within the included studies, but also in the proportion of studies (33 of 53) excluded at the level of full-text review due to a lack of definition or operationalization of the concepts of interest. Additionally, it is clear that the topic is complex with layered disagreements on what constitutes a side/adverse effect or event. Moreover, this review confirms that the research process for studying harms is more complex and less developed than efficacy research in healthcare (26).

Questions around dosage issues and the aggravation of symptoms as part of healing are not addressed further within this scoping review, as there was little information on these topics to extract from the included studies. The topic of dosage in manual therapies has been discussed by Chaitow (2016) recently, with recommendations for further study and consideration of the degree of load in applications such as compression, stretch, and mobilization or manipulation (27). Agreement within and across fields of manual therapy is yet to be achieved with respect to what constitutes a harmful application and outcome.

Studies did not typically address issues of causation, although the notion that using the term “adverse event” or “patient safety incident” circumvents the need to establish causation is addressed in the literature elsewhere (25). Common conclusions and recommendations drawn by the authors of the included studies centre around the need for a patient-centred approach, understanding of contextual issues including the therapeutic relationship, treatment expectations,

and patient and provider perspectives in what is harmful and what is healing. Recommendations for future research include the ongoing and pressing need for standardization of definitions and common classification schemas.

Lastly, the information from the included studies demonstrates that minor, potentially negative consequences of engaging in “hands-on” manual therapy are common. Increased pain or aggravation of symptoms is not uncommon, although whether it is expected, acceptable, or necessary remains in dispute. Psychological sequelae ranging from positive (relaxation or euphoria) to negative (crying or disorientation) offer an interesting area for future risk and benefit analysis discussions. In MT especially, a state of relaxation is a well-known bonus effect of the treatment of musculoskeletal conditions.

The finding of this study that best reflects the ongoing debate within the literature is that data on adverse events lacks either sufficient detail or uniform interpretation for proper understanding of the phenomenon. These findings are consistent with Gorrell et al. in their systematic review of the reporting of adverse events in spinal manipulation trials and also with Turner et al. in their evaluation of the completeness of CAM trial safety reporting (28).

Carlesso et al. (13) and Gorrel et al. both conclude, as we do, that not only is there too much variation in the nomenclature used but that some terms are simply not logically appropriate. Likewise, we suggest that “side effect,” though not infrequently used in the literature on manual therapy safety, is not appropriate because it denotes a causal relationship that cannot be argued for in this type of research and it could equally describe a positive or a negative outcome. Gorrel et al. point out that the CONSORT guidelines themselves define an adverse event as a harmful side effect and therefore may mislead researchers about the appropriateness of using these terms interchangeably.

Study Strengths and Limitations

This scoping review has several limitations that must be considered when drawing conclusions about the current knowledge and practices in manual therapy patient safety taxonomy research.

As Weeks and Strudsholm described in their scoping review of CAM literature, many terms pertaining to unconventional manual therapies are not well indexed, and we too found that a large number of irrelevant articles were retrieved in the original search (29). Another limitation results from the English-language restriction that clearly excludes the contribution of studies beyond the Western part of the globe. Decision making regarding inclusion and exclusion criteria also limits the generalizability of the current research, and curtailed extraction of data from some studies that could be informative to a different research question. For example, we excluded a study on Shiatsu that offered a thoughtful and helpful typology on adverse events from an energy healing paradigm as we deemed that the intervention did not fit our definition of “hands-on” manual therapy. While the inclusion of this study would not change the conclusions of this review, it is important to note.

The study’s main strengths lie in the careful use of protocol and tools developed by Vonville (retrieved January 1, 2016) for systematic review (18) and the rigorous use of the York framework for scoping review (30). Collecting and synthesizing the current knowledge in defining and classifying patient safety incidents with respect to patient outcomes in “hands-on” manual therapy approaches provides rich data to deepen the understanding of this topic. Our search strategy was comprehensive and surveyed the literature broadly. The search yielded studies containing important information for mapping the key definitions and classification schemas, characteristics and types of evidence, and gaps present in the current research.

Conclusion

Mapping the current knowledge and practices in identifying, defining, and classifying patient safety incidents (adverse events) in massage and manual therapies documented in peer-reviewed research literature reveals that the study of “hands-on” manual therapy PSIs, while garnering increased attention in the medical literature from diverse therapeutic fields, still suffers from a lack of uniform definitions of terms related to patient safety and events. There is no commonly adopted taxonomy to describe adverse events. To date, the commitment to drawing clearly defined and operationalized treatment intervention and patient outcomes is equivocal in the literature. The utility of the research suffers from this.

Researchers must make decisions on what nomenclature and classification frameworks to adopt. Further, taxonomies should be developed and used, and the means used to grade impact on the patient should be described in detail to increase our understanding of the concept of harm. Such research is necessary in the field of MT in order to enhance client-centred care by communicating risks and benefits. The groundwork of exploring the definitions and classifications within the research of other manual therapy fields (as provided in this scoping review) is an important step in a patient safety research, education, and practice culture.

References: Chapter 5

1. World Health Organization. WHO Patient Safety - programme areas [internet]. Available from: <http://www.who.int/patientsafety/about/programmes/en/>.
2. Baker GR. Report of the working group on methods and measures for patient safety. World Health Organization, 2007.
3. World Health Organization. Working paper: preliminary version of minimal information model for patient safety. 2014 Contract No.: WHO/HIS/SDS/2014.7.
4. World Health Organization. Information model for patient safety incident reporting systems: expert review meeting summary report. University of Tokyo, 2012 Contract No.: WHO/HIS/SDS/2014.6.
5. Cambron J. A, Dexheimer J., Coe P., Swenson R. Side-effects of massage therapy: a cross-sectional study of 100 clients. *J Altern Complement Med.* 2007;13(8):793-96.
6. Rozmovits L, Mior S, Boon H. Exploring approaches to patient safety: the case of spinal manipulation therapy. *BMC Complement Altern Med.* (2016) 16:164;16(164).
7. Ijaz N, Boon H, Muzzin L, Welsh S. State risk discourse and the regulatory preservation of traditional medicine knowledge: the case of acupuncture in Ontario, Canada. *Soc Sci Med.* 2016;170:97-105.
8. Beard P, Hoffman CE, Ste-Marie M. Canadian Incident Analysis Framework [Internet]. Edmonton, AB: Canadian Patient Safety Institute; 2012. Available from: <http://www.patientsafetyinstitute.ca/>.
9. Canadian Patient Safety Institute. Topics [Internet]. Canadian Patient Safety Institute; [cited 2016 July 7, 2016]. Available from: <http://www.patientsafetyinstitute.ca/en/Topic/Pages/Patient-Safety-Incident.aspx>.
10. Canadian Patient Safety Institute. The Safety Competencies Framework; (August 21, 2016). Available from: <http://www.patientsafetyinstitute.ca/en/toolsResources/safetyCompetencies/Pages/default.aspx>.
11. Kania-Richmond A, Menard MB, Barberree B, Mohring M. "Dancing on the edge of research" – What is needed to build and sustain research capacity within the massage therapy profession? A formative evaluation. *J Bodywork Movement Therap* [Internet]. 2016:[1-10 pp.]. Available from: <http://www.sciencedirect.com/science/article/pii/S1360859216301115>.
12. Cresswell KM, Panesar SS, Salvilla SA, Carson-Stevens A, Larizgoitia I, Donaldson LJ, et al. Global research priorities to better understand the burden of iatrogenic harm in primary care: an international Delphi exercise. *PLoS Med.* 2013;10(11):6.
13. Carlesso LC, MacDermid JC, Santaguida LP. Standardization of adverse event terminology and reporting in orthopaedic physical therapy: Application to the cervical spine. *J Orthop Sports Phys Ther.* 2010 //;40(8):455-63.
14. Vohra S, Kawchuk GN, Boon H, Caulfield T, Pohlman KA, O'Beirne M. SafetyNET: An interdisciplinary research program to support a safety culture for spinal manipulation therapy. *Eur J Integrat Med.* 2014 8//;6(4):473-7.
15. Carnes D. What can osteopaths learn from concerns and complaints raised against them? A review of insurance and regulator reports. *Int J Osteopath Med.*
16. Zhang J, Shang H, Gao X, Ernst E. Acupuncture-related adverse events: a systematic review of the Chinese literature. *Bull World Health Organ.* 2010;88(12):915-21.
17. Colquhoun HL, Levac D, O'Brien KK, Straus S, Tricco AC, Perrier L, et al. Scoping reviews: time for clarity in definition, methods, and reporting. *J Clin Epidemiol.* 2014 12//;67(12):1291-4.
18. VonVille HM. Excel workbooks for systematic reviews 2016 [March 1 2016]. Available from: http://libguides.sph.uth.tmc.edu/excel_SR_workbook.

19. Vonville HM. Excel workbook to calculate Cohen's kappa for screener inter-rater reliability [Internet]. University of Texas School of Public Health Library; 2015. Available from: http://libguides.sph.uth.tmc.edu/excel_SR_workbook.
20. World Health Organization. More than words. Final technical report conceptual framework for the International Classification for Patient Safety. 2009.
21. Carlesso LC, Cairney J, Dolovich L, Hoogenes J. Defining adverse events in manual therapy: an exploratory qualitative analysis of the patient perspective. *ManTher*. 2011 Oct;16(5):440-6. PubMed PMID: 21377403.
22. Carnes D, Mars TS, Mullinger B, Froud R, Underwood M. Adverse events and manual therapy: a systematic review. *ManTher*. 2010 Aug;15(4):355-63. PubMed PMID: 20097115. Epub 2010/01/26. eng.
23. Baskwill A. A guiding framework to understand relationships within the profession of massage therapy. *J Bodywork Movement Therap*. 2015;In Press, Corrected Proof, Available online 17 December 2015.
24. Gowan-Moody DM, Leis AM, Abonyi S, Epstein M, Premkumar K. Research utilization and evidence-based practice among Saskatchewan massage therapists. *J Complement Integr Med [Internet]*. 2013; 10(1):[1-10 pp.].
25. Carlesso LC, Gross AR, Santaguida PL, Burnie S, Voth S, Sadi J. Adverse events associated with the use of cervical manipulation and mobilization for the treatment of neck pain in adults: a systematic review. *ManTher*. 2010 Oct;15(5):434-44. PubMed PMID: 20227325. English.
26. Allen E, Chandler C, Mandimika N, Barnes K. Eliciting adverse effects data from participants in clinical trials. *Cochrane Database of Systematic Reviews*. 2013 (5).
27. Chaitow L. Dosage and manual therapies – Can we translate science into practice? *J Bodywork Movement Ther*. 2016 4//;20(2):217-8.
28. Turner L-A, Singh K, Garritty C, A T, E M, L W. An evaluation of the completeness of safety reporting in reports of complementary and alternative medicine trials. *BMC Complement Altern Med* 2011;11:1-10.
29. Weeks L, Strudsholm T. A scoping review of research on complementary and alternative medicine (CAM) and the mass media: Looking back, moving forward. *BMC Complement Alternat Med*. 2008;8(43).
30. Arskey H, L OM. Scoping studies: Towards a methodological framework. *Int J Soc Res Methodol*. 2005;8(1):19-32.

CHAPTER 6: KNOWLEDGE TRANSLATION AND STAKEHOLDER CONSULTATION

No problem can withstand the assault of sustained thinking.

—Voltaire

This chapter addresses the dissertation research's third objective. By building on the findings of the scoping review in the previous chapter and the focus group investigation findings in Chapter 4, this chapter focuses on reflection and discussion of how the findings of the dissertation aid the patient safety culture of the profession of MT in Canada. Specifically, the integrative knowledge translation process, including knowledge creation and action with participation and feedback from key stakeholders in the Canadian massage therapy community, are described.

6.1 Introduction

In this dissertation research, knowledge was created with the support and engagement of multiple stakeholders with their input on action and activities for use and dissemination. This comprehensive stakeholder involvement facilitated the development of relationships between potential users of the research and the researcher. Knowledge translation (KT) occurred throughout this project and future actions are planned with respect to assessing barriers to further knowledge translation, implementing the new knowledge, and monitoring and evaluating the impact of the research within the Canadian MT community.

The chapter begins with a description of the integrated knowledge translation (IKT) and the KT translation process on which the work presented here is based. Next, a brief introduction to general knowledge translation and its associated terms is given. This is followed by a description

of the phases and nature of stakeholder involvement for knowledge exchange. Dissemination activities are listed next to aid understanding of knowledge translation efforts. The chapter then describes the methods and results of the final stakeholder consultation exercise. Finally, the highlights and key messages of the knowledge translation and stakeholder consultation are summarized.

6.1.1 INTEGRATED KNOWLEDGE TRANSLATION AND THE KNOWLEDGE TRANSLATION PROCESS

Gagliardi et al. describe IKT as the process of forming trusting relationships between researchers and decision-makers to ensure a shared vision, better understanding, and improved uptake of new knowledge (1). Factors shown to enable good IKT outcomes include infrastructure and capacity with good leadership and support of champions (1). Dedicated funding and formalized branding with a staged approach are also thought to be important for successful IKT(1). Approaches include committees and working groups, presentations and conferences, and written materials like evidence briefs (1).

The Canadian Institute of Health Research (CIHR) defines knowledge translation as “a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge to improve the health of Canadians, provide more effective health services and products and strengthen the health care system” (2, 3). Stated simply, it is “about raising knowledge users’ awareness of research findings and facilitating the use of those findings” (3). The CIHR explains that IKT relies on stakeholder collaboration in its research processes, and can include “the development or refinement of the research questions, selection of the methodology, data collection and tools development, selection of outcome measures, interpretation of the findings, crafting of the message and dissemination of the results”(3). The Canadian Research Data Centre Network (CRDCN) describes knowledge transfer as “encourag[ing] and facilitat[ing] the adoption of evidence-informed practices and public policies(4)“ through engaging with stakeholders “to strengthen the relationships between social scientists and potential users of the knowledge they generate (4).”

The Canadian Institute for Work and Health (IWH) defines their preferred term, “knowledge transfer and exchange (KTE)”, as “a process of exchange between researchers and stakeholders/knowledge-users designed to make relevant research information available and

accessible and accessible to stakeholders for use in practice, planning and policy-making” (5). Further, IWH states that in their KTE practice “stakeholders are involved early in the research process to provide guidance to shape the research questions and information about the context in which research results are likely to be used” (5).

One of the most common models of knowledge transfer is the exchange model: this model “requires that some kind of relationship exists between those who generate research knowledge and those who might put the knowledge to use” (6). This particular “approach to doing research” (3) is well-suited to MT because of its emphasis on mutual learning between researchers, practitioners, and policy-makers. In a field where research literacy and capacity is still quite low, opportunities to expand both research and its utilization are of great benefit.

As Graham et al. state, “the primary purpose of KT is to address the gap between what is known from research and knowledge synthesis and implementation of this knowledge by key stakeholders with the intention of improving health outcomes and efficiencies of the health care system” (7). In their seminal work on knowledge transfer and exchange, Graham et al. stress the importance of making an early connection between decision-makers and researchers to ensure that the right questions are asked (7). An alternate model of knowledge translation and transfer has various individual stakeholders contributing at different points in the research project. Graham et al. describe this process as “complex and dynamic” and “fluid and permeable” (7), and the work described in this chapter follows this second model. The framework has been divided into two components: knowledge creation and action. In the knowledge creation phase, knowledge is generated by a funnel where “research [is] being sifted through filters at each phase so that, in the end, only the most valid and useful knowledge is left” (7). Figure 6.1 (adapted from Graham et al.) depicts the process followed in this research.

As Figure 6.1 illustrates, knowledge creation in this conceptual framework requires inquiry, synthesis, and the production of tools tailored to users’ knowledge needs. Graham et al. describe this as first, second, and third generation knowledge. Stakeholder feedback indicates what, to whom, by whom, how, and with what effect the knowledge should be shared (8, 9).

The second phase in this conceptual framework is the action cycle that results in the implementation or application of the knowledge. The action cycle components are based on theories and models of change known as “planned action”. Three action phases were followed in this research. They are: 1) Identify a problem that needs addressing; 2) Identify, review, and select the knowledge or research relevant to the problem; and 3) Adapt the identified knowledge or research to the local context.

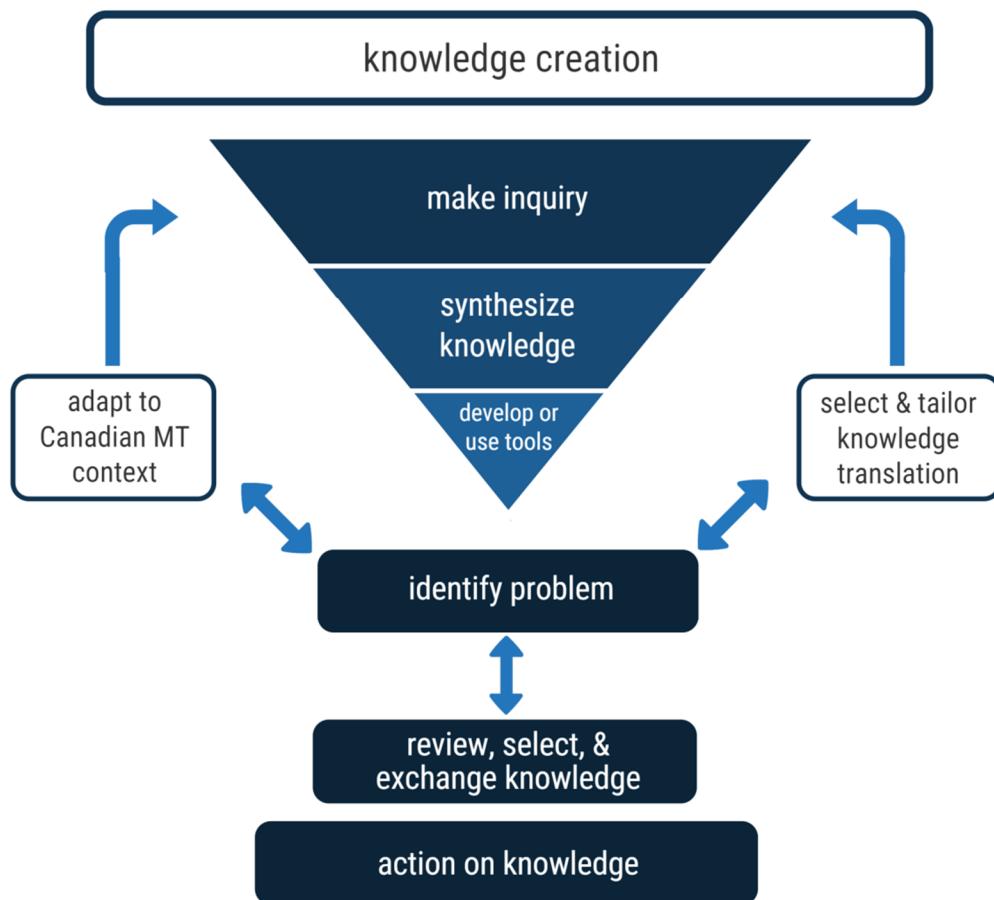


Figure 6.1 Knowledge Translation Process (adapted from Graham et al.)

6.1.2 KNOWLEDGE CREATION AND ACTION

The early experiences and staging of the research mirrors Graham et al.'s description of first generation knowledge creation where “the phase of knowledge inquiry represents the unmanageable multitude of primary studies or information of variable quality that is out there and that may or may not be easily accessed” (7). The first action steps follow this framework, of identifying a problem. Second generation knowledge in this research was created by conducting studies. Third generation knowledge was created through feedback at dissemination activities and through the consultation exercise. The second and third action phases included the investigation with the focus group, the scoping review, and the consultation with stakeholders. Through the iterative integration of the research's methods and analysis, gaps in knowledge were identified and subsequently supplemented with knowledge adapted to the local context of MT in Canada. The specific research activities corresponding to the stages of the conceptual model are given next.

6.1.3 STAKEHOLDER CONSULTATION HISTORY AND PROCESS

A proposal for the research project described by this dissertation was presented to the Board of Directors (BOD) and Executive Director of the Massage Therapist Association of Saskatchewan (MTAS) to solicit their feedback and formal support of the research question and approach. As a result, a motion to support a research project investigating adverse events in the practice of MT was passed at the annual strategic planning meeting. This occurred as I was seeking a research topic for doctoral study and, in my new role on the MTAS board as Research Director, simultaneously undertaking safety-related research tasks pertaining to legislation to regulate MT.

The KT process in this research, therefore, can be said to have started alongside the MTAS decades-long mission devoted to achieving self-regulatory status as a healthcare profession for MT in Saskatchewan. Thirty years ago it seemed to be common knowledge amongst MTs that the main barrier to regulation was the Saskatchewan Ministry of Health's steadfast refusal to consider legislating MT as a healthcare profession unless the stakeholders pursuing self-regulatory status could demonstrate a ‘risk of harm’ from MT. At that time, there was very little research capacity among the professional leadership and very little understanding or direction regarding how the organization would or could provide this evidence. Research literacy was low among leaders and practitioners: the lack of knowledge and the lack of experience searching and

synthesizing the literature were both barriers, as was the lack of access to databases. To the best of my knowledge, leaders were unaware of the systematic review of massage safety published in 2003, only learning about it through this dissertation's research activities.

My own research capacity began with the submission of a thesis as a partial requirement for a Master of Science degree in Community Health and Epidemiology and subsequent acceptance into the doctoral program in Population Health Science. Early in the program, in consultation with my doctoral research supervisor about the ongoing discussions at the MTAS board table regarding the Ministry's adamant request for evidence of risk of harm, it was decided that a proposal to study adverse events in MT may serve the needs of the field of MT and the requirements of a PhD thesis. A brief proposal of the project was presented to the BOD at the annual strategic planning meeting and a motion was passed to support a research project to investigate adverse events in the practice of MT.

Following this, an evidence brief based on a narrative review of the literature on massage-related harm was prepared for MTAS, with the goal of submitting it to the Saskatchewan Ministry of Health. The response of the Ministry was favourable, with an additional request for further information on the literature's relevance to the Saskatchewan and Canadian context. The creation of the draft Saskatchewan *Massage Therapy Act* may reflect the positive response of the government to that submission. Therefore, insofar as the Ministry is a stakeholder in the safety of MT practice in Saskatchewan, they can also be considered part of the IKT stakeholders for this project. At the first level of stakeholder involvement with the provincial professional association and, indirectly, with the Ministry of Health of the Government of Saskatchewan, this project sought and succeeded in doing what CIHR considers so important: to “demonstrate the benefits of the investment [in this case MTAS association support and positive Ministry feedback] in health research by moving research into policy, programs and practice” (3).

The next form of collaboration and exchange occurred with the main Canadian funders of MT research. The Massage Therapy Research Fund, supported primarily by the College of Massage Therapists of Ontario, has identified patient safety as one of their research priorities. A proposal

for the project was submitted for their annual grant competition and funds were successfully secured, with reviewers expressing the importance and timeliness of the project.

As part of the grant application, a formal letter of support for the project was submitted on behalf of the College of Massage Therapists of British Columbia (CMTBC) and the Registered Massage Therapist Association of British Columbia, two organizations who expressed interest in the project after hearing the MTAS Executive Director speak about the proposed study at a meeting of the Canadian Massage Therapy Alliance. Numerous communications and meetings by email and telephone between the researchers and the Registrar, Deputy Registrar, and a Board member culminated in a strategy to collaborate to identify and refine the research questions and methods. As a further consequence of this exchange, I was invited to deliver an oral presentation at the Annual General Meeting of the CMTBC on the topic of patient safety as one of the sessions for the corresponding Education Day. Ethics approval was obtained from the University of Saskatchewan REB-Beh to collect data from workshop participants for my research question. As part of the mutual exchange of knowledge, participants accrued continuing competency credits by successfully answering quiz questions about patient safety in MT generated from the workshop's learning objectives.

The Board and staff of the CMTBC became early collaborators, particularly through their feedback on the proposed methods for the qualitative study and their agreement that board and staff would participate in a focus group investigation. The Registrar provided valuable feedback on the ethics application for the University of Saskatchewan REB-Beh regarding the study's use of the Education Day workshop collaboration and the focus group with the CMTBC board and staff. Details of the focus group investigation methods and results are described in Chapter 4.

Throughout the project there were opportunities to disseminate findings, answer questions, and solicit feedback from stakeholders (including audiences at conferences and both peers and faculty at University research presentations). Interest in the topic and generous feedback from fellow researchers, other health care providers, and MTs was valuable and informed the iterative process of the research. For example, engagement with pain management physicians and anesthesiologists at the Canadian Pain Society's 37th Scientific Meeting (May 24-27, 2016) in

Vancouver, British Columbia, lead to further email exchanges with three prominent experts about the safety and effectiveness of MT for acute and chronic pain patients, and significantly advanced my research. At the dissemination events, many audience members were surprised to learn that there were numerous published cases of serious, even life-threatening, events attributed to massage. Informal conversations also elicited views that massage is too often painful and therefore regarded as undesirable by patients. These responses informed additional research questions.

6.1.4 DISSEMINATION ACTIVITIES

A total of five oral presentations based on this research were delivered. Three of the oral presentations were made locally to University faculty and students as well as MT research symposium delegates. The remaining two oral presentations occurred nationally at interdisciplinary integrative medicine research symposia. Three poster presentations based on the research were presented: one international integrative medicine audience, one national organization (Canadian Pain Society), and one local interdisciplinary audience at a provincial conference on pain management. A detailed list of the dissemination activities is given in Appendix F.

6.1.5 FINAL STAKEHOLDER CONSULTATION EXERCISE METHODS AND RESULTS

A final stakeholder consultation exercise was undertaken as part of the IKT process of this research. Arksey and O'Malley's framework for scoping reviews includes stakeholder consultation as a parallel element (10). Along with additional refinements offered by Levac et al. (11), Colquhoun et al. (12), Daudt et al. (13), and Brien et al. (14), this framework was used to conduct the project's stakeholder consultation. An important aspect of facilitating knowledge transfer is gaining insight on what, to whom, by whom, how, and with what effect should research knowledge be transferred (8, 9). Consultation with stakeholders is an integral part of scoping study methodology (11, 12, 15) and can be used to support knowledge translation (8).

Setting and Participants

The participants of the stakeholder consultation exercise were drawn from the attendees of an oral presentation of the scoping review at the 9th Canadian Interdisciplinary Network for

Complementary and Alternative Medicine Research (INCAM) Symposium in Toronto, Ontario and attendees of a meeting of the Massage Therapy Special Interest Group (MT-SIG) held in conjunction with the symposium. INCAM is the Canadian Chapter of the International Society for Complementary Medicine Research. The biennial INCAM Research Symposia attracts both national and international researchers, clinicians, educators, and leaders in integrative healthcare. The MT-SIG is comprised of individuals who are interested in MT research. INCAM has several special interest groups on various topics such as osteopathy, naturopathy, and massage therapy, and the organization states that “SIGs are meant to be a collaborative space where IN-CAM members with a similar interest in a topic area can come together and work on a research-related project or activity” (16).

Procedures

The stakeholder consultation process spanned activities from Western to Eastern Canada and from the beginning to the end of the project. Stakeholder views were incorporated into the study design. The specific exercise described here pertains to the solicitation of stakeholder feedback about the results of the scoping review study presented by the lead author (DGM) to attendees of the oral research presentation session of the 9th INCAM Research Symposium: Expanding Person-Centred Care Through Integrative Health (Toronto, November 2016). Attendees were informed that extra time had been granted to the presenter to facilitate discussion and feedback if the attendees were willing to serve as consultants and offer their feedback on the project and the study findings. Thus, the stakeholder consultation took place during and following a 30-minute oral presentation on the scoping review as part of the symposium presentation (see Appendix H). The stakeholders included fellow researchers, MT association representatives, media representatives, and MTs involved in a MT special interest group. Oral presentation attendees included approximately 25 national research symposium attendees including clinicians, researchers, and anyone with an interest in the topic of patient safety in MT massage therapy. Approximately 20 individuals, many of whom were also in attendance at the oral presentation, attended the Massage Therapy Special Interest Group (MT-SIG) workshop as part of the INCAM Research Symposium. These individuals (mostly based in Ontario) included MTs, researchers, educators, natural health practitioner association leaders, industry media representatives, and association leaders.

This MT-SIG workshop was the final setting for the stakeholder consultation exercise. At the beginning of the of the 1.5-hour meeting, the lead author (DGM) informed the participants of the purpose and objective of the stakeholder consultation and asked for their participation (see Appendix C). Group members were provided with an overview of the scoping review's main findings. The scoping review's purpose—to explore current knowledge and practices in identifying, defining, and classifying adverse events in massage and manual therapy research literature—was also shared with the workshop participants (Appendix C). Participant feedback on the research findings and their views on knowledge transfer needs were solicited. Questions framing the stakeholder consultation are provided in Appendix C. Participants were also invited to contact the researchers by email with any additional feedback, views, and opinions. Written notes were taken by one of the researchers (AL) during the SIG meeting; additional feedback from the oral research presentation attendees was collected from team members (AB and AL) by the lead author (DGM). The results of the stakeholder consultation were collated from the notes and comments describing the views of the stakeholders and their suggestions for knowledge translation.

While stakeholder consultation essentially began with the focus group investigation that informed subsequent steps in this research project, three important steps facilitated stakeholder consultation as part of the scoping study. First, the general characteristics of the studies included in the scoping review were analyzed and reported at the stakeholders' review. Secondly, the research question and its results were reviewed for the stakeholders. Information on current knowledge and practice in defining and classifying patient safety incidents (adverse effects) in massage and manual therapies was summarized and described for the stakeholders. Third, a discussion of the scoping study's results and their implications for future research on MT practice, education, and policy was offered for stakeholder review and feedback.

The results of the final stage, namely, the stakeholders' views and opinions, show what needs to be done to enhance the culture of patient safety in the field of MT in Canada. The key messages from the consultation are that knowledge from this study should be translated to regulators, practitioners, educators, and the public in a variety of mediums and forums for education and

use. Stakeholders' responses indicated that the study was interesting and likely to be of value to the profession of MT. It was also suggested that a glossary of WHO preferred terms should be distributed to practitioners and educators. A noted suggestion was to publish knowledge from the study in popular professional magazines (e.g. *Massage Therapy Canada*) for wide and easily accessible knowledge transfer and research dissemination.

One of the stakeholder consultation participants stated that information about basic foundational knowledge about patient safety was badly needed. This participant said that “practitioners are often ‘in the weeds’ when it comes to knowledge of safety research; what is needed is teaching on the basics.” The need for public education was also discussed. Some participants mentioned that MT patients sometimes endanger themselves with a “no pain/no gain” attitude and that public education would be valuable and helpful to individual practitioners and lead to a better understanding of the role of the RMT in healthcare. Lastly, stakeholders enthusiastically suggested that regulators should be informed of the research results via the researcher and research publications in order to influence standards and reporting in a more uniform and meaningful way.

6.2 Knowledge Translation and Summary

The purpose of the stakeholder consultation was to engage individuals and groups interested in current practices and in new knowledge about patient safety in MT: this was done to invite input and feedback about the research and to solicit views of knowledge translation approaches. The objective was met as stakeholders enthusiastically engaged with the topic. Some stakeholders expressed surprise that harm can occur from exposure to massage, while others expressed concern that massage too often hurts. As MT research in general is a nascent field, with patient safety especially understudied, the knowledge creation and action undertaken is novel and significant.

One of the highlights of the knowledge translation was the discovery that trust played a significant role in building relationships with others interested in the research. Engaging with others about the research allowed for the deepening of mutual trust between the researcher and various stakeholders including MTs, other healthcare professionals, researchers, and policy-

making leaders. The importance of trust was also a highlight of the findings of the focus group investigation reported on in Chapter 4. Trust was also mentioned by numerous authors from other manual therapy professions' research in the scoping study reported on in Chapter 5.

Engaging with interested individuals about the research at conferences and symposia allowed for profound interprofessional insight into the current state of the MT profession and into future steps in the field to best serve the healthcare needs of Canadians. It is hopeful that the eventual users of this research and the patients served by MTs will benefit from this interaction of trust and mutual learning, sharing, and contribution.

Discussion and collaboration with various members of the Canadian MT stakeholder community took place throughout this research, beginning with developing and then refining the research questions with local Association leaders, feedback from the funders, and collaborative effort with one of the Canadian regulator groups. The selection of the research methods, which included mixed methods, necessitated an expanded time frame for completing the research and was made possible with support (including financial) of the two oldest and largest regulator groups in Canada. It was initially anticipated that developing tools for the recording and reporting of adverse events in MT would be part of the research process, with contribution by research participants. However, as the findings unfolded, it became apparent that further steps were needed before their knowledge could be disseminated: mutual learning between the researchers and potential users would be required prior to engaging stakeholders in tool development exercises. Stakeholder contributions helped shape the draft messages for future dissemination of the studies' results; this was especially true of the final exercise. All these contributions reflect well-known principles of knowledge translation. Working with the stakeholders to produce a taxonomy based on existing frameworks, the findings of the focus group investigation and the findings of the scoping review is the next step that will be undertaken.

References: Chapter 6

1. Gagliardi AR, Berta W, Kothari A, Boyko J, Urquhart R. Integrated knowledge translation (IKT) in health care: a scoping review. *Implement Sci.* 2016;11(1):38.
2. Canadian Institute of Health Research. Knowledge Translation [Internet]. [January 29 2017]. Available from: <http://www.cihr-irsc.gc.ca/e/29418.html>.
3. Canadian Institute of Health Research. Guide to knowledge translation planning at CIHR: integrated and end-of-grant approaches [Internet]. 2017. Available from: <http://www.cihr-irsc.gc.ca/e/45321.html>.
4. Canadian Institute of Health Research. Canadian Research Data Centre Network (CRDCN) Knowledge Transfer [Internet]. [February 15, 2017]. Available from: <http://www.cihr-irsc.gc.ca/e/49911.html>.
5. Knowledge Transfer: Institute for Work and Health; [February 25th, 2016]. Available from: <https://www.iwh.on.ca/knowledge-transfer-exchange>.
6. Reardon R, Lavis J, J G. From Research to Practice: A Knowledge Transfer Planning Guide. Institute for Work and Health. 2006.
7. Graham ID, Logan J, Harrison MB, Straus SE, Tetroe J, Caswell W, et al. Lost in knowledge translation: time for a map? *J Contin Educ Health Prof.* 2006;26(1):13-24.
8. Grimshaw JM, Eccles MP, Lavis JN, Hill SJ, Squires JE. Knowledge translation of research findings. *Implement Sci.* 2012;7(1):50.
9. Lavis J, Permanand G, Oxman A, Lewin S, Fretheim A. SUPPORT Tools for evidence-informed health Policymaking (STP) 13: Preparing and using policy briefs to support evidence-informed policymaking. *Health Res Policy Syst.* 2009;7(Suppl 1):S13. PubMed PMID: doi:10.1186/1478-4505-7-S1-S13.
10. Arskey H, L OM. Scoping studies: Towards a methodological framework. *Int J Soc Res Methodol.* 2005;8(1):19-32.
11. Levac D, Colquhoun HL, O'Brien KK. Scoping studies: advancing the methodology. *Implement Sci* [Internet]. 2010; 6(69). Available from: <http://www.implementationscience.com/content/5/1/69>.
12. Colquhoun HL, Levac D, O'Brien KK, Straus S, Tricco AC, Perrier L, et al. Scoping reviews: time for clarity in definition, methods, and reporting. *J Clin Epidemiol.* 2014 12//;67(12):1291-4.
13. Daudt H, van Mossell C, Scott SJ. Enhancing the scoping study methodology: a large, inter-professional team's experience with Arksey and O'Malley's framework. *BMC Med Res Methodol* 2013;13(48).
14. Brien S, Lorenzetti D, Lewis S, Kennedy J, Ghali W. Overview of a formal scoping review on health system report cards. *Implement Sci* [Internet]. 2010; 5(2):[about 12 p.].
15. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *Int J Soc Res Methodol.* 2005;8(1):19-32. Pubmed Central PMCID: PubMed PMID: 16677313.
16. Interdisciplinary Network of Complementary and Alternative Medicine Research. INCAM Research Network Special Interest Groups. Available from: <http://www.incamresearch.ca/content/special-interest-groups-sig>.

CHAPTER 7: DISCUSSION

Long-range goals keep you from being frustrated by short-term failures.

—James Cash Penney

7.1 Introduction

The decades long discourse among the massage therapy (MT) community in Canada regarding the lack of standardization of provider and intervention underscores a need for research about the potential public safety ramifications of non-uniform standards and absence of legislatively derived authority to regulate the profession across the country. This research explored and examined important stakeholders' views on patient safety and the terminology and classification schemas used by various experts, including regulators, researchers, therapists, educators, and leaders. An essential first step in promoting a patient safety culture in MT, promulgated with discourse informed by research, is to develop common language. Seeking to make internationally developed definitions, classifications, and taxonomies meaningful in the field of MT is an important contribution to the scholarship in patient safety.

MT in Canada is situated as somewhat of a dialectical opposition of mainstream and unconventional healthcare. MT in Canada shares mainstream healthcare service characteristics such as significant usership among the population, referrals from GPs, insurance coverage and self-regulatory status as healthcare providers in some provinces in Canada. It is also commonly categorized and included as CAM (Complementary and Alternative Medicine) or Complementary and Integrative Health Care (CIHC) (1). MT users also fit within the characterization of CAM users identified by Davis et al. whereby there are two types of users: those who use it for illness and those who use it for wellness (2). Massage is widely used and like other therapies, patient safety assessment is challenged when there is a range rather than uniformity of organizations that regulate practitioners (3). This is an impediment to the systematic and rigorous collection of patient safety incident data in MT. Additionally, MT research in general is a nascent field. MT scholarship lags behind other healthcare professions with evidence of decades of delay in actualizing research utilization as compared to the fields of nursing, physiotherapy, and chiropractic (4).

In a systematic review of MT for patients with musculoskeletal complaints, Bervoet et al. conclude that “massage is not clearly more or less beneficial than other commonly used treatments for musculoskeletal disorders” (5). In a meta-analysis on MT effects Moyer et al. found that massage had statistically and clinically significant effects on anxiety and depression (6). These general effects on both state anxiety (such as apprehension, tension, and worry), and stable characteristics of anxiousness (known as trait anxiety) are underexplored in research (7). Of particular relevance to this dissertation is Moyer et al.’s conclusion that the question of patient safety is an important component of future benefit-risk analysis.

This study had three objectives: 1) to explore massage therapy (MT) regulators’ views on patient safety and adverse events (AEs) in the practice of MT; 2) to explore taxonomies for understanding, evaluating, or reporting patient safety incidents (adverse events) in existing published literature on massage and manual therapies and compare available massage and manual therapy patient safety incident taxonomies with an internationally developed framework in order to summarize and collate the results; and 3) to reflect on and discuss how the findings of the dissertation aid the patient safety culture of the profession of MT in Canada, including knowledge translation and transfer. The objectives are reflected upon within the thesis, which comprises two unpublished journal manuscripts, in the following way: Chapter 4 examined Canadian MT regulations perceptions on patient safety issues and understanding of AEs and a thematic model of safe massage representing the views of the research participants was developed; Chapter 5 built on the results of the previous chapter by mapping the literature on the definition and classification of AEs to synthesize information in comparison with internationally developed patient safety frameworks and models. Chapter 6 discussed a comprehensive stakeholder consultation within an integrated knowledge translation approach that shares input and feedback from the MT community about the knowledge created and recommended actions.

In this final chapter, a synthesis of the studies’ key findings, in light of what is known from the literature, will be presented along with a discussion of the limitations and strengths of the research and implications and recommendations for future research, policy-making, and practice in the field of MT. The overall aim of this dissertation is to deepen the understanding of patient

safety incidents (adverse events) in MT in order to advance the reporting, monitoring, and prevention of harmful incidents in MT in Canada and other jurisdictions where massage is used as a health care intervention.

7.2 Summary of Key Findings

A key finding of this thesis is that massage can hurt and it can harm. Like other forms of “hands-on” manual therapies such as acupuncture, spinal manipulative therapy, and joint and soft tissue mobilization, both procedural pain during treatment and the occurrence of outcomes of minor and temporary symptoms such as increased pain and dysfunction are common but understudied. The identification, definition and classification of AEs in MT warrants further development. Another key finding is that competing narratives based on different opinions or opposing philosophies concerning roles, expectations, and authority are a barrier to a robust safety culture as interpretations of patient safety issues vary. A final finding is that there are areas of consensus, including the use of simple taxonomies for the identification, definition, and classification of patient safety incidents (adverse events) for patient outcomes using common data elements as recommended in the International Classification for Patient Safety (ICPS): these areas of consensus offer solutions for advancing patient safety.

7.2.1 MASSAGE: IT CAN HURT AND IT CAN HARM

Integration of the three stages of the thesis results show that massage, as it is commonly applied in Canada, is sometimes experienced as painful during treatment and/or after a treatment session. Our results show that the “hands-on” treatment applied by MTs (which typically includes the manual perturbation of the soft-tissues including muscles, tendons, ligaments, skin, fascia, nerves, and blood vessels as well as the mobilization of joints) is subject to the consideration of both necessary discomfort and unfortunate sequelae. It is apparent from our results that decision makers (such as the regulators of MT and the stakeholders with whom we consulted) are confident that adhering to practice standards and education of therapists and patients are keys to determining which practices are necessary discomfort and which are unfortunate sequelae.

Conversely, there is little to no discussion of procedural pain in the terminology, definitions, or taxonomies for understanding patient safety and adverse events in the scoping review’s included

studies. There appears to be very little research regarding procedural pain in practices and professions that use manual therapies in patient care. The need to improve the identification and management of pain produced by manual physiotherapy procedures was identified by von Baeyer and Tupper (8). Procedural pain is a novel topic in the field of MT research.

There was also little or no discussion of the concept of dosage as it applies to the planned application of manual therapies (including massage) by the participants in our qualitative investigation and stakeholder consultation nor was there any emphasis on this concept in the studies included in the scoping review. The consideration of dosage issues in massage and manual therapy is a relatively novel concept. Chaitow recently expressed the need for further research regarding safe loading of tissues in manual therapy treatment (9).

That temporarily worsening symptoms could constitute a healing crisis indicative of a shift toward homeostasis was a concept offered as a means of understanding adverse events in some of the manual therapy research studies included in the scoping review: however, this concept did not appear within the perspectives shared by the regulators in our focus group or the stakeholders feedback on our findings. The experience of a healing crisis may be described as a natural process where things get worse before they get better. The concept of a healing crisis is used in some forms of traditional healing practices such as Shiatsu (10), but it has not been emphasized in MT studies.

Our findings also clarify that massage can cause harm, as evident in regulators' shared experiences and in the massage-specific research in the scoping review's included studies. These findings are consistent with numerous anecdotes of harm shared with the researchers by MT users at dissemination events. Insofar as harm is defined as "impairment of structure or function of the body and/or any deleterious effect arising there from ... includ[ing] disease, injury, suffering, disability and death," then our findings provide evidence that harm, albeit usually minor and temporary, does also occur in the provision of MT health services.

Cases of injury, as determined by Canadian MT regulators, are reported in publicly-available documents but lack detailed descriptions of the patient safety incidents for research and learning

purposes. The regulators were confident that reducing harm can be best managed with regulations to set and enforce standards of practice for RMTs. In the systematic review of patient safety in massage, Ernst states that the “majority of adverse effects were associated with exotic types of manual massage or massage delivered by laymen” (11). Thus, the regulators’ views have some support from research.

Myofascial or musculoskeletal pain is a common problem in the population and a condition that Canadian MTs routinely assess and treat. Myofascial pain syndromes are also commonly treated with drugs or trigger point injection: MT could also be used to overcome the barriers to exercise and engaging in normal activities of daily living caused by the patients’ experience of pain. If so, the practical benefits of massage may be seen as the widening of the therapeutic window through which patients can access exercise and rehabilitation in order to improve function and manage longstanding or recurrent pain. Considered in this light, massage that produces pain will need to be carefully considered with respect to its appropriateness in securing beneficial outcomes in practice. While effect sizes in meta-analyses of MT demonstrate the treatment’s effectiveness in many populations (6, 12) it is possible that the inclusion of individuals with hypersensitive pain conditions that have low tolerance for massage in research may diminish the observed effects.

The concept of the therapeutic window has not, to the best of my knowledge, been explored in massage and other manual therapy patient safety research. In medicine, the therapeutic window refers to the pharmacological dosage ranging between too little and too much or between that which is enough to be effective and that which is toxic. Existing research in massage has demonstrated that moderate pressure is required (13), providing some guidance for the lower thresholds of the window. What has not been articulated or established is the dosage that has “toxic” or adverse effects. I am aware of no research evidence for guidance regarding the therapeutic merit or prognostic value of painful massage.

There are a small number of studies in chiropractic research that have investigated the association of common adverse events and desired clinical outcomes. The findings offer an interesting avenue for consideration for future MT research. Rubinstein et al. found an association between short-term poorer outcomes and the occurrence of common “benign”

adverse events (14). Hurwitz et al. also found that participants who experienced common adverse reactions had poorer clinical outcomes (15).

7.2.2 COMPETING NARRATIVES

According to the literature (Chapter 2), manual therapy experts' opinions of adverse events are based on "competing narratives," a helpful term used by Rozmovits et al. to describe disparate viewpoints in understanding and interpreting issues in patient safety. These disagreements on what constitutes an adverse event serve as a barrier to a uniform patient safety culture within and between professions that use manual therapy for patient care. This awareness of competing narratives or differences in point of view is evident in the findings of manual therapy studies soliciting the views of health care professionals in Canada, the UK, and New Zealand (16-20), in studies exploring the views of patients of manual therapy and Japanese healing bodywork (10, 21-23), and among regulators, profession leaders, and insurers of osteopathic care in the UK (24). This concept of competing narratives is a key theme of this dissertation's findings. The results of both the qualitative investigation and the scoping review provide further evidence of the presence of differing points of view when MT is included for consideration in the study of patient safety.

The main findings highlight the salience of several important issues to understanding patient safety in MT. As the dissertation's studies demonstrate, expectations, roles, and authority issues co-create the competing narratives about adverse events. Because patient safety in the profession of MT is a new and novel topic, this dissertation adds to what is currently known about competing views in patient safety.

Set within the context of the Canadian MT profession, these issues appear to exert influence at various levels. Namely, patient safety both impacts and is affected by research and scholarship, policy and decision making concerning the profession, the practice of professional MTs, and the patient experience. These issues can be seen as barriers to assuring patient safety in MT but also as direction for potential solutions for creating a cohesive patient safety culture that aids the delivery of safe and effective care. The views shared by stakeholders in consultation about this

research highlight that the views of therapists, patients, and regulators should be informed by knowledge translation of this work.

MT scholarship and research is a recent field, and there is a shortfall of patient safety research compared to research on benefits. Within MT, in particular, and CAM, in general, several studies have attempted to promote clarity in terminology and classification using standardization protocols and taxonomic development for other practice and research issues in MT (25-27). Further, a paper reporting the views of an expert panel involved in defining complementary and alternative medicine states that “[d]efinition and description both require careful choice of terminology and assessment of encoded values” (27). This dissertation offers a first perspective on the values of those involved in the field of MT with respect to patient safety.

Values are closely related to expectations, and one of the main findings of this dissertation is that the disparate expectations of MTs in the Canadian healthcare context may provide a barrier to patient safety. In their study with osteopathy regulators, association leaders and insurers in the UK, Leach et al. document their participants’ belief that the expectations of osteopathic patients may sometimes be unrealistic (24). For example, expecting quick relief of pain and not expecting any worsening of pain was thought to lead to dissatisfaction and complaints. The need to better communicate about treatment expectations in physical therapy was echoed by Carlesso et al. in Canada (28).

On the other hand, the tendency to change or adapt practice to suit the expectations of the patients instead of adhering to practices supported by either evidence from research or clinical experience is a barrier to implementing evidence-based practice generally (29) and may present a problem in executing safe practices in massage and manual therapies. This dissertation highlights evidence of opposing attitudes among and between patients and practitioners. A view expressed by our research participants and stakeholder consultants was that some patients and/or therapists have a “no pain, no gain attitude,” while others have significant concerns over common and transient patient safety concerns such as increased pain or bruising, not knowing if this is normal or not.

The results of this dissertation highlight that discussions about patient safety and risk of harm in massage and manual therapies are unbalanced. Notably, physician referral rates to MTs are high relative to other CAM therapies (30) but the regulators in this study expressed concern that massage may often be erroneously viewed as harmless. This view is consistent with other research that revealed that few individuals felt it likely that massage could lead to any harm (31-33). This overarching view that massage is benign may explain the surprised reactions among our stakeholders in the knowledge translation events and consultation exercise which disseminated information about the nature and extent of massage-related patient safety incidents in the literature. That some stakeholders appeared shocked to learn about the serious, life-threatening, massage-related adverse events that are documented in the literature is evidence of the underdevelopment of patient safety related knowledge in the field.

Role confusion was a concern expressed by the regulators in our qualitative study. Our participants shared views that the role of the Registered Massage Therapist (RMT) as an important team member in managing individuals' health concerns may be misunderstood or undervalued by the public. This opinion was tied with concern for potential threats to public safety. Issues of public perception were also uncovered by Shroff and Sahota in their study exploring the role of MTs in the healthcare landscape in British Columbia (34). While not directly related to patient safety, the nebulous role of the RMT is evident in misunderstandings of identity where MTs are confused with sex workers and must compete with unlicensed massage providers for public patronage.

Exploring the relationship between role and patient expectations and outcomes is a main focus of the findings from the qualitative investigation. The Federation of Massage Therapy Regulatory Authorities of Canada (FOMTRAC), the highest authority in the profession of MT in Canada, defines the role this way:

Registered massage therapists—RMTs—help people by maintaining, rehabilitating, and augmenting physical function, or by relieving pain and promoting health. RMTs do this by assessing soft tissue and body joints, and by providing treatment that includes manipulation, mobilization, and other manual methods. RMTs work with people of all ages and conditions. They work in clinics, hospitals, retirement homes, care facilities, and in private settings such as home-based clinics or spas. RMTs are licensed by a provincial

regulatory college that derives its authority from legislation. They are accountable to the college for their professional behaviour, which includes demonstrating continuing competency and acting in the best interests of their patients (35).

Issues of authority (particularly who has the means and privilege to contribute to the discussion about safety in MT) are an interesting feature of this investigation. The mixed method research approach used in this dissertation allowed for the collection and synthesis of views from authority sources, namely, regulators, researchers and interested stakeholders. The results show that MT is understudied in patient safety research and that patient safety is understudied in MT research.

In order to shift authority in MT research to massage therapist researchers, there needs to be capacity building in the profession of MT (1). Currently, when patient safety research about massage is published, it is unlikely to involve authorship by MTs. Numerous shortcomings in the literature ensue. Others have made similar observations, noting that only attention-grabbing unique events get published and that they tend to be authored by the physicians that treat the complications (36, 37). This highlights the dramatic cases and leads to the underreporting of the more common cases that do not require medical attention and, therefore, fail to be recorded in the literature (36).

It is often not clear to the expert massage therapist reading research reports of safety if the intervention described relates to the practice of a Canadian MT and/or if the provider characteristics match those required of a professional massage therapist. Patient safety events in the literature are often due to incompetence or ignorance and often involved untrained lay persons. An expert massage therapist would note that harmful incidents often follow non-standard practices and contravene the practice standards of all regulated health care professionals in Canada. The opportunity for knowledge exchange with the Saskatchewan Ministry of Health and the MTAS regarding both the relevance of published cases of harm to the Canadian context and how regulation mitigates the risk of harm done in preparation for undertaking this research shows that there is a desire for a critical and rigorous examination of the topic. Experts from other fields, particularly chiropractic, have lamented the misclassification of provider and intervention and the damage this does to the reputation of the profession (38).

Similarly, discussions of safety in regard to manual therapy treatment approaches like spinal manipulative therapy (an approach outside the scope of practice of MTs in Canada) are often criticized as being heavy-handed with alarmist attitudes (39). In contrast, discussions of safety in massage are often dismissive in nature with concerns about potential harm more likely to be viewed as a tempest in a tea pot. In regard to reflections on practice when a health care provider becomes aware of an adverse event or a potential safety incident, Thiel and Bolton declare, “[I]n many ways, a patient safety incident can be defined by: ‘That was a threat to my patient’s well-being, and I don’t want it to happen again’” (40). It can be argued that all those who care for people’s health, including MTs, are responsible to safeguard patients’ well-being. In their study on risk factors for acupuncture AE, Chung et al. conclude that “better understanding of the phenomenon” could provide the necessary information for communication to patients about risks and benefits as well as “permit[ting] more refined quality assurance, targeted training and support for practitioners for further improvements in acupuncture treatment” (41). This conclusion aligns with the conclusions drawn from this dissertation pertaining to MT.

7.3 Professionalization, Legislation, and Safety

Enforceable practice and competency standards, derived from legislative regulation, are the common means to secure public protection. In MT, this is missing in all but four Canadian provinces. Barberree, a Canadian massage therapist researcher, states that “regulation must occur in the context of the larger health professional landscape” (42). The development of a uniform professionalization ethos across the nation, where the best interests of the patients and the public are paramount in all decisions made for practice and for policy, is needed in order to fit in the healthcare context. “An element of professionalization is the development of a body of knowledge and the integration of that knowledge into practice,” states Baskwill, another Canadian massage therapist researcher describing the need for support for capacity building in MT (43). Professional socialization affirms a necessary public service ethos, and the road to enacting the role of a Registered Massage Therapist in Canada is increasingly infused with patient-centred and evidence-informed decision making as is appropriate for all healthcare professionals (44, 45).

In Canada membership into regulatory colleges and member associations of the Canadian Massage Therapy Alliance require a minimum 2200-hour curriculum and a successful practice examination that tests applicants on inter-jurisdictional practice competencies. However, in provinces without legislative *Acts* for title protection, anyone can call themselves a massage therapist. Pre-service practical curriculum in most Canadian MT schools focuses largely on the classical European-based hands-on application of soft-tissue and joint mobilization for assessment and treatment of pain and dysfunction or for health promotion (historically and commonly known as Swedish or Classical). The use of electro-therapeutic agents and devices are taught in some jurisdictions or are out of scope in others. Continuing education in Canada, a mandatory requirement for registration with regulatory colleges and some MT associations, is offered inclusive of a broad scope of practice. Offered courses can include training in the use of tool-based modalities such as cupping or scraping devices, or alternative systems of healing from other countries and traditions such as Shiatsu, craniosacral therapy, Thai massage, and structural alignment and fascia-based systems of treatment such as Rolfing. The non-uniformity of provider training and intervention standards severely challenges the conduct of high quality research in MT.

7.3.1 PATIENT SAFETY INCIDENT DEFINITIONS AND CLASSIFICATION

The results of this dissertation show that identifying adverse events by clearly defining patient safety incidents is challenging; yet, there is evidence that some commonalities exist and consensus could be obtained. Two common practices in the multi-disciplinary manual therapy research on adverse events are consistent with the recommendation of the WHO International Classification of Patient Safety conceptual framework and the minimum information model (MIMS). Duration, severity, intensity, and impact on function were commonly used key data elements consistent with the WHO, as was the use of simple hierarchical classification schemas (taxonomies) to order description of events. The use of simple numeric scales to assess the levels of these elements is also common practice.

Two common practices in the research included in the scoping review run counter to the WHO ICPS framework. The first relates to the nomenclature whereby “adverse event” is still the most used term. The second is that no taxonomies in our included studies used any of the International

coding systems recommended by the MIMS. The term “adverse event” was familiar language to the participants in the qualitative study. Likewise, our focus group participants did not mention the use of codes for recording and collating complaints of harm that arise.

Recent studies have adapted definitions from international taxonomies such as the WHO ICPS and ICH for use in facilitating patient safety culture, research, and practice (46-48), but none have included MT. There is little question that the main focus of existing international frameworks and models for healthcare is medical care (49-51). The WHO’s International Classification of Functioning, Disability, and Health (ICF)(52) may prove additionally useful for informing and directing research in the area of MT practice and AEs. The WHO ICPS suggests using the ICF for describing important data elements; likewise, researchers in other fields that use manual therapies as an important basis for rehabilitation medicine practice have suggested using the ICF as a basis for organizing rehabilitation medicine research (152, (53) and as a unifying model for conceptualizing rehabilitation as a health strategy (54). In the MT literature, it has been suggested that the ICF be integrated into research, education, and practice (55) and as a tool for MT education (56).

The ICF is a taxonomic model based on an integrative biopsychosocial model of human functioning, disability, and health. The model components consist of a top-level concept of health disorder which influences the next level of “functioning.” This is characterized as encompassing body function and structures (including mental functioning), activities and participation, with all the above subject to environmental and personal factors. The body function and structures domain of the model describes the physical and/or physiological impairment that has occurred (52). “Impairment” or “impairments” is/are a concept accepted by and familiar to MTs (56). Examples include impaired body structures and functions such as loss of sensation, pain, scarring, inflammation, reduced joint mobility, anxiety, and depression (52, 56).

The activities and participation domains in the model include such things as washing and dressing, lifting and carrying objects, engaging in family and social relationships, recreation, and leisure. Examples of factors within the “environment” context domain of the ICF include work

and role requirements: in turn, these factors reciprocally relate to the experience of dysfunction. For example, a parent of small children may experience a lifting impairment differently than a non-parent office worker. Personal factors are important to context and include, for example, coping and behaviour strategies which have been shown to impact health outcomes.

The potential link to adverse events in MT practice is evident in the following ICF model description given by Munk and Harrison: “The ICF framework considers impairments in body functions and systems in relation to the activities that are restricted, and how those restrictions, as a whole, influence a person’s participation in life” (55). One can see how iatrogenic disordered health (an adverse event) influences patient function, including varying levels of impact and activity levels involving specified body function and structures, and a demonstrable impact on participation in life activities.

Additionally, Munk and Harrison point out that the ICF may be ideally suited to MT as a framework, as its construction clearly allows for and recognizes individual variability in outcomes (55). In a similar vein, Stucki et al. speak about the “experience” of disability as a critically important component in understanding human functioning and disability. The dynamic interplay between the domains represented in the model provide an excellent vehicle for representing this variable experience in both good and bad outcomes.

Although the paper by Munk and Harrison has been available in the free access peer-reviewed online *International Journal of Therapeutic Massage and Bodywork* since 2010, it has not, in my opinion, made the impact in MT that it should have. It may be that applying a broad stroke to cover outcomes research applications, MT education, and MT clinical practice applications of the ICF in one publication was overly ambitious and detracted from the obvious usefulness of this model for MT and MT adverse events. Whether the utility of the ICF to MT has been overlooked or is just experiencing a slow diffusion of innovation (as has been seen in adoption of evidence-based practice and research utilization in MT) (4) it could, in my opinion, prove useful. Indeed, it could help solve a MT problem articulated over two decades ago in population health, namely, “there being no set of intellectual categories in which to assemble such data, [because of which] they are ignored” (57).

7.4 Next Steps: Recommendations for Research, Policy, and Practice

7.4.1 RESEARCH RECOMMENDATIONS

In formulating recommendations for the future, much can be learned from research and scholarship in other professions that use manual means as patient care, see similar patient populations, and seek and provide similar beneficial patient outcomes. For example, in a recent study Gorrel et al. state that “risk disclosure involves communicating known effects, material risks, discomforts and side effects, the frequency of such effects, and the limits of the information provided” (58). It must be acknowledged that this cannot be achieved without a proper understanding of the “non-catastrophic” patient safety incidents that occur. A necessary step in calculating incidence is being able to identify and classify events to operationalize and measure both the outcome of interest and the exposure.

One of the aims of this dissertation was to compare what is known and practiced as compared to international standards and recommendations. The WHO states the importance of shifting the focus from hospital and surgeries to include community-based healthcare and provides examples of family practice, pharmacy, midwifery, and home care (59). MT in the Canadian context is another example of understudied community-based care.

The authors of the WHO minimum information model (MIMS) suggest that areas for further research include the identification of common values for the draft data categories as well as the translation of information collected using the information models for adding value to practice and policy improvements for reducing harm (60). An improved patient safety culture in healthcare is seen as a priority goal on the international stage (61). Making internationally accepted frameworks and models meaningful within the Canadian MT context addresses the local need to learn from adverse incident description and reporting in MT in Canada, as well as informing future initiatives to improve practice, education, and policy. Developing a taxonomy is the next step in this research program.

There is a need to use appropriate research designs to conduct of patient safety research in MT. While several Cochrane reviews examine adverse events as an outcome, it is well known that the

restrictive inclusion criteria and small sample size of most RCTs decrease the utility of this research design in investigating adverse events. Most current safety-related research pertaining to MT is in the form of case reports and systematic reviews of case reports. Other research designs, including prospective studies, are needed. Broad intra-professional consensus on identifying, defining, and classifying adverse events is needed to advance all research in the field of MT. Inter-professional consensus would aid in interprofessional collaboration in research, practice, education, and policy-making.

7.4.2 POLICY RECOMMENDATION

In Canada, the uniform recording and reporting of patient safety incidents would serve to protect the public if used in the development of learning systems for practitioner, public, and leadership education regarding safety. Canadian RMTs can contribute knowledge regarding patient safety that is essential to understanding the current and potential role of MTs in healthcare. Our stakeholders felt strongly that the results of this research should be presented to and used by Canadian regulators. The Federation of Massage Therapy Regulatory Authorities (FOMTRAC) should make uniform and explicit recording and reporting of patient safety incidents, based upon internationally accepted taxonomic elements, the standard in Canada.

Second, the MT profession in Canada faces challenges of disparate policies regarding student education and training standards as well as uneven evaluation processes for licensure across the country. This is also evident in disparate continuing competency requirements in regulated and non-regulated practice environments. Graham et al. state clearly that “[T]he implications of knowledge translation for continuing education in the health professions include the need to base continuing education on the best available knowledge”(62). National uniformity in the domain of patient safety competencies would be a significant development for the field.

7.4.3 PRACTICE RECOMMENDATIONS

There is a need for standardized education, training, and regulation of massage therapists in Canada. Addressing and solving the ongoing problem of lack of standardization in title and licensure must take place in parallel with the promotion of high quality education programs with

standardized curricula. In turn, this will facilitate uniform practice standards across the country with the development of a robust culture of safety and effectiveness.

In practice, a better understanding of patient safety will aid therapists in securing informed consent and will raise awareness of the conflicting beliefs, attitudes, and narratives formed by stakeholders in safe and effective care. Practitioner education about patient safety is needed. Evidence-based practice, meaning practice that is informed by research evidence, clinical experience, and patients values regarding issues of dosage, the therapeutic window, procedural pain, pain science, and concepts of health and healing should be applied.

7.5 Strengths and Limitations

A major strength of this research is the use of mixed methods in conducting the studies exploring patient safety in MT. The power of mixed methods research lies within its unique capacity to investigate complex constructs such as safety. The research gains value from the commonly cited benefit of mixed methods research—specifically, that mixing methodologies allows for “complementary strengths and non-overlapping weaknesses” (63) which results in improved understanding (64). The project began with an inductive approach of exploring the views of regulatory authorities: the inferences from these specific experiences informed the need for a more deductive approach to investigate the general claims about adverse events in patient safety made by manual therapy researchers and specifically applying to MT. A synthesis of the findings was then taken into the MT and researcher community in the stakeholder consultation. In this way, this work represents an attempt to explore and examine the issue of patient safety with a mixed paradigm of inquiry.

Others have stated that inconsistent terminology in patient safety research is a barrier in searching the literature and that complex strategies are required (3). It has been argued that this is especially true of CAM-related research (65). The comprehensive search strategy in the scoping review is a strength of the research as is the thorough literature review that attempts to address what is known from massage and other professions that use manual therapy methods.

Fonnebo suggests a new path for research in CAM (37). MT fits the description of a therapy widely used but not well researched and in need of scholarly inquiry. The stages proposed by Fonnebo are: clinical practice to studying context, paradigms, philosophical understanding, utilization, the study of safety status, comparative effectiveness, component efficacy, and biological mechanisms. This research fits into the first three steps as recommended by Fonnebo.

This study was limited in scope to the topic of direct clinical health risks. Review of the literature has underscored that harm in health services may comprise direct and indirect clinical health risks (harmful incidents). Indirect health risks may be summarized as the opportunity costs that occur when the wrong treatment is applied at the wrong time by the wrong person. Examples include variability in training and education of practitioners leading to a lack of awareness of limitations, lack of referral, and questionable advice (66). Non-health risks of using health services also occur and include economic harm or exploitation of patients (66). These are important topics for future research.

7.6 Conclusion

Exploring patient safety in MT using mixed methods research deepened the understanding of patient safety in MT. The specific objectives set to achieve this purpose were: to explore MT regulators' views on patient safety and AEs in the practice of MT and to explore taxonomies for understanding, evaluating, or reporting patient safety incidents (adverse events) in existing massage and manual therapies' published literature with a comparison to internationally developed frameworks and models. The final objective was to reflect on how the dissertation's findings aid the patient safety culture of MT in Canada, including knowledge translation and transfer. The research presented in this dissertation may help to provide the foundational knowledge to build informed views on safety in MT, and manual and CAM therapies in general. As evidence supporting the benefits of MT to the health of Canadians continues to mount, so too does the evidence that MT is not without risk to the public. Arguments for or against the need for public protection have historically lacked cogency as there has been very little scholarship behind what are often highly polarized views.

The proportion of the population using MT services for healthcare purposes is increasing and includes the vulnerable elderly and children. At the same time, there is a growing number of published cases of serious adverse events from exposure to massage. The events reported in the literature include vertebral artery dissection, stroke, spinal cord injury, venous thromboembolism, paralysis, spinal fracture, and organ damage.

Given that the professional practice of MT is maturing and the research culture is growing, this project is timely and important. Utilization of the knowledge here by regulators and researchers in order to make internationally meaningful recording and reporting systems for patient safety incidents in MT would constitute a valuable contribution to the MT field. It can be predicted that the experience of all stakeholders is improved with a clear culture of safety. Study findings will also be useful in aiding the development of prevention strategies to reduce adverse events related to MT and will help guide safe, quality-service delivery. Enhancing research utilization in education and competency training (as other professions that utilize manual means of patient care such as physiotherapy and chiropractic have done for a longer period of time than MT) is an example of the development of knowledge translation in education, practice and policy. Uniform regulation of the profession of MT in Canada will be necessary for full accountability for safe patient care.

Numerous stakeholders, including regulators, practitioners, educators, researchers, patients and insurers, will benefit from clarity about patient safety in MT in Canada. A greater understanding of perspectives on adverse events is a necessary first step to create practice guidelines benefitting health care professionals and practicing MTs. A taxonomy of adverse events in MT may also aid interprofessional teams in education and collaboration and with developing uniform informed consent to MT care.

Community-based health services safety research, underrepresented in AE research, will be further advanced by this study. This study will contribute to the knowledge base of all fields of health service delivery that utilize massage as a therapeutic intervention, including MT, chiropractic, physiotherapy, and osteopathy. The study of harmful incidents in MT is novel, necessary, and useful in promoting a culture of patient safety. More research is needed in order

to ensure patients, MTs, referring health professionals, regulators, and politicians are supported in evidence-informed decision-making.

While MT is used by millions of Canadians, there is a need to apply knowledge from research to serve safety, quality, and practice improvement. As per “Knowledge is the Enemy of Unsafe Care,” the WHO report that served as a foundation for this research, it can be concluded that the Canadian MT community of experts in research, education, practice, and policy-making are poised to apply and further explore the knowledge gleaned from research to enhance their informed authority and promote a robust culture of safety and quality care.

These are the first steps in the creation of quality regulated care provided by mature healthcare professions. Further discussion and consensus on assessing patient safety incidents with agreed upon definitions and taxonomy for classification will assuage the difficulties in moving a patient safety agenda forward by providing a foundation against which to test competing narratives of harm. The results of this research can be used in the creation of a framework to disseminate to practitioners, regulators, educators, and MT leaders for consideration. Future research should seek to investigate consensus among the Canadian MT expert community on the development of useful tools for recording and reporting patient safety incidents. Further investigation regarding the role of MT in population health should include the view of patients on safety issues in MT.

Our bravest and best lessons are learned through misadventure!

—Amos Bronson Alcott

References: Chapter 7

1. Kania-Richmond A, Menard MB, Barberree B, Mohring M. "Dancing on the edge of research" – What is needed to build and sustain research capacity within the massage therapy profession? A formative evaluation. *J Bodywork Movement Therap* [Internet]. 2016:[1-10 pp.]. Available from: <http://www.sciencedirect.com/science/article/pii/S1360859216301115>.
2. Davis MA, West AN, Weeks WB, Sirovich BE. Health Behaviors and Utilization among Users of Complementary and Alternative Medicine for Treatment versus Health Promotion. *Health Services Research*. 2011;46(5):1402-16.
3. Pilkington K, Boshnakova A. Complementary medicine and safety: A systematic investigation of design and reporting of systematic reviews. *ComplementTher Med*. 2012 February;20(1-2):73-82. PubMed PMID: 2012072279.
4. Gowan-Moody DM, Leis AM, Abonyi S, Epstein M, Premkumar K. Research utilization and evidence-based practice among Saskatchewan massage therapists. *J Complement Integr Med* [Internet]. 2013; 10(1):[1-10 pp.].
5. Bervoets DC, Luijsterburg PAJ, Alessie JJN, Buijs MJ, Verhagen AP. Massage therapy has short-term benefits for people with common musculoskeletal disorders compared to no treatment: a systematic review. *J Physiother*. 2015;61(3):106-16.
6. Moyer C, Rounds J, JW H. A meta-analysis of massage therapy research. *Psychol Bull*. 2004;130(1):3-18.
7. Moyer C. Affective Massage Therapy. *Int J Ther Massage Bodywork* [Internet]. 2008; 1(2). Available from: <http://www.ijtmb.org/index.php/ijtmb/article/view/30/39>.
8. von Baeyer CL, Tupper SM. Procedural pain management for children receiving physiotherapy. *Physiother Can*. 2010 Fall 10/18;62(4):327-37. PubMed PMID: PMC2958071.
9. Chaitow L. Dosage and manual therapies – Can we translate science into practice? *J Bodywork Movement Ther*. 2016 4//;20(2):217-8.
10. Long AF, Esmonde L, Connolly S. A typology of negative responses: a case study of shiatsu. *ComplementTher Med*. 2009 6//;17(3):168-75.
11. Ernst E. The safety of massage therapy. *Rheumatology*. 2003;42:1101-6.
12. Furlan A, Giraldo M, Baskwill A, Irvin E, Imamura M. Massage for low-back pain. *Cochrane Database of Systematic Reviews*. 2015.
13. Field T, Diego M, Hernandez-Reif M. Moderate pressure is essential for massage therapy effects. *Int J Neurosci*. 2010;120(5):381-5.
14. Rubinstein SM, Knol DL, Leboeuf-Yde C, van Tulder MW. Benign adverse events following chiropractic care for neck pain are associated with worse short-term outcomes but not worse outcomes at three months. *Spine*.33(25):E950-6. PubMed PMID: 19050572.
15. Hurwitz E, Morgenstern H, Vassilaki M, Chiang L. Adverse reactions to chiropractic treatment and their effects on satisfaction and clinical outcomes among patients enrolled in the UCLA Neck Pain Study. *J Manipulative Physiol Ther*. 2004;27(1):16 - 25. PubMed PMID: doi:10.1016/j.jmpt.2003.11.002.
16. Carlesso L, Bartlett DJ, Padfield B, Chesworth BM. Cervical Manipulation and Informed Consent: Canadian Manipulative Physiotherapists' Opinions on Communicating Risk. *Physiother Can*. 2007 01/01//;59(2):86-96.
17. Carlesso LC, Macdermid JC, Santaguida PL, Thabane L, Giulekas K, Larocque L, et al. Beliefs and practice patterns in spinal manipulation and spinal motion palpation reported by Canadian manipulative physiotherapists. *Physiother Can*. 2013;65(2):167-75.
18. Rozmovits L, Mior S, Boon H. Exploring approaches to patient safety: the case of spinal manipulation therapy. *BMC Complement Altern Med*. (2016) 16:164;16(164).

19. Carnes D, Mullinger B, Underwood M. Defining adverse events in manual therapies: a modified Delphi consensus study. *ManTher*. 2010 Feb;15(1):2-6. PubMed PMID: 19443262.
20. McDowell JM, Johnson G, Hale L. Measuring practitioner opinion on adverse reactions to acupuncture. *Australian J Acupunct Chinese Med*. 2011;6(2):28.
21. Carlesso LC, MacDermid JC, Santaguida PL, Thabane L. A survey of patient's perceptions of what is "adverse" in manual physiotherapy and predicting who is likely to say so. *J Clin Epidemiol*. 2013 Oct;66(10):1184-91. PubMed PMID: 23856189. Epub 2013/07/17. eng.
22. Carlesso LC, Cairney J, Dolovich L, Hoogenes J. Defining adverse events in manual therapy: an exploratory qualitative analysis of the patient perspective. *ManTher*. 2011 Oct;16(5):440-6. PubMed PMID: 21377403.
23. Rajendran D, Bright P, Bettles S, Carnes D, Mullinger B. What puts the adverse in 'adverse events'? Patients' perceptions of post-treatment experiences in osteopathy--a qualitative study using focus groups. *ManTher*. 2012 Aug;17(4):305-11. PubMed PMID: 22425134.
24. Leach J, Fiske A, Mullinger B, Ives R, Mandy A. Complaints and claims against osteopaths: a baseline study of the frequency of complaints 2004–2008 and a qualitative exploration of patients' complaints 2011 [Nov 1, 2016]. Available from: http://www.osteopathy.org.uk/uploads/complaints_and_claims_against_osteopaths_2004-2008_public.pdf
25. Porcino A, MacDougall C. The integrated taxonomy of health care: classifying both complementary and biomedical practices using a uniform classification protocol. *Int J Ther Massage Bodywork* [Internet]. 2(3):[18-30 pp.].
26. Sherman K, Dixon M, Thompson D, Cherkin D. Development of a taxonomy to describe massage treatments for musculoskeletal pain. *BMC Complement Alternat Med*. 2006;6(1):24. PubMed PMID: doi:10.1186/1472-6882-6-24.
27. Panel on Definition and Description CRMC. Defining and describing complementary and alternative medicine. Panel on Definition and Description, CAM Research Methodology Conference, April 1995. *Alternat Ther Health Med*. 1997;3(2):49-57. PubMed PMID: 9061989.
28. Carlesso LC, MacDermid JC, Santaguida LP. Standardization of adverse event terminology and reporting in orthopaedic physical therapy: Application to the cervical spine. *J Orthop Sports Phys Ther*. 2010 //;40(8):455-63.
29. Hannes K, Staes F, Goedhuys J, Aertgeerts B. Obstacles to the implementation of evidence-based physiotherapy in practice: A focus group-based study in Belgium (Flanders). *Physiother Theory Practice*. 2009 2009/01/01;25(7):476-88.
30. Ezzo J. What can be learned from Cochrane systematic reviews of massage that can guide future research? *J Altern Complement Med*. 2007;13(2):291-5.
31. Astin JA, Marie A, Pelletier K, Hansen E, Haskell WL. A review of the incorporation of complementary and alternative medicine by mainstream physicians. *Arch Intern Med*. 1998; 158(21):2303-10.
32. Crock RD, Jarjoura D, Polen A, Rutecki GW. Confronting the communication gap between conventional and alternative medicine: A survey of physicians' attitudes. *Altern Ther Health Med*. 1999 Mar 1999;5(2):61-6. PubMed PMID: 204814441; 10069090. English.
33. Verhoef M, Page S. Physicians' perspectives on massage therapy. *Can Fam Physician*. 1998;44:1018 - 20.
34. Shroff F, Sahota I. The perspectives of educators, regulators and funders of massage therapy on the state of the profession in British Columbia, Canada. *Chiropract Man Therap* [Internet]. 2013; 21(2). Available from: <http://www.chiromt.com/content/21/1/2>.
35. Canada FoMTRAO. What is an RMT? [January 14, 2016]. Available from: <http://www.fomtrac.ca/whats-an-rmt/>.

36. Lao L, Hamilton GR, Fu J, Berman BM. Is acupuncture safe? A systematic review of case reports. *Alternat Ther Health Med*. 2003 January/February;9(1):72-83. PubMed PMID: 2003042790.
37. Fonnebo V, Grimsgaard S, Walach H, Ritenbaugh C, Norheim AJ, MacPherson H, et al. Researching complementary and alternative treatments--the gatekeepers are not at home. *BMC medical research methodology*. 2007 Feb 11;7:7. PubMed PMID: 17291355. Pubmed Central PMCID: PMC1800863. Epub 2007/02/13. eng.
38. Wenban AB. Inappropriate use of the title 'chiropractor' and term 'chiropractic manipulation' in the peer-reviewed biomedical literature. *Chiropractic & osteopathy*. 2006;14(1):16.
39. Wenban A. Re: Gouveia LO, Castanho P, Ferreira JJ. Safety of chiropractic interventions. A systematic review. *Spine* 2009;34:E405-13. *Spine*. 2010;35(4):467-8. PubMed PMID: 20160620.
40. Thiel H, Bolton J. The reporting of patient safety incidents—first experiences with the chiropractic reporting and learning system (CRLS): a pilot study. *Clin Chiropract*. 2006;9(3):139-49.
41. Chung KF, Yeung WF, Kwok CW, Yu YM. Risk factors associated with adverse events of acupuncture: a prospective study. *Acupunct Med*. 2014 01 Dec;32(6):455-62. PubMed PMID: 25271149.
42. Barberree B. Reigniting the flame: research on Alberta's long quest for regulation. *Massage Therapy Canada*. 2017.
43. Baskwill A. A guiding framework to understand relationships within the profession of massage therapy. *J Bodywork Movement Therap*. 2015; In Press, Corrected Proof, Available online 17 December 2015.
44. Clouder L. Becoming professional: exploring the complexities of professional socialization in health and social care. *Learn Health Social Care*. 2003;2(4):213-22.
45. Gowan-Moody D, Baskwill A. Report on policy issues concerning the regulation of massage therapy in Canada. The Federation of Massage Therapy Regulatory Authorities of Canada (FOMTRAC), 2006 May. Report No.
46. Marchand AM. A literature review of pediatric spinal manipulation and chiropractic manipulative therapy: evaluation of consistent use of safety terminology. *J Manipulative Physiological Therapeut*. 2015;38(9):692-8. PubMed PMID: 22951268.
47. Vohra S, Kawchuk GN, Boon H, Caulfield T, Pohlman KA, O'Beirne M. SafetyNET: An interdisciplinary research program to support a safety culture for spinal manipulation therapy. *Eur J Integrat Med*. 2014 8//;6(4):473-7.
48. Pohlman KA, O'Beirne M, Thiel H, Cassidy JD, Mior S, Hurwitz EL, et al. Development and validation of providers' and patients' measurement instruments to evaluate adverse events after spinal manipulation therapy. *Eur J Integrat Med*. 2014 8//;6(4):451-66.
49. Sherman H, Castro G, Fletcher M, Hatlie M, Hibbert P, Jakob R, et al. Towards an international classification for patient safety: the conceptual framework. *Qual Assur Health Care*. 2009 February 1, 2009;21(1):2-8.
50. Thomson R, Lewalle P, Sherman H, Hibbert P, Runciman W, Castro G. Towards an international classification for patient safety: a Delphi survey. *International journal for quality in health care : journal of the International Society for Quality in Health Care / ISQua*. 2009 Feb;21(1):9-17. PubMed PMID: 19147596. Pubmed Central PMCID: PMC2638754. Epub 2009/01/17. eng.
51. Runciman W, Hibbert P, Thomson R, Van Der Schaaf T, Sherman H, Lewalle P. Towards an international classification for patient safety: key concepts and terms. *Qual Assur Health Care*. 2009 February 1, 2009;21(1):18-26.
52. *International Classification of Functioning, Disability and Health: ICF*. Geneva: WHO: World Health Organization, 2001.
53. Stucki G, Reinhardt JD, Grimby G. Organizing human functioning and rehabilitation research into distinct scientific fields. Part II: Conceptual descriptions and domains for research. *Journal of*

- rehabilitation medicine : official journal of the UEMS European Board of Physical and Rehabilitation Medicine. 2007 May;39(4):299-307. PubMed PMID: 17468802. Epub 2007/05/01. eng.
54. Stucki G, Cieza A, Melvin J. The International Classification of Functioning, Disability and Health (ICF): a unifying model for the conceptual description of the rehabilitation strategy. *Journal of rehabilitation medicine : official journal of the UEMS European Board of Physical and Rehabilitation Medicine*. 2007 May;39(4):279-85. PubMed PMID: 17468799. Epub 2007/05/01. eng.
 55. Munk N, Harrison A. Integrating the International Classification of Functioning, Disability, and Health Model into Massage Therapy Research, Education, and Practice. *Int J Ther Massage Bodywork [Internet]*. 2010; 3(4):[29-36 pp.].
 56. Andrade C-K. *Principles of Outcome-Based Massage™*. Outcome-Based massage: putting evidence into practice. Third Edition ed. Philadelphia: Lippincott Williams & Wilkins; 2014. p. 3-15.
 57. Evans R, Stoddart G. Producing health, consuming health care. *Soc Sci Med*. 1990;31:1347-63.
 58. Gorrell LM, Engel RM, Brown B, Lystad RP. The reporting of adverse events following spinal manipulation in randomized clinical trials—a systematic review. *The spine journal : official journal of the North American Spine Society*. 2016.
 59. Cresswell KM, Panesar SS, Salvilla SA, Carson-Stevens A, Larizgoitia I, Donaldson LJ, et al. Global research priorities to better understand the burden of iatrogenic harm in primary care: an international Delphi exercise. *PLoS Med*. 2013;10(11):6.
 60. World Health Organization. Working paper: preliminary version of minimal information model for patient safety. 2014 Contract No.: WHO/HIS/SDS/2014.7.
 61. World Health Organization. Patient safety research: a guide for developing training programmes. 2012.
 62. Graham ID, Logan J, Harrison MB, Straus SE, Tetroe J, Caswell W, et al. Lost in knowledge translation: time for a map? *J Contin Educ Health Prof*. 2006;26(1):13-24.
 63. Johnson R, Onwuegbuzie A, Turner L. Toward a definition of mixed methods research. *J Mix Methods Res*. 2007;1(2):112-33.
 64. Plano Clark V, Creswell J, O'Neil Green D, Shope R. Mixing quantitative and qualitative approaches: an introduction to emergent mixed methods research. In: Nagy Hesse-Biber S, Leavy P, editors. *Handbook of emergent methods*. New York: The Guilford Press; 2008. p. 363-87.
 65. Weeks L, Strudsholm T. A scoping review of research on complementary and alternative medicine (CAM) and the mass media: Looking back, moving forward. *BMC Complement Alternat Med*. 2008;8(43).
 66. Wardle JL, Adams J. Indirect and non-health risks associated with complementary and alternative medicine use: An integrative review. *Eur J Integrat Med*. 2014 8//;6(4):409-22.

APPENDIX A: LETTER OF INVITATION CONSENT

Letter of Invitation; Consent Form for Focus Group

March 20, 2014

Study Title: “Patient safety in community-based health care: understanding adverse events in massage therapy”.

Dear College of Massage Therapists of British Columbia (CMTBC) Board and staff,

My name is Donelda Gowan-Moody. I am a Saskatchewan massage therapist and doctoral student in the College of Medicine at the University of Saskatchewan. I am conducting a research study as part of the requirements of my degree in Population Health Sciences, and I would like to invite you to participate. This study is sponsored by the CMTBC who have provided funds for my travel and accommodation costs.

I am studying adverse events in massage therapy. As you know, patient safety is of paramount importance in the delivery of healthcare and while massage therapy is known to be a safe form of care, there is a dearth of published research. To better understand the nature and extent of adverse events, a data reporting framework and tools are required. Proper measurement and recording of safety-related data in research rests on agreed upon terminology, descriptions and definitions of what constitutes adverse outcomes. There is a need to more fully understand the views and opinions of important stakeholders, including health care regulators. The results of this study will be useful to inform massage therapy practice, education and policy with respect to both monitoring and prevention of adverse events.

If you decide to participate, you will be asked to participate in a group discussion with up to 12 of your fellow CMTBC Board members or staff members about the nature and meaning of adverse events in massage therapy. In particular, you will be asked questions about your views

and opinions about what makes a massage-therapy-related experience “adverse” from your perspective as a massage therapy regulator.

The meeting will take place at lunch time at the CMTBC Annual General Meeting/Education Day on April 13th, 2014 in Vancouver, BC and should last about an hour. The session will be audio taped so that I can accurately reflect on what is discussed. The tapes will only be reviewed by members of the research team who will transcribe and analyze them. They will then be destroyed.

You do not have to answer any questions that you do not wish to. There are no known or anticipated risks to you by participating in this research. Although you probably won't benefit directly from participating in this study, we hope that others in the community/society in general will benefit by the promotion of public safety in massage therapy practice. Participation is confidential. Study information will be kept in a secure location at the University of Saskatchewan Department of Community Health & Epidemiology, in the office of Dr. Leis. The results of the study may be published or presented at professional meetings, but your identity will not be revealed.

Although we may report direct quotations from the focus group, all identifying information including names, affiliation and position with the CMTBC will be removed from our report. The researcher will undertake to safeguard the confidentiality of the discussion, but cannot guarantee that other members of the group will do so. Please respect the confidentiality of the other members of the group by not disclosing the contents of this discussion outside the group, and be aware that others may not respect your confidentiality. Your participation is voluntary and you can answer only those questions that you are comfortable with. Whether you choose to participate or not will have no effect on your position with the CMTBC or how you will be treated. You may withdraw from the research project for any reason, at any time without explanation or penalty of any sort. Should you wish to withdraw during the focus group, due to the interactive nature of the discussion, any information that you have contributed prior to your withdrawal will remain in the study material.

Please keep this letter for your record. If you have any questions concerning the research project, or would like a summary of the results when the study is done, please feel free to contact the researchers at the numbers provided below. You may contact me by phone at 1-306-270-4268 or email at: d.gowanmoody@usask.ca or my faculty advisor, Dr. Anne Leis by phone at 1-306-966-7878 or email at: anne.leis@usask.ca if you have study related questions or problems. This project was approved on ethical grounds by the University of Saskatchewan Behavioral Research Ethics Board. Any questions regarding your rights as a participant may be addressed to the Research Ethics Office toll free at 1-888-966-2975 or ethics.office@usask.ca .

Thank you for considering participation in this study.

With kind regards,

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Study Title: “Patient safety in community-based health care: understanding adverse events in massage therapy”.

Consent to Participate:

Your signature below indicates that you have read and understand the description provided; I have had an opportunity to ask questions and my questions have been answered. I consent to participate in the research project. A copy of this Consent Form has been given to me for my records.

Name of Participant

Signature

Date (dd/mm/yy)

Researcher's Signature

Date (dd/mm/yy)

A copy of this consent will be left with you, and a copy will be taken by the researcher.

Thank you for your participation in this important study.

If you have any questions concerning the research project, or would like a summary of the results when the study is done, please feel free to contact the researchers at the numbers provided below. You may contact me by phone at 1-306-270-4268 or email at: d.gowanmoody@usask.ca or my faculty advisor, Dr. Anne Leis by phone at 1-306-966-7878 or email at: anne.leis@usask.ca if you have study related questions or problems. This project was approved on ethical grounds by the University of Saskatchewan Behavioral Research Ethics Board. Any questions regarding your rights as a participant may be addressed to the Research Ethics Office toll free at 1-888-966-2975 or [**ethics.office@usask.ca**](mailto:ethics.office@usask.ca) .

Sincerely,

Donelda Gowan-Moody, MSc, PhD student

APPENDIX B: FOCUS GROUP GUIDE

Focus Group Topic Guide

Questions and Prompts

Is there anything inherently unique about massage as a modality or massage therapy as a profession when you think about patient safety or when thinking about adverse events?

What are the elements of patient safety that massage therapists need to be aware of? What are the contexts and constructs that we should be looking at?

Are there shared norms and values? What is and is not an adverse event?

What does 'adverse' mean when included in the expression 'adverse events' ?

What constitutes an adverse event in massage therapy (MT)?

What type of massage therapy-related experiences would you consider to be potentially adverse or negative?

APPENDIX C: STAKEHOLDERS CONSULTATION SUMMARY

PRESENTATION AND PARTICIPANT QUESTIONS

Review of objectives:

The objectives of the stakeholder consultation are:

- A) To solicit your feedback and input on our study
- B) to solicit your suggestions on knowledge translation approaches based on the results of our scoping review - specifically what, to whom, by whom; how and with what effect should the knowledge from this research be transferred.

Introduction:

In our scoping study we asked the following research question: what is the current knowledge and practice in defining and classifying patient safety incidents (adverse events) in massage and manual therapies in the medical literature regarding patient outcomes as characterized by the WHO minimum information model regarding type of harm, degree of harm and social and/or economic impact?

Background:

WHO Conceptual Framework for the International Classification for Patient Safety

The purpose of the International Classification for Patient Safety (ICPS) is: to enable categorization of patient safety information using standardized sets of concepts with agreed definitions, preferred terms, and the relationships between them based on an explicit domain ontology. It is designed to facilitate the description, comparison, measurement, monitoring, analysis and interpretation of information to improve patient care, and for epidemiological and health policy planning purposes.(1)

In essence, the ICPS is “designed to be a genuine convergence of international perceptions of the main issues related to patient safety...[such that] [A]ctions taken to reduce risk represent the collective learning from the information classified in all 10 classes necessary to result in system improvement, reduction of risk and improvement in patient care (1).

ICPS Preferred Terms and Definitions:

- A **patient safety incident** is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. The use of the word “unnecessary” in this definition recognizes that errors, violation, patient abuse and deliberately unsafe acts occur in healthcare. These are considered incidents. Certain forms of harm, however, such as an incision for a laparotomy, are necessary. Incidents arise from either unintended or intended acts. A harmful incident (adverse event) is an incident that results in harm to a patient
- **Harm** implies impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or psychological.
- Disease is a physiological or psychological dysfunction
- Injury is damage to tissues
- Suffering is the experience of anything subjectively unpleasant.
- Disability implies any type of impairment of body structure or function, activity limitation and/or restriction of participation in society
- **Safety** is the reduction of risk of unnecessary harm to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment.
- **Patient outcome** is the impact upon a patient which is wholly or partially attributable to an incident. Where harm has occurred, the degree of harm is the severity and duration of any harm, and any treatment implications, that result from an incident

Degree of Harm:

None – patient outcome is not symptomatic or no symptoms detected and no treatment is required.

Mild – symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention

Moderate –requiring intervention or causing permanent or long term harm or loss of function.

Severe –requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long term harm or loss of function

Death – on balance of probabilities, death was caused or brought forward in the short term by the incident.

Questions for Stakeholders:

Do you think this study has value?

Are the results of the study important?

What, to whom, by whom, how, and with what effect should the knowledge be shared?¹

¹ Lavis J, Permanand G, Oxman A, Lewin S, Fretheim A. SUPPORT Tools for evidence-informed health Policymaking (STP) 13: Preparing and using policy briefs to support evidence-informed policymaking. Health Research Policy and Systems. 2009;7(Suppl 1):S13

APPENDIX D: LIST OF INCLUDED STUDIES

2867. Carlesso LC, MacDermid JC, Santaguida PL, Thabane L. A survey of patient's perceptions of what is "adverse" in manual physiotherapy and predicting who is likely to say so. *Journal of Clinical Epidemiology*. 2013;66(10):1184-91. PubMed PMID: 23856189.
2869. Carnes D, Mullinger B, Underwood M. Defining adverse events in manual therapies: a modified Delphi consensus study. *Manual Therapy*. 2010;15(1):2-6. PubMed PMID: 19443262.
- 3029 Senstad O, Leboeuf-Yde C, Borchgrevink C. Frequency and characteristics of side effects of spinal manipulative therapy. *Spine*. 1997;22(4):435-40; discussion 40-1. PubMed PMID: 9055373.
3165. Carlesso LC, Cairney J, Dolovich L, Hoogenes J. Defining adverse events in manual therapy: An exploratory qualitative analysis of the patient perspective. *Manual Therapy*. 2011 October;16(5):440-6. PubMed PMID: 2011472410.
3234. Eriksen K, Rochester RP, Hurwitz EL. Symptomatic reactions, clinical outcomes and patient satisfaction associated with upper cervical chiropractic care: A prospective, multicenter, cohort study. *BMC Musculoskeletal Disorders*. 2011;12 (no pagination)(219). PubMed PMID: 2011599018.
3400. Paanalahti K, Holm LW, Nordin M, Asker M, Lyander J, Skillgate E. Adverse events after manual therapy among patients seeking care for neck and/or back pain: A randomized controlled trial. *BMC Musculoskeletal Disorders*. 2014 12 Mar;15 (1) (no pagination)(77). PubMed PMID: 2014288695.
3418. Pohlman K, O'Beirne M, Thiel H, Cassidy JD, Mior S, Hurwitz E, et al. Development and validation of instruments to evaluate adverse events after spinal manipulation therapy. *Journal of Alternative and Complementary Medicine*. 2014 May;20 (5):A49. PubMed PMID: 71474727.
3432. Rajendran D, Bright P, Bettles S, Carnes D, Mullinger B. What puts the adverse in 'adverse events'? Patients' perceptions of post-treatment experiences in osteopathy - A qualitative study using focus groups. *Manual Therapy*. 2012 August;17(4):305-11. PubMed PMID: 2012303406.
3451. Rubinstein SM, Leboeuf-Yde C, Knol DL, de Koekkoek TE, Pfeifle CE, van Tulder MW. The Benefits Outweigh the Risks for Patients Undergoing Chiropractic Care for Neck Pain: A Prospective, Multicenter, Cohort Study. *Journal of Manipulative and Physiological Therapeutics*. 2007 July;30(6):408-18. PubMed PMID: 200738967
3522. Walker BF, Hebert JJ, Stomski NJ, Clarke BR, Bowden RS, Losco B, et al. Outcomes of usual chiropractic. the OUCH randomized controlled trial of adverse events. *Spine*. 2013 15 Sep;38(20):1723-9. PubMed PMID: 2013612801.
3986. McDowell JM, Johnson G, Hale L. Measuring practitioner opinion on adverse reactions to acupuncture. *Australian Journal of Acupuncture and Chinese Medicine*. 2011;6(2):28.
3987. McDowell JM, Johnson GM, Hale L. Adverse reactions to acupuncture: policy recommendations based on practitioner opinion in New Zealand. *New Zealand J Physiother*. 2013;41:94-101.
3988. Thiel H, Bolton J. The reporting of patient safety incidents—first experiences with the chiropractic reporting and learning system (CRLS): a pilot study. *Clinical Chiropractic*. 2006;9(3):139-49.
3989. Cambron JA, Dexheimer J, Coe P, Swenson R. Side-Effects of Massage Therapy: A Cross-Sectional Study of 100 Clients. *The Journal of Alternative and Complementary Medicine*. 2007;13(8):393-6.

APPENDIX E: SEARCH STRATEGIES

Search Strategies

Ovid Medline

Provider/Interface	Ovid
Database	Medline®
Date searched	2016-02-15 Auto Alert set
Database update	1946 to February Week 3 2016
Search developer(s)	DGM/VD
Limit to English	Yes

1	exp Musculoskeletal Manipulations/ or physical therapy modalities/ or muscle stretching exercises/
2	Acupuncture Therapy/ or acupuncture/ or chiropractic/ or exp meridians/
3	(massage or “manual therapy” or mobili?ation).mp.
4	(manipulati* adj (therap* or medicine)).mp.
5	(acupuncture or acu-puncture or needling or acupressure).mp.
6	((neck or spine or spinal or cervical or chiropract* or musculoskeletal* or musculo-skeletal*) adj3 (adjust* or manipul* or mobiliz* or mobilis*)).mp.
7	(massag* or reflexolog* or rolfing or zone therap*).mp.
8	(Nimmo or trigger point).mp.
9	(cupping or Gua sha or Tui Na or Tuina or (Thai adj3 massage) or Shiatsu or anma or (lomilomi or lomi-lomi)).mp.
10	(cyriax or friction therap* or Graston technique).mp.
11	(Bowen technique or Trager).mp.
12	((strain adj counterstrain) or (neuromuscular therap* or post-isometric relaxation or muscle stretching technique or muscle energy technique* or Proprioceptive Neuromuscular Facilitation*)).mp.
13	(cranio-sacral or cranosacral or cranio sacral therapy).mp.
14	(effleurage or petrissage or tapotment).mp.
15	(osteopathic* adj (therap* or medicine)).mp.
16	(bodywork* or therapeutic touch or myotherapy).mp.

17	or/1-16
18	exp Heart Massage/
19	17 not 18
20	prostate/ or carotid/ or uterine/ or perineal/ or vaginal/ or eye rubbing.mp.
21	19 not 20
22	classification/ or data collection/ or common data elements/ or datasets as topic/ or records as topic/
23	terminology as topic/
24	current procedural terminology/ or healthcare common procedure coding system/ or “international classification of diseases”/ or “international classification of functioning, disability and health”/
25	taxonomy.mp.
26	classification.mp.
27	information model.mp.
28	typology.mp.
29	incident report*.mp.
30	terminology.mp.
31	22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
32	exp Risk Management/ or patient harm/ or patient safety/
33	iatrogenic disease/ or symptom flare up/
34	pain measurement/
35	treatment failure/ or failure to rescue, health care/
36	((adverse or undesirable or harm*) adj3 (effect* or reaction* or event* or outcome*)).mp.
37	symptomatic reaction*.mp.
38	patient safety incident*.mp.
39	patient harm*.mp.
40	patient injur*.mp.
41	side effect*.mp.
42	(safe or safety).mp.
43	or/32-42
44	21 and 31 and 43
45	exp animals/ not humans/
46	44 not 45
47	limit 46 to english

AMED

Provider/Interface: OVID

Database: AMED (Allied and Complementary Medicine)

Date searched: February 25, 2016 Auto Alert set

Database update: 1985 to February 2016

Search developers: DGM/VD

Limit to English: yes

1	exp musculoskeletal manipulations/
2	physical therapy modalities/ or exp manipulation/ or massage/ or exp mobilisation/ or muscle stretching exercises/
3	acupuncture therapy/ or acupoints/ or acupressure/ or needling/ or cupping/
4	(massage or "manual therapy" or mobili?ation).mp.
5	(manipulati* adj (therap* or medicine)).mp.
6	(acupuncture or acu-puncture or needling or acupressure).mp.
7	((neck or spine or spinal or cervical or chiropract* or musculoskeletal* or musculo-skeletal*) adj3 (adjust* or manipulat* or mobiliz* or mobilis*)).mp.
8	(massag* or reflexolog* or rolfing or zone therap*).mp.
9	(Nimmo or trigger point).mp.
10	(cupping or Gua sha or Tui Na or Tuina or (Thai adj3 massage) or Shiatsu or anma or (lomilomi or lomi-lomi)).mp.
11	(cyriax or friction therap* or Graston technique).mp.
12	(Bowen technique or Trager).mp.
13	((strain adj counterstrain) or (neuromuscular therap* or post-isometric relaxation or muscle stretching technique or muscle energy technique* or Proprioceptive Neuromuscular Facilitation*)).mp.
14	(cranio-sacral or craniosacral or cranio sacral therapy).mp.
15	(effleurage or petrissage or tapotment).mp.
16	(osteopathic* adj (therap* or medicine)).mp.
17	(bodywork* or therapeutic touch or myotherapy).mp.
18	or/1-17
19	prostate/ or carotid/ or uterine/ or perineal/ or vaginal/ or eye rubbing.mp.

20	18 not 19
21	classification/ or data collection/ or records/
22	nomenclature/
23	taxonomy.mp. [mp=abstract, heading words, title]
24	classification.mp.
25	information model.mp.
26	typology.mp.
27	incident report*.mp.
28	terminology.mp.
29	or/21-28
30	adverse effects/
31	((adverse or undesirable or harm*) adj3 (effect* or reaction* or event* or outcome*)).mp.
32	patient safety incident*.mp.
33	patient harm*.mp.
34	patient injur*.mp.
35	side effect*.mp.
36	or/30-35
37	20 and 29 and 36
38	limit 37 to english

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations

Provider/Interface Ovid
Database Medline®
Date searched February 25 2016 Auto Alert Set
Database update February 24 2016
Search developer(s) DGM
Limit to English Yes

1	exp Musculoskeletal Manipulations/ or physical therapy modalities/ or muscle stretching exercises/
2	Acupuncture Therapy/ or acupuncture/ or chiropractic/ or exp meridians/
3	(massage or "manual therapy" or mobili?ation).mp.
4	(manipulati* adj (therap* or medicine)).mp.
5	(acupuncture or acu-puncture or needling or acupressure).mp.
6	((neck or spine or spinal or cervical or chiropract* or musculoskeletal* or musculo-skeletal*) adj3 (adjust* or manipulat* or mobiliz* or mobilis*)).mp.
7	(massag* or reflexolog* or rolfing or zone therap*).mp.
8	(Nimmo or trigger point).mp.
9	(cupping or Gua sha or Tui Na or Tuina or (Thai adj3 massage) or Shiatsu or anma or (lomilomi or lomi-lomi)).mp.
10	(cyriax or friction therap* or Graston technique).mp.
11	(Bowen technique or Trager).mp.
12	((strain adj counterstrain) or (neuromuscular therap* or post-isometric relaxation or muscle stretching technique or muscle energy technique* or Proprioceptive Neuromuscular Facilitation*)).mp.
13	(cranio-sacral or craniosacral or cranio sacral therapy).mp.
14	(effleurage or petrissage or tapotment).mp.
15	(osteopathic* adj (therap* or medicine)).mp.
16	(bodywork* or therapeutic touch or myotherapy).mp.
17	or/1-16
18	exp Heart Massage/
19	17 not 18
20	prostate/ or carotid/ or uterine/ or perineal/ or vaginal/ or eye rubbing.mp.
21	19 not 20
22	classification/ or data collection/ or common data elements/ or datasets as topic/ or records as topic/
23	terminology as topic/

24	current procedural terminology/ or healthcare common procedure coding system/ or “international classification of diseases”/ or “international classification of functioning, disability and health”/
25	taxonomy.mp.
26	classification.mp.
27	information model.mp.
28	typology.mp.
29	incident report*.mp.
30	terminology.mp.
31	22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
32	exp Risk Management/ or patient harm/ or patient safety/
33	iatrogenic disease/ or symptom flare up/
34	pain measurement/
35	treatment failure/ or failure to rescue, health care/
36	((adverse or undesirable or harm*) adj3 (effect* or reaction* or event* or outcome*)).mp.
37	symptomatic reaction*.mp.
38	patient safety incident*.mp.
39	patient harm*.mp.
40	patient injur*.mp.
41	side effect*.mp.
42	(safe or safety).mp.
43	or/32-42
44	21 and 31 and 43
45	exp animals/ not humans/
46	44 not 45
47	limit 46 to English

Ebsco CINAHL® Search Strategy

Provider/Interface	Ebsco
Database	CINAHL Plus with Full Text: Cumulative Index to Nursing and Allied Health Literature
Date searched	February 25 2016 Auto Alert Set
Database update	February 25 2016
Search developers	DGM/VD
Limit to English	Yes

S47	S25 AND S32 AND S45
S46	S25 AND S32 AND S45
S45	S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44
S44	side effect
S43	patient injury
S42	patient injur
S41	patient harm
S40	patient safety incident
S39	symptomatic reaction
S38	adverse outcome
S37	adverse reaction
S36	adverse event
S35	adverse effect
S34	((adverse or undesirable or harm) N3 (effect or reaction or event or outcome)).mp.
S33	(MH Adverse Health Care Event)
S32	S26 OR S28 OR S29 OR S30 OR S31
S31	Terminology
S30	Typology
S29	information model
S28	Classification
S27	Taxonomy
S26	(MH "Classification") OR (MH "Common Data Elements")

S25	S23 NOT S24
S24	prostate/ or carotid/ or uterine/ or perineal/ or vaginal/ or eye rubbing
S23	S21 NOT S22
S22	(MH “Heart Massage”)
S21	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20
S20	muscle stretching
S19	(bodywork or therapeutic touch or myotherapy)
S18	(osteopathic* N (therapy or medicine))
S17	effleurage or petrissage
S16	(cranio-sacral or craniosacral or cranio sacral therapy)
S15	((strain adj counterstrain) or (neuromuscular therapy or post-isometric relaxation or muscle stretching technique or muscle energy technique or Proprioceptive Neuromuscular Facilitation))
S14	Trager Technique
S13	Bowen technique
S12	(cyriax or friction therapy or Graston technique)
S11	Shiatsu or anma or (lomilomi or lomi-lomi)
S10	(Thai N3 massage)
S9	cupping or Gua sha or Tui Na or Tuina
S8	Nimmo or trigger point
S7	massage or reflexology or Rolfing
S6	acupuncture or acu-puncture or needling or acupressure
S5	((neck or spine or spinal or cervical or chiropract* or musculoskeletal* or musculo-skeletal*) N3 (adjust* or manipulati* or mobiliz* or mobilis*))””
S4	(manipulati* N (therap* or medicine))
S3	massage or “manual therapy” or mobili?ation
S2	(MH “Myofascial Release”) OR (MH “Reflexology”) OR (MH “Craniosacral Therapy”) OR (MH “Rolfing”) OR (MH “Trager Method”)(MH “Reiki”) OR (MH “Therapeutic Touch”) OR (MH “Bowen Technique”)
S1	(MH “Massage+”) OR (MH “Manual Therapy+”) OR (MH “Chiropractic+”) OR (MH “Acupuncture”) OR (MH “Meridians+”) OR (MH “Osteopathic Medicine”) OR (MH “Physical Medicine”) OR (MH “Joint Mobilization”) OR (MH “Trigger Point”)

Ovid EMBASE® Search Strategy

Provider/Interface	Ovid
Database	Embase Classic+Embase
Date searched	February 25 2016 Auto Alert set
Database update	1947 to 2016 February 22
Search developers	DGM/VD
Limit to English	Yes

1	exp *manipulative medicine/ or *acupuncture/ or *physiotherapy/ or *joint mobilization/ or *chiropractic practice/ or *chiropractor/ or *chiropractic/ or *physiotherapy practice/ or *physiotherapist/ or *massage/ or *acupressure/ or *Shiatsu/ or *Tuina/ or *osteopathic medicine/
2	((manual adj therap*) or physiotherap* or osteopath* or chiropract*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
3	(massage or Shiatsu or Tuina or Tui Na or anma or lomilomi or lomi-lomi or cupping or Gua sha).mp.
4	(reflexolog* or Rolfing or zone therap*).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
5	(Thai adj3 massage).mp.
6	(acupuncture or acu-puncture or needling or acupressure).mp.
7	(Nimmo or trigger point or cyriax or friction therap* or Graston technique).mp.
8	(Bowen technique or Trager).mp.
9	((strain adj counterstrain) or (neuromuscular therap* or post-isometric relaxation or muscle stretching technique or muscle energy technique* or Proprioceptive Neuromuscular Facilitation*)).mp.
10	(cranio-sacral or craniosacral or cranio sacral therapy).mp.
11	(effleurage or petrissage or tapotment).mp.
12	(bodywork* or therapeutic touch or myotherapy).mp.
13	or/1-12
14	exp Heart Massage/
15	13 not 14
16	prostate/ or carotid/ or uterine/ or perineal/ or vaginal/ or eye rubbing.mp.
17	15 not 16

18	*adverse outcome/ or *patient safety/ or *risk assessment/ or *treatment response/ or *outcome assessment/ or *health hazard/
19	(adverse adj reaction).tw.
20	(adverse adj event*).tw.
21	(adverse adj effect*).tw.
22	(adverse adj outcome*).tw.
23	(adverse adj response*).tw.
24	or/18-23
25	(taxonomy or typology or consensus or framework or terminology or definition or classif*).tw.
26	*disease classification/ or disease severity/
27	25 or 26
28	17 and 24 and 27
29	(exp animal/ or nonhuman/) not exp human/
30	28 not 29
31	limit 30 to English

SCOPUS

Provider/Interface	Elsevier
Database	Scopus
Date searched	February 25 2016 Auto Alert set
Database update	February 25 2016 Auto Alert set
Search developers	DGM/VD
Limit to English	Yes

<p>(TITLE-ABS-KEY (“patient harm*” OR “patient safety” OR “patient safety incident**”)) OR (TITLE-ABS-KEY (“adverse effect*” OR “adverse reacti* OR “adverse event*)) OR (TITLE-ABS-KEY (“adverse outcome*” OR “symptomatic reaction*” OR “side effect*”))) AND ((TITLE-ABS-KEY (classif* OR taxonomy OR typology)) OR (TITLE-ABS-KEY (terminology OR defin*))) AND (((TITLE-ABS-KEY (“orthopedic physiotherapy” OR “orthopaedic physiotherapy” OR “orthopedic physical therapy” OR “orthopaedic physical therapy” OR “motion therapy” OR “rehabilitation”)) OR (TITLE-ABS-KEY (“passive mobilization” OR “passive movement therapy”)) OR (TITLE-ABS-KEY (“instrument assisted soft-tissue manipulation” OR “instrument assisted soft tissue manipulation” OR “soft tissue therapy” OR “soft-tissue therapy” OR “joint mobilization” OR “joint mobilisation” OR “joint manipulation”)) OR (TITLE-ABS-KEY (physiotherapy OR “physical therapy” OR “spin* manipulation” OR “soft tissue mobilization” OR “soft-tissue mobilization” OR “soft tissue manipulation” OR “soft-tissue manipulation”))) OR ((TITLE-ABS-KEY (“musculoskeletal manipulations” OR “physical therapy modalities” OR “muscle stretching exercises” OR “acupuncture therapy” OR acupuncture OR chiropractic OR meridians OR massage OR “manual therapy” OR mobilisation OR mobilization OR needling OR acupressure)) OR (TITLE-ABS-KEY (“Graston technique” OR “Bowen technique” OR trager OR “neuromuscular therapy” OR “post-isometric relaxation” OR “muscle energy technique” OR “Proprioceptive Neuromuscular Facilitation”)) OR (TITLE-ABS-KEY (nimmo OR “trigger point” OR cupping OR gua sha OR tui na OR tuina OR “Thai massage” OR shiatsu OR anma OR lomilomi OR lomi-lomi OR cyriax OR “friction therapy”)) OR (TITLE-ABS-KEY (mobilisation OR mobilization OR needling OR acupressure OR massage OR “massage therapy” OR reflexology OR rolfing)) OR (TITLE-ABS-KEY (“musculoskeletal manipulations” OR “physical therapy modalities” OR “muscle stretching exercises” OR “acupuncture therapy” OR acupuncture OR chiropractic OR meridians OR massage OR “manual therapy”)) OR (TITLE-ABS-KEY (massage OR “manual therapy” OR mobilisation OR mobilization OR needling OR acupressure OR massage OR “massage therapy” OR reflexology OR rolfing OR nimmo OR “trigger</p>

	point" OR cupping OR gua sha OR tui na OR tuina)))) AND (LIMIT-TO (SUBJAREA , "HEAL")) AND (LIMIT-TO (LANGUAGE , "English"))
--	--

PEDro

Provider/Interface The George Institute for Global Health
Database PEDro
Date searched 2016-02-23
Database update 1 February 2016
Search developers DGM/VD
Limit to English Yes

	("adverse event*" AND "stretching, mobilization, manipulation, massage" "adverse effect*" AND "stretching, mobilization, manipulation, massage" adverse event* AND acupuncture adverse effect* AND acupuncture
--	--

ProQuest

Provider/Interface ProQuest
Database Dissertations & Theses Global
Date searched February 24 2016
Database update February 24 2016
Search developers DGM/VD
Limit to English Yes

	((ab(adverse) AND ab(((massage OR "manual therapy") OR physiotherapy)) OR ab((chiropractic OR acupuncture)) OR ab(osteopath) AND ab((taxonomy OR classification))) AND la.exact("English")) AND la.exact("English") AND la.exact("English")
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Non-Database Searches Yielding New Studies

Data Source		Results
Vendor/ Interface	Database	New
Author Search	n/a	2
bibliographies	bibliographies	1
Elsevier	Scopus	0
ISI	Web of Science	0
Handsearching and/or Conferences	handsearching journals & conference proceedings	1
Google	Google Scholar	1
Total		5

APPENDIX F: LIST OF DISSEMINATION ACTIVITIES

Oral Presentations

- Gowan-Moody D, Baskwill A, Leis A. Exploring massage and manual therapy patient safety incident (adverse event) taxonomies: a scoping review. 2016 INCAM Research Symposium: Expanding Person-Centred Care through Integrative Health Research. November 18-19, 2016. Toronto, Ontario.
- Gowan-Moody, D. Understanding adverse events in massage therapy: a focus group investigation. Department of Community Health & Epidemiology. Student Research Day. Royal University Hospital SaskTel Theatre. February 5, 2015. Saskatoon, Saskatchewan.
- Gowan-Moody, D. Are we playing fast and loose with patient safety in MT? A review of the literature. 2nd MTAS Interdisciplinary Research Symposium. March 28th, 2015 Saskatoon, Saskatchewan.
- Gowan-Moody, D. Patient safety in massage therapy: a literature review. Department of Community Health & Epidemiology. Student Research Day. Royal University Hospital SaskTel Theatre. February 13, 2014, Saskatoon, Saskatchewan.
- Gowan-Moody D, Leis A. Adverse events in massage therapy: perspectives from a focus group IN-CAM Research Symposium: The Next Wave of Complementary and Integrative Medicine and Health Care Research. Nov 6-8, 2014, Calgary, Alberta.

Poster presentations on the research findings:

- Gowan-Moody D, Leis A. Exploring Pain-related Patient Safety Incidents (Adverse Events) in Massage Therapy. The International Congress on Integrative Medicine and Health (ICIMH), Las Vegas, Nevada, USA May 17–20, 2016
- Gowan-Moody D, Leis A. Can it hurt? Reports of pain-related adverse events in massage therapy. The Canadian Pain Society 37th Scientific Meeting, May 24-27, 2016. Vancouver, British Columbia.
- Gowan-Moody D, Leis A. Can it hurt? Reports of pain-related adverse events in massage therapy. 6th Conference on Implementing Best Practices for Pain Management in Saskatchewan. November 3-4, 2016. Regina, Saskatchewan.

APPENDIX G: GLOSSARY OF PRACTICE TERMS

Aromatherapy: Aromatherapy uses chemical aromatics extracted by distillation, pressing and purifying, or diffusion. The oils are usually inhaled or put directly onto the skin in a diluted form²

Chinese Medicine: a complex medical system that describes the physiology, pathology, diagnosis, and treatment of the human body in intricate and mutually related, energetic terms¹

Chiropractic: a holistic health care approach that prioritizes mechanical and muscular disorders, particularly those that involve the spine¹

CranioSacral Therapy is an approach where practitioners use their hands to release built up tensions within the body, associated with the craniosacral system (the liquids and membranes that support the functionality of the brain and spinal cord)¹

Hydrotherapy: a water-based therapy where steam, ice, or hot or cold water is used to reduce stress, to increase comfort, and to improve overall health¹

Lomilomi is an ancient Hawaiian massage system that is part of the Hawaiian healing tradition, in which physical, mental, emotional, and spiritual health are considered and treated as one unit¹

Naprapathic Medicine is a system of healthcare that employs Manual Medicine, Nutritional Counseling and Therapeutic Modalities, specializing in the treatment of pain caused by Connective Tissue Disorders³

Osteopathy: the holistic study of how the body's muscular and skeletal system can be altered to support better health¹

Reiki is a Japanese energy technique, with Tibetan origins, where an emphasis is placed on the body's natural ability to heal itself. The practitioner gently places their hands in various positions on the head and body with the intention of healing on a physical, mental, and emotional level¹

² Natural Health Practitioners of Canada. Holistic Health Guide Glossary [cited 2017 May 5]. Available from: <https://www.nhpcanada.org/for-the-public/holistic-health-guide/glossary.html?page=glossary>.

³ National College of Naprapathic Medicine. What is Naprapathic Medicine. [Internet] {cited May 3, 2017} Available from <http://napmed.edu/about/naprapathicmedicine/>

Reflexology is based on the ability to enable healing in one body part or organ (a reflex response) by stimulating specific points on the body. The most common is foot reflexology, where practitioners stimulate the reflex points on the feet to trigger stimulation in a corresponding organ or structure. However, reflexology may also be performed on the hands or ears¹

In **Shiatsu**, the practitioner primarily uses the thumbs and palms of the hands as a means of effecting therapeutic changes to the energy systems of the body¹

Swedish massage: many Western massage specializations originate from the Swedish style. This style uses characteristic gliding motions, following the direction of blood flow towards the heart to induce relaxation¹

Thai Massage involves particular stretches and strokes, performed on clothed clients on floor mats or low tables. It opens the joints and stimulates blood flow. This involves at least 104 postures, from yogic origins¹

Tuina combines soft-tissue massage, acupressure, and other manipulation techniques that realign the musculoskeletal and ligamentous relationships. The focus is to help the body heal through regulating or stimulating the flow of energy through the Chinese Meridian Theory and to stimulate or relax the musculoskeletal system to optimize the health of the client¹

APPENDIX H: STAKEHOLDER CONSULTATION PRESENTATION

Exploring massage and manual therapy patient safety incident (adverse event) taxonomies : a scoping review.

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Background

- All healthcare carries inherent risk (Bayne et al, 2012)
- Consensus and clarity regarding definitions to identify and classify these adverse events is lacking (WHO, 2009)
- The use of simple descriptive taxonomies to collect safety event data is advocated (Baker, 2007)

WHO International Classification for Patient Safety (ICPS)

- Standardized sets of concepts with agreed definitions, preferred terms, and the relationships between them
- To facilitate the description, comparison, measurement, monitoring, analysis and interpretation of information to improve patient care, and for epidemiological and health policy planning purposes

Why this study?

- Professional Clinical experience
- Trainee Research Experience
- Identified research priority (Summit 2012; MTRF)

Knowledge Gaps

- A comparison of taxonomies across professions that use 'hands-on' manual therapy has not been examined.
- 'Hands-on': soft-tissue mobilization or therapeutic massage of the skin, muscles and connective tissue, mobilization or manipulation of the joints and spine and various forms of physical perturbation of the human body by needles or other instruments.

Overall Study Purpose

- To explore the applicability and meaningfulness of internationally accepted adverse event terms and taxonomies for the Canadian massage therapy profession.

Study Objectives

- 1) to explore taxonomies for understanding, evaluating or reporting harmful patient safety incidents (adverse events) in existing massage and manual therapies published literature
- 2) to compare available taxonomies with an internationally developed framework and minimal information model's patient outcome domain

Research Question

- What is the current knowledge and practice in identifying, defining and classifying patient safety incidents (adverse events) in massage and manual therapies in the literature regarding patient outcomes as characterized by the WHO minimum information model regarding type of harm, degree of harm and social and/or economic impact?

Scoping Review Design

- Five stages:
- identify the research question
 - identifying the relevant material
 - select studies
 - chart the data/data extraction
 - collate, summarize and report the results

Study Method

- Ten peer-reviewed electronic databases - MEDLINE, MEDLINE IN-PROCESS, EMBASE, CINAHL, SCOPUS, PEDRO, AMED, and ProQuest Theses & Dissertations, WOS, Google Scholar limited to English.
- bibliographies, citations and key authors were searched.

Methods

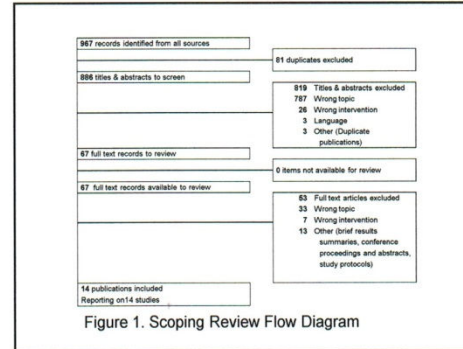
- Excel screening tools
- Agreement: Cohen's kappa .89
- Inclusion/exclusion criteria were applied independently by two reviewers and qualitative information extracted and charted
- Descriptive numerical analysis included the nature of the research found
- Qualitative thematic analysis identified emerging themes

Inclusion Criteria

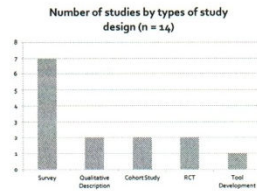
- Reports that provided specific details of the definition of the concept (adverse event), described a detailed taxonomic representation of patient safety incidents in 'hands-on' manual therapy and the taxonomic means of categorizing the outcome in terms of type, degree of harm, and patient impact were selected for inclusion in the final scoping review results.

Results

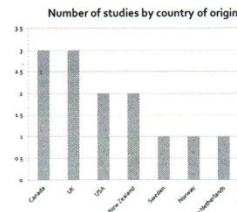
Descriptive numerical:



Numeric Descriptive Results



Results



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References

- Baker G. R., Norton P. G., Flintoft V., Blais, R., Brown, A., Cox, J., Etchells, E., Ghalib, W. A., Hébert, P., Majumdar, S. R., O'Brien, M., Palacios-Derflinger, L., Reid, R. J., Sheps, S. & Tamblyn, R. (2004). The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *Canadian Medical Association Journal*, 170, 1678-1686
- World Health Organization (2009). *Final Technical Report for the Conceptual Framework for the International Classification for Patient Safety v.11*. Geneva, Switzerland: Author. Retrieved from http://www.who.int/patientsafety/iax/2009/07/15/99_full_report.pdf
- Andrew Chang et al. "The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events." *International Journal for Quality in Health Care*, no. 2 (2005): 95-105
- Ernst E. The safety of massage therapy. *Rheumatology*. 2003;42:1101-6
- Posadzki P, Ernst E. The safety of massage therapy: an update of a systematic review. *Focus on Alternative and Complementary Therapies*. 2012;18(1):27-32
- Grant KE. Massage safety: injuries reported in Medline relating to the practice of therapeutic massage -1965-2003. *J Bodyw Mov Ther*. 2003;7(4):207-212
- Verhoef M, Page S. Physicians' perspectives on massage therapy. *Can Fam Physician*. 1998;44:2018-20.