An appraisal of adverse event reporting systems in chiropractic

A thesis presented in candidature for the degree of
Master of Research

By

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ABSTRACT

Heath care disciplines aim to deliver care that is free from harm. Adverse event reporting is a part of this effort. However, systems that record adverse events have developed differently across disciplines. Worldwide, chiropractic has been slow to develop adverse event reporting systems. There are currently no Australian-based chiropractic adverse event reporting systems.

The aims of this project are to describe the components of the current chiropractic adverse event reporting systems, to compare these systems to adverse event reporting systems in other health disciplines and to outline the design and testing of an Australian-based chiropractic adverse event reporting system.

Data collected by the chiropractic systems is similar in nature to data collected by other systems with a high rate of practitioner non-compliance across both types of systems. There is no data collected on the total number of chiropractic interventions being administered.

Designing a chiropractic adverse event reporting system that collects data on all interventions including those with and without adverse events would enable accurate assessments of the incidence of adverse events associated with chiropractic intervention. The design and method for testing of an Australian-based adverse event reporting system is described.

Candidate Statement

I certify that the work incorporated in this thesis has not been submitted for a higher degree to any other university or institution.

I certify that the work presented in this thesis is my own work except as acknowledged in the text.

Signed  Date 24 March 2017

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List of Abbreviations

AADRRS	Australian Adverse Drug Reaction Reporting System
ADRS	Australian Adverse Drug Reaction Reporting System
AECC	Anglo-European College of Chiropractic
AEFI	Adverse events following immunisation
AERS	Adverse event/s reporting system
ADL	Activities of daily living
AE	Adverse event
BCA	British Chiropractic Association
CAM	Complementary and alternative medicine
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control
CDER	Center for Drug Evaluation and Research
COCA	Chiropractic & Osteopathic College of Australasia
CPiRLS-UK	Chiropractic Patient Incident Reporting and Learning System
CRLS-UK	Chiropractic Reporting and Learning System
CRLS-Swiss	Chiropractic Reporting and Learning System
FAERS	FDA Adverse Event Reporting System
FDA	Food and Drug Administration
IRIS	Incident Reporting and Investigation Scheme
IOM	Institute of Medicine
MALT	Morbidity Audit and Logbook Tool
Manips	Manipulations
MCA	McTimoney Chiropractic Association
MIMPS	Minimal Information Model for Patient Safety
MIMS	Monthly Index of Medical Specialities
Mobs	Mobilisations
MT	Manual therapy
NA	Not asked
NHS	National Health Service UK
PIRLS	Patient Incident Reporting and Learning System

PSI	Patient safety incident
RACS	Royal Australasian College of Surgeons
RCA	Root cause analysis
SCA	Scottish Chiropractic Association
SMS	Short message service
SMT	Spinal manipulative therapy
TGA	Therapeutic Goods Administration
UCA	United Chiropractic Association
VAERS	Vaccine Adverse Event Reporting System
WHO	World Health Organization

1. Introduction

1.1 Preface

The absence of a chiropractic adverse event reporting system (AERS) has been cited as a shortcoming of the profession in Australia.(1) In March 2014, the Medical Journal of Australia published a letter that highlighted the lack of an AERS for chiropractic in Australia. The letter stated that in healthcare AERSs are crucial for maintaining quality and safety.(1) More than two years have passed since that letter was published and there is still no chiropractic AERS in Australia.

1.15 Overview of thesis

Starting point: Disparate areas of medicine criticise chiropractic for not developing an AERS in Australia as their area of medicine has done.

Aim: To compare what data point the existing AERS in chiropractic collect with the data points collected by a set of disparate mainstream healthcare AERS.

Method: Initially a scoping study will be conducted to find if there are AERS in chiropractic and what data points they collect. The chiropractic AERS will be compared to six AERS from a variety of healthcare disciplines. The six non-chiropractic AERS were chosen for their widespread use and representative of the disciplines that criticise chiropractic for not developing AERS.

1.2 Background

In 1999, the American Institute of Medicine (IOM) now known as the US National Academy of Medicine, released a report titled 'To Err is Human'. The report generated worldwide attention with the sensational finding that in the US between 44,000 and 98,000 deaths were occurring annually due to medical errors.(2) The report was seen as a call to action by the patient safety movement with a number of commentators referring to the report as the trigger of the modern patient safety movement.(3-15) Five years after its release the report has been credited with an increase in the number of patient safety publications and research awards related to safety.(6) Incident reporting systems are now included in many health services as understanding incidents is seen as an essential part of improving patient safety.(16-18) As an example, the incidence of central line bloodstream infections in

intensive care units fell by over 80% since the introduction of an adverse event reporting system.(8) Despite this type of success, other areas of healthcare have not progressed as quickly towards introducing an AERS.(8) Chiropractic is one example where the progress of implementing an AERS has been relatively slow.

Implementing an AERS is considered part of the normal development of a health profession, with AERSs in use in both hospital and non-hospital settings including surgery, pharmacology, nursing and dentistry. The situation is somewhat different in complementary and alternative medicine (CAM) where the only stand-alone AERS is in chiropractic, considered one of the largest alternative health care professions in the world.(19)

Chiropractic has three AERSs currently in use or under development: the Swiss Critical Reporting and Learning System (CRLS-Swiss) launched in late 2007; the Chiropractic Patient Incident Reporting and Learning System (CPiRLS-UK) launched in the UK in late 2007; and SafetyNET, a conglomeration of research projects designed to support the development of a patient safety culture for providers of spinal manipulative therapy (SMT) in North America. SafetyNET, which is still under development, arose out of the absence of high quality data relating to adverse events associated with SMT and is the creation of a large multi-disciplinary team of physiotherapists, chiropractors and medical specialists based in Alberta, Canada.

In 2011, access to CPiRLS-UK was extended to members of the Chiropractic & Osteopathic College of Australasia (COCA) giving Australian chiropractors their first exposure to an operational AERS. In 2013, the European Chiropractors' Union provided their members with access to CPiRLS-UK. The focus of the Swiss and UK systems was on identifying errors and potential errors and educating practitioners about the circumstances and characteristics of those errors, whereas SafetyNET is the first system to include an active surveillance reporting component.(20) An active surveillance system will record details at every patient encounter to document the intervention and the presence or absence of adverse events.(20) One benefit of including this component is that it has the potential to generate information about the incident rates of adverse events.

Before describing how our understanding of the risks associated with chiropractic intervention can be improved, a brief outline of the history of adverse event reporting in other healthcare systems will help to place chiropractic AERSs in context.

1.3 History of adverse event reporting in health care

The concept of reporting adverse events or 'incidents' was first described by Flanagan, a psychologist, in 1954. He referred to the "critical incident technique", a concept that was used during and after the Second World War by the United States Army & Air Forces in their 'Aviation Psychology Program'.(21) It involved the development of a procedure for making systematic analyses of the causes of good and poor performance. Flanagan asserted the procedure was very effective in obtaining information from individuals about their own errors.(22)

By the 1970s, incident reporting systems had been developed in dentistry, medicine and nursing. Critical incident reporting was first used in the field of anaesthesia in 1978 with the specific aim of improving patient safety.(23) This development represented a paradigm shift as it proactively pursued 'what could go wrong' rather than just investigating 'what did go wrong'. Some credit this approach as being the forerunner of current critical incident reporting systems in medicine.(24)

While this early work provided the foundation upon which modern incident reporting systems in medicine are based, reflection on performance by all healthcare practitioners is considered vital for advancing patient safety and healthcare quality. Non-medical industries continue to improve incident reporting systems and these improvements could be used to inform the development of AERSs in healthcare.(25)

For example, the success of the Aviation Safety Reporting System relies on three factors.(26) That:

- Reporting is safe (pilots are immune from disciplinary action if they report promptly)
- Reporting is simple (a one-page report is often sufficient)
- Reporting is worthwhile (experts analyse the confidential reports and disseminate recommendations to pilots and the Federal Aviation Administration) (26)

In 2015, a report titled '*Continuous Improvement of Patient Safety: The Case for Change in the NHS*' commissioned by the UK Health Foundation outlined the components of an effective safety system in healthcare.(10) It included the following elements:

- Measurement and monitoring
- Improvement and learning
- Engagement and culture
- Strategy and accountability

The US National Patient Safety Foundation's 2015 report titled '*Free from Harm: Accelerating Patient Safety Improvement Fifteen Years After - To Err Is Human*' (11) included the following recommendations about patient safety:

- Ensure that leaders establish and sustain a safety culture
- Create a centralised and coordinated approach to patient safety
- Create a common set of safety metrics that reflect meaningful outcomes
- Prioritise funding for research in patient safety and implementation science
- Address safety across the entire care continuum
- Support the health care workforce
- Partner with patients and families for the safest care
- Ensure that technology is safe and optimised to improve patient safety

The configuration of AERSs within healthcare has continued to reflect elements from outside health and resulted in increasing government support for their development.

1.4 Improving our understanding of the risks associated with chiropractic intervention

Informed consent procedures in healthcare require practitioners to warn patients of the material risks associated with a proposed intervention or treatment. For an assessment of risk to be accurate, it requires data that is up to date as both practitioners and patients make decisions about care based on these assessments.

Currently the main sources of evidence used to assess the risk of an adverse event associated with spinal manipulative therapy (SMT) are insurance claims data and case reports published in the scientific literature. There is a problem relying on data from randomised controlled trials that include SMT as a large percentage of them fail to report adverse events despite reporting being included in clinical guidelines.(27,28) Under-

reporting of harm data in clinical trials is not limited to trials that involve SMT.(29,30) Likewise, not all chiropractic adverse events that occur in clinical practice result in an insurance claim. As the current systems do not include mandatory reporting, some incidents remain unreported and therefore, current estimates of risk are based on incomplete data. A similar situation exists in other disciplines such as orthopaedic physical therapy which is considered safe based primarily on a lack of reported harms.(31)

In order to produce reliable adverse events data, estimates should be based on reporting systems that include compulsory reporting of all clinical interactions.

The aim of this thesis is twofold:
To describe the components of the current chiropractic adverse event reporting systems.
To compare these systems to the adverse event reporting systems in other health disciplines.

The initial report on the characteristics of the three AERSs designed for use by chiropractors will include an analysis of their components and whether they meet the minimum requirements identified for a reliable AERS.

The minimal requirements identified for a reliable AERS were drawn from two sources. The first set of criteria was formulated as a result of the CRLS-UK trial.(12) The second is from the 2015 Guideline from the World Health Organisation, The Minimal Information Model for Patient Safety (MIMPS).(10)

1.5 Barriers to using AERSs

As background to reporting results from a literature review on chiropractic AERSs, a brief description of the barriers that have been identified as influencing the uptake of an AERS in other health disciplines will familiarise the reader with some of the issues facing chiropractic AERSs.

Within the setting of metropolitan public hospitals, a number of barriers have been identified as influencing the uptake of an AERS.(13)(32) These include:

- Time restraints

- Unsatisfactory processes
- Deficiencies in knowledge
- Cultural norms
- Inadequate feedback
- Beliefs about risk
- Perceived lack of value in the process

Other industries such as defence and manufacturing use root cause analysis (RCA) to identify faults and problems. This method of problem solving identifies the root causes of faults or problems and has been adopted in healthcare as a way of investigating errors and adverse events.(33-35) An Australian example of the barriers encountered in using RCA to investigate errors and adverse events was the NSW Safety Improvement Program where the most frequent difficulty reported by health professionals in relation to using AERSs was lack of time, followed by insufficient resources, difficulties with colleagues and poor feedback.(36) Respondents criticised the approach's inability to solve complex interpersonal interaction problems which were identified as a source of many errors in medicine.(36) Furthermore recommendations arising from safety programs were often not promptly and usefully communicated.(32, 36)

Medico-legal barriers

Another barrier to the uptake of an AERS are the medico-legal aspects to reporting. One of the main challenges facing the advocates of robust incident reporting systems in medicine is the "Two cultures problem".(37) The term refers to the deep division between the medical malpractice and patient safety movements. The legal culture around medical malpractice involves a punitive, individualistic, adversarial approach that is at odds with the non-punitive, systems-oriented, cooperative strategies adopted by leaders of the patient safety movement. This clash of cultures acts as an impediment to the introduction of an AERS and obstructs improvements in the quality of healthcare.(37)

This chapter has covered the background, history, minimum requirements and barriers associated with AERSs in non-chiropractic disciplines. The following chapter will outline the three chiropractic AERSs.

2. Scoping study

2.1 Aim and Rationale

The aim of this scoping study is to identify existing adverse event reporting systems in chiropractic and describe their characteristic features. The study will also identify some of the barriers to the reporting of incidents by chiropractors.

The rationale for this scoping study lies in the importance of understanding the type and characteristics of chiropractic adverse event reporting systems and whether these systems have achieved their aims.

2.2 Methods for the scoping study

A literature search for articles on adverse event reporting systems in chiropractic that have been published in the scientific literature up until September 2016.

The following keywords were searched:
Adverse event OR adverse effect OR incident OR patient safety. This list was combined with AND reporting AND chiropractic.
Citation lists of relevant articles were also reviewed.

Information sources
Literature searches of all articles published up to September 2016 were conducted using PUBMED, Scopus and Ovid MEDLINE.

Inclusion criteria
The search was confined to articles published in English or with an English translation included. Papers that discussed the need for, the development of and the implementation of adverse event reporting systems in chiropractic were included for review.

Exclusion criteria
Articles that discussed adverse events in chiropractic but did not comment on reporting or reporting systems were excluded from this review. Articles not in English or without an English translation were also excluded.

Screening methods

Titles and abstracts were reviewed. Relevant articles from the citation lists of the discovered articles did not reveal any articles that had not been found in the original searches. Full-text articles were obtained for all articles that met the eligibility criteria.

Quality appraisal strategy

A single investigator (CB) reviewed the full-text articles. Descriptions of the characteristic features of an AERS were compared with the features of the existing chiropractic systems. These comparisons will provide a basis for the appraisal of the quality of the three AERSs. Many of the articles included a description of the processes associated with implementing an AERS.

2.3 Results of the scoping study

Study selection

Following a keyword search of the databases, 68 articles were identified. After eliminating duplicates and applying the inclusion/exclusion criteria, 25 articles remained.

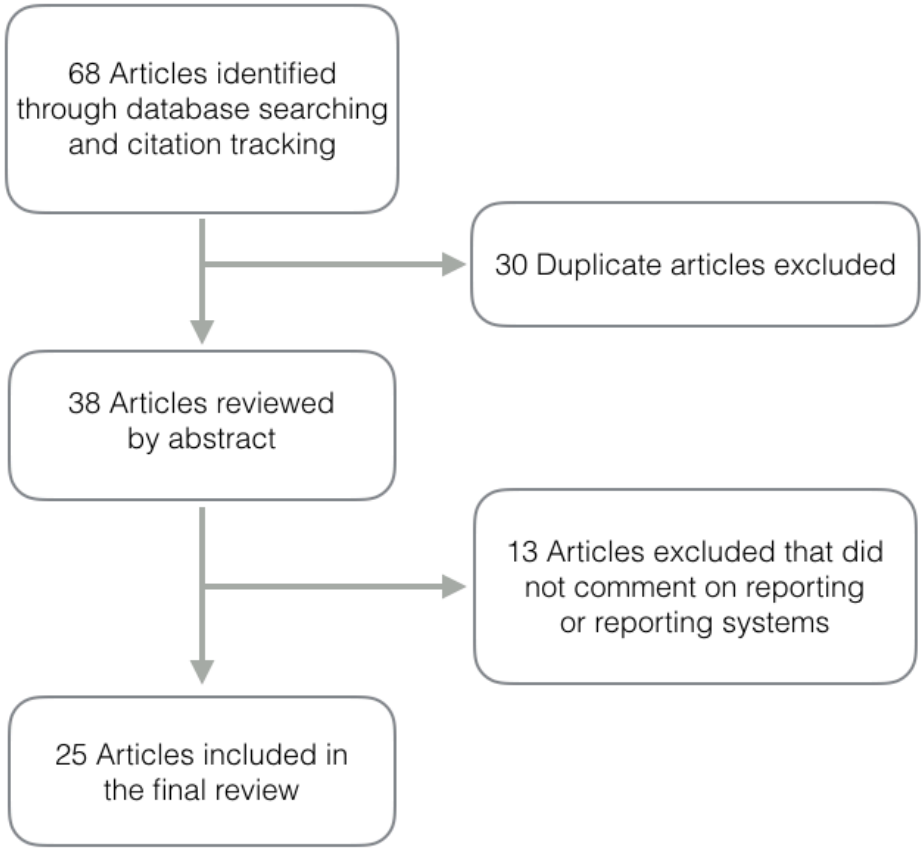

Figure 1 Article selection flow diagram

Three AERSs currently in use or being developed for chiropractors were identified by the study. They were: CPiRLS-UK, CRLS-Swiss and SafetyNET (Canada). Table 1 describes the information that each system collects. CRLS-UK 2005 was the pilot program for the current CPiRLS-UK system and has been included in the table for completeness and to illustrate the evolution of the systems.

The challenge facing the description of the data is that all three systems allow the user to provide a descriptive passage as part of the reporting process. This includes whatever information the reporter deems relevant. For the purposes of comparing the three systems this review focused on the questions that were formally asked *i.e.* what information did each AERS specifically ask.

Table 1. Information collected by chiropractic adverse event reporting systems

	CRLS-UK Inactive	CPiRLS-UK Active	CRLS-Swiss Active	SafetyNET-Canada Under development
When is report made?	Triggered by AE	Triggered by AE or near miss	Triggered by AE	Each consultation
Gender?	Yes	Yes	Yes	Yes
Date of birth / age?	Yes	Yes	Yes	Yes
Date of Report?	Yes	No	No	No
Date of Incident?	Yes	No	Yes	Yes
Presenting condition/s?	No	No	No	Yes
Previous MT (< 1week)?	No	No	No	Yes
Duration of treatment?	No	No	No	Yes
Number of manipulations/region?	No	No	No	Yes
Number of mobilizations/region?	No	No	No	Yes
Mechanical device used?	No	No	No	Yes
Other MT?	No	No	No	Yes
Other non-MT?	No	No	No	Yes
Was there an AE?	Not asked - AE triggers the use of this AE reporting system	Not asked - AE triggers the use of this AE reporting system	Not asked - AE triggers the use of this AE reporting system	Yes, asked, because SafetyNET is not only a AERS but an active surveillance system
How long after MT did AE occur?	No	No	No	Yes
Where did the Incident happen?	Yes	Yes	Yes	No
Details of what happened?	Yes	Yes	Yes	Yes

Why did it happen?	Yes	Yes	Yes	Yes
How did it happen?	Yes	Yes	Yes	Yes
Possible immediate cause?	Yes	Yes	Yes	Yes
Possible underlying cause?	Yes	Yes	No	Yes
Action immediately after AE?	Yes	Yes	Yes	Yes
Action taken in the longer term?	Yes	Yes	Yes	Yes
Was the patient harmed?	No	Yes	No	No
Grade of harm?				
Low/Mild	Yes	No	No	Yes
Moderate	Yes	No	No	Yes
Serious	No	No	No	Yes
Death	Yes	No	No	Yes
Near miss	Yes	Yes	No	No
Potential Incident	No	Yes	No	No
Describe residual effect?	No	No	No	Yes
Treatment required?	No	No	No	Yes
Has the AE resolved?	No	No	No	Yes
Assessment of relationship b/t suspected cause and incident?	Yes	Yes	Yes	No
History of medication?	No	No	No	Yes
Concurrent treatment?	No	No	No	No
Family history?	No	No	No	No
Current health status?	No	No		Yes
Past health status?	No	Yes	No	No
Keywords to describe incident?	No	Yes	No	Yes
Could incident be avoided?	No	Yes	No	No
Frequency of encountering this type of incident?	No	No	No	Yes
Reason for patient visit?	No	No	No	Yes
Diagnosis for treatment?	No	No	No	Yes
Has this patient experienced previous AE to manual therapy?	No	No	No	Yes
Comorbidities?	No	No	No	Yes
ADLs affected?	No	No	No	Yes
Self-care affected?	No	No	No	Yes
Was patient hospitalised?	No	No	No	Yes
Has the event caused you to make changes to your practice?	No	No	No	Yes
Patient PRE consult form?	No	No	No	Yes
Patient POST consult form?	No	No	No	Yes

CRLS: Critical Reporting and Learning System; CPiRLS: Chiropractic Patient Incident Reporting and Learning System; AE: Adverse Event; MT: Manual Therapy; ADL: Activities of Daily Living.

2.4 Discussion of scoping study

2.4.1 Development of an adverse event reporting system in chiropractic

This scoping study uncovered four AERSs used or planned for use by chiropractors. They were:

i. CRLS-UK
ii. CPiRLS-UK
iii. CRLS-Swiss
iv. SafetyNET-Canada

i. CRLS-UK

In 2006, Thiel and Bolton reported the first AERS for chiropractic.(38) The motivation for creating this system was in response to a call for improved patient safety across all aspects of healthcare. Development of this system was guided by the UK National Patient Safety Agency's 2004 document titled 'Seven Steps to Patient Safety' and distributed by the British Chiropractic Association (BCA). The developers were chiropractic academics who were in a position to introduce the system to final year clinical students at the Anglo-European College of Chiropractic (AECC).(38) In August 2005, 1100 members of the BCA and 63 final year students enrolled in the program at AECC were given access to the new system. Utilisation rates by the UK chiropractors were disappointing with only eight reports from seven chiropractors collected during the first four months of data collection.(38) The researchers commented that such a low number of reported incidents did not allow for any meaningful statistical analysis of the data.(38) The system had a better take-up among the AECC students where 225 individual patient safety incidents (PSIs) were reported following 19,108 patient contacts, a rate of 1.2%. Of the PSIs reported by the students, 64% were incidents where the student felt no harm had occurred to the patient. The most common PSI reported was associated with 'misuse of therapeutic equipment' (32%) followed by 'treatment intervention' (31%).(38) As part of reporting, students also graded the harm to the patient as 'near miss', 'low', 'moderate', 'severe', or 'death'.(38)

The CRLS-UK has been discontinued.

ii. CPiRLS-UK

Following the development of CRLS-UK, a second system known as the Patient Incident Reporting and Learning System (PIRLS) was developed by the McTimoney College of Chiropractic and launched by the McTimoney Chiropractic Association in 2007.(39) This

system extended incident reporting in the UK to a further 600 chiropractors. In an attempt to improve the ease and accessibility of incident reporting as well as enhance the learning elements incorporated in this new system, The College of Chiropractors (now The Royal College of Chiropractors), the three UK educational institutions *i.e.* the AECC, the University of South Wales - Welsh Institute of Chiropractic, and the McTimoney College of Chiropractic agreed to collaborate with the four UK professional associations, the BCA, the United Chiropractic Association (UCA), the Scottish Chiropractic Association (SCA) and the McTimoney Chiropractic Association (MCA) in a joint venture to develop a common online reporting system named the 'Chiropractic Patient Incident Reporting and Learning System' (CPiRLS-UK).(39) The evolution of this system is outlined in Figure 2.

The CPiRLS-UK is still in use today.

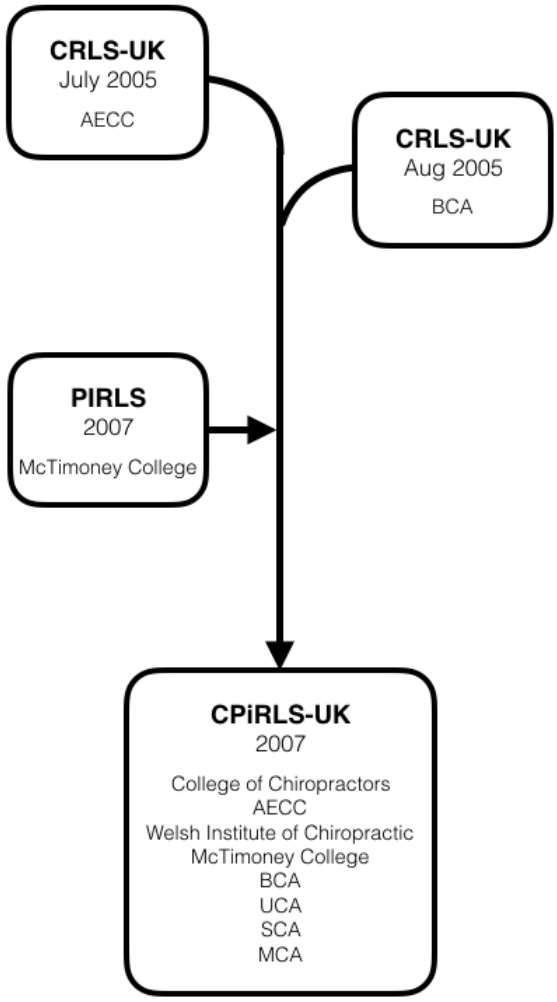

Figure 2 Evolution of CPiRLS-UK

CRLS: Critical Reporting and Learning System; PIRLS: Patient Incident Reporting and Learning System; CPiRLS: Chiropractic Patient Incident Reporting and Learning System; AECC: Anglo-European College of Chiropractic; BCA: British Chiropractic Association; UCA: United Chiropractic Association; SCA: Scottish Chiropractic Association; MCA: McTimoney Chiropractic Association.

iii. CRLS-Swiss

The first AERS for chiropractors in Switzerland, launched by Wangler and Zaugg in September 2007, was an attempt to promote a patient safety culture among Swiss chiropractors.(40) The project was initially introduced at the 2007 Swiss National Continuing Education Convention as a way to assess the competency of Swiss chiropractors in relation to patient safety issues. The researchers used four instructional approaches: written documentation, lectures including a short movie, large and small group discussions on patient safety and safety culture, and feedback by experts. The results showed that the biggest challenge facing the introduction of an AERS for Swiss chiropractors was in shifting the culture from blame to trust. Other challenges included that reporting and learning must be judged as important by practitioners and that safety and quality needed to be integrated into training on a regular basis.(39, 41)

CRLS-Swiss initially differed from the CPiRLS-UK in that it directed the chiropractor to describe an adverse event or incident on first reflection without categorisation. This meant that the user simply reported what went wrong and described any initial action taken. The system relied upon regular, timely and effective feedback by experts regarding the reported action.(39) Since its inception, CRLS-Swiss has been modified and now includes incident categories. It is still in use today

iv. SafetyNET-Canada

SafetyNET is an interdisciplinary group of North American researchers interested in studying the safety of spinal manipulative therapy (SMT). Their goal is to develop and support a culture of safety for regulated healthcare practitioners who administer SMT.(20) The SafetyNET group has four teams: qualitative, legal, clinical and basic science.

The first project lead by the qualitative team, explored the existing safety culture around SMT. The project identified the goals and potential barriers associated with patient safety reporting. The second project lead by the legal team, looked at barriers created by the threat of litigation. The third project lead by the clinical team, was concerned with the initiation of active surveillance identification and reporting of potential harms by both providers and patients. The fourth project lead by the basic science team, is investigating the mechanisms of action of SMT that relate to harms.(20) SafetyNET which is still under development, will include a learning component designed to promote a culture of patient safety amongst

providers of SMT. However, this component is yet to be reported on in detail. There are clear challenges with developing the SafetyNET project into a AERS to be used by chiropractors more broadly. In particular the legal team working with the active surveillance team is concerned with identifying potential legal risks to participation in regards to confidentiality of the data collected. They note that this is a novel area that has only recently been tested in the courts in Canada. If other countries seek to adopt the SafetyNET system as a AERS then the unique legal implications of local legal systems will need to be considered. The clear danger is that SafetyNET proposes to gather such detailed information about a clinical encounter that the information could be used against a practitioner in litigation. If this is seen as a danger of the system it is unlikely that there will be good compliance with using the system.

2.4.2 Definitions of adverse events

SafetyNET has identified a major methodological flaw in the design of the existing chiropractic AERS in that they use unclear definitions when reporting adverse events associated with manual therapy.(42) In approaching this issue, SafetyNET's first step was to define the terms that were to be used in the new system. The factors necessary for a meaningful assessment and description of an adverse event are:

(i) Seriousness
(ii) Causality
(iii) Preventability
(iv) Patient disposition

These factors were adapted or modified from a number of sources: 'Seriousness' from the National Cancer Institute; 'Causality' from the definition used by the World Health Organization; 'Preventability' was adopted from Baker and Norton (43); and 'Patient disposition' was taken from the National Institute of Arthritis and Musculoskeletal and Skin Diseases.(42) The problem of unclear definitions is not unique to manual therapy. Researchers in the field of surgery who monitor surgical outcomes remark that harmonisation of definitions and severity classifications would enhance quality-improvement programs.(44)

Under SafetyNET, a grading system is being adopted for each factor.(20, 42) For Seriousness, the levels are:

- *Mild*: Asymptomatic or mild symptoms, self-care only (e.g. ice/heat, over-the-counter analgesic);
- *Moderate*: Limiting age-appropriate activities of daily living (e.g. work, school) OR sought care from a medical doctor;
- *Severe*: Medically significant but not immediately life-threatening; temporarily limits self-care (e.g. bathing, dressing, eating) OR urgent or emergency room assessment sought; and
- *Serious*: Results in death OR a life-threatening adverse event OR an adverse event resulting in inpatient hospitalisation or prolongation of existing hospitalisation for more than 24 hours. It resulted in a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.

For Causality, the levels are:

- *Certain*: A clinical event occurring in a plausible time relationship to treatment, which cannot be explained by concurrent disease or other drugs or therapies;
- *Probable/likely*: A clinical event with a reasonable time sequence to treatment, unlikely to be attributed to concurrent disease or other drugs or therapies;
- *Possible*: A clinical event with a reasonable time sequence to treatment, but which could also be explained by concurrent disease or other drugs or therapies; and
- *Unlikely*: A clinical event with a temporal relationship to treatment which makes a causal relationship improbable and in which drugs, other therapies or an underlying disease provide plausible explanations.

For Preventability, the levels are:

- Virtually no evidence of preventability;
- Slight to modest evidence of preventability;
- Preventability not quite likely (< 50/50, but ‘close call’);
- Preventability more than likely (> 50/50, but ‘close call’);
- Strong evidence of preventability; or
- Virtually certain evidence of preventability.

For Patient disposition, the levels are:

- Resolved, no sequelae;

- Adverse event still present - no treatment;
- Adverse event still present - being treated;
- Residual effects present - no treatment;
- Residual effects present - treated;
- Death; or
- Unknown.

In manual therapy, one of the problems associated with using standardised definitions for adverse events is that they do not include the patient's perspective.(45, 46)

2.4.3 Aspects of AERS design

Key domains, items, and sub-items.

Table 1 describes the key components of each of the four AERs analysed. It highlights that SafetyNET is more proscriptive compared to the other three systems as it asks direct questions about the incident being reported. In order to assess the relationship between exposure and outcome, SafetyNET has developed separate patient and provider instruments that include the following domains:

(i) Details of the intervention, including anatomical location and dose;
(ii) Details of any adverse event reported, including time of occurrence, seriousness and patient disposition; and
(iii) Potential confounders, including a patient's underlying health concerns plus any other therapies used.

Active and passive systems

Systems designed to gather data on adverse events can be regarded as active or passive. Active systems are set up to gather data such as reviewing hospital discharge documents or post-marketing drug or device surveillance. They allow for early identification and assessment of adverse events. It is considered better to review events at or near the time of occurrence so that any subsequent intervention can be preventative with respect to future harm.(47) Passive systems are designed for provider reporting only and rely on a practitioner recognising the adverse event and reporting it. The majority of AERSs operate as passive systems.

Patient reporting

While the majority of passive reporting systems are designed for provider reporting only, SafetyNET also includes the capacity for patients to report adverse events.(42) Gathering data directly from patients is particularly important given that health care providers have demonstrated poor reporting of adverse events in the past.(42) Patients are an under-utilised source of information about adverse events.(48) SafetyNET acknowledges that in an ideal scenario a report of an adverse event from a patient should come directly to a third party such as a researcher, as patients may be reluctant to report adverse events directly to the provider of the intervention.(42)

Under-reporting

A criticism of passive reporting systems such as CPiRLS-UK and CRLS-Swiss is that they are prone to under-reporting.(42) The past 9 years of operation has produced 160 Adverse event/incident reports on the CPiRLS website. In contrast, the Therapeutic Goods Administration (TGA) in Australia receives more than 16,500 reports per year. Without an indication of where these reports come from both figures are meaningless. However, they are very different in scale. One solution may be to develop active surveillance systems in chiropractic which would improve both the quality and quantity of adverse event reporting and provide data that can be evaluated in a meaningful way.(42)

The power of the SafetyNET system compared to CPiRLS-UK and CRLS-Swiss is that it prospectively collects manual therapy exposure data on all patients, whether or not an adverse event occurred.(42) This allows for comparison on a case-control basis. It does not collect information on near misses or potential incidents. The aims of SafetyNET are to identify, mitigate, and reduce adverse events associated with manual therapy intervention.(20) Its focus is on what actually happened and does not allow speculation on what almost or potentially could have happened. SafetyNET is the first chiropractic AERS that has the capacity to accurately assess the rate of adverse events. The system will provide useful information for both the profession and healthcare regulators as it will capture data on when an adverse event occurred.

Different focus to previous systems

A consequence of the design of SafetyNET is that it does not include some of the more idealistic characteristics of previous AERSs that followed the paradigm shift introduced by Cooper in proactively pursuing what 'could' go wrong.(23) The older chiropractic AERSs did

not attempt to capture incident rate data as they relied on practitioners 'opting in' to generate a report. The older systems encouraged reports on adverse events that almost or could have potentially happened, referring to such incidents as 'near-misses' and 'potential incidents'. As has been suggested above, the data reflects the intention of the system's designers. These older systems gathered information on 'potential incidents' but made no attempt to compare the number of incidents against the number of clinical encounters, illustrating they were designed more as educational or learning systems rather than measuring systems. Their focus was on identifying risks and facilitating a conversation within the profession about these risks and how they could be reduced.

Legal issues

The creators of SafetyNET were aware of the ‘two cultures problem’ (37) when designing their system. This relates to the opposing objectives of the medical malpractice and patient safety movements. SafetyNET attempted to address this issue with a dedicated legal team of researchers. One of the stated aims of this team was to explore how existing litigation might affect the patient safety research environment. An obvious concern for an AERS is that if the information is recorded it creates the potential for the same information to be subpoenaed by a plaintiff’s lawyers in pursuit of an action in negligence. If such a situation continued, uptake of the system would be affected as practitioners would no longer consider the system ‘safe’ for their use.

Barriers

Members of the SafetyNET team recently conducted a survey of 81 paediatric chiropractors about the barriers to implementing a reporting and learning system for paediatric consultations.(49) They noted that the biggest barriers to participating in an AERS was time pressure and patient related concerns. Interestingly a large proportion of this group reported that ‘fear of blame’ was not a major barrier to reporting (68%).(49) The researchers noted that these findings contradicted previous reports that ‘fear of blame’ was a major barrier to reporting adverse events. In their study, the researchers acknowledged that their results may have included non-response bias and that those that responded already held a positive view about participating in a reporting and learning system.(49)

2.5 Conclusion of scoping study

The development of an AERS in chiropractic shows an evolutionary trend towards a more robust system. Where CPiRLS-UK and CRLS-Swiss have an emphasis on 'learning', SafetyNET is designed as a reporting, learning and measuring system capable of providing detailed, useful information on adverse events. It also has the potential to produce incidence rates of adverse events associated with chiropractic intervention. This information is important to the chiropractic profession as it has the potential to inform and improve practice.

Future

SafetyNET is yet to report results from the field. The number of practices that the team can successfully recruit to the project and the volume of data will determine the impact of the system. There is scope to run similar programs in other jurisdictions. As the country with the third largest number of chiropractors after the United States and Canada, it is appropriate to consider developing and implementing an AERS in Australia. Factors which are difficult to quantify but often critical to the uptake of a new AERS are the current political climate in healthcare and any unrest within the profession locally, both of which have been known to influence uptake.

3. Non-chiropractic adverse event reporting systems

Improving patient safety is a principal goal of healthcare policy and practice with adverse event reporting part of this goal.(9) A variety of methods have been used to report adverse events across different disciplines. Examples include systems that are paper-based, electronic, online, open, closed, voluntary, mandatory, provider driven, manufacturer initiated and patient based. These methods reflect the different priorities of each discipline. While the overarching goal is patient safety, systems are designed to view adverse event reporting from different perspectives. Injury prevention, practitioner discipline, influencing practitioner behaviour and opportunities to learn and improve practice are all examples of these different perspectives.

Local factors may also play a role in determining the design of an AERS. Government and/or legislative requirements can influence design by mandating specific requirements that have to be met or included in an AERS. As a developed nation with a high penetration of information and communication technology, Australia is capable of gathering, recording and disseminating high quality health data which supports research and 'continuous learning'.(50)

This chapter examines these factors and how they have impacted the design of existing Australian AERSs. The following systems were examined as they represent well established and well utilised AERS across a range of healthcare areas. This thesis acknowledges that the following systems are not disciplines similar to chiropractic.

3.1 Australia - Therapeutic Goods Administration

In Australia, the Therapeutic Goods Administration (TGA) is part of the Federal Government's Department of Health.(51) The TGA receives reports with regard to adverse events involving medicines, vaccines or medical devices.(51, 52)

The TGA can incorporate adverse event reports from anyone. Each year the TGA receives more than 16,500 reports of suspected adverse events to medicines and vaccines and more than 4,000 reports of suspected adverse events involving medical devices.(52) Most adverse event reports are made by pharmaceutical companies and medical device

suppliers. Other reporters include state and territory health departments, hospitals, health professionals and consumers.(52)

There are a number of ways that reports can be made to the TGA. To report a side effect of a medicine or a vaccine, consumers are encouraged to submit the report online. Health professionals can submit a report to a range of authorities depending on the nature of the event. These include the Australian Adverse Drug Reaction Reporting System (ADRS), Monthly Index of Medical Specialities (MIMS) Online or the National Adverse Events Following Immunisation (AEFI) reporting system.(52,53) Medical device users are encouraged to report problems and incidents online using the 'Medical Device Incident Report' form.(52,53) Sponsors and manufacturers are directed to report events directly to the TGA using their online reporting system.(52-54)

The type of information that can be reported to the TGA ranges from basic contact information to detailed symptoms. Reporters are encouraged to provide as much detail as possible, but at bare minimum are asked to provide the following:

- contact details of the reporter (name, address, phone number)
- patient identifier (such as initials, date of birth or age, but not their full name)
- details of the product involved
- details of the suspected adverse event

Reports of an adverse event related to medicines and/or vaccines are entered into the 'Australian Adverse Drug Reaction Reporting System' (ADRS) usually within two working days of submission. A unique ID is generated for each event and a letter of acknowledgment sent to the reporter. Reports of an adverse event related to a medical device are recorded in the 'Incident Reporting and Investigation Scheme' (IRIS).(52) Information recorded in IRIS includes the adverse event, the therapeutic good involved, and any other relevant information such as medical history, laboratory results and how the adverse event was managed.(52)

All adverse events are assessed for risk with the information used by the TGA to identify safety signals. When the TGA identifies a signal, it undertakes a detailed evaluation to establish the possible role of the therapeutic good in causing the adverse event.(52)

Three months after a report has been entered into the ADRS or IRIS database, the information is transferred to a publicly accessible and searchable 'Database of Adverse Event Notifications'. The three month time lag enables the TGA to check and analyse the information from the original report.(52)

If the TGA identifies a safety concern relating to a therapeutic good, it can take regulatory action to ensure that the product continues to have an acceptable level of safety, efficacy/performance and quality. The TGA also seeks to ensure that health professionals and the public are aware of any safety concerns and any changes to the availability and recommended use of the product.(52)

Actions that the TGA can take in response to a safety concern include:

- informing health professional and consumers through alerts and articles in publications such as 'Medicines Safety Update' and 'Medical Devices Safety Update';
- requiring changes to product labelling, or adding warnings, precautions and adverse event information to the 'Product Information' and 'Consumer Medicine Information';
- cancelling the registration of the product, or limiting the population in which it can be used; and/or
- requiring the sponsor to undertake post-marketing studies to investigate the safety concern if more information is needed before a judgement can be made about the need for further action.

As the TGA administers a system for consumer level reporting it was deemed appropriate to include in this comparison as this type of reporting is an increasing trend in AERSs.

3.2 Australia - Royal Australasian College of Surgeons

The Australian College of Surgeons has promoted the establishment of a culture of peer review amongst surgeons.(55) In Australia surgeons are accustomed to discussing complications and errors from surgery on a regular basis at morbidity and mortality conferences. This includes use of morbidity audits and logbooks.

The Morbidity Audit and Logbook Tool (MALT) collects data on clinical activities and outcomes, analyses the data using performance indicators and outcome parameters, allows peer review to identify improvements and produces feedback to participants to facilitate self-reflection.(56, 57) All surgeons who work in Australian hospitals must participate in a peer-reviewed surgical audit annually as part of their continuing professional development obligations.(58) The Royal Australasian College of Surgeons facilitates self-auditing of surgical outcome data with MALT and has been doing so for over 15 years.(56, 58)
As MALT is a specialty driven AERS with unique demands of the specialy it was deemed appropriate to include in this comparison as it may offer guidance in the development of a AERS for chiropractors.

3.3 U.S. - Department of Health and Human Services

The U.S. Food and Drug Administration (FDA), a division of the U.S. Department of Health and Human Services, developed the FDA Adverse Event Reporting System - FAERS (59)
This database was designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products. The FAERS adheres to the international safety reporting guidelines issued by the International Conference on Harmonisation.(59)
Practitioners and patients voluntarily report adverse events to FAERS and/or the manufacturers. Manufacturers who receive a report are required by law to send the report to the FDA. All reports received by the FDA are entered into FAERS.(59)

The reports in FAERS are assessed by clinical reviewers in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). If a safety concern is identified, further evaluation is performed using other databases. The FDA can take regulatory action such as updating labelling, restricting the use of a drug, communicating new safety information to the public or removing a product from market.(59)

A limitation of this system is the uncertainty surrounding the cause of the adverse event being reported. The FDA system does not require that a causal relationship be proven between the product and the event. Reports may not have enough detail to adequately evaluate an event nor can the cumulative data be used to calculate incidence rates.(59)

The FDA and the U.S. Centers for Disease Control and Prevention (CDC) maintains a national vaccine safety surveillance program called the Vaccine Adverse Event Reporting

System (VAERS).(60) The VAERS serves as an early warning system that detects possible safety issues with U.S. vaccines by collecting information about adverse events (possible side effects or health problems) that occur following vaccination. Systems such as the VAERS are crucial to ensure that vaccines are safe and maintain the trust of the public.(61-64) The VAERS was created in 1990 in response to the US National Childhood Vaccine Injury Act. If any health problem happens after vaccination, doctors, nurses, vaccine manufacturers, and/or any member of the general public can submit a report to the VAERS.(60)

Six AERSs currently in use in mainstream healthcare were selected for more in depth review in this thesis. They were: the TGA's 'Report a side effect of a medicine' for consumers, the TGA's Users Medical Device Incident Report, the Australian Adverse Drug Reaction Reporting System, the Royal Australian College of Surgeons Morbidity Audit and Logbook Tool, the FDA's Adverse Event Reporting System and the Vaccine Adverse Event Reporting System. Table 2 describes the information that each system collects.

Table 2. Mainstream healthcare adverse event reporting systems

	TGA - Side effect med Consumer	**TGA - AADRRS Practitioner**	**TGA - Medical device**	**RACS - MALT**	**FDA - FAERS US Consumer**	**FDA - VAERS US**
Reporter	Open - Patient or associate	Health professional or public	Open - Patient or associate	Attending Surgeon	Open - Patient or associate	Open - Vaccine provider, Patient/Parent. Manufacturer or Other
Report is made:	When a person feels that they have suffered a side effect	When a health professional in aware of an adverse drug reaction	When a person feels that they have suffered adverse event involving a medical device	Post surgery	AE associated with marketed drug and biological products, (Not vaccines)	After an apparent adverse event following vaccination
ID & Contact						
Reporter's first name	Required	Required	Required	Self managed logbook	Required	Required
Reporter's family name	Required	Required	Required	Self managed logbook	Required	Required
Reporter's email address	Required ('No email address' is an option)	Optional	Optional	Self managed logbook	Required	Optional
Reporter's postal address	Required	Required	Required	Self managed logbook	Required	Required
Reporter's phone number	Required	Optional	Required	Self managed logbook	Required	Required
Reporter's position/occupation	Not asked	Required	Optional	Self managed logbook	Not asked	Not asked
Consent to providing name and position to manufacturers?	Not asked	Not asked	Yes / No An answer is required	Not asked	Yes / No	Not asked
Patient details						
Who had the side effect/adverse event?	Options are 'Me' or 'Someone else'	ID or initials	Asked to NOT give patient name	Full name and DOB	Required	Full name and DOB and address
Initials of the person who had side effect	Required			N/A	Optional	N/A
Sex of the person who had the side effect	Yes	Gender - required	Optional	Gender	Optional	Yes
Date of birth or age	Yes	Required	Optional	Yes	Optional	Yes
Weight	Yes	Optional	Optional	No	Optional	Birth weight for child <5
Ethnicity	Not asked	Optional	Not asked	Optional	Optional	Not asked
Which State were you in when the side effect started?	Options of Australian States			Hospital recorded	Optional	US County where administered
Medicines						
What was the medicine?	Required	Required	N/A	Type of Anaesthetic	Required	Required
AUST L or AUST R number	Yes	Optional	N/A	N/A	N/A (USA)	N/A (USA)
Batch number	Yes	Optional	N/A	N/A	Optional (not asked)	Required
Strength	Yes	Optional	N/A	N/A	Optional (not asked)	N/A
Number of doses		Optional	N/A	N/A	Optional (not asked)	N° of previous doses
Type of dose		Optional	N/A	N/A	Optional (not asked)	Route/Site
Frequency of dose		Optional	N/A	N/A	Optional (not asked)	N/A

OR Please describe	Description		N/A	N/A	Optional (not asked)	
When did the medicine use start?	Date	Optional	N/A	N/A	Optional (not asked)	List all vaccines given on date of vaccination on form Also asks for any other vaccinations within the 4 weeks prior
Still taking the medicine?	Yes/No		N/A	N/A	Optional (not asked)	N/A
Reason for use of medicine?	Description	Optional - description	N/A	N/A	Optional (not asked)	Vaccination
Were you taking anything else when the side effect happened?	Yes/No If Yes -> Description		N/A	N/A	Optional (not asked)	Other medications?
About the adverse event						
What was the side effect?	Required - Description	Required - Description		N/A	Required - Description	Required - Description
When did the side AE start?	Date			N/A	Optional (not asked)	AE onset date
How serious was the side effect/adverse event? Severity?	Not serious Mild or slightly uncomfortable Uncomfortable Short term effect bad enough to affect everyday activities Caused significant or long term incapacity			N/A	Optional (not asked)	Patient died Life threatening illness Required emergency room/doctor visit Required hospitalisation Resulted in prolongation of hospitalisation Resulted in permanent disability None of the above
Did the AE require attention from a health professional or admission to hospital?	Advice (option) Admission (option)			N/A	Optional (not asked)	Asked
Did you, or anyone else, change what you were taking as a result of the AE?	Yes/No If Yes -> Description			N/A	Optional (not asked)	N/A
How was the AE treated?	Description			N/A	Optional (not asked)	Description
What was the outcome of the side effect/adverse event?	Recovered Recovered with some lasting effects Getting better Side effect continuing Unknown			N/A	Optional (not asked)	Patient recovered? Yes / No / Unknown
More details						
Please tell us about any medical history which could be relevant to this report:	Description				Optional (not asked)	Description Asks - illness at time of vaccination, pre-existing

						physician diagnosed allergies, birth defects, medical conditions
Is there anything else you would like to tell us that you think might be important?	Description				Optional (not asked)	Description Asks - AE following vaccination history in patient and siblings
Surgery details						
Surgical timeframe	N/A	N/A	Optional	Start & End time of surgery. Time hrs/mins	Optional (not asked)	N/A
Admission date	N/A	N/A	Optional	Yes	N/A	N/A
Admission Category	N/A	N/A	Optional	From option list	N/A	N/A
Unplanned Readmission	N/A	N/A	Optional	From option list	N/A	N/A
Funding Type	N/A	N/A	Optional	From option list	N/A	N/A
ASA Grade	N/A	N/A	Optional	From option list	N/A	N/A
Wound Infection Risk	N/A	N/A	Optional	From option list	N/A	N/A
Type of Anaesthetic	N/A	N/A	Optional	From option list	N/A	N/A
Prophylaxis	N/A	N/A	Optional	Yes	N/A	N/A
Final Diagnosis	N/A	N/A	Optional	Yes	N/A	N/A
Pathological Diagnosis	N/A	N/A	Optional	Yes	N/A	N/A
Unplanned ICU admission	N/A	N/A	Optional	From option list	N/A	N/A
Return to Theatre	N/A	N/A	Optional	From option list	N/A	N/A
Discharge Date	N/A	N/A	Optional	Yes	N/A	N/A
Admission Outcome	N/A	N/A	Optional	From option list	N/A	N/A
Mortality Classification	N/A	N/A	Optional	From option list	Optional	N/A
Recurrence Date	N/A	N/A	Optional	Yes	N/A	N/A
Discussed at MDM	N/A	N/A	Optional	From option list	N/A	N/A

TGA: Therapeutic Goods Administration; Side effect med: Report a side effect of a medicine; AADRRS: Australian Adverse Drug Reaction Reporting System; Medical Device: Users Medical Device Incident Report; RACS: Royal Australasian College of Surgeons; MALT: Morbidity Audit and Logbook Tool; FDA: U.S. Food & Drug Administration; FAERS: FDA Adverse Event Reporting System; VAERS: Vaccine Adverse Event Reporting System

4. Results of comparison between chiropractic and mainstream healthcare AERS.

A number of adverse event reporting systems are currently in use in mainstream healthcare in Australia. They have been developed over a number of years and include multiple improvements to their original design. Comparing the results of an analysis of the three chiropractic AERSs with AERSs currently in use in mainstream healthcare will highlight the strengths and weaknesses of the chiropractic AERSs.

Minimum requirements

A set of minimum requirements for reporting adverse events and near misses was formulated as a result of the CRLS-UK trial.(12) These included:

- What happened? (description of event/near miss; severity of actual or potential harm; people and equipment involved)
- Where did it happen? (location)
- When did it happen? (date and time)
- How did it happen? (details of immediate cause(s))
- Why did it happen? (details of underlying, or root cause(s))
- What actions were taken? (immediate and longer term)
- What was the impact of the event? (harm to patient, practitioner, organisation, others)
- What factors did, or could have, minimised the impact of the event?

These questions had been modified from the UK Department of Health document 'Building a Safer NHS for Patients'.(38)

Table 3 reports the results from an analysis of the recommendations of adverse event reporting systems in chiropractic against recommendations from a number of non-chiropractic systems.

Table 3. Analysis of recommendations for adverse event reporting systems in chiropractic

	CRLS-UK Inactive	CPiRLS-UK Active	CRLS-Swiss Active	SafetyNET-Canada Under development
From aviation safety				
Reporting is safe	Yes (anonymous)	Yes (anonymous)	Yes (anonymous)	Yes (anonymous)
Reporting is simple	Yes - 2 pages, 16 questions	Yes - Online, 13 questions	Yes - Online, 10 questions	Yes - 1 page, unless moderate or higher, then 3 pages
Reporting is worthwhile	Yes	Yes	Yes	Yes
From NHS (UK) 2015				
Is there measurement?	No	No	No	Yes - number of mobs/manips
Is there monitoring?	Yes	Yes	Yes	Yes
Promote improvement and learning?	Yes	Yes	Yes	Yes
Promote strategy and accountability?	Yes	Yes	Yes	Yes
From NPSF (US) 2015				
Established by leaders?	Yes	Yes	Yes	Yes
Centralised and co-ordinated?	Yes	Yes	Yes	Yes
Common set of safety metrics?	Yes - Grading of harm 5 point scale (including 'potential' incident)	Yes - Grading of harm 3 point scale (including 'potential' incident)	No	Grading of harm 4 point scale
Address safety across the entire care continuum?	No	No	No	Potentially
Support health care workforce?	Yes	Yes	Yes	Yes
Partner with patients and families for safest care?	No	No	No	No
Ensure that tech is safe and optimised to improve patient safety	No - paper based	Yes - online	Yes - online	Yes - online
Minimum data set suggested by CLRS-UK				
What happened?	Yes	Yes	Yes	Yes for AEs 'moderate and higher'
Where? (Location)	Yes	Yes	Yes	No
When?	Yes	No	Yes	Yes, in narrative
How?	Yes	Yes	Yes	Yes, in narrative
Why?	Yes	Yes	Yes	Yes, in narrative
What actions were taken?	Yes	Yes	Yes	Yes, in narrative
Impact of the event?	Grading the harm	Was the patient harmed?	No	Yes
Factors that could have minimised the impact?	No	No	No	Yes

CRLS: Critical Reporting and Learning System; CPiRLS: Chiropractic Patient Incident Reporting and Learning System; AE: Adverse event; Mobs: Mobilisations; Manips: Manipulations.

While there are common points across all of the systems analysed such as patient demographic information and details about the adverse event, there are a number of data points that are specific to the particular intervention the AERS is designed to report on such as the type of anaesthetic in MALT or the number of manipulations and region to which they applied in SafetyNET.

There has been significant commentary that AERSs are not achieving their aim of improving patient safety. A recurrent criticism is that an AERS may capture too much information causing a problem with over-reporting especially when the success of a system relies upon its ability to process the reports and deliver high quality and timely feedback. A key question when designing a system is: What are the minimum information data points necessary for an effective AERS?

In 2005, the World Health Organization published a draft guideline for adverse event reporting and learning systems.(65) In 2015 the draft was followed by the release of the 'Minimal Information Model for Patient Safety Incident Reporting and Learning' (MIMPS).(10, 66) This document listed the ten elements necessary for an adverse event reporting and learning system. They were:

1. Patient information
2. Incident time
3. Incident location
4. Cause(s)
5. Aggravating factor(s)
6. Mitigating factor(s)
7. Incident type
8. Incident outcomes
9. Resulting actions
10. Reporter's role

Table 4 lists the nine AERSs reviewed by this thesis and assesses their compliance with the ten elements of MIMPS.

Table 4. Compliance of AERSs with the WHO's Minimal Information Model for Patient Safety

		CPiRLS-UK	CRLS-Swiss	SafetyNET	TGA-Side effect med	TGA-AADRRS	TGA-Med device	MALT	FAERS-US Consumer	VAERS-US
1	Patient information	Gender D.O.B.	Gender D.O.B.	Gender D.O.B.	Name req Contact details req Gender D.O.B. Wt	ID or initials Gender D.O.B. Wt Ethnicity State	Gender D.O.B. Wt Specifies - no name	Name Gender D.O.B.	Optional	Name Gender D.O.B. Address
2	Incident time	NA	Yes	Yes	Yes	Reaction onset date	Yes	Yes	Optional	Yes
3	Incident location	Yes	Yes	NA	Which Aust state when side effect started?	NA	NA	Yes Which hospital?	Optional	US County where vaccine administered
4	Cause(s)	Yes	Yes	Yes	Not asked, may be in narrative	NA	NA			
5	Aggravating factor(s)	NA	NA	NA	Taking anything else? Medical History	NA	NA	Wound infection risk from an option list Type of anesthetic	Optional (not asked)	Other meds?
6	Mitigating factor(s)	NA	NA	NA	Not asked, may be in narrative	NA	NA	Prophylaxis		
7	Incident type	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
8	Incident outcome	Yes	Yes	Yes	Yes Categories	Yes Categories	Yes brief description	Yes from option list	NA	Recovered?
9	Resulting actions	Yes	Yes	Yes	Advice or Admission? How treated?	NA	Yes brief description	Yes	NA	Yes
10	Reporter's role	Yes	Yes	Yes	No	Yes	Optional	Yes Surgeon		No

NA: Not asked, this information maybe have been reported in the narrative description; D.O.B.: Date of birth; Wt: Weight

As can be seen in Table 4, critical adverse event information such as aggravating and mitigating factors are not directly included in all three chiropractic AERS. This does not mean that the systems do not collect this information, as the reporter may provide these details in their narrative. However, future AERSs should follow the WHO guidelines about the minimum information needed to adequately assess an adverse event. Relying on a quality narrative from the reporter is a poor strategy that does not guarantee capture of all necessary information. Adopting the WHO categories means that an AERS is more likely to capture data that is capable of being used to analyse the cause of the adverse event.

There has been some debate about the number of categories and that too many may make a system cumbersome and discourage uptake of the system by practitioners. Initially CRLS-Swiss had no categories and encouraged their reporters to provide a narrative of what occurred. However, the system has since been updated and now includes categories.

5. Discussion

5.1 Findings

The aim of this thesis was to analyse the current chiropractic AERSs and compare them to AERSs used in other disciplines. Results from this analysis suggest there is no 'gold standard' for an AERS and that each one has its own benefits and shortcomings depending on the nature of the industry it relates to. In the absence of a 'gold standard', this thesis examined six medical AERSs commonly used in Australia and the US. Examination highlighted the key features of each system and compared them with the main features of the AERSs designed for use in chiropractic.

Results from this analysis show that chiropractic AERSs collect similar data to medical AERSs with both disciplines suffering from a level of under-reporting. A principal goal of patient safety reporting systems is to identify issues that if addressed early, can help to avoid future errors that may lead to harm. In guidelines for developing adverse event reporting systems, the World Health Organization notes that "Although each event is unique, there are likely to be similarities and patterns in sources of risk which may otherwise go unnoticed if incidents are not reported and analysed." (65)

There appears to be no consensus as to the best process for reporting adverse events in healthcare. However, a lack of consensus should not hold back efforts to design and implement more effective systems.(67) The types of adverse event reporting include active reporting by front line care givers; reporting from indicators within administrative data; audits of clinical charts; and triggers from medical record systems.(68)

While all reporting systems appear to have problems, one approach that could be adopted for improving AERSs in healthcare is that of ‘improvement’ sciences (69) which seek to create practical learning that makes a timely difference to patient care.(70-72) The main aim of improvement sciences is to determine which improvement strategies work to ensure effective and safe patient care. The most basic application of improvement sciences is to identify what has not worked in the past and why.

5.2 Issues with the current AERSs

There is a disparity between the number of reports being generated in healthcare and the rate of meaningful evidence-based changes in practice.(67) This may be because the systems are often so overwhelmed by the volume of reports that they become incapable of fulfilling their aim of producing recommendations to improve healthcare safety.(73)

Thomas *et al*. noted that the ineffective use of data together with a lack of publications reporting the findings from this data may be the cause of the lack of evidence-based change.(4) In Australia, incident reporting may not be meeting the objective of enabling continuous improvement in safety and quality because the information gathered in the incident reports is often inadequate for sophisticated analyses.(4)

With respect to chiropractic it is fair to say that the current AERSs are yet to deliver sufficient data to warrant recommendations for changes in practice.

Limitations of incident reporting systems

There are a number of limitations related to incident reporting systems. They include: under-reporting, a low level of detection, inaccurate incidence data and barriers for uptake.

In 2001, Shaw and Coles noted that under-reporting was a significant challenge for adverse event and incident reporting systems.(74) For example, safety indicators are often under-reported in hospital incident reporting systems.(75) A recent study of 527 intern and resident medical trainees at Boston Medical Center reported significant under-utilisation of the hospital's electronic AERS by junior doctors.(5) Shojania highlighted that inadequate reporting often has more to do with human rather than electronic factors.(76) The junior doctors in the Boston study reported that the main barriers to reporting were not knowing what and how to report, a perceived lack of effectiveness of the reporting and the competing demands on their time.(5)

Chiropractic AERSs face similar challenges with respect to reporting by practitioners.

In 2016, Pohlman *et al*. surveyed 81 chiropractors who identified time pressure (96%) and the potential to create a negative perception in patients (80.5%) as the top two barriers to participating in patient safety reporting and learning systems. Regulatory implications and not knowing what to report were also reported as barriers while only 12% of those surveyed believed reporting was unnecessary.(49)

Incident reporting systems are designed to enable the classification of incidents and the identification of common incident types. However, a 2011 study reported that many AERSs provided little useful information on the underlying aetiology of the events being reported.(4)

Shojania noted that one of the problems with incident reporting systems was that they only detected a small percentage of the targeted problems with a large percentage of reports associated with routine events. This problem was particularly marked among physicians who stated they didn't have enough time to fill out the reports and didn't feel reporting was useful.(76)

A fundamental problem with chiropractic AERSs is that while they collect information on individual events, they do not collect data on the total number of interventions administered and are therefore unable to estimate adverse event incidence rates.(76) Furthermore, chiropractic AERSs typically detect such small numbers of targeted events so that minor changes in reporting practices produce large changes in the apparent incidence of an event.(76)

In 2004, the most common barriers identified by nurses and doctors for reporting incidents included time constraints, unsatisfactory processes, deficiencies in knowledge, cultural norms, inadequate feedback, beliefs about risk, and a perceived lack of value in the process.(32) In 2016, the reasons why the same group of professionals did not use AERSs were remarkably similar to those reported in 2004 and included beliefs about the consequences of reporting (lack of feedback following reporting, impact on professional reputation, relationships and career progression), the emotional impact of fear and worry and factors related to the mechanics of reporting such as time, resources and ease of reporting.(77)

In 2016, a panel of eleven international patient safety experts identified five themes as being associated with poor patient safety incident reporting practices.(3) They were: inadequate report processes, lack of adequate medical engagement, insufficient action, inadequate funding and institutional support, and failure to incorporate new technology.

While not an issue for chiropractic, the unexpected large volume of reports generated by some medical AERSs has led to a failure in reporting due to system overload. As nurses are more likely to undertake training and participate in reporting incidents, they express more favourable attitudes toward reporting compared to doctors.(78) Traditionally medical culture has been less transparent and favoured dealing with incidents ‘in-house’.(32) By failing to adequately engage doctors in reporting, owning and leading the incident reporting process, hospital-based systems have created a reporting bias towards nurses.

If practitioners think that reporting is of low value they won't report. The current systems have focused on reporting with insufficient emphasis on action or feedback. An example of when practitioners feel that an AERS is of low value is when they perceive that reporting does not result in useful feedback.(77) The lack of meaningful action is one of the factors that has led to under-reporting of meaningful incidents.

Under-resourcing has also contributed to the failure in dealing with the high volume of reports. Non-processing of reports leads to delays in analysing data and formulating recommendations. The delay raises concerns over the accountability of the reporting system and any ensuing action.

A repeated theme for the future of incident reporting systems is that improvements should be possible as technology improves and reporting becomes more efficient. A criticism often made about AERSs that capture patient safety data is that the collection is done according to organisational or 'discipline-specific' lines and that these systems are often inflexible and difficult to change.(79) It could be argued that proposing a new chiropractic adverse event system could propagate this problem. While the aspiration of avoiding the pitfalls of a ‘discipline-specific’ system may help with designing better systems, chiropractic and arguably all manual therapy adverse event data collection systems currently lag so far behind other areas of healthcare that the primary focus should be to design a robust system that is capable of delivering useful data rather than being concerned with whether the system is too ‘discipline-specific’.

5.3 Challenges facing an Australian chiropractic AERS

A significant hurdle facing the introduction of an Australian chiropractic AERS is that the vast majority of Australian chiropractors are in private practice. Having the majority of a profession in private practice increases challenges associated with the uptake of an AERS as time and resources are more limited in smaller operations than in larger institutional settings. Introducing an AERS appears to be more successful in hospitals where there is an evolving patient safety culture, institutional rules and accountability exist, and sufficient staff are available to task one group with primary responsibility for the system.

Adverse event reporting systems are lacking in mainstream primary care. In 2013, a study investigating why so little progress had been made into researching iatrogenic harm in primary care offered the explanation that primary medical care was perceived to be less risky than secondary care.(80) This was despite landmark epidemiological investigations that alerted the international community to key areas of hospital-based care associated with morbidity.(2)

A reason for the paucity of research into chiropractic AERSs may be that chiropractic is also be perceived as less risky than hospital-based medical care. Sheikh *et al.* criticises such perceptions as indicative of a failure to distinguish between relative and absolute measures of risk. They point out that a large proportion of medical care occurs in primary community care settings and that the overall burden of iatrogenic harm is likely to be substantially higher in those settings compared to a hospital-based setting.(80) The analogy may not hold true for chiropractic in Australia as the profession only treats approximately 16% of the broader community compared to general practitioners who treat up to 88%.(81, 82)

<u>Impact of detailed information on health consumers</u>

An example of how an AERS can impact consumer beliefs is in the field of vaccination. One of the reasons why people hesitated in reporting adverse events following vaccination was the lack of trust that vaccine harms were being adequately documented and reported. A 2016 study designed to assess if data from the vaccine adverse event reporting system (VAERS) could be used to increase the trust that vaccine harms were adequately researched and disclosed to the public exposed three groups of people to different levels of information about vaccination. All 3 groups read an information sheet about the vaccination from the Centers for Disease Control (CDC). Two groups were given additional information.

The first group was given summary data of AEs associated with the vaccine. The other group received full detailed reports of serious adverse events with this vaccine from 2013. The results showed that the participants who read the information sheet alone significantly increased their perception of vaccine benefit and decreased their perception of risk. The group that were exposed to the summary data about serious AEs in addition to the general information sheet showed more trust in the CDC and a greater acceptance of the vaccine relative to the group who had received only the information sheet. Interestingly the group who were exposed to the detailed VAERS reports significantly reduced their trust in the CDC and vaccine acceptance.(83) It could be argued that a randomly selected group of people may have been ill equipped to assess detailed AE data. This view has been used as an argument for the importance of an AERS that includes expert summaries and recommendations from the data.

A high quality AERS that generates information about the risks associated with different chiropractic interventions, should assist patients in making informed choices about each intervention. However, the above example of the VAERS illustrates how information may need to be appropriately presented and contextualised for specific audiences.

5.4 Patient safety movement

The current patient safety movement took its initial cues from the aviation industry and their practices around incident reporting.(84) However, since its inception healthcare safety reporting has been seen by some as stumbling and not delivering the level of benefits that had been predicted and expected. The patient safety movement could benefit from reviewing the progress made in this industry over the last twenty years. Mitchell *et al.* asserts that aviation enjoys a 'culture of reporting' even at the front line where once a report is submitted, front-line workers can choose to resolve the issue themselves in the knowledge that the report will also go to a central, independent investigation unit who have the power to intervene where appropriate.(3) Mitchell argues that if healthcare organisations are to learn from other adverse events systems they must have "an appropriate safety culture and a true accountability to deliver safe patient care. It is imperative to ensure that adverse event reporting is more than fulfilling regulatory requirements."(3)

5.5 Opportunities for further research

In order for the uptake of a chiropractic AERS to be high, the system must be reliable and produce accurate data. To do this requires testing of any new system before it is released to the broader profession. The Macquarie University chiropractic teaching clinics offer an excellent opportunity to capture a comprehensive data set including the number and type of chiropractic procedures and any adverse events encountered. The opportunity to provide an accurate estimate of incident rates for different categories of adverse events associated with chiropractic should not be overlooked.

Prior to implementation of a patient safety surveillance system, retrospective chart review (medical record review) was the only way to identify an adverse event or incident.(85) However, this type of review has poor utility for ascertaining how or why things went wrong as the relevant information is often not recorded.(86) An effective AERS would need to combine the benefits of chart review with those of an active surveillance system.

5.6 Chiropractic AERS design

Future direction

Some healthcare commentators argue there is too much reporting of minor incidents that are known and expected and that patients are fore-warned about. In response to an overwhelming level of reporting minor incidents and the fact that doctors that should report often do not, some researchers have suggested that AERSs should adopt a 'sample' or 'burst' approach to reporting. This type of reporting has been shown to be more successful at encouraging healthcare workers to report incidents as it involves intensive reporting over a limited period of time and is less onerous for the staff charged with completing the reports.(87) Furthermore, adequate training has also shown to improve uptake of such a system at least in the short-term.(88) Advocates of this approach argue that the current systems do not capture sufficient detail that can be used to make significant improvements in practices.

Chiropractic clearly does not currently suffer from the problem of excessive reporting. If the profession improves its patient safety culture this could change and lead to excessive reporting especially of 'minor' incidents. Notwithstanding, the chiropractic profession needs a way of producing accurate estimates of the incidence of adverse events. To achieve this, a 'closed-loop' system capable of capturing data from all clinical encounters over a set time

period is required. A student intern clinic could be a suitable setting to test such a 'closed-loop' adverse event reporting system. Rajendran *et al.* showed this was feasible in a busy osteopathic teaching clinic.(89) Repeating this study in a chiropractic teaching clinic would deliver data capable of improving safety by providing researchers with a model that could be tested in a setting that is close to clinical practice such as a practice-based research network. However, as serious AEs are rare in chiropractic practice it is anticipated that a protracted period of time will be required for the surveillance of clinical encounters to generate data on serious AEs in a chiropractic teaching clinic.

Adopting this approach would help to address one of the barriers to participating in an AERS *i.e.* that practitioners don't know what to report. A study based in a teaching clinic would help to identify events that warrant reporting. As a lack of standardisation between systems has been shown to undermine the comparability of adverse event data in the pharmaceutical industry,(90) the best outcome for chiropractic might be to standardise reporting across all manual therapy disciplines *i.e.* chiropractic, osteopathy and physiotherapy. This approach might reduce the level of selection bias as practices that agree to participate in testing a new AERS have been shown to be more proactive in incident reporting.(91)

Level of detail

As previously reported, the World Health Organization's 'Minimal Information Model for Patient Safety Incident Reporting and Learning' (MIMPS) identified ten elements necessary for an AERS.(10, 66) These elements should be included in the design of any new system. The three chiropractic systems include most of these categories but only collect information on aggravating and mitigating factors indirectly as part of an open narrative report. A new chiropractic AERS should include questions that will directly extract data in all ten categories. Any new system must ask enough questions to provide sufficient detail to permit classification of the event with the goal being to determine if further investigation is required.(76) This would only require minor modifications to the existing AERSs in chiropractic to comply with the MIMPS recommendations.

Classifying the same adverse event under different categories is not unique to manual therapy.(92, 93) Carnes *et al*. concluded that classifying adverse events in manual therapies was difficult without context or detail.(94) As reported in Chapter 2, SafetyNET addresses this problem by proposing a single set of definitions for each adverse event. A strength of any new chiropractic AERS would be to promote the use of a common classification system

that allows comparisons of adverse events data across countries.(66) To achieve this, the system could adopt the WHO's MIMPS 'Incident Types' terminology. Calculating adverse event incidence rates will then enable the profession to better identify specific factors that could help to improve the outcome of interventions.(95)

Features of a proposed Australian AERS for chiropractors

As mentioned previously, it is appropriate to be guided by improvement sciences in the development of any new AERS.(69) Technology should also be used to overcome some of the challenges currently facing AERSs. Researchers have recently trialled new technology that is capable of reviewing text-based medical records.(96) Such technology may facilitate review of existing adverse event data stored in patient records.

In patient-centred care, the active role of the patient is recognised and encouraged. However, advances in safety can often ignore the patient's perspective.(97) It would therefore be appropriate for any new AERS to incorporate patient reports in addition to practitioner reports. It is possible to build a hybrid system that achieves this. A new system should be online so that processing reports and feeding back to the profession and community at large are made easier. The criticism that online systems exclude some participants is becoming less relevant today with the increasing uptake of technology across most age groups.

In a university-based clinical trial, follow-up of the initial report could adopt a structured root-cause analysis approach. This is in keeping with Shojania's suggestion that the real targets of AERSs should be the rare and more serious events that may reveal important system problems. It is these events that require investigation by adequately trained personnel (76) who can identify which adverse events should be followed up at a later date.(98)

An example of this type of reporting was the Western Australian trial for reporting of adverse vaccine responses where the vaccine developers appreciated the need to be able to rapidly detect adverse events after the introduction of a new vaccine.(99, 100) In this trial, researchers compared mobile phone short message service (SMS) messaging to voice telephone interviews for active surveillance of adverse events following immunisation. The trial reported that participants were more responsive to SMS messaging than telephone interviews. Interestingly the researchers commented that the telephone interviews gave more detail with regard to an event such as a local injection site reaction compared to the

SMS approach.(101) A similar trial of SMS-based active monitoring for influenza vaccine was also successfully conducted in Western Australia.(102)

Active surveillance

It is common place for pharmaceutical companies to employ active surveillance methodologies to monitor adverse events associated with new drugs or vaccines.(99, 100) The proposition is that the initial trial of a novel closed-loop chiropractic AERS in a university-based clinic also include an active surveillance component. While this may produce additional challenges, online questionnaires have previously been used as a checklist to collect self-reported adverse event data in an osteopathic teaching clinic.(103)

Extrapolating incidence data from adverse event reports that are not based on accurate information about the number of procedures performed (inaccurate denominator) or that lack adequate acknowledgement of the extent of underreporting of incidents (inaccurate numerator) can lead to unreliable assessments of the balance between risk and benefit. The closed-loop approach may afford the unique opportunity to address this problem.

An 'ideal' system.

Drawing on the knowledge and experience of the Australian Patient Safety Foundation, Runicman wrote that an ideal AERS should include the following: an independent organisation to coordinate patient safety surveillance; agreed frameworks for patient safety and surveillance systems; common, agreed standards and terminology; a single, clinically useful classification for things that go wrong; a national repository for information covering all health care from all available sources; mechanisms for setting priorities at local, national and international levels; a just system which caters for the rights of patients, society and healthcare practitioners and facilities; separate processes for accountability and 'systems learnings'; the right to anonymity and legal privilege for reporters; systems for rapid feedback and evidence of action and mechanisms for involving and informing all stakeholders.(86)

Runciman also highlighted the point that "Many of the things which go wrong in health care occur quite rarely as isolated cases and only present a coherent picture when the information is aggregated".(86) He recommended that a large database, aggregating adverse events from many sources would be required to characterise these individually rare but collectively important low frequency events.(86) Any new AERS should therefore be compatible with the existing AERSs databases.

Managing minor AEs in SMT

Many incidents do not warrant investigation as isolated incidents. The primary targets of an incident reporting system are the more rare events that reveal important system problems that are unlikely to be revealed by other means.(104) Root cause analysis questions are useful in these cases but are better asked by personnel trained in adverse event investigation, not front-line users who are charged with reporting the incident.(76) This approach supports the proposed chiropractic AERS hybrid model with an active surveillance component.

Carnes *et al*. concluded that nearly half of the patients that seek manual therapy experience adverse events that are short-lived and minor.(105) Any proposed AERS for manual therapy needs to address this issue and have the ability to record expected, short-duration, minor reactions to treatment. This is analogous to vaccine AERSs where they need to monitor expected, short-lived, minor localised reactions at an injection site just in case these events are the precursors of more serious events.

Effective feedback

Adverse or incident reporting systems must produce 'actionable feedback that visibly improves the system'.(106) It has been noted by a number of writers that a commonly cited reason for not participating in AERSs is that practitioners perceive the process does not generate useful outcomes.(3-5, 7) Commentators have also noted that when a system becomes overloaded with reports of minor incidents that are routine and expected, the system is unable to generate useful feedback and recommendations. (3-5, 7) Benn *et al*. identified a number of requirements for the design of effective feedback systems that included the role of leadership, the credibility and content of information, effective dissemination channels, the capacity for rapid action and the need for feedback at all levels of the organisation.(106) These elements represent additional challenges to the introduction of a new AERS for chiropractic.

5.7 Patient safety culture

While there is an established culture of morbidity and mortality meetings amongst surgeons,(55) that in itself is not an indicator of quality as one study showed that 13% of intraoperative complications were not recorded in the clinical notes.(107) It has been

suggested that the culture of morbidity and mortality meetings in the hospital setting represents a governance resource that is underutilised.(108)

The success of a new chiropractic AERS is linked to the possibility of development of a deeper patient safety culture amongst chiropractors. Like primary care medical practitioners, chiropractors may have been drawn into believing that adverse events only occur in the high-risk patient population that generally do not seek chiropractic care. This attitude means that safety culture and information dissemination must be addressed at the same time as any new reporting system is implemented.(109) 'Sample' or 'burst reporting may help to address this issue by facilitating the uptake of a new system.(87)

6. Conclusion

The aim of this thesis was to compare existing adverse event reporting systems in mainstream healthcare with those in chiropractic. As an AERS enhances patient safety, having an Australian-based AERS would improve safety and herald further development of the profession locally. With no 'gold standard' and suggestions that AERSs have not delivered on the promise of making healthcare safer, any new system needs to incorporate the effective aspects of existing systems whether they come from inside or outside health.

The AERSs currently operating in chiropractic represent admirable initial work in a challenging field. However, they do not appear to have had any significant impact on patient safety practices within the profession. While the short-comings of these early systems may be the product of how they developed, SafetyNET is poised for implementation and represents the next stage in an attempt to address the deficiencies identified in the earlier systems.

Mandating participation increases uptake of an AERS but does not necessarily correlate with improvements in the delivery of care. We propose a novel AERS in chiropractic be developed in Australia that addresses the shortcomings identified in the existing systems. We suggest that a trial of the proposed system in a university teaching clinic will provide the basis for testing a full-scale system that has the potential to impact chiropractic clinical practice and patient safety more broadly.

The challenge of testing and introducing such a system includes changing the patient safety culture of chiropractors; encouraging and engaging chiropractors to participate in event/incident reporting and designing a system that is perceived as worthwhile and able to generate timely and useful feedback at the same time as ensuring the system is quick and easy to interact with.

Addressing these challenges will provide evidence that can be used to answer the critics who continue to question the safety of chiropractic intervention.

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