



Aboriginal and Torres Strait
Islander Health Practice
Chinese Medicine
Chiropractic
Dental
Medical
Medical Radiation Practice
Nursing and Midwifery
Occupational Therapy
Optometry
Osteopathy
Pharmacy
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Psychology

Australian Health Practitioner Regulation Agency

Contributing to risk-based Chinese medicine regulation in Australia

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Establishing the risk profile

Requested by:

Chinese Medicine Board of Australia

Authored by:

AHPRA Research Unit

Approved by:

National Director, Strategy and Research

Foreword

National Boards work in partnership with the Australian Health Practitioner Regulation Agency (AHPRA) to implement the National Regulation and Accreditation Scheme (NRAS) for regulating health practitioners in Australia.

The Research Unit (RU) of AHPRA, on behalf of the Chinese Medicine Board of Australia (CMBA), conducted a research project to develop an evidence base from which to establish a risk profile for the profession of Chinese medicine.

The project involved a combination of:

- a literature review (analysing international evidence in particular); and,
- a critical analysis of AHPRA's notifications and complaints data (for current national regulatory evidence).

The report that follows outlines the findings from this project, including that the practice of Chinese medicine is generally safe in contemporary regulatory environments, such as Australia. However, there are a number of limitations in the applicability of these findings, including:

- while the size of the profession has been doubled over the last two decades, both the numbers of Chinese medicine practitioners in Australia (<1% of the regulated health workforce under NRAS) and the incidence rate of notifications are low; and
- the comparatively limited literature associated with quality of care and patient safety concerning Chinese Medicine practice.

It is also important to note that the report includes evidence of both Australian and international risks and issues, some of which have minimal relevance in the Australian practice setting. This is due to practice controls (e.g. the regulation of health professions, the restriction of drugs and poisons, etc.), different training and education, a different dominant model of health care in Australia, and quite specific public understanding and expectations around healthcare.

Despite the above limitations, the CMBA sees this report as valuable initial work to educate the profession and to highlight potential areas for the development of future regulatory responses including Continuing Professional Development (CPD) and clinical guidance.

This preliminary analysis of notifications also sets the scene for further research including a more in-depth review at the available data, perhaps per examination of:

- comparative data from other health professions, and
- links with sub-factors such as education level, experience of practitioners, location, age, gender and English proficiency.

The CMBA is committed to improving its effectiveness as a risk-based regulator and welcomes feedback. Please provide your comments by contacting Ms Debra Gillick, Executive Officer CMBA, debra.gillick@ahpra.gov.au

I also would like to take this opportunity to thank Paul Shinkfield and the Research Unit for the excellent work they did for this project.



Professor Charlie Xue

Chair

Chinese Medicine Board of Australia

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Summary report

1. Purpose

The Chinese Medicine Board of Australia (the Board) is currently developing a risk profile on the practice of Chinese medicine in Australia. To support the Board in establishing a base for this profile, evidence of both Australian and international risks and issues has been collated into this report.

All data in this report has been de-identified and some results have been removed prior to publication to protect data confidentiality. The removal of this data does not alter the findings or conclusions of the report.

2. Project structure

The Board and the AHPRA Research Unit (RU) jointly agreed that a research project based on available international and national evidence would achieve best results if conducted through a combination of:

- A literature review (analysing international evidence in particular), and,
- A review of the Australian Health Practitioner Regulation Agency (AHPRA) notifications and complaints data (for current national regulatory evidence).

This approach aims to provide complementary evidence that may be used to develop a suitable risk profile of Chinese Medicine practice in Australia. For the purposes of this report, a risk profile is defined as the quantitative assessment of the risks from the practice of Chinese Medicine to the Australian public, relevant to the regulation of the profession.

This report is compiled of research undertaken by the RU, along with feedback from the Board, including input from its research advisory group (advisory group).

2.1 Literature review

The literature review was focused on three key research questions:

1. What are the main risks arising from Australian Chinese Medicine services or treatments?
2. Are particular Chinese Medicine therapies safe in clinical practice?
3. What regulatory inputs are effective in ensuring particular Chinese medicine treatments are practised safely?

The literature review was conducted using research databases and facilities available to AHPRA. Grey literature was sourced from internet-based publications.¹ The literature review focused on those articles most relevant to the Australian regulatory context, published after the year 2000.

Based on guidance and consultation with the advisory group, the literature search was focused around:

1. Adverse events (AEs), patient safety and regulation for Chinese Medicine practice;
2. Specific Chinese Medicine techniques (especially acupuncture and moxibustion); and
3. Commonly prescribed Chinese herbal medicines.

Additional evidence was included from recent studies involving professions with more-established evidence bases, such as medicine.

It is important to note that this literature review was strictly limited to articles originally written in English. Due to the nature and history of Chinese Medicine, this limitation may present a possible bias. However, the inclusion of two recent studies (from 2010¹ and 2012²), which review the Chinese-literature on acupuncture-related AEs, reduce this potential bias.

¹ The Fourth International Conference on Grey Literature in Washington, DC, in October 1999 defined grey literature as follows: "That which is produced on all levels of government, academics, business and industry in print and electronic formats, but which is not controlled by commercial publishers." [Internet] Accessed 12/12/17. Available at: <http://www.greylit.org/about>

2.2 Notifications and complaints analysis

The analysis of Australian data was based on the study of all closed notifications and complaints collected by AHPRA between the Board's inception in 1 July 2012 and 31 December 2016. Analysis involved a broad quantitative approach, followed by a deeper dive of selected notifications. This analysis of notifications involved a detailed examination of file notes, and required coding to determine the nature and true extent of harms to the public. In this case, the standardised patient safety event taxonomy (PSET) developed for the Joint Commission on Accreditation of Healthcare Organizations was used.

The coding of harms in relation to notifications allow for appropriate regulatory actions to be identified (for example, in the notification triage process and subsequent assessment investigations). This is the first notification study conducted by AHPRA in which harms were coded and analysed, and is part of a broader strategic effort to integrate a harm classification into analytical reports produced by the RU. This information may then be incorporated into AHPRA's taxonomy and standardised risk-based reporting.

3. Strengths and Limitations

Limitations of the literature review include:

- The limited number of publications associated with quality of care and patient safety in Chinese Medicine comparatively, there is a greater volume of literature available in the general orthodox medicine literature since the patient safety movement began in the late 1990s.
- Filtering of retrieved papers by publication in English.

The strengths of the notifications analyses performed by the RU include the complete range of notifications data available. There was a general improvement in data quality after July 2012, however, information on legacy matters is limited. Additional patient safety coding is still required to maximise the value of the data, particularly in small samples of notifications and more particularly regarding harms.

4. Findings

The literature review indicates that:

- The Chinese Medicine practice is recognised as safe, although patient safety in this discipline appears to be highly dependent on the regulatory settings within jurisdictions.
- The incidence of high-impact serious or fatal sequelae to usual Chinese Medicine treatments is relatively rare.
- There is limited evidence that acupuncture is a high-risk technique, except perhaps for pneumothorax.
- Despite the risk of low-grade burns, the practice of moxibustion appears to be relatively safe.
- The highly toxic substances available in the Chinese Medicine pharmacopoeia are only used in rare conditions.
- Herbs and other compounds used in Chinese Medicine, which contain potentially toxic substances, are used in very small quantities in clinical practice. In Australia, the retail supply of many potentially toxic materials is blocked for Chinese Medicine practitioners by the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP, or "The Poisons Standard")³
- The main risks from herbal products involve: the illegal inclusion of western medicines in Chinese herbal medicines, the contamination of naturally sourced materials with heavy metals or pesticides, or from the omission of an ingredients list and/or the amounts required.³
- AEs due to Chinese herbal medications have not been reported systematically, either by a jurisdiction or in the (English) literature. Hence AEs are difficult to track and study.
- Adverse drug reaction reporting in Australia is limited and does not currently include severity of the AE. Reporting systems also vary internationally and the lack of reliable denominators makes it extremely difficult to compare AE statistics across different regions and contexts.

Specifically, in terms of the regulatory context, the literature suggests that:

- It would be beneficial to further develop the monitoring and reporting of AEs and adverse drug reaction (ADR) systems. For example, to include information on the severity of the AEs within the Australia's Therapeutic Goods Administration's Database of Adverse Event Notifications (DAEN) reporting system. There are currently overlapping systems in the Australian regulatory framework with respect to the regulation of Chinese Medicine practitioners and therapeutic goods. Federally, the regulation of drugs (in this case Chinese herbal medicines) and matters related to adverse reactions, technically falls under the Therapeutic Goods Administration (TGA). However, the prescription, dispensing and administration of Chinese herbal medicines (by Chinese medicine practitioners) are matters that are more likely to involve the Chinese Medicine Board of Australia and AHPRA under the National Law.
- The risks associated with acupuncture should be considered in association with the skills and experience of the administering practitioner, and the relative level of development of the regulatory environment in which the practitioner operates. Although the literature suggests acupuncture to be relatively safe, the number of serious complications and mortality encountered must also be considered.
- Chinese Medicine practitioners should be more aware of sequelae that may arise from their practice, and there is a need for better communication between Chinese Medicine practitioners and those who treat persons affected by AEs.
- Trained Chinese Medicine practitioners with knowledge of the therapeutic use of Chinese herbal medicines, the expected responses observed from these medicines, and the dosages involved, need to contribute towards the TGA reporting system. This will allow for the better use of Chinese herbal medicines where practitioners prescribe treatments with more confidence and respond to concerns accurately and more authoritatively. This includes a better understanding of the following:
 - The mechanisms and timing of various types of reactions (such as allergies and toxic responses).
 - The interactions between Chinese herbal medicines and pharmaceutical drugs.
 - The traditional Chinese medicine concepts and related interpretation of Chinese medicine effects.

Analysis of notifications and complaints relating to Chinese medicine practitioners for the reference period showed that:

- A total of 188 notifications and complaints were received and closed between 1 July 2012 and 31 December 2016. Of these, 56 were included in the deep-dive study.
- Where stream² was known, 57% related to conduct, 39% related to performance, and only 4% related to health.
- The three most common issue categories were: clinical care (29%); National Law breach (25%); and boundary violations (11%).
- Similar to most other AHPRA professions, the notification rate for male Chinese Medicine practitioners is 1.8 times higher than for female practitioners.
- The practitioner age distribution for notifications in the deep-dive dataset was bimodal with peaks between the ages of 36-45 and 51-65 years old.
- Most of the notifications were associated with low or no detectable levels of harm. Furthermore, where harm was recorded at a moderate level, it was mostly temporary.
- The issue categories with the greatest number of number of harms were clinical care, boundary violations and communication.
- There were no notable differences in harm by practitioner registration type or division.
- Regulatory outcomes did not appear to be related to the severity of harm related to the notification.

² When a notification is received by AHPRA, it is assigned a *stream* based on the dominant issue identified within the grounds for notification. The three streams of health, performance and conduct are supported by definitions within the National Law.

Full report

5. Context

5.1 Brief

Simply put, a risk profile outlines the number of risks, type of risks and potential effect of risks or threats to an entity at a given time. Depending on the type of risks identified, here the entity may be interpreted as the Chinese Medicine Board of Australia (the Board), the Australian Health Practitioner Regulation Agency (AHPRA) or the Australian public. Therefore, for the purposes of this report a risk profile is a quantitative assessment of the risks from the practice of Chinese Medicine to the Australian public, relevant to the regulation of the profession. The Board requested a research project from the Board and the AHPRA Research Unit (RU) to help it establish a risk profile of the practice of Chinese medicine in Australia, based on available international and national evidence.

It was jointly agreed that this was best achieved through a combination of a literature review and a review of AHPRA's notifications and complaints data (for current national regulatory evidence).

This approach aims to provide complementary evidence that may be used to develop a suitable risk profile of Chinese Medicine practice in Australia.

This report has been compiled by research undertaken by the RU, along with feedback from the Board and input from the advisory group.

All data in this report has been de-identified and some results have been removed prior to publication to protect data confidentiality. The removal of this data does not alter the findings or conclusions of the report.

6. Literature review

6.1 Research questions and method

This scoping literature review is not intended as a systematic literature review⁴ but rather as a means to locate and describe recent research to help situate Chinese Medicine practitioner regulation in relation to other examples of health practitioner regulation.

Based on guidance and consultation with the advisory group, the literature review was focused on three key research questions [specific concepts and terms suggested by the advisory group and/or the Board's Executive Officer are listed in brackets].

1. *What regulatory inputs have been effective in ensuring particular Chinese medicine therapies and treatments are practised safely?* [patient safety, AEs, competency, regulation]
2. *What are the main risks arising from Australian Chinese medicine practitioners or treatments?* [acupuncture, moxibustion, pneumothorax, herbal]
3. *Are particular Chinese medicine therapies safe in clinical practice?* [adverse drug reactions]

The literature review was conducted using full-text peer-reviewed research databases and facilities available to AHPRA. This includes Medline, CINAHL Plus with full text, and AMED databases. Additional references⁵ were obtained from the Journal of Continuing Education in the Health Professions, BMJ Quality and Safety and the Journal of Medical Regulation as well as grey literature, sourced from a wide variety of internet-based publications. Searches were limited to papers published after the year 2000, any landmark papers published prior to 2000 that were referenced by these primary references methods, were also sourced where possible. In addition to articles relating to Chinese Medicine, where relevant, evidence was also sourced from recent, high-quality studies involving professions with more-established evidence bases, such as medicine.

It is important to note that this literature review was strictly limited to articles originally written in English. Due to the nature and history of Chinese Medicine, this limitation may present a possible bias. However, the inclusion of two recent studies (from 2010⁶ and 2012⁷), which review the Chinese-literature on acupuncture-related adverse events (AEs) reduce this potential bias.

6.2 Limitations

Typically, systematic biases occur when using AE search filters to detect articles on AEs, compared to searching for AE involving procedures, diagnostics or medical devices.⁸ However, this bias was not observed with acupuncture, as papers relevant to acupuncture outnumbered papers relating to AEs concerning Chinese herbal medications. This is probably due to the prominence of the term *acupuncture* in the titles in the Chinese medicine literature dealing with such procedural AEs.

6.3 Findings

A search of the literature on AEs in Chinese Medicine shows that the incidence of high impact serious or fatal sequelae to usual Chinese Medicine treatments is relatively rare. This is somewhat expected since Chinese medicine interventions, broadly speaking, are neither very invasive (for example, procedures usually do not require conventional general anaesthetics), nor are they highly toxic in common practice. Although the traditional Chinese Medicine pharmacopoeia contains highly toxic substances in potentially harmful doses, these appear to be endorsed only for rare conditions. The main risks from herbal products in current practice appear to arise from contamination with drugs, toxins or heavy metals, or not containing the listed ingredients in the amounts as specified.⁹

Not being an orthodox Western health discipline, the English-language literature documents a shorter history of conventional research. Compared to the evolution of orthodox Western medicine over the past several centuries, the science of traditional Chinese medicine has developed in a more empirical form, over many centuries. However, modern scientific experimental approaches are catching up in the field. Similar to Western medicine, while most of research is directed at showing efficacy and effectiveness of treatments, there is a comparatively smaller fraction of the literature that examines quality of care, including the incidence and prevalence of AEs. Fortunately, some of the more important research relating to risk of traditional Chinese Medicine has been performed in Australia, so it is directly applicable to the research aim.

6.3.1 Acupuncture adverse events: non-registered practitioners

In the 1990s, the most frequent AEs from acupuncture, reported in the international literature were infections, with hepatitis B being the most prevalent of these.¹⁰

In 2000, on the cusp of registration for Chinese Medicine practitioners in Victoria, Bensoussan and others investigated the nature and frequency of AEs that occur as a result of the practice of both acupuncture and Chinese herbal medicine in Australia.¹¹ Compared with earlier international reports, the most common AEs reported were severe gastrointestinal symptoms, fainting and dizziness and significant skin reactions. The shift away from the previous tendency to reporting infection AEs probably shows the benefits of the shift by that time to a general utilisation of disposable sterilised needles, rather than the earlier practice of re-use and sterilisation.

Regrettably, the Australian researchers used a fairly imprecise method, surveying both medical practitioners and non-medical practitioners who self-reported that they practised traditional Chinese medicine. The researchers calculated comparative rates of AE as one event per 1,009 consultations for non-medical practitioners and 1 per 368 for medical practitioner. Overall, the rate was equivalent to 0.15 AE per 100 treatments. This survey had two major problems: (i) the low response rates and (ii) that it used the “practice lifetime” of practitioners surveyed as a denominator. This ran the risk of recall bias and lack of generalisability, decreasing confidence in the reliability of their results. Adverse events due to acupuncture accounted for about 80% of all AEs reported, which reflects the substantially larger proportion of surveyed practitioners who reported using acupuncture. Therefore, doubts exist on how the true risk associated with traditional Chinese Medicine, as practised in Australia at the time.

More thought-provoking is the reporting by practitioners of a number of serious AEs in this study that included: central nervous system (CNS) effects (for example, numbness and palsy), hepatotoxicity, renal toxicity, and death. Equally, results from a self-reported survey of the type used in this research needs to be interpreted with caution. For example, there was no validation concerning mortality from CNS effects. The reported number of between 19 deaths and 37 may be questionable, but these are worth considering nonetheless. It is notable that this study was performed before the formal regulation of Chinese Medicine in Australia, the Chinese Medicine Registration Board in Victoria first began in 2001 and registration commenced in 2002.

In 2010, a systematic review by Ernst (without language restrictions)¹² investigated all case reports and case series relating to serious AEs, that is, any unwanted clinical outcome that needed medical/surgical attention or led to death. Reports of AEs due to injecting drugs into acupuncture points were excluded. The researchers identified a reasonable number of studies of acupuncture that revealed 95 cases of AEs.

These were grouped into three main categories: infection, trauma and other AEs. Of these, 5 patients died (having consulted practitioners for relatively minor conditions), 38 infections were reported (mainly bacterial infections that responded well to antibiotics), and of the 42 cases of organ trauma found, the most prevalent was pneumothorax. While most patients recovered fully, 4 patients died from their pneumothorax. The 'other' AEs comprised a wide range of different outcomes, from contact dermatitis with trigeminal neuralgia to cerebrospinal fluid (CSF) fistula and epileptic fits.

6.3.2 Acupuncture adverse events: registered practitioners

A large prospective study of acupuncture conducted in the United Kingdom in 2001 reported an incidence rate of 6.84 AEs per 100 treatments.¹³ This study detected problems down to a minor level, with the most common minor AEs were bleeding, needling pain, and aggravation of symptoms; aggravation was followed by resolution of symptoms in 70% of cases.¹³ This study recruited registered medical practitioners and physiotherapists who used acupuncture as an adjunct to their usual practice.

In 2001, a Japanese systematic review of papers published between 1987 and 1999 found an overall rate of 0.14 AEs per 100 treatments.¹⁴ Most of the AEs reported involved licensed acupuncturist, with a minority arising from treatments by medical practitioners. The most frequent single type of AE reported was pneumothorax. Of these, 44% occurred during or immediately after needling. The second most frequent AE was spinal cord injury. Of the 18 cases of pneumothorax, 10 were caused by accidental needle breakage; six were caused by intentional needle breakage (embedded needle). The practice of embedding needles seems to be common in Northern Asia, but is not accepted practice in Australia. It should be noted that (sub)arachnoid needling, retention of broken acupuncture needles or use of herbal injections are not accepted Chinese medicine practice in Australia and are not taught in Australian approved programs of study. The third most frequent AE was acute hepatitis B (however, this may be influenced by literature published before the widespread use of disposable needles).

In a German cohort study reported in 2004, a rate of 7.54 AEs per 100 treatments involving acupuncture. This study involved 12,000 physicians in private practice who had held a certificate in traditional Chinese acupuncture, requiring at least 140 hours of formal acupuncture training¹⁵. In this well-conducted study of outpatients, the researchers observed a crude rate of Serious Adverse Events (SAE) to be 0.24 per 100 treatments. SAE included death, acute general infection that resulted in hospitalisation, stroke, cardiovascular disease and a number of hospitalisations for unspecified conditions. The number of deaths was 5% of that expected statistically, that is, nine recorded vs. 180 expected.

In another 2004 study in the United Kingdom, over a three-month period, a prospective national study of 6,348 acupuncture patients in the United Kingdom showed a rate of 107 AEs (95%CI: 100-115) per 1,000 patients or 0.13 AE per 100 treatments. Only three patients reported a serious AE. The most common events reported were severe tiredness and exhaustion, pain at the site of needling, and headache. Overall, the study concluded that "*acupuncture is a relatively safe intervention when practised by regulated practitioners*".¹⁶

A 2010 prospective study of licensed Oriental Medicine Doctors (OMDs) practising acupuncture in Korea found a rate of 3.2 AEs per 100 treatments. Only OMDs who have studied for six years and are licensed are able to perform acupuncture treatments in South Korea.¹⁷

This study enrolled 13 OMDs and followed them for five weeks. The participating practitioners reported the number of acupuncture treatment sessions administered and patients encountered every week. AEs, when they occurred, were reported using a record form designed by the researchers. Of the treatments during which an AE occurred, 65% of treatments were ended, and 63% of the AEs diminished or disappeared. Of the remaining cases of AEs in which treatment was continued, 80% of patients AEs diminished or disappeared. The most common AE was haemorrhage, experienced in 32% of AE cases. Except for the 3% of patients taking non-steroidal anti-inflammatory drugs, there was no other possible factor that could cause bleeding. All haemorrhage events disappeared within one day, and there were no cases of reoccurrence. The second most common event was hematoma formation (28%). Acupuncture treatment was stopped in half of the cases of hematoma and continued in the other half. Needle-site pain was recorded in 13% of AEs. There was a bias toward AE reports in female patients, but the authors note that this probably reflects the preponderance of female patients who attend for acupuncture in South Korea.

The authors noted their observations were subject to a number of potential biases. Their rate of 3.2 AE per 100 treatments was lower than the English and German studies cited above. As a general rule in

patient safety studies, AEs tend to be overestimated when investigated via patient surveys, and they tend to be underestimated when they are investigated via practitioner reports.

Another study published in 2010 by Zhang *et al* examined the Chinese-language literature for acupuncture-related AEs. Three Chinese databases were searched:

4. Chinese Biomedical Literature Database, (1980–2009)
5. Chinese Journal Full-Text Database, (1980–2009)
6. Weipu Journal Database, (1989–2009).

Case reports, case series, surveys and other observational studies were included if they reported factual data, but review articles, translations and clinical trials were excluded.¹⁸

Similar to other studies cited, acupuncture-related AEs were classified into three categories: traumatic, infectious and 'other'. Also similar to other studies cited, the most frequent AEs were pneumothorax, fainting, subarachnoid haemorrhage and infection. The most serious ones were cardiovascular injuries, subarachnoid haemorrhage, pneumothorax and recurrent cerebral haemorrhage. There were 14 deaths reported.

Even if there is gross under-reporting, the rates reported represent a very small incidence/prevalence of deaths and SAEs if one considers that in one year alone (2009) there were estimated to be 900 million Chinese medicine consultations in China, of which acupuncture plays a significant part.¹⁹

The authors observed that most traumatic events were caused by improper manipulation in high-risk acupuncture points and that the depth of needle insertion is crucial to a safe outcome or not. For example, in pneumothorax, the lung surface is about 10 to 20 mm beneath the skin in the region of the medial scapular or mid-clavicular line. The narrow margin for error may explain the fact that pneumothorax coupled with the potential severe sequelae was the most frequently reported serious AEs in this study.

Other traumatic complications, such as subarachnoid haemorrhage, cardiovascular injuries or perforation of the gallbladder, can also be caused by excessively deep needle insertion.¹⁸

It is also worth remarking that the demographics of the practitioners may have had a bearing on the frequency of AE reports. Of the 87 Chinese-language articles in the review that reported traumatic events, 59 (70%) provided information about the acupuncturists. Of these 59 articles, 68% (40) indicated that the acupuncturists were practising in village clinics or rural hospitals when they performed the procedures that caused the traumatic events. All infections reported were associated with acupuncturists in rural areas. In China, the authors note, acupuncturists in rural and urban hospitals have a great disparity in clinical skills.¹⁸ Acupuncturists practising in rural hospitals, township health centres or village clinics may only rarely receive formal education in medical colleges.

This may have a bearing on some Chinese-educated Australian practitioners, but otherwise is presumably not directly comparable with local educational accreditation criteria or, in particular, regulatory standards in Australia.

Also worth noting is that SAEs were more often identified from case reports but not surveys or prospective observational studies. This may go some way to explain the underreporting in the Australian study cited. The authors also suggest that this may explain the low rates of reported serious acupuncture-related AEs in the studies surveyed.¹⁹

Zhang and colleagues also observe that bleeding and pain during needling are reported less often in the Chinese-language than in the English-language literature, perhaps because practitioners in China consider such events as too trivial to report. Infections (primarily hepatitis) after acupuncture are reported frequently in the English-language literature, but relatively rarely in the Chinese-language literature, even though non-disposable acupuncture needles are still used in China. It is therefore possible that in China acupuncture-related infections are under-reported. Of the 87 Chinese-language articles that reported traumatic injuries in this study, 72 (about 70%) were authored not by the acupuncturists themselves, but by the physicians who treated the AEs. None of the articles reporting infections were authored by the acupuncturists, as opposed to 16 of the 20 (80%) reports of AEs other than trauma or infection.¹⁸

Again, the authors inferred that under-reporting of such events in the Chinese-language literature is likely to be higher than in the English-language literature.¹⁸ Although it is very useful for comparison to have a review of the Chinese-language literature in English, there are several limitations with this study. Principal

of these is the impossibility of determining a denominator, that is, the total number of acupuncture treatments practised over the study period, which might serve in calculating incidence or prevalence rates. Based on the number of hospitals and likely numbers of patients visiting these hospitals for acupuncture treatments, in all probability the rates of reported AE are very small indeed, and likely to be less than reported by the other studies cited here. Regrettably, such a comparison based on available data is not possible.

Another review of the Chinese-language literature in an English-language paper is that by He and others from 2012.²⁰ The He review searched specifically for case reports of acupuncture associated AE in four mainstream Chinese-language databases:

7. Chinese Journal Full-text Database (1949-2010)
8. China Biomedical Literature Database (1978-2010)
9. Chinese Technology Journal Database (1989-2010)
10. Wanfang (1998-2010).

From 167 papers from 1956 to 2010, referring to 1,038 cases, the researchers found that the most frequent AEs reported were syncope (468 cases), pneumothorax (307 cases), and subarachnoid haemorrhage (64 cases), from which 35 patients died.

The He paper presents a slightly different pattern from the papers reviewed. One positive difference was a presentation of the age profile of patients who experienced AE. Perhaps counter-intuitively, there were no AE observed occurring in patients less than 56 years old and 90% were aged >90. Hence, although not commented on by the authors, the incidence of syncope in this age group of patients may possibly be associated with advancing age. The authors also in their analysis ascribed the causal factors to mental tension in the patient, incorrect technique and poor sterilisation. Similar to some other papers, the most common reported tissue injury in the He paper was pneumothorax. Most primary diseases of the patients who had experienced pneumothorax included peri-arthritis of shoulder, cervical spondylosis, stiff neck, intercostal neuralgia, as might be expected in patients in older age groups.

Different to other papers however, He *et al* identified the acupuncture points associated with these incidents: Feishu (BL13), Jianjing (GB21), Ganshu (BL18), Tiantu (CV22), Tianding (LI17), Jiuwei (CV15), Quyuan (SI13), Futu (LI18), Dingchuan (EX-B1), Quepen (ST12), Zhongfu (LU1), Fengmen (BL12), Gaohuang (BL43), Dabao (SP21), Shencang (KI25), and Ashi acupuncture points on the shoulders. Causal factors identified included excessive inserting depth, improper acupoints selection or changing position during retaining needles; of the outcomes where identified, 252 of the 307 cases recovered completely and six died.

In the He paper, as with others retrieved for this review, limitations were noted. The existence of a causal link between acupuncture and these AEs is uncertain. The researchers observed that most of the cases reported in China are not in any standard format. Therefore, critical information such as qualifications of the acupuncturist, depth of the needling, and angle of the needling is unclear in the Chinese-language literature.

In a 2013 global study, Xu and colleagues searched for case reports of acupuncture-related AE sought to identify not only individual cases or outbreaks of acupuncture AEs but also to try to ascertain causes, with a view to reducing risk in future. Uniquely amongst the studies reviewed, the authors were also able to compare their results with a previous review that they performed some 10 years previously.²¹

The Xu study found that infections accounted for the majority (78%) of complications or adverse reactions. This study, looking from 2000 to 2011, discerned between infections described with as outbreaks (62%) and isolated instances (16%). Incidents were reported in 17 countries and regions including Korea with reported 162 cases, Canada 33, Hong Kong 7, Australia 8, Japan 5, Taiwan 5, UK 4, and USA 6. Most of the papers did not report the practitioner's training, but four cases were treated by individuals with no medical training or license.²²

Compared with their previous study, the authors also found that the routes of infection had changed over time. In the 10 years covered in this study, they found that 191 infections occurred in five outbreaks of bacterial infection caused by skin contact with un-sterilised equipment and dirty towels, in unhygienic clinical settings. In their previous findings, hepatitis cross-infections from patient to patient due to reused needles (94 cases reported in four outbreaks) were the most frequent source of infection. They ascribe the decrease in hepatitis cases to the greater regulation of acupuncture practice resulting in widespread use of single use needles and guidelines such as clean needle technique. The authors consequently point to greater risks that appear in their later study to be arising from poor skin preparation. For instance they cite

three cases, including one report from a practitioner who admitted that the patient's skin at the acupuncture point was not cleaned prior to the needle insertion and later found local muscle infection which led to septicaemia and subsequent death of the patient from multi-organ failure after a few weeks.

This also highlights the difficulty in these kinds of studies where AEs of this kind may go undetected, or not ascribed (be it by a coroner or doctor providing a death certificate) to treatment where the sequelae occur at some time after the cause, such as in this case. Other cases of infection as sequelae to poor acupuncture technique may only be detected where there is a formal investigation, such as a public health contact tracing instigated for an outbreak. For example in an Australian case report cited in the Xu study, an outbreak of eight cases of invasive Methicillin-resistant *Staphylococcus aureus* (MRSA), six of them were associated with acupuncture. After extensive investigation, the investigators of the outbreak concluded that it most likely resulted from a breakdown in sterile technique during the acupuncture procedure and that the MRSA was probably transmitted from the practitioner to the patients. At two time points fifteen months apart, that practitioner had been positively colonised with the MRSA strain that caused the infection.

A later (2014) paper in this series, focusing on acupuncture AEs in China, but including other adverse complications, reviewed the frequency and severity of incidents reported in acupuncture treatment from 1980 to 2013.²³ Again, any case reports of acupuncture-related complications and AEs from the scientific literature were classified according to the type of complication and AE, circumstance of the event and long-term patient sequelae. Although slightly different set of definitions applied in this study when compared to others considered above, the researchers found that over the 33 years of literature surveyed, 182 incidents were identified in 133 relevant papers. They noted internal organ, tissue, or nerve injury were the main complications of acupuncture, especially pneumothorax and central nervous system injury. AEs also included syncope, infections, haemorrhage, allergy, burn, aphonia, hysteria, cough, thirst, fever, somnolence, and broken needles.

Limitations in the search strategy and identification of AE identification were similar to those identified previously, but the authors also noted the possibility that the incidence of AE is under-reported due to the lack of an effective accident reporting system.

The most recent systematic review focusing on acupuncture AEs, from June 2017, came from Chan and colleagues collaborating from Hong Kong, mainland China and Canada. This review was the only one that published its protocol design a priori, under the PROSPERO protocol,²⁴ however, it was confined to English-language publications. The research question was: "*Are acupuncture and related therapies safe in clinical practice?*". The researchers searched mainly MEDLINE and EMBASE with search filters related to systematic review and adverse effects, in addition to search keywords for acupuncture and related therapies. No publication period restrictions were applied during the search. The Chan review was therefore well-conducted, and included most of the papers canvassed above. The main findings were based on 17 studies, from 1996 to 2015, covering case reports, case series, and randomised controlled trials describing various types of acupuncture. The authors deemed the methodological quality of the reviews as mediocre overall. From the standpoint of the AHPRA review, most reviews in this genre have been variable in the standards of reporting.

Chan and others identified four major categories of AEs, as summarised in Table 1, below.

Table 1. Synthesis of results from Chan et al.

AE Category	Number of reviews	Median number of cases	Median number of deaths
Organ or tissue injuries	13	36	4
for example, pneumothorax	8	25.5	3
Infections	11	17	0.5
for example, hepatitis	3	94	1
Local AEs or reactions	12	8.5	Nil
for example, contact dermatitis or local allergic reactions	9	4	-
Other complications	11	21	Nil
for example, dizziness or syncope	8	10.5	-

As noted in the commentary regarding the other reviews, the lack of full details concerning patient numbers in the included studies, or because AEs arose from case reports, it was not possible for the authors to perform meta-analysis, calculate or compare useful indicators such as incidence rates, related confidence intervals (CIs), or p-values. While the authors noted that most reviews considered acupuncture to be relatively safe (as has the reviewer above), considering the number of serious complications and mortality encountered, they are more cautious in proclaiming acupuncture as risk-free.

Accordingly, they considered that patients can be at great risk from acupuncture. While there was little information to identify which body sites or patient factors carried greater risk, they offered guidance that practitioners “*should pay ample attention to risk stratifying patients based on their medical history and other relevant characteristics.*” They also exhorted that there are other potential areas of improvement including enforcing stricter sterile needle practices, improving patient education about common and/or serious risks, and enhancing practitioner recognition of acute complications. On a more practical level the authors suggested that practitioner should be more aware of sequelae that may arise from their practice, and called for better communication between Chinese medicine practitioners and those who treat those affected by acupuncture AE.

As will be seen in the notification analysis, this last point can clearly be improved upon in Australia.

6.3.3 Moxibustion and cupping

Together with acupuncture, moxibustion and cupping are important complementary techniques that of traditional Chinese Medicine, and are commonly used in Australia. The widening acceptance of these techniques, like acupuncture, requires ongoing safety assessment from a regulatory perspective. Moxibustion is a traditional Chinese Medical treatment using the heat of burning moxa to stimulate acupuncture points. It is considered safe and effective and is widely used throughout the world. The increasing use of moxibustion has drawn attention to the procedure’s AEs. Of the 308 AEs found in the study by Xu *et al*, only four arose from moxibustion and there were 10 cupping-related AEs.²²

The systematic review by Xu *et al*, in 2014, found 64 cases of AEs focusing on moxibustion alone in 24 articles, reported in six countries. Scant evidence of AEs arising from moxibustion can be found in these cases, leading to several outcomes. AE outcomes included burns (most prevalent), allergies (2nd most prevalent), infection, coughing, nausea, vomiting, foetal distress, premature birth, basal cell carcinoma (BCC), ectropion, hyperpigmentation and, rarely, even death.²⁵ The authors point to risk factors related to moxibustion such as the position, duration, distance between moxa and skin, proficiency of the practitioners, conditions of the patients, presence of smoke. In their view, even the environment of treatment can affect the safety of moxibustion. The authors suggested that improving practitioner skill and regulating operations may reduce the incidence of adverse reactions and improve the security of moxibustion.

A 2012 report of a Japanese survey of acupuncture and moxibustion clinics found the top three AEs for moxibustion were accidental and unintentional burn injury (24.0%), singed hair (15.5%), and singed clothes (15.0%).²⁶ It should be noted that these results refer to the proportion of respondents reporting, not the frequency of AEs. The authors ascribed the moxa AEs more commonly to negligence, in comparison to acupuncture AE, and found that there was a qualitative association with those practitioners who did not subscribe, nor were aware of safety periodicals.

In 2016, there was a case series report of burns victims who had received moxa treatment. In 59 patients, there were 68 burn sites. Superficial second-degree burns were present at 21 sites, deep 2nd or 3rd degree burns at 44 sites, and unknown burns at three sites. The most common sites were the lower extremities, abdomen, and upper extremities.²⁷

In this study, the most commonly reported burns were from where the patients applied the moxa to themselves (45.7%), followed by Oriental medicine practitioners (38.9%).

The most common reason for moxibustion was pain. Only the burn site was significantly associated with burn depth, and non-abdominal sites were 9.37 times more likely to involve deep burns (vs. abdominal sites).²⁷

Another Japanese study reported in 2017, involved a prospective multicentre study of acupuncture and moxibustion AEs. From 14,039 sessions, involving 232 practitioners and 2,180 patients, there were 847 AEs (6.03%) recorded over a period that varied between five to seven months. Most of the AEs that occurred were mild and transient, and no serious AEs were reported.

While these findings suggest that the practices of acupuncture and moxibustion are relatively safe, at least in Japanese educational facilities, no clear conclusions can be made due to the small number of surveyed patients and the possibility of a reporting bias in each facility. The authors suggest that, if in future there was an AE reporting system established using the worldwide web, it would be easier to conduct a much larger-scale and longer-period survey. Furthermore, it may be preferable to require all acupuncture practitioners to register and report all designated AEs.

6.3.4 Adverse events reported in acupuncture and moxibustion – discussion

To do no harm is a key prerequisite of ethical behaviour of health practitioners. In complementary and alternative health care especially, it has been identified to encompass at least three components:

- Direct harm — resulting in adverse patient/client outcomes including side effects, medicine interaction or encouraging withdrawal of current therapy.
- Indirect harm — as the result of delay in implementing appropriate treatment or by creating unreasonable expectations that might otherwise discourage patients and their families from accepting and dealing effectively with their health problem.
- Economic harm — encouraging expenditure on ineffective, unnecessary or unsafe medicines and therapies without providing an awareness of the unproven nature of the treatment or modality being offered. This could also lead to direct or indirect harm if money is otherwise no longer available for living essentials or more appropriate health care management²⁸.

The list of potential harms from acupuncture is extensive,²⁹ although from these studies, the prevalence is relatively low. Ideally, of course, the incidence and prevalence would be as close to zero as possible. The kinds of trauma include: penetrating the stomach cavity, epidural haematoma, pneumothorax, medulla spinalis injury, puncture of liver, puncture of heart, cardiac tamponade, myositis ossificans, vascular injury, popliteal arteriovenous fistula, spinal cord trauma, intracranial haemorrhage, lumbar epidural haematoma,²⁵ transverse myelopathy, haemothorax, compartment syndrome arterial injury, deep vein thrombosis, popliteal artery occlusion, pseudoaneurysm, subarachnoid haemorrhage and medulla trauma.²⁵ Often in patient safety, for example, monitoring of sentinel events in a jurisdiction like Victoria, some types of AEs might be classified as “never” events. These are where certain adverse occurrences need mandatory reporting and special investigation, such as root cause analyses. The term “Never Event” was first introduced in 2001 by the U.S. National Quality Forum (NQF), in reference to particularly shocking medical errors (such as wrong-site surgery) that should never occur. Over time, the list has been expanded to signify AEs that are unambiguous (clearly identifiable and measurable), serious (resulting in death or significant disability), and usually preventable.³⁰ As yet, there is no such sophistication in the recording or learning from AEs in Chinese Medicine in any Australian jurisdiction.

Infections attributed to acupuncture are also wide-ranging, including: endocarditis, multiple epidural abscesses, cervical epidural abscess, paraplaegia caused by spinal infection, septic arthritis, cervical subdural empyema, hepatitis and contact dermatitis, skin infection, chronic inflammatory granuloma, bacterial meningitis. Miscellaneous events reported are: hypotension, nausea, vomiting and fainting, death, severe asthma, tiredness, drowsiness, pain, severe headache or migraine, severe sleeplessness, diarrhoea, and so on.²⁵

Because of the widely varying methods across study types, it is difficult to compare the published rates of acupuncture AEs across studies and, therefore, countries.

From the perspective of this review, there is no evidence that acupuncture in itself is a particularly high-risk technique. One possible exception to this general rule would be practices that involve the deliberate breakage and retention of needles, which have a potential to migrate and cause internal organ damage e.g. spinal cord. This technique has not been found to be an issue so far in AHPRA notifications data.

The other main area of concern, borne out by our notifications analysis, is the risk of pneumothorax. One unique study found in our search employed Magnetic Resonance Imaging (MRI) to compare and contrast mean measured depths of 11 acupuncture points around the neck and shoulder region of 394 patients.²⁵ It was found that participants with higher body mass index (BMI) had greater depths. Further, when taking BMI into consideration, depths in male participants generally were greater than in female participants. The authors concluded by recommending acupuncture practitioners consider information such as this to prevent complications when providing treatment to their patients.²⁵

So far as a conclusion regarding acupuncture and patient safety is concerned, one from the Chinese-language study is worth quoting:

“Acupuncture can be considered inherently safe in the hands of well-trained practitioners. However, there is a need to find effective ways to improve the practice of acupuncture and to monitor and minimize [sic] the health risks involved.”

6.3.5 Regulation of Herbal and other Chinese medicines

Use of Chinese medications is often surveyed in the context of Complementary and Alternative Medicines (CAM). There is evidence that CAM are widely used in Australia and that alternative medicine use is more common in those reporting use of orthodox prescribed medicines and those in rural and remote areas, where access to regular medical services may be lower.³¹

Data from the Australian study by Bensoussan and others previously cited demonstrated that Chinese herbal medicine appears to have a much-safer profile than orthodox pharmaceutical drugs.

In 2010, Wu and others made recommendations for reporting adverse drug reactions and AEs of traditional Chinese medicine. In that paper, they noted the difference between an AE and adverse drug reaction (ADR).³² These terms are traditionally used in conventional (occidental) patient safety literature and increasingly in the Chinese medicine literature since 2000. We therefore adopt the definitions used in that paper.

For the purposes of this review, we define an ADR as:

a harmful reaction that is not related to the purpose of using an approved drug or traditional medicine, which arises when that drug is administered at an approved dose according to established procedures.

An AE as defined by Wu et al is:

Any individual event in which a drug hurts a patient or harms the patient's health.

AEs can, therefore, be seen to encompass both ADRs and harms resulting from quality problems or incorrect use. In that way, AEs connote harms, which is the reason for a regulator's existence.

While China has established a complete online monitoring system for ADRs, the equivalent system in Australia is the Therapeutic Goods Administration's (TGA) Database of Adverse Event Notifications (DAEN) reporting system, which focuses on medicines and medical devices.

As Parker noted in the early days of the regulation of Chinese Medicine practice in Australia, Chinese herbal medicines and other complementary formulations are still not subject to the same rigorous assessment as orthodox prescription medicines.³³

The view of the orthodox medical community may be represented by the Australian Medical Association (AMA), which currently presents a position (see Box 1) on the regulation of complementary medicines, including Chinese medicine.

Box 1. Position statement on: Complementary medicine – 2012 (current)

The majority of complementary medicines do not meet the same standards of safety, quality and efficacy as mainstream medicines as they are not as rigorously tested. Information about the level of testing and evidence should be easily accessible by medical practitioners, consumers and complementary medicine practitioners.

In the absence of sufficient efficacy data, it is essential there be clear and true statements regarding the efficacy and standards of evidence relied on, including accurate labelling.

Government agencies such as the Therapeutic Goods Administration (TGA) and educational bodies such as the National Prescribing Service should ensure information on the safety, quality, efficacy and cost effectiveness of complementary medicines is readily available to consumers and health practitioners.

Consumers and health practitioners should ensure they promptly report any adverse events they suspect are caused by a complementary medicine to the TGA.

The TGA should collate and make available information about adverse events to all health practitioners so that they can inform patients of the potential risks.

In risk based regulation, low risk complementary medicines are not subject to the same level of regulation as orthodox medicines. Known toxic agents such as aconite are generally not available to Chinese Medicine practitioners in Australia, if they are scheduled substances (in the SUSMP)

Low risk Chinese herbal medicines can be entered on the ARTG through a self-declaration process provided the active ingredients and indications (uses) meet with prescribed requirements. If they contain any ingredients other than those prescribed or those for use with more serious conditions, then they are assessed by the TGA before entry on the Australian Register of Therapeutic Goods (ARTG).

Hence, under Australian law, where a product is licensed, every complementary medicine is assessed for the safety and quality of its ingredients, but not always for efficacy. Only complementary medicines that are deemed high risk are assessed for efficacy. The TGA does this by looking at data from clinical trials supplied by the manufacturer. There is potentially a regulatory crossover when looking at AEs or safety matters arising from Chinese medications and safety of practice in prescribing, dispensing or administering these substances.

For the purposes of this paper, the focus will be on issues pertaining to Chinese Medicine practice using medicines and not on issues pertaining to registration or listing by the TGA. Nonetheless, there are a number of ways that harm may arise from Chinese herbal medicines, some similar and some that slightly differ from those arising from acupuncture:

- Poor standard of care – something arising in the health, performance or conduct domains under the National law. These are the type of harms that we search for in the notifications analysis.
- Indirect harm – relying on complementary therapies alone may delay a diagnosis or medical treatment. In the case of serious illnesses, such as cancer, a delay can lead to serious complications or death. These types of issues were found to be the most serious type of AEs in a survey of CAM literature review by RU last year. This type of harm is much more difficult to identify and to determine causality, even in a notifications analysis. Especially if it is a cultural norm for example because of their faith in a traditional approach, many patients will either not realise, or at least not seek to blame or claim.
- Side effects – Chinese herbal medicines can cause unwanted and potentially dangerous adverse effects. These may range from allergic to other kinds of idiosyncratic reactions. If at all, harms arising from medications are easier to identify if they arise proximally to taking a substance, less so for delayed or cumulative toxic effects.
- Contamination or adulteration – substances from steroids to strychnine have been detected in Chinese herbal preparations; botanical misidentification may be a considered to be related to this category.

- Drug interactions – Chinese herbal medicines can interact with over-the-counter and prescription medications. Adverse events from interactions may be preventable if a practitioner takes a suitable medical history. Particular care needs to be taken in patients who take anticoagulant medicines such as warfarin or anti-inflammatory medicines such as aspirin.
- Financial harm – there will be a potential waste of money if any Chinese medicine is not effective or appropriate. The TGA and the Australian Competition and Consumer Commission have strict guidelines on claims made by companies. However, there is no protection under Australian law if a product is bought from overseas.

Shi and others performed an analysis of ADR and associated costs in hospitalised patients in China.³⁴ Table 2 shows the top 20 drugs that caused adverse reactions in rank order from this study. It can be seen that most risk is associated with western medications and the highest traditional medication comes in at number 8 before others are ranked from number 15 within the top 20. The listed traditional medications are given by injection, which are likely to have a greater potential risk of harm than oral medications that are commonly used in Australia. Bearing in mind the lower proportion of Chinese medicines use in Australia would render this ranking not locally comparable, but the table shows the potential for harm that exists.

Table 2. Top twenty pharmaceuticals that caused ADRs in Chinese hospitalised patients

Generic names	No.	Percent
Levofloxacin	192	7.0
Aminomethylbenzoic acid	176	6.4
Vitamin K1	89	3.3
Cefathiamidine	52	1.9
Mezlocillin	48	1.8
Cefoperazone	47	1.7
Ciprofloxacin	45	1.6
Shenmai injection	42	1.5
Compound amino acid	40	1.5
Iopromide	40	1.5
Sodium Aescinate for injection	36	1.3
Diammonium glycyrrhizinate	33	1.2
Cefoperazone sodium and sulbactam sodium for injection	33	1.2
Pefloxacin	33	1.2
Shengmai injection	31	1.1
Shuganning injection	31	1.1
Tanreqing injection	31	1.1
Cefoxitin	31	1.1
Ornithine aspartate	30	1.1
Shuanghuanglian for injection	28	1.0
Tiopronin	27	1.0

Generic names	No.	Percent
Matrine	27	1.0
Cefotiam	27	1.0
Ceftazidime	27	1.0
Ceftizoxime	25	0.9
Cefotiam	25	0.9
Enoxacin gluconate	25	0.9
Piperacillin sodium and sulbactam sodium/three triazole	24	0.9
Fosfomycin	24	0.9
Azithromycin	23	0.8
Potassium aspartate and magnesium	23	0.8
Vitamin B6	23	0.8
Aztreonam for injection	22	0.8
Yadanzi youru zhusheye	20	0.7

Source: Shi Qing-Ping et al

Adverse events leading to harm in community practice using traditional medicines are sometimes difficult to track down specifically to a cause arising from Chinese herbal or other complementary medications. Appropriateness in prescribing needs to be assessed by peers, which is an advantage that Boards have in assessing the quality of a practitioner's practice under the National law. As for idiosyncratic adverse reactions or allergies, for example, or delayed reactions, the source of AEs from medication can be difficult to study.

6.3.6 Adverse drug reactions (ADR) in Chinese medicine

There has been a steady development of drug safety monitoring in China, with the Drug Administration Law of the People's Republic of China (PRC) (2001). From a very low base at the turn of the century, the incidence of ADR reports in China has increased to almost 700,000 per annum in 2009 and 1.398 million ADR/ADE case reports in 2015, including 393,000 new and serious cases 28.2% of the total.³⁵ About 10–15% of the ADR reports received by the National Centre are related to traditional Chinese Medicine drugs and mainly pertaining to the formulated products. In certain cases, the suspension of a particular traditional Chinese Medicine preparation is decided by the China Food and Drug Administration (CFDA).

Presently, the Chinese ADR reporting system might be said to constitute an active pharmacovigilance system, mirroring those established for conventional Western medicines.³⁶ While this system might be used to focus better monitoring and risk-benefit management for post-marketing traditional Chinese medicine drugs in China, how that intelligence may be accessed in Australia is yet to be explored.

In Australia, however, the TGA's DAEN reporting system, which is similar to the CFDA ADR reporting, obviously represents a small volume of reporting. Through this system, the TGA receives AE reports associated with medicines and medical devices, from a wide range of sources, including members of the public, general practitioners, nurses, other health professionals and the therapeutic goods industry.³⁷ Searching the medical devices for acupuncture or Chinese Medicine yields no records. Searching the DAEN (medicines), however, for reported adverse reactions to Chinese herbal medicines from 2001-2017 yields the following:

- Number of reports (cases): 117 (multiple AEs have been reported for some patients).
- Number of cases with a single suspected medicine: 87 (where the TGA judges there is a possibility that the medicine caused the AE).

- Number of cases where death was a reported outcome: 2 (these reports of death may or may not have been a result of taking a medicine). The causes of death are listed as cerebral infarction and hypoglycaemia (hypoglycaemic encephalopathy).

There are significant limitations to the AE information contained in DAEN. The search results do not indicate severity of the AE. The lack of denominators, such as prescriptions made or the number of patients taking a particular medication, also drastically limit the usefulness of these data.

The ADR reports contain information summarising the kinds of effects based on the Medical Dictionary for Regulatory Activities (MedRA) for example, the MedRA “System organ class” and MedRA “Reaction term”. Hence an AE resulting in a facial rash would be listed under “skin and subcutaneous tissue disorders” and “swelling face”.

The TGA cautions that for the purpose of reporting, the causal relationship of taking the medication and the ADR is not necessarily established, nor is information usually collected on all medicines that the subject of the notification may be taking at the time. Additionally, it is likely that in common with regular pharmaceutical ADR reporting, that the number of AE reported is a small proportion of those that occur.

The standard DAEN report does not list the medicine or how many reports by medicine. It is possible to perform searches by each type of medicine.

Some examples of the DAEN outputs are shown in Tables 3 and 4, below.

Table 3. DAEN output for an ADR report involving Wuji Baifeng Wan

Case number ⁱ	Report entry date ⁱⁱ	Age (yrs) ⁱⁱⁱ	Gender ^{iv}	Medicines reported as being taken ^v	MedDRA reaction terms ^{vi}
172111	02/01/2002	38	F	<ul style="list-style-type: none"> • Wuji Baifeng Wan (Chinese Medicines) - Suspected • Ventolin (Salbutamol) - Not suspected 	<ul style="list-style-type: none"> • Anxiety • Cold sweat • Euphoric mood • Palpitations

Table 4. DAEN output for an ADR reports involving combinations of Chinese herbal medicines

Case number ⁱ	Report entry date ⁱ	Age (yrs) ⁱⁱⁱ	Gender ^{iv}	Medicines reported as being taken ^v	MedDRA reaction terms ^{vi}
191615	27/10/2003	74	M	<ul style="list-style-type: none"> • Cathay Herbal Long Dan Xie Gan Wan Gentiana (Chinese Medicines) - Suspected • Lipitor (Atorvastatin) - Suspected • Tong Ren Tang Psoriasis Suppressor (Ke Yin Wan) (Chinese Medicines) - Suspected • Tripterigium (Herbal Medicines) - Suspected 	<ul style="list-style-type: none"> • Tubulointerstitial nephritis
212316	07/10/2005	55	F	<ul style="list-style-type: none"> • Tong Ren Tan Tinnitus Herbal Treatment (Liu Wei Di Huang Wan) (Chinese Medicines) - Suspected • Tong Ren Tang Women's Treasure Pills (Kun Bao Wan) (Chinese Medicines) - Suspected 	<ul style="list-style-type: none"> • Malignant hypertension • Pupils unequal • Retinal haemorrhage • Vision blurred
243284	29/07/2008	44	F	<ul style="list-style-type: none"> • Tian Wang Bu Xin Dan (Chinese Medicines) - Suspected 	<ul style="list-style-type: none"> • Hepatitis
251768	02/06/2009	-	F	<ul style="list-style-type: none"> • Shen Neng Sheng Hua Wan (Chinese Medicines) - Suspected • Tian Wang Bu Xin Dan (Chinese Medicines) - Suspected 	<ul style="list-style-type: none"> • Headache

A better understanding of (i) the mechanisms and timing of various reactions (such as allergies and toxic responses), (ii) interactions between Chinese herbal medicines and pharmaceutical drugs, and (iii) the traditional Chinese medicine concepts and related interpretation of Chinese medicine effects (such as mutual contraindications in Chinese medicine combinations) may make it possible to better use Chinese herbal medicines as prescribed treatments with more confidence and respond to concerns accurately and authoritatively.³⁸

The role that the Board might play in facilitating the better understanding of AEs from acupuncture, Chinese herbal medicines and other Chinese Medicine techniques will be informed by understanding any patterns of complaints, described below.

7. Notifications analysis

7.1 Background

Chinese Medicine joined the National Registration and Accreditation Scheme (the National Scheme) in July 2012. Notifications and complaints data relating to Chinese Medicine practitioners are an important source of information for regulatory decision-making, especially where harm or potential harm is demonstrated. This analysis relates to all notifications and complaints received by AHPRA within the reference period of 1 July 2012 to 31 December 2016.

During this reference period, the Chinese Medicine Board Australia and AHPRA managed the registration of all Chinese Medicine practitioners, and all notifications relating to Chinese Medicine practitioners (except those managed by the Health Professionals Councils Authority in New South Wales or the Office of the Health Ombudsman in Queensland, which are co-regulatory jurisdictions).

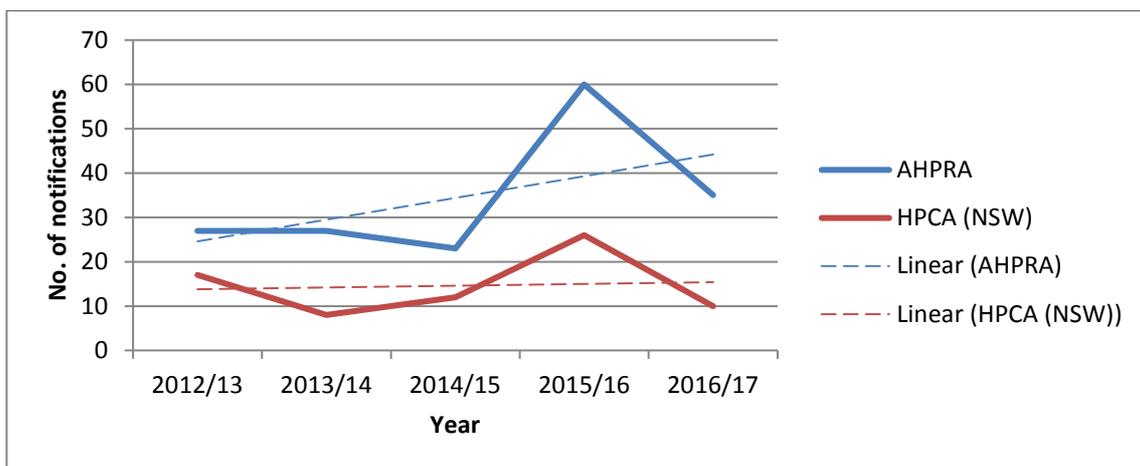
In NSW, the Health Professional Councils Authority (HPCA) and the Health Care Complaints Commission (HCCC) work together to assess and manage complaints about practitioners' conduct, health or performance that relate to practitioners primarily registered in NSW. AHPRA has a limited role in accepting mandatory notifications that occur in NSW and referring them to the HCCC. Similarly, co-regulation with the Office of the Health Ombudsman (OHO) in Queensland, which commenced in 2014, means there are notifications dealt with by the Office which are not available for review by AHPRA. While the lack of NSW and OHO data is a limitation to the present analysis, an extended project may be possible in the future once arrangements for data access can be made with the co-regulators.

For research purposes, a data extract (master extract) was provided by AHPRA's Business Services directorate based on information mainly held within AHPRA's "Pivotal"³⁹ database, and processed in a manner consistent with AHPRA's Corporate Reporting rules (some RU- business rules were required to improve data quality and coherence). This master extract contains critical categorical registration data for all practitioners registered in Australia since the establishment of the National Scheme, and core categorical data for all notifications managed by AHPRA and the Boards.

Due to existing data sharing agreements, AHPRA also receives a minimal set of categorical unit-record data (including practitioner ID, date received, issue category and outcome and stream) for those cases that are primarily managed by the HPCA or OHO. This allowed AHPRA to include these cases in the initial broad notification analyses, but not in the deep-dive analysis as we do not have access to the free-text case information regarding these complaints.

This extract also includes many notifications that were received prior to 1 July 2010 but transitioned across at the time of commencement into the National Scheme. Notifications prior to 2012 have not been counted in this analysis. Figure 1 shows that, while annual incidence is low compared to other NRAS professions, since 2012 there is an increasing trend in notifications received by AHPRA regarding Chinese Medicine practitioners, whereas the overall level of complaints in NSW is relatively unchanged.

Figure 1. Board Notifications to AHPRA (blue) and HPCA (red), by date received [N=172]*.



*Note: Notification numbers may vary slightly from Annual Reports due to slightly different business rules

7.2 Broad quantitative study

Table 5 shows the breakdown of notifications by stream and by notification category.

Table 5. Chinese medicine notification categories by stream and category (2012/13-2016/17).

Stream	Category	Count
Conduct		67
	National Law Breach	15
	NLO – Managed under Part 8	9
	Billing	7
	Boundary Violation	7
	Clinical Care	6
	Behaviour	5
	Offence	4
	Communication	3
	Documentation	3
	Other	8
Performance		46
	National Law Breach	7
	Clinical Care	15
	Communication	4
	Documentation	4
	Infection/Hygiene	4
	Other	12
Health		4
	Health Impairment	4
Unknown		71
Total		188

7.3 Notifier gender

Of those notifications where the gender of the notifier was known, 72% of notifiers were female, and of these 45% notified about conduct matters and 38% concerning performance. It is interesting to note that these percentages are very similar to the overall notification rates by stream, which indicates there are minimal gender differences in the notification profile by stream.

7.4 Deep-dive

To better understand the factors that might be driving the increasing trend in Board notifications which in turn relate to increased risk of public harm, a deep-dive analysis of notifications was performed. This analysis of notifications involved a detailed examination of case file notes in AHPRA's TRIM records management system, in order to as much as possible determine the nature and true extent of harms.

7.4.1 Scope

Of the 188 notifications and complaints in the previous analysis, the following exclusion criteria were applied. Any matter that met at least one of these criteria, was excluded from the deep-dive analysis:

- Matters referred to and/or only dealt with by the Office of the Health Ombudsman in Queensland or the NSW Health Professional Councils Authority (this is because we did not have access to the full case file for these matters).
- Matters that did not contain sufficient particulars to proceed to assessment or investigation, or where the Board decided there were no grounds for notification.
- Those cases where there were duplications, such as where one practitioner had more than one notification concerning the same incident or event. These situations also included where there were disputes between practitioners, Chinese medicine or otherwise, say in a dispute about social media or other practice issues.
- Purely advertising matters as these are usually dealt with by the AHPRA Statutory Offences Unit

7.5 Findings

A total of 56 notifications (out of the original 188) resulted after the exclusion criteria were applied. Outcomes from these notifications are shown in Table 6. Collectively, these matters essentially represent the most serious end of the spectrum of regulatory burden experienced by the Board.

Table 6. Outcomes from final Board study dataset

Outcome	Number
No further action	16
Caution	12
Impose conditions	9
Tribunal	7
Other	12
Total	56

Table 7 shows the notifications counts by jurisdiction. As an aid, the number of registered Chinese Medicine Practitioners as at June 30, 2016 is also included. South Australia appears to have a higher notification rate than the other states, however given the smallness of numbers this should be considered indicative only.

Table 7. Number of notifications and registrations by jurisdiction (for the deep-dive study set)

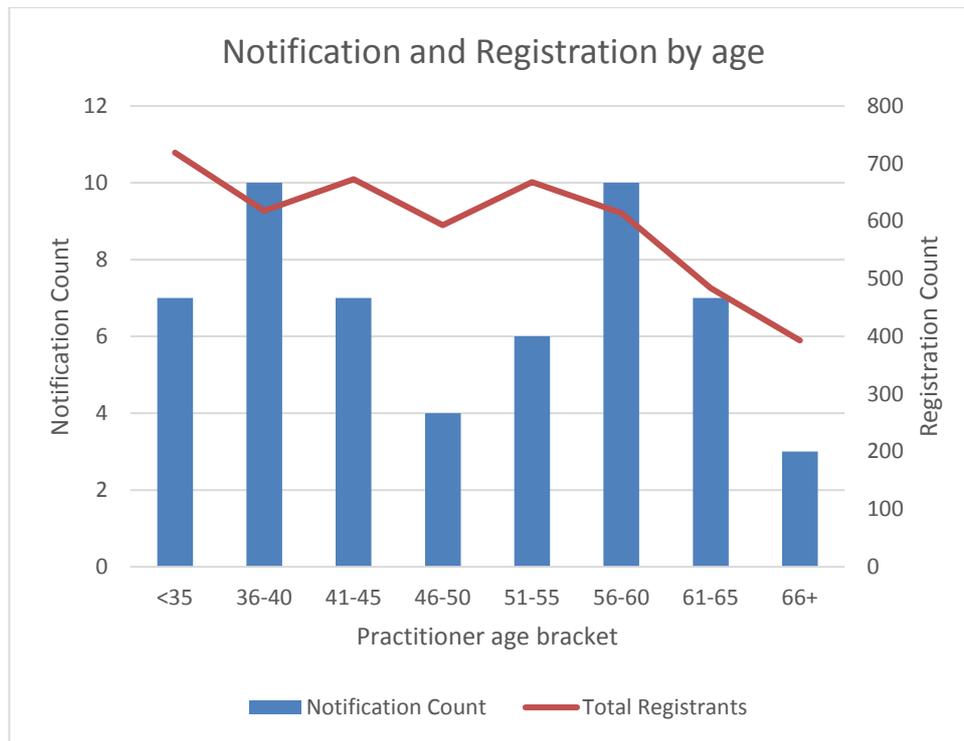
Jurisdiction	Number of notifications	Registered Practitioners (June 30, 2016)
Vic	25	1,289
Qld	16	862
SA	8	183
Other	7	353
Total (excl NSW, QLD)	56	2,687

Figure 2 depicts the frequency distribution of age group and gender of the notified practitioners. The distribution is bimodal with peaks between the ages of 36-45 and 51-65. As an indication of the age denominator profiles, the red line is the total registrant base (including NSW and Qld) for June 30, 2016. Comparing the notification counts with this denominator, shows that these the notification rates peak for the age bracket 36-45, as well as the age brackets 55-60 and 61-65 years.

Furthermore, it can be seen that the overall ratio of notifications by gender is 3:2, male to female. Given that there are generally 20% more female registered Chinese medicine practitioners than male practitioners, it means that the notification rate for male practitioners is about 1.8 times higher than for female practitioners. This difference in notification rates by gender is similar to what is observed in most of the other professions regulated by AHPRA.

Furthermore, the increased notification counts and rates for practitioners aged 56-60 year olds, is also similar to what is seen in other professions.

Figure 2. Distribution of notifications by practitioner age group (N=55)



Notes: The blue bars depicts the counts of all deep dive notifications received during the reference period (N=56) excluding one notification where the gender of the practitioner was unknown. For reference, the red line indicates the number of practitioners registered as at June 2016.

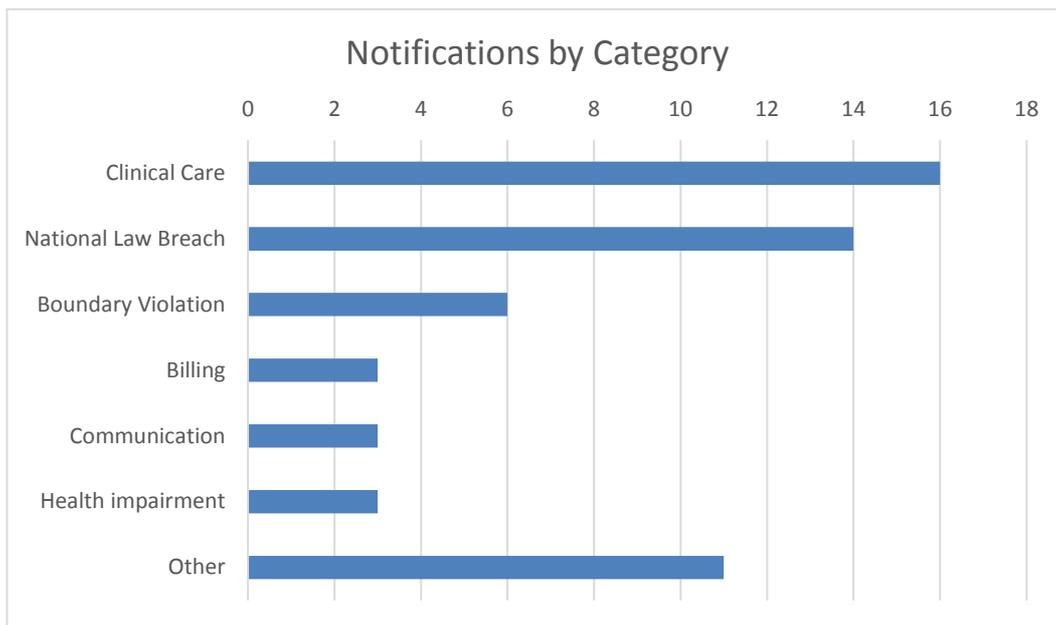
Examining the notifications by notification stream and practitioner gender, Table 8 shows that there were more matters concerning conduct (63%) than performance (25%), and more male practitioners where conduct was an issue (Note that the numbers do not necessarily add up to 56 as some cases were coded as both conduct and performance.)

Table 8: Notifications by stream and gender

Stream name	Female	Male	Total
Conduct	14	22	35
Performance	6	8	14
Health	<4	<4	<4

The breakdown of notifications by issue category is shown in Figure 3.

Figure 3. Board notifications broken down by issue category (N=56)



Note: AHPRA codes notifications into a range of different categories. However, for confidentiality reasons, in this table notification counts for all the less frequent categories have all been aggregated in 'other' category.

Harm Analysis

Consistent with AHPRA's aims to be a risk-based regulator, all notifications in the deep-dive dataset were classified on a harm scale using the Patient Safety Event Taxonomy (PSET) developed by Chang *et al* for the Joint Commission on Accreditation of Healthcare Organizations.⁴⁰ This classification requires separate coding of the level of psychological and physical harms coding each on a scale of 1 to 10, and then these two fields are combined into a single aggregate 10-point scale which corresponds to the most severe of these two dimensions.

As harm levels are not typically recorded in Pivotal, two members of the RU coded each of the 56 cases separately. As there was considerable similarity between the two, the table shows only the value recorded by the primary coder. It is expected that future efforts for other RU analytical reports will further develop this coding process. This will allow for more reliable and defensible harm ratings, including the reporting of inter-rater agreement.

Further note that for this harm coding taxonomy:

- ***Minimal temporary harm applies to physical harm***
- ***Mild temporary harm applies to psychological harm***

It can be seen from the results of this pilot coding exercise in Table 9, that most of the notifications resulted in low or no detectable levels of harm. Where harm was recorded at a moderate level, mostly it was only temporary. In only three cases was the sequelae coded as more serious than moderate-temporary in nature.

Furthermore, there does not appear to be any notable difference in severity of harms by the gender of practitioner who was the subject of the notification.

Table 9. PSET Scale of harms for deep dive notifications (N=56) by gender.

Harm level	Female	Male	n/a	Total
No harm	16	22		38
Mild temporary harm. Minimal temporary harm	-	-		6
Mild permanent Harm Moderate Temporary Harm	4	4	1	9
Moderate Permanent Harm Severe Temporary Harm Severe Permanent Harm Death	-	-		3
Total	20	26	1	56

Note: Some cells in this table have been suppressed for confidentiality reasons.

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