# Adverse reactions to acupuncture: policy recommendations based on practitioner opinion in New Zealand

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## ABSTRACT

Acupuncture risk/benefit assessment relies heavily on the accurate reporting of negative outcomes. For such reports to be valid they must employ standardised terms which hold the same meaning and weighting for each reporting practitioner. A postal questionnaire was undertaken to explore the understanding of descriptive and evaluative terms associated with adverse reactions to acupuncture held by a sample of New Zealand acupuncture practitioners. Volunteers were sought from the Physiotherapy Acupuncture Association of New Zealand (PAANZ) (n=287) and Medical Acupuncture Society of New Zealand (MASNZ) (n=58). Data were analysed using descriptive methods and a series of item reduction and decision rules. The response rate was 42% (n=135) with a moderate endorsement (48%) for the preferred definition of an adverse reaction being *any adverse effects possibly related to acupuncture making treatment necessary or severely interfering with the patient's wellbeing.* Vomiting, seizure and convulsion were all classified to be 'adverse reactions' in a categorisation task carried out by the respondents. A low consensus of opinion was displayed when respondents considered timeframes for reporting and patient perception was weighted as the least important factor in the decision to report an adverse reaction. Recommendations are made for future adverse reaction to acupuncture reporting policy formation based on these research findings.

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## INTRODUCTION

Media coverage of large contemporary epidemiological studies highlighting harm due to medical management, has brought the concept of 'adverse reactions' to the fore (Small and Barach 2002). This concept, which was originally defined for the drug pharmacovigilence in Western medicine (Alvarez-Requejo et al 1998), also has relevance to the domain of acupuncture.

The frequency of adverse reactions to acupuncture (ARA) has been extensively reported in studies ranging geographically from Australia (Bensoussan et al 2000) to China (Zhang et al 2010) to population sub-groups as disparate as paediatrics (Adams et al 2011) and adult outpatients (Endres et al 2004). However, the wide variation in the terminology, particularly in relation to the definition of an adverse reaction to acupuncture, greatly limits any ability to draw comparisons between such studies (White 2004). The problem of gaining accurate information about adverse reactions to acupuncture is compounded further by the loose and synonymous use of nomenclature of terms such as 'adverse reaction', 'adverse event', 'adverse effect', 'complication' and 'side effect' (White 2004).

It is not known if the key terms used to describe a negative outcome to acupuncture are held in the same regard by practitioners and interpreted with the same relative weighting or meaning (MacPherson et al 2004, Norheim and Fonnebo 2000). It is interesting to note that although researchers have surveyed patients' understanding of an 'adverse reaction', (Ernst et al 2004, MacPherson et al 2004, Park et al 2009, Witt et al 2009) practitioner awareness and comprehension has been neglected. Norheim and Fonnebo (1996) indirectly reflected on practitioners' concepts of an 'adverse reaction' by investigating the experiences of doctors and acupuncturists regarding adverse reactions to acupuncture. In this latter study, practitioners were asked to reflect and retrospectively report on the question, "Have you ever in your practice met patients with acupuncture adverse effects?" and volunteered information on reactions they had witnessed and perceived to have been adverse (Norheim and Fonnebo 1996).

Both Western and traditional Chinese acupuncturists still lack accepted standards and systems for the collection and reporting of adverse reactions that utilise standardised disease classification systems and include sufficient detail of the event to establish causality (Lee et al 2005). Early knowledge about the safety of acupuncture has arisen primarily from largely anecdotal evidence and case reports of adverse effects (Ernst and White 2001, Vincent 2001). Internationally, there is scarce information on reporting systems used for adverse reactions to acupuncture, with researchers tending to collect reports on a national basis to try to establish incidence rates (Ernst and White 2001, Park et al 2010, White et al 2001a). Sound safety processes are imperative with the acceptance of and demand for acupuncture increasing (Pirotta et al 2000, Charles 2007).

In New Zealand (NZ) 3.6% of all physiotherapy-related treatment injuries accepted by the Accident Compensation

Corporation (ACC) between 2005 and 2011 were acupuncture-related, with three claims deemed to be of a major consequence according to ACC's level of harm criteria (Johnson et al 2012). Although guidelines for case reporting (Peuker and Filler 2004) and neurophysiological mechanisms based classification of adverse reactions to acupuncture (McDowell et al 2011a) have been proposed, there is little evidence that they have been adopted into national guidelines or common practice for all practitioners in NZ to date. Physiotherapists practicing acupuncture in NZ have the opportunity to participate in a voluntary reporting system promoted by Physiotherapy New Zealand (PNZ) though no such scheme exists for general medical practitioners in this country. Confusion over the adverse reaction terminology pertaining to acupuncture is likely to be an influential factor in the number and type of incidents registered with PNZ.

There is a need to clarify the terminology relating to adverse reactions to acupuncture internationally, and more specifically within the NZ context, in order to develop a more robust adverse reaction reporting system for acupuncture practitioners. This paper reports on a survey of a sample of NZ physiotherapy and general medical practitioner acupuncturists (hereafter called "practitioners"). The aims of the survey were threefold: 1, to identify whether the practitioners had a preferred definition for an adverse reaction to acupuncture, 2, interpreted key words pertaining to the concept (being prone to synonymy) in the same way and 3, which signs and symptoms were considered to be adverse reactions. Additional information was sought on reporting thresholds and time frames to establish whether under or over reporting occurred within the group. The intention was to make policy recommendations based on their responses.

## METHODS

### Questionnaire development

A custom-designed questionnaire examining descriptive and evaluative terms associated with adverse reactions to acupuncture held by practitioners, comprising 101 items, was developed for the purposes of this research (McDowell 2007). The questionnaire development and retest reliability of the visual analogue scales (VAS) and categorisation tasks used in the questionnaire have been described previously (McDowell et al 2011b).

#### *Survey Participants*

The members of the Physiotherapy Acupuncture Association of New Zealand (PAANZ), a special interest group of the PNZ (n=287) and the members of the Medical Acupuncture Association of New Zealand (MASNZ), a special interest group of the Royal College of General Practitioners (n=58) were selected to be surveyed as identifiable subgroups. At the time of the survey, PAANZ and MASNZ had the most readily accessible memberships out of the 14 identifiable acupuncture groups practising in NZ and were, at this time, two of only four groups with a registration body providing scope and standards of practice.

The majority of PAANZ and MASNZ members, regardless of whether they were practising traditional Chinese and Western acupuncture, would have had an undergraduate education based on a Western medical paradigm and an assumption was made here that this group would be familiar with medical adverse reaction terminology. Exclusion criteria were applied to those individuals who had participated in the pilot study (McDowell et al 2011b), along with those members of PAANZ or MASNZ who were neither physiotherapists nor general practitioners. Participants were required to be residing in NZ at the time of the survey. It was estimated that a response rate of 60% could be achieved from the PAANZ and MASNZ groups giving a margin of error of 7.2%.

The University of Otago Human Ethics Committee granted ethics approval for the survey (no: 06/302). Both PAANZ and MASNZ consented to forward the questionnaires to their members on behalf of the principal researcher. All participants provided written informed consent prior to undertaking the survey.

#### *Procedure*

The delivery of 319 questionnaires, introductory letter, written consent form and a return envelope was administered by the PAANZ and MASNZ secretariats. On their return a research assistant separated the consent forms from the questionnaires to maintain participant anonymity from the principal researcher. Reminder group emails regarding completion of the questionnaire were sent 14, 28 and 40 days working days following the initial mail out in order to optimize the response rate.

#### *Data analysis*

Data from the survey results were recorded using SPSS-13.0 (SPSS Inc., Chicago, IL). The descriptive characteristics (means, medians, standard deviations (SD) and ranges) were calculated for the questions on population demographics reporting timeframes and thresholds. A VAS was used to assess the synonymy of key terms ratings of symptoms as an adverse reaction and agreement level with six adverse reaction-reporting statements. These were also subjected to descriptive data analysis and an *a priori* decision process (McDowell et al 2011b).

Levels of endorsement were calculated by recording absolute and cumulative frequencies of item selection using ranking responses regarding definition preference, seriousness of key terms and factors influencing adverse reaction reporting. A three step decision rule (Fernandez and Boyle 2001) was applied to the symptom and sequelae categorisation task responses (McDowell et al 2011b).

The internal consistency of responses was assessed by comparing the results of the question evaluating ratings of symptoms as an adverse reaction to acupuncture to the symptom categorisation task. The best indicator of the location of central tendency was taken from the question evaluating rating of symptoms of an adverse reaction to acupuncture. If the difference between the mean and median exceeded 1.4 VAS points then the median was taken as the best indicator of central tendency for the comparison. Here it was reasoned that symptoms that were rated highly as being adverse reactions would be categorised similarly in both tasks. The free text generated in response to the question examining agreement with adverse reaction reporting statements was searched for key comments and the frequency of their appearance was assigned to identifiable themes.

## RESULTS

One hundred and thirty five of the 319 eligible members who met the study inclusion criteria responded to the questionnaire, giving a response rate of 42%. One hundred and twenty three responses were from the PAANZ group (123/287, 46%) and 12 from the MASNZ group (12/58, 23%), yielding a sex proportionate and a moderately sex proportionate sample of the memberships respectively.

### *Data quality*

A total of 101 items from 18 questions per questionnaire were tabulated. Missing data for responses were low (range 0 to 12.3% per question). A total of 125 of a possible 12690 responses were missing (2%). Forty four percent of respondents endorsed all 101 responses (100% complete data), 26% missed one response, 5% missed out two responses and 10% missed out three responses. The calculated margin of error for this study with the 42% response rate was 8.6% (Rumsey 2003).

### *Questionnaire responses*

The demographics of the PAANZ and MASNZ respondents are summarised in Table 1. The mean age of the respondents was 42.7 years (SD 9.6; range 24-75 years), with a mean year of acupuncture experience of 10.7 (SD 7.1; range 0.3-35 years). In terms of personal experience, 113 respondents (84%) had observed an adverse reaction in their own patient cohort, with a further 44% (60/144) recalling an experience of an adverse reaction in colleagues' patients. Only 27% of respondents had ever reported an adverse reaction, with typically only one report (20/135, 15%) in the entirety of their career.

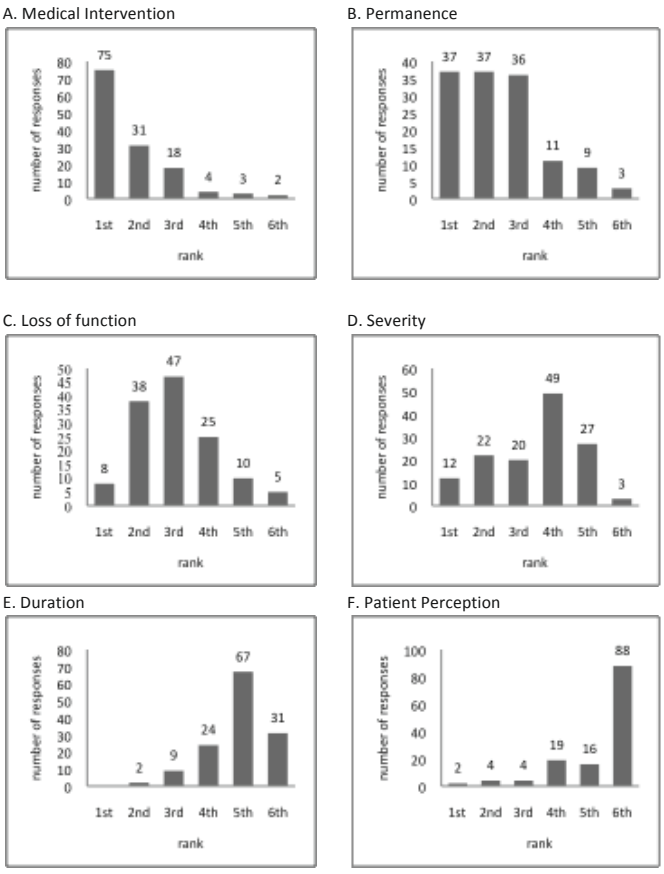
**Table 1: Demographics of survey respondents (n=135)**

| | | Frequency (max n=135) | Percent (%) |
|---|---|---|---|
| Sex | Male | 29 | 21.5 |
| | Female | 106 | 78.5 |
| Ethnicity | Cook Island Maori | 1 | 0.7 |
| | Maori | 3 | 2.2 |
| | Other | 21 | 15.6 |
| | New Zealand European | 107 | 79.3 |
| Highest acupuncture qualification | NZQA Qualification | 5 | 3.7 |
| | MASNZ Course | 6 | 4.4 |
| | Other | 8 | 5.9 |
| | University qualification | 26 | 19.3 |
| | PAANZ Introductory course | 90 | 66.7 |
| Area of practice | Public | 15 | 11.1 |
| | Private | 120 | 88.9 |

The data yielded a moderate consensus level amongst the respondents (~48% - based on a first or second preference option) for their preferred definition of an adverse reaction to acupuncture (*any adverse effects possibly related to acupuncture making treatment necessary or severely interfering with the patient's wellbeing*).

Fifty six percent of the respondents rated *the need for medical intervention* as the most important factor when making the determination to report an adverse reaction (Figure 1A-F). Seventeen percent of respondents indicated they would report a 'mild' adverse reaction. Levels of reporting increased to 71% when the adverse reaction was viewed in the context of being 'moderate' and to that of 98%, in the case of 'severe' (Table 2). A wide variation of up to 10 days between respondents in the threshold of symptom duration before they would initiate a report, regardless of whether the adverse reaction was considered to be a complication, side effect, or adverse reaction was reported.

**Figure 1A-F: Ranking of significance held by survey respondents (n=135) of the factors A. medical intervention, B. permanence, C. loss of function, D. severity, E. duration and F. patient perception, on the reporting of an adverse reaction to acupuncture**




The sequelae of pneumothorax, infection, pseudoaneurysm, neuropraxia and fainting showed a lack of internal consistency between being rated as an 'adverse reaction' and their assignation into the 'adverse reaction' domain. Only three sequelae were able to be categorised as an 'adverse reaction' (vomiting, convulsion and seizure) while 20 symptoms displayed bimodal or multimodal distributions across the key categories of 'malpractice', 'side effect', 'complication' and 'adverse reaction' (Table 3). Vasovagal responses commonly witnessed with

**Table 2: Reporting patterns of survey respondents when considering quantifier and key word combinations to describe an adverse reaction (n=135)**

| Reporting of | | Agree | Disagree | No response |
|---|---|---|---|---|
| | | Frequency max (n=135) (%) | Frequency max (n=135) (%) | Frequency max (n=135) (%) |
| Mild | Side effects | 1 (0.7) | 132 (97.8) | 2 (1.5) |
| | Complications | 17 (12.6) | 116 (85.9) | 2 (1.5) |
| | Adverse reactions | 17 (12.6) | 116 (85.9) | 2 (1.5) |
| Moderate | Side effects | 49 (36.3) | 84 (62.2) | 2 (1.5) |
| | Complications | 83 (61.5) | 49 (36.3) | 3 (2.2) |
| | Adverse reactions | 96 (71.1) | 37 (27.4) | 2 (1.5) |
| Severe | Side effects | 124 (91.9) | 9 (6.7) | 2 (1.5) |
| | Complications | 131 (97) | 2 (1.5) | 2 (1.5) |
| | Adverse reactions | 132 (97.8) | 1 (0.7) | 2 (1.5) |

needling failed to be categorised (faint, feeling cold) despite their frequency in practice and practitioners disagreed whether pneumothorax was malpractice (50%) or a complication (36%).

'Complication' was ranked as the key term with the second most serious connotation by 49% of respondents but was given a considerably lower ranking (ranked fourth with 37%) when the quantifier 'moderate' was applied (Figure 2A-F). Thirty six percent of respondents would not report a moderate complication, while only 27% would not report a moderate adverse reaction (Table 2).

The sequelae of pneumothorax, cardiac tamponade, infection, pseudoaneurysm, and neuropraxia were ranked strongly as being adverse reactions (median values 4.8, 4.8, 4.7, 3.8, and 3.7 VAS points respectively) yet failed to be recognised as such under the domain of an adverse reaction in the categorisation task. The use of quantifier and qualifiers altered reporting thresholds and timeframes, and respondents demonstrated wide standard deviations when considering key terms for synonymy (range 2.25 – 3.23 VAS points), highlighting a divergence of opinion and interpretation of meaning (Table 4).

The results indicated that the MASNZ respondents required mild or moderate reactions to be present for longer (mean 16, SD 26 days) than the PAANZ respondents (13, SD 10 days) before making the decision to report. The MASNZ respondents considered the symptom of fainting to be less serious than the PAANZ group, ranking fainting on average 2.2 VAS points lower than their counterparts as 'being an adverse reaction'. The MASNZ respondents also displayed less extreme opinions on the statements pertaining to adverse reaction reporting and the synonymy of the terms 'malpractice' and 'side effect' to the term 'adverse reaction'. Unlike the PAANZ group the MASNZ respondents weighted permanence (50%) and loss of function (50%) above that of the need for medical intervention as important factors in their decision to report an adverse reaction.

## DISCUSSION

The results of the survey conducted on the NZ practitioners who were sampled confirmed the suspicion of under-reporting

**Figure 2A-F: Ranking signifying perceptions of seriousness of the key terms used to describe an adverse reaction to acupuncture held by survey respondents (n=135) in the case of A. adverse event, B. complication, C. adverse event, D. adverse reaction, E. adverse effect and F. side effect**

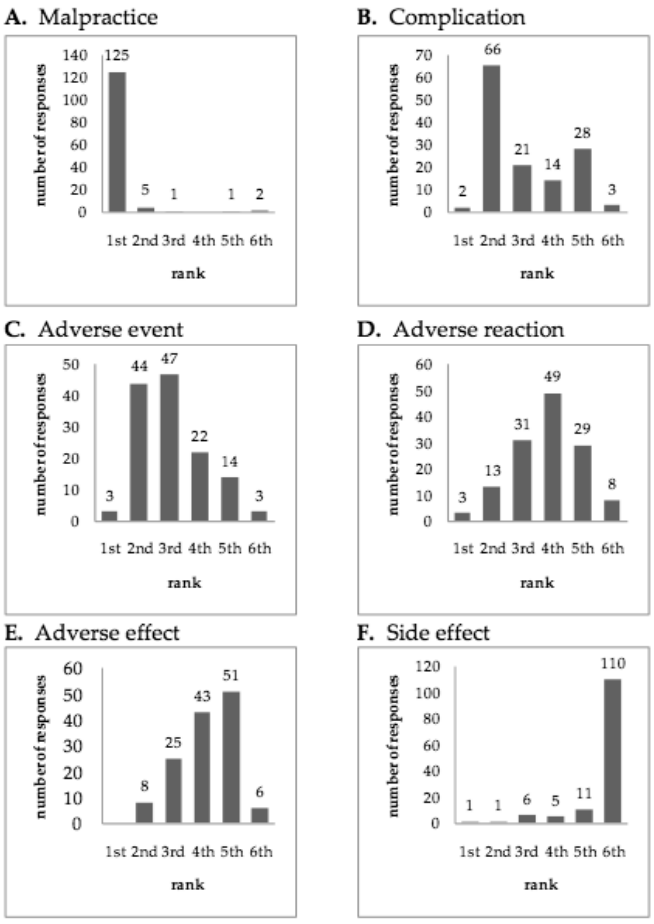


**Table 3: Categorisation status of acupuncture symptoms according to the domains of known side effect, adverse reactions, complication and malpractice.**

| Distribution | Symptoms | Domains (max n=135) | | | |
|---|---|---|---|---|---|
| | | Known side effect | Adverse reaction | Complication | Malpractice |
| Unimodal* | Sleepiness | 124 | 8 | 1 | - |
| | Euphoria | 120 | 4 | | - |
| | Point bleed | 115 | 5 | 11 | - |
| | Tiredness/malaise | 111 | 16 | 5 | - |
| | Sweating | 101 | 26 | 5 | - |
| | Pain at needle site | 100 | 21 | 14 | - |
| | Bruising | 88 | 22 | 24 | - |
| | Vomiting | 18 | 104 | 7 | - |
| | Convulsion | 1 | 101 | 24 | 4 |
| | Seizure | - | 98 | 24 | 4 |
| | Perichondritis | 1 | 36 | 67 | 19 |
| | Spinal cord lesion | - | 5 | 10 | 108 |
| | Hepatitis | 2 | 5 | 17 | 99 |
| | Forgotten needle | 3 | 9 | 16 | 87 |
| | Cardiac Tamponade | - | 14 | 21 | 72 |
| Bimodal** | Faint | 49 | 78 | 9 | - |
| | Feeling cold | 70 | 37 | 8 | 1 |
| | Headache | 39 | 72 | 20 | - |
| | Paraesthesia | 19 | 63 | 39 | 5 |
| | Pneumothorax | - | 19 | 49 | 69 |
| Multimodal** | Abscess | - | 25 | 62 | 30 |
| | Aggravation of symptoms | 58 | 58 | 20 | - |
| | Endocarditis | - | 18 | 23 | 47 |
| | Granuloma | 8 | 34 | 35 | 1 |
| | Haematoma | 41 | 58 | 36 | 2 |
| | Infection | 1 | 34 | 63 | 32 |
| | Insomnia | 51 | 48 | 14 | - |
| | Myositis | 6 | 47 | 52 | 9 |
| | Nausea | 63 | 57 | 11 | - |
| | Neuropraxia | 3 | 48 | 54 | 21 |
| | New symptoms | 20 | 51 | 27 | - |
| | Osteomyelitis | - | 23 | 42 | 32 |
| | Peritonitis | - | 23 | 35 | 38 |
| | Pseudoaneurysm | 3 | 25 | 33 | 12 |
| | Psychiatric disturbance | 7 | 57 | 30 | 1 |

*achieving categorization; **failing categorisation

of adverse reactions to acupuncture. It was found only 27% of respondents had ever formally reported such an event to an external body, even though 84% of respondents recalled seeing an adverse reaction in one of their own patients. The respondents in this study also expressed uncertainty about reporting reactions of a minor nature and were unclear about the boundaries between their documentation in patient notes and reporting to an external body. The level of under-reporting identified in this current study is in keeping with 39-90% levels reported in the drug literature (Alvarez-Requejo et al 1998, Belton et al 1995, Pirmohamed et al 1998, Sweis and Wong 2000) even though drug-drug and multi-drug interactions tend to result in higher reporting levels (Leone et al 2010).

Overall, the respondents in this survey considered that physiological responses to acupuncture fell outside the domain of an adverse reaction agreeing with Yamashita et al (1999) who considered that symptoms and sequelae, such as pain at the needle site and minor bleeding, were an inevitable consequence

**Table 4: The median, mean (standard deviation) and difference between median and mean scores from the visual analogue scales for the perceived synonymy of key terms associated with adverse reactions to acupuncture held by survey respondents (n=135)**

| | Median | Mean (SD) | Difference between median and mean scores |
|---|---|---|---|
| Adverse effect & adverse reaction | 3.7 | 3.0 (2.3) | 0.7 |
| Adverse event & adverse reaction | 1.5 | 0.8 (3.2) | 0.7 |
| Complication & adverse reaction | -1.3 | -0.8 (2.9) | 0.5 |
| Side effect & adverse reaction | -2.0 | -1.0 (3.2) | 1.0 |
| Medical error & adverse reaction | -4.7 | -3.5 (2.8) | 1.2 |

Ranking on a +5 to -5 visual analogue scale: An *a priori* decision was made to interpret the VAS score responses as being strongly negative if they fell between –5.0–3.5, moderately negative between 3.5–2.1, and mildly negative between 2.1–0.7. Corresponding interpretations were given for scores in the affirmative direction with neutral being interpreted between –0.7 and 0.7.

to acupuncture even in careful standard treatment. While some authors argue that neither the expectancy (White et al 2001b) nor transience (MacPherson et al 2001) of a physiological response should preclude it from classification as an adverse reaction, practitioners often decline to report their presence due to their minimal influence on the patient's well-being, and their "commonality" (Grabowska et al 2003). Whilst patients may beg to differ (Odsberg et al 2001), respondents in this study weighted the patients' perception as being the least important factor in the determination to make an adverse reaction report. GP's were less influenced by the need to seek medical intervention as a factor in reporting. Potentially this could be due to their ability to use their own medical skill to address the reaction or their greater years average of acupuncture experience.

In this study, there was only a moderate consensus level of (48%) for the definition *'any adverse effects possibly related to acupuncture making treatment necessary or severely interfering with the patients well-being'*. Some researchers have used broad umbrella definitions with sub-classifications to fully describe their concept of an adverse reaction to acupuncture (MacPherson et al 2001, Melchart et al 2004, White et al 2001a) in order to deal with the complexities of generating an all-encompassing definition. Melchart et al (2004) prefaced a broader general definition "any adverse event possibly related to acupuncture", before sub-classifying further, using the definition endorsed by the respondents above to describe 'serious adverse effects'. The use of such sub-classifications may be a practical solution allowing the separation of technically preventable reactions (malpractice/negligence) and minor transient reactions (which respondents felt should not be reported to an external body), from unpredictable serious adverse reactions.

An alternative method of sub-classification is already utilised by the pharmacological profession, where adverse drug reactions are defined as either Type A or Type B reactions (Medicines and Healthcare Products Regulatory Agency 2005). From a neurophysiological perspective, Type A acupuncture adverse reactions such as fainting or vomiting could be considered an augmentation of the physiological actions of acupuncture, being dose dependent (number of needles, retention time, stimulation) and readily reversible on reducing the dose or withdrawing the needle/treatment (McDowell et al 2011a). Type B acupuncture adverse reactions could encompass any bizarre and unpredictable responses distinct from the known reactions to or effects of acupuncture (McDowell et al 2011a), leaving practitioner error as a category to explain tissue trauma such as pneumothorax, cardiac tamponade, and pseudoaneurysm. Utilising this framework could reduce the difficulties established by this survey with the interpretation of nomenclature by practitioners in NZ.

It is not known how many physiotherapists or general practitioners, practise acupuncture without maintaining a membership with their respective professional acupuncture bodies. Other professional and lay acupuncture groups practicing in NZ at the time of survey were not included and reporting discrepancies may not be inferred nationwide. Consequently, a noted limitation to this study was that study cohort was not representative of the entire population of practising acupuncturists within NZ. A sample bias may be inferred by the utilisation of the PAANZ and MASNZ groups who had accessible secreteriats known to the author at the time of the survey. The survey did not establish whether English was a second language, which also may have had some bearing on the practitioners' ability to interpret the terminology used in the questionnaire.

It is recognised that clinicians may feel more protective of a modality which is heavily incorporated into their practice, and therefore have a vested interest in under reporting problems (White et al 2001a). However, it may also be argued that PAANZ and MASNZ members are more likely to report adverse reactions than non-members due to their commitment to postgraduate education and professional development, their ready access to policy documents on acupuncture safety, along with exposure to professional newsletters. A sample bias may also be inferred due to the volunteer nature of participant recruitment, with their motivation to be involved with the study due to a personal interest in the subject or a sense of responsibility to the profession. No attempts were made to identify barriers to ARA reporting within the groups surveyed.

The strengths of the current research lie in the original nature of the investigation undertaken and specificity to the two NZ professional groups, which were surveyed. It is the authors' position that attempts to establish incidence rates are meaningless unless it is determined that practitioners are interpreting and reporting ARA's homogenously. Further, to the authors' knowledge, there are no such reports of research examining practitioners' opinion and interpretation of acupuncture adverse reaction nomenclature available in the research literature. Nor has any comparable research investigated the decision threshold for reporting an adverse reaction, in particular, the timeframe for which a symptom must be present before a decision is made to report it. The relatively homogenous physiotherapy acupuncture population available in NZ, which were devoid of political or legislative boundaries

such that exist in other countries such as Australia (personal communication Leigh McCutcheon) or the United States of America (personal communication Frank Gargano), made it an ideal sample for the current study.

Since the completion of this survey the principal author has designed a new adverse reaction reporting template which has been adopted by PNZ. PAANZ members have had safety guidelines updated (PAANZ 2011 and 2013) and presentations on ARA definitions in special interest group conferences. Further research may be warranted to investigate why the NZ practitioners considered patient perception as the least important factor in their decision to report and adverse reaction, what reporting barriers may exist and what actual incidence rates could potentially be, given the under reporting acknowledged by this survey group.

## CONCLUSION

Adverse reaction reporting should be encouraged within all professional acupuncture groups in NZ, with the aim of improving reporting rates to enable the collection of meaningful data for such reflection and research. Reaching a consensus on the use of common terminology is the first step towards the standardisation of adverse reaction to acupuncture reporting, which will in turn assist future research in the areas of safety and incident patterns.

Based on the research findings and within the bounds of the acknowledged study limitations, recommendations may be made to improve adverse reaction to acupuncture reporting patterns in NZ and to assist reporting policy development: *'Any adverse effects possibly related to acupuncture making treatment necessary or severely interfering with the patients well being'* is recommended as the definition of choice for an adverse reaction to acupuncture for NZ practitioners. The terms side effect and complication should be avoided.

The term 'adverse reaction' should be used to describe the negative outcome from the perspective of acupuncture itself and, that of an 'adverse event', to describe the negative outcome from the perspective of the patient.

Participation in future adverse reaction reporting systems should be fostered by using only that nomenclature in reporting forms which has been established as being meaningful and constructive to those practitioners who will be required to work with it.

Qualifiers should be predefined within reporting systems so as to standardise scales of seriousness and severity. Further practitioner consensus is required on whether common vasovagal responses to needling should be also be included in acupuncture adverse reaction reporting systems.

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## KEYPOINTS

- There are differences in the way that NZ acupuncture practitioners interpret the concept of an adverse reaction to acupuncture and associated terminology.
- The variations in interpretation are important factors in reporting thresholds and the types of symptoms and sequelae that are reported.
- The recommendation is made that NZ acupuncture practitioners use the adverse reaction to acupuncture definition *'Any adverse effects possibly related to acupuncture making treatment necessary or severely interfering with the patients well being'.*

## CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest to declare.

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