

### Australian Association of Musculoskeletal Medicine

#### PO Box 5714 Manly QLD 4179

Dr Anne Tonkin Chair, Medical Board of Australia GPO Box 9958 Melbourne VIC 3001 20<sup>th</sup> June 2019

Dear Dr Tonkin,

Thank you for the opportunity to participate in the *public consultation on clearer* regulation of medical practitioners who provide complementary and unconventional medicine and emerging treatments.

The Australian Association of Musculoskeletal Medicine (AAMM) is an association of medical practitioners with the objectives of promoting research into, and knowledge of, the causes, mechanisms, diagnoses, treatment and other aspects of disorders of the musculoskeletal system.

The committee has discussed the questions the Medical Board has posed for discussion, and submits the following answers:

1. Do you agree with the proposed term 'complementary and unconventional medicine and emerging treatments'?

If not, what term should be used and how should it be defined?

No. These are three very separate terms describing three distinctly different types of practice. It is confusing and inaccurate to group them all together. Furthermore, conflating these terms is prejudicial. Each of these terms needs to be separated and defined clearly. For example, how do we determine whether a treatment is conventional or unconventional, complementary or mainstream, emerging or established? Is it the level of evidence, consensus agreement or some other process? This has not been clearly explained. The early controversy surrounding the role of H. pylori in peptic ulcers and non-use of beta-blockers in heart failure only 30 years ago are two cases in point.

We regularly see new research contradicting the findings of previous "gold standard" studies. The credibility of research outcomes can be strongly affected by factors such as biases and pharmaceutical company influence.

Perhaps instead of using these labels, these treatments could be defined by their level of evidence. This should reflect the current level of evidence and avoid prejudice or judgement.

2. Do you agree with the proposed definition of complementary and unconventional medicine and emerging treatments – 'any assessment, diagnostic technique or procedure, diagnosis, practice, medicine, therapy or treatment that is not usually considered to be part of conventional medicine, whether used in addition to, or instead of, conventional medicine. This includes unconventional use of approved medical devices and therapies.'

#### If not, how should it be defined?

No. Putting all three of these practices together confuses the definition and puts them all in the same category. They are very different approaches, with different levels of research, evidence and acceptance. They should not be considered as the same entity.

#### Complementary

Used by many doctors with research and evidence to support its use. By definition, complementary medicine is used in addition to "conventional" medicine, not instead of (that would be considered "alternative" medicine) eg fish oil. Many "conventional" treatments are drug-based and are classified as such because of evidence from double blind, placebo-controlled, crossover trials. This adds a layer of bias since a majority of these trials are industry funded and only undertaken if a drug is patentable. Such trials do not lend themselves to many areas of medical practice. There is an inherent evidence bias against these other areas, despite mechanistic and observational data to support their use. Codifying them separately will potentially exacerbate this difference and deprive patients of cheaper, safer, more effective ways to promote their health.

#### Unconventional

How is this defined? What percentage of doctors needs to be using a treatment to decide whether it is conventional or unconventional? Who decides if a treatment is conventional or unconventional? There is a great danger in using subjective definitions of "conventional" vs "unconventional" and merely applying a label that is not clearly defined.

#### Emerging

Most "proven" treatments began as emerging treatments. Smaller scale observational studies demonstrating positive effects lead to research questions being formulated and studies initiated to try and understand the observed outcomes. It takes time, funding and resources to gather evidence on a larger scale. Defining treatments by their level of evidence rather than applying these labels would be more informative and accurate.

# 3. Do you agree with the nature and extent of the issues identified in relation to medical practitioners who provide 'complementary and unconventional medicine and emerging treatments'?

The issues identified are not unique to this group of medical practitioners. They apply to ALL medical practitioners. The current guidelines adequately cover the issues mentioned.

There is a significant danger of legislative apartheid, whereby entrenched practice is subjected to inferior examination because it is considered "conventional". Outdated practices that are not supported by evidence will potentially be tolerated, whilst "complementary" practices will have a higher barrier of entry. Furthermore, it is widely accepted that historically entrenched paradigms tend to blind current adherents to new scientific evidence that challenges their approach. This is likely to be reinforced by codifying "complementary" and "emerging" practice separately to "conventional" practice. We are not in favour of such division.

4. Are there other concerns with the practice of 'complementary and unconventional medicine and emerging treatments' by medical practitioners that the Board has not identified?

No. All doctors should adhere to the same code of conduct and standard of care.

## 5. Are safeguards needed for patients who seek 'complementary and unconventional medicine and emerging treatments'?

The same safeguards should apply to ALL medical practitioners and ALL patients. The principles of good medical care are the same ie proper assessment and informed consent. Patient safety should always come first, and the current guidelines ensure that this is the case. Separating this group creates an unnecessary division with a separate set of standards, which will be unclear and potentially highly subjective.

Complementary medicines have been shown to be comparatively safer than pharmaceutical drugs and medical procedures. Significantly less adverse drug reactions are reported for complementary medicines.

## 6. Is there other evidence and data available that could help inform the Board's proposals?

Our committee wishes to comment on the board's concern about Platelet Rich Plasma (PRP). We note that there is a rich body of peer reviewed research in relation to its musculoskeletal applications, which is growing rapidly, including meta-analyses and other recognised level 2 evidence. Some of the recent articles are listed below.

These show that PRP is at least comparable and even exceeds the effects of the current standards, intra-articular steroid and hyaluronic acid. These studies are all very recent and yet very reputable. This is an example of an emerging technique that

is rapidly becoming an important part of musculoskeletal and sports medicine, and orthopaedics. Does the board really want to put restrictions on the development and proving of new techniques that are likely to reduce pain and suffering and, as in this case, have the possibility of reducing surgery? There is a lot of debate currently about the necessity, efficacy and safety of the thousands of knee arthroscopies that are performed in Australia. PRP is a safe, effective, evidence-based technique that could help thousands of patients with debilitating knee osteoarthritis.

#### **Articles**

Current Reviews in Musculoskeletal Medicine (2018) 11:624–634 Current Clinical Recommendations for Use of Platelet-Rich Plasma Adrian D. K. Le, Lawrence Enweze, Malcolm R. DeBaun and Jason L. Dragoo

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6220007/

Current Reviews in Musculoskeletal Medicine December 2018, Volume 11, Issue 4, pp 566–572 | Platelet-Rich Plasma: Review of Current Literature on its Use for Tendon and Ligament Pathology. Cameron Kia, Joshua Baldino, Ryan Bell, Alim Ramji, Colin Uyeki, and Augustus Mazzocca <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6220011/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6220011/</a>

Current Reviews in Musculoskeletal Medicine December 2018, Volume 11, Issue 4, pp 607–615 | Platelet-Rich Plasma and the Knee—Applications in Orthopedic Surgery, Wasserman A, Matthewson G, MacDonald P. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6220003/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6220003/</a>

Current Reviews in Musculoskeletal Medicine December 2018, Volume 11, Issue 4, pp 583–592 | Clinical Update: Why PRP Should Be Your First Choice for Injection Therapy in Treating Osteoarthritis of the Knee, Corey S. Cook and Patrick A. Smith

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6220006/

Pain Med. 2019 Mar 7 [Epub ahead of print] Meta-analysis Comparing Platelet-Rich Plasma vs Hyaluronic Acid Injection in Patients with Knee Osteoarthritis. Han Y, Huang H, Pan J, Lin J, Zeng L, Liang G, Yang W, Liu J. <a href="https://academic.oup.com/painmedicine/advance-article/doi/10.1093/pm/pnz011/5372482">https://academic.oup.com/painmedicine/advance-article/doi/10.1093/pm/pnz011/5372482</a>

Orthopade. 2019 Mar;48(3):239-247. Intra-articular injections of platelet-rich plasma, hyaluronic acid or corticosteroids for knee osteoarthritis: A prospective randomized controlled study. Huang Y, Liu X, Xu X, Liu J. <a href="https://www.ncbi.nlm.nih.gov/pubmed/30623236">https://www.ncbi.nlm.nih.gov/pubmed/30623236</a>

7. Is the current regulation (i.e. the Board's Good Medical Practice) of medical practitioners who provide complementary and unconventional medicine and emerging treatments (option one) adequate to address the issues identified and protect patients?

Yes.

8. Would guidelines for medical practitioners, issued by the Medical Board (option two) address the issues identified in this area of medicine?

No. They are unnecessary, poorly conceived and potentially prejudicial.

9. The Board seeks feedback on the draft guidelines (option two) – are there elements of the draft guidelines that should be amended? Is there additional guidance that should be included?

N/A

10. Are there other options for addressing the concerns that the Board has not identified?

No.

11. Which option do you think best addresses the issues identified in relation to medical practitioners who provide complementary and unconventional medicine and emerging treatments?

We are in support of Option 1.

Option 1 – Retain the status quo of providing general guidance about the Board's expectations of medical practitioners who provide complementary and unconventional medicine and emerging treatments via the Board's approved code of conduct.

Option 2 - Strengthen current guidance for medical practitioners who provide complementary and unconventional medicine and emerging treatments through practice-specific guidelines that clearly articulate the Board's expectations of all medical practitioners and supplement the Board's Good medical practice: A code of conduct for doctors in Australia.

Other - please specify.

In summary, our association feels strongly that there is no need to change the current guidance for medical practitioners. The existing code of conduct informs and guides ALL medical practitioners to ensure high standards of care and patient safety.

The current requirement for there to be adequate informed consent has served us well for many years, allowing doctors to be a part of developing new techniques and patients to choose to be a part of that if they want. If the board feels that excessive claims of benefit are being made, the board can invoke the current guidelines under section 3.5, where the whole issue of informed consent is already adequately covered.

Yours sincerely,



Dr Michael Ellis Acting President Australian Association of Musculoskeletal Medicine