Early development of the Australia & New Zealand Musculoskeletal (ANZMUSC) Clinical Trials Network

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Arthritis and other musculoskeletal conditions place an immense burden on the world's population. They account for 18.3% of years lived with disability globally (1). They affect 30% (>6.9 million) Australians (2), and are the most common reason for accessing healthcare services in Australia. Arthritis Australia estimates that arthritis alone currently costs the health system \$5.5 billion annually (3), with 52,000 people out of the labour force due to arthritis in 2015 (4, 5). In New Zealand, nearly 1 in 6 people (531,000 people) aged 15 or older were living with arthritis in 2010, with an estimated total cost of NZ\$3.2 billion (1.7% of GDP)(6).

Despite the enormous individual and societal impact of musculoskeletal conditions, they receive less research focus compared with other health priorities (7, 8). For example, annual funding through the Australian National Health and Medical Research Council from 2010 to 2014 awarded ~\$25 million for arthritis research, compared to ~\$110 million for cardiovascular research and ~\$70 million each for diabetes and mental health (9). Similarly, in New Zealand the Health Research Council invested 7% of its budget in musculoskeletal conditions compared with 14% for vascular disorders and 12% for cancer in the 2013/14 year (10). The major reason for underfunding of musculoskeletal research appears to be a relative lack of research capacity and hence relatively fewer grant applications compared to other fields rather than as a result of the quality of the submissions. In 2014, 16% of 159 arthritis-relevant NHMRC applications were successful compared with 18% of 730 cardiovascular, 19% of 409 diabetes, and 16% of 504 mental health applications 10).

Similar to other areas, it is likely that much research effort in the musculoskeletal field is wasted, due to addressing low priority questions, failure to take account of existing evidence, insufficient consideration of potential for bias in study design, publication bias, and biased or incomplete reporting and interpretation of results (11). Examples of vast delays in translating musculoskeletal research into clinical practice include continued use of ineffective arthroscopic debridement for knee osteoarthritis (12, 13), continued overdiagnosis and over-treatment of non-specific low back pain (14), suboptimal treatment of gout (15), under-utilisation of non-pharmacological and lifestyle management strategies for

osteoarthritis (16), and under-treatment to prevent re-fracture following minimal trauma fracture (17).

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Better alignment of musculoskeletal research and implementation efforts with an emphasis on those research questions with the greatest gaps in evidence and practice, alongside a significantly increased and appropriately skilled musculoskeletal research workforce, is needed if we are to meet the rapidly growing health needs of these conditions. Such an approach would also reduce research waste, and definitively answer the most impactful research questions in this field. To meet these challenges, we formed the Australia and New Zealand Musculoskeletal (ANZMUSC) Clinical Trials Network, a multidisciplinary collaboration of leading and emerging clinical researchers, consumers and other stakeholders. This paper describes ANZMUSC's early development, structure, goals and aims to provide a stimulus for others interested in establishing similar networks.

How did we begin?

Australia and New Zealand have about 35 established national clinical trials networks including 13 collaborative cancer groups (18). Many are global leaders in their disciplines, having performed high-impact trials that have changed practice, improved outcomes and saved money. Given the extent of clinical trial network success in Australia and New Zealand, and the lack of any similar network for musculoskeletal clinical trials in this region,

in 2012 we assembled a steering group to consider the merits of a national collaborative network and the steps that would be needed to make it a success.

To establish the need for a network, we reviewed the scope, funding and publication of Australian investigator-initiated musculoskeletal clinical trials performed in Australia (19). Our review identified that the NHMRC project grant scheme had funded an average of 5.8 new musculoskeletal trials per year between 2009 and 2013 inclusive. This accounted for only 0.8% of all trials and 0.8% of allocated funding for this scheme. There were 128 Australian-initiated musculoskeletal trials registered in a trial registry in 2011 or 2012, most commonly for osteoarthritis (n = 45), low back or neck pain (n = 17) or osteoporosis (n = 12); and most commonly investigating physical therapy and/or exercise (n = 55), followed by drug therapies (n = 33) and surgery (n = 23). Compared with all registered trials that included recruitment in Australia, the median trial population size of musculoskeletal trials was generally smaller (65 versus 100 participants), suggesting they were likely to be underpowered to identify clinically worthwhile treatment effects if these are truly present.

Over the same period, 30 out of 565 (5.3%) randomised trials published among 37 leading general medical and musculoskeletal-specific journals were initiated in Australia. Similar to the Australian-initiated trials registered during this time, about half were for osteoarthritis (n = 14), and about half were investigating physical therapies (n = 14).

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There were no implementation trials investigating interventions to improve uptake of research findings into practice among either the registered or published trials. Overall, few reflected priorities based on the greatest evidence or evidence-practice gaps, in general were not focused on novel and/or promising interventions, and many were of doubtful clinical relevance, suggesting likely research waste.

Our review not only identified the need for a collaborative network, but also focused our attention on the necessity to develop a national research agenda that prioritised the most important questions for musculoskeletal health (20). Importantly, while better coordination of research activities and better resourcing and direction of funding were needed, inclusion of all relevant stakeholders including clinicians and patients, was essential to improve the appropriateness of research questions, and improve acceptance and facilitate adoption of the findings. We therefore sought the involvement of clinician and consumer organisations from the outset, and also invited trialists from New Zealand to join the collaboration.

Development of the ANZMUSC Clinical Trial Network

The first ANZMUSC Summit took place in April 2015 in Melbourne. Musculoskeletal clinical trialists from diverse clinical backgrounds and affiliated with 22 universities in Australia and New Zealand, as well as various research institutes and hospitals, made up the majority of the 100 attendees. Additional participants representing NHMRC, Departments of Health (NSW, WA), the Australian Commission on Safety & Quality in Health Care, Australian

Clinical Trials Alliance (ACTA), and health insurers (Medibank Private) also attended. Attendance at the summit was free. Summit goals were to develop an agreed vision and mission statement and a set of values, and identify clearly achievable goals for the next year a plan for how these goals would be realised.

In preparation for the summit, we invited 243 Australian and New Zealand musculoskeletal clinical trialists to complete a web-based survey. As well as demographic and research interest questions, we elicited their interest in being part of a collaborative network and potential perceived benefits of network membership.

One hundred and twelve trialists completed the survey (response rate 46%). Respondents were from all Australian states and territories other than Northern Territory in Australia, and 17 (15%) were from New Zealand. Disciplines included general practice, rheumatology, orthopaedic surgery, physiotherapy, chiropractic, nursing, podiatry, pharmacy, pharmacology, psychology, rehabilitation, endocrinology, occupational therapy, occupational medicine, exercise and sports medicine, osteopathy, exercise physiology, biostatistics, health economics, epidemiology, with the largest group being physiotherapists.

Two thirds of respondents (74/112) were interested in belonging to a network while a quarter (28/112) were undecided. Respondents indicated a wide variety of potential benefits of ANZMUSC membership across six themes: collaboration and networking;

funding; learning, gaining experience and peer review; priority setting; advocacy for musculoskeletal diseases and research; and avoidance of duplication. Taking this as tacit approval to proceed, we named our network, set up a website (www.anzmusc.org), and designed a logo.

The summit report can be accessed in full on our website. In brief, the program comprised a mix of presentations and large and small group discussion facilitated by two clinical trial networks outside of the musculoskeletal field. They outlined the value of clinician investigator-led networks that undertake important public-good research, and different types of network models. Following several breakout and feedback sessions, summit participants agreed upon the ANZMUSC vision, mission and values (Table 1). There was agreement that the Steering Group should become the Executive Committee with addition of a New Zealand member, and one-year goals were identified.

Subsequent summits have taken place in Sydney (April 2016), Adelaide (May 2017) and Melbourne (March 2018)(full summaries on website). Small registration fees cover meeting costs and consumer attendance. A pre-meeting workshop on consumer engagement in clinical research was included in 2016 and early career researcher professional development breakfasts in 2016 and 2018. At the second summit, we reached agreement on the structure, function and governance of ANZMUSC (96% agreement), as well as its membership, including the role of consumers (100% agreement for the Consumer Advisory

Group Terms of Reference), endorsement process (85% agreement) and publication policies (83% agreement).

Each summit includes open forum sessions where trial proposals for potential ANZMUSC endorsement are presented and discussed. Each proposal is reviewed prior to the meeting by two experienced researchers and a consumer, and their feedback is presented alongside the presentation of the protocol. In 2016 we submitted a successful application for an NHMRC-funded Centre of Research Excellence (CRE) for ANZMUSC. The ANZMUSC NHMRC CRE was officially launched by the Hon Greg Hunt MP, Minister for Health at the fourth summit in March 2018.

Structure of the ANZMUSC Clinical Trial Network

The ANZMUSC structure is shown in Figure 1. The Executive Committee has overall responsibility for coordinating the activities of the ANZMUSC Clinical Trials Network and oversees management of the CRE. Any CRE chief investigators not already holding key roles within ANZMUSC were invited to increase their involvement. As a result an implementation expert was added to the Executive (SG) and two mentors for the Consumer Advisory Group were appointed (MF, LM). A full-time network manager has been employed since 2016. She manages the day-to-day activities including communication with members, and organisation of the annual summit.

The Scientific Advisory Committee provides scientific and methodological advice and feedback on either proposals that have been submitted for presentation at an ANZMUSC Scientific Meeting Open Forum or submitted for ANZMUSC endorsement. It also reviews applications for ANZMUSC research fellowships. The Consumer Advisory Group is responsible for providing advice and guidance to ANZMUSC members and the Executive Committee regarding the consumer/patient perspective, research priorities, and issues of importance to consumers with musculoskeletal conditions. It provides consumer input on all trials submitted to ANZMUSC for presentation at the annual summit and for endorsement. Members comprise consumer representatives from across Australia and New Zealand with lived experience of musculoskeletal conditions and people involved in delivering services to the community. The External Advisory Group comprises trial, capacity building and knowledge translation experts to advise on research directions and implementation of outcomes.

There are two categories of ANZMUSC membership. Full membership is for individuals based in Australia or New Zealand, who have published at least one peer-reviewed clinical trial. Associate membership is open to individuals who are non-clinical trial researchers and those who do not fulfil the criteria for full membership. This category also includes professional organisations, consumer organisations and individual consumers. Currently there are 122 full members across 23 disciplines affiliated with 30 universities, 31 hospitals and 17 research institutes. There are 139 associate members including consumers and

consumer organisations, professional associations, funders, and policy makers. All states and territories in Australia other than Northern Territory is represented, as are all major geographic regions in New Zealand.

ANZMUSC endorsed trials

ANZMUSC endorsement criteria include a requirement that a trial addresses an area of research priority and is of importance to consumers or patients. It must be of high scientific quality and have the potential to change practice, be multi-centre, involve at least one ANZMUSC full member, and to be eligible the trial must not have started recruitment. Endorsement has been given to six trials to date and two have published protocols (21, 22). Five have been awarded NHMRC funding and one has been funded by an NHMRC-Medical Research Future Fund grant.

NHMRC Centre of Research Excellence for the ANZMUSC Clinical Trial Network (2018-22) and early progress

The objectives of the NHMRC ANZMUSC Centre of Research Excellence are outlined in Table 2. Currently there is one CRE-funded PhD scholar, a part-time Practitioner Fellow jointly funded by ANZMUSC and the Queen Elizabeth Hospital Foundation, and a Masters scholar funded by a Chiropractic Australia and Chiropractic & Osteopathic College of Australasia scholarship. Another part-time Practitioner Fellowship and full-time network manager are funded by leveraged funds from the Sydney Local Health District. One additional

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postdoctoral fellow or Practitioner Fellow is to be appointed and two additional PhD scholarships, one jointly funded by ANZMUSC and Musculoskeletal Australia, and the other funded by Medibank Health Insurance, are to be awarded.

CRE seeding grants for up to three projects that either value-add to existing research aligned with ANZMUSC priorities, or that have potential to lead to future trial proposals will be awarded annually. Operational support (project management, design, statistics and health economics advice) for ANZMUSC-endorsed trials and members is also funded by the CRE. A web-based consumer research register, funded by Musculoskeletal Australia, is also in the pilot phase.

To inform our research agenda, we have completed a systematic review of 49 prioritysetting exercises identifying research topics for musculoskeletal conditions (23). We concluded that methodologic limitations and lack of actionable research questions limited their usefulness. We have begun development of a multi-attribute priority setting tool for ranking musculoskeletal research questions. Preliminary work has included an online Delphi study of ANZMUSC members that identified specific attributes that make a research question important. This was followed by a face-to-face workshop involving 22 participants (consumers, clinicians, researchers, funders, health insurance provider), to agree on a final draft framework for evaluating the importance of a research question and descriptors of categories for each attribute. The final phase will confirm reliable application of the

framework, and use discrete choice experiments to develop the scoring system based upon the relative importance (weights) of each attribute and its categories. The advantages of the new tool over current methods of prioritisation include its transparency, minimisation of bias relating to which stakeholders participate in the process, and the ability to incorporate new topics within a priority agenda when needed, and we expect it will be able to be applied in other research fields. The full methods and results of this project will be reported separately.

Summary

This paper describes the formation and early development of the ANZMUSC Clinical Trials Network. A long-lasting benefit will be a significantly increased musculoskeletal research workforce and infrastructure, and improved trial quality in order to meet the rapidly growing burden of musculoskeletal diseases. Each of our goals will be achieved using innovative methods with involvement of consumers, policy and knowledge translation partners. By ensuring a focus on trials of highest importance and quality, and fostering strong links with clinical and consumer groups, we will reduce research waste and provide definitive answers to the most pressing questions in our field.

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Table 1 The vision, mission and values of the Australia and New Zealand Musculoskeletal

(ANZMUSC) Clinical Trial Network and one year goals in 2015

Vision	To optimise musculoskeletal health through high quality,
	collaborative clinical research.
Mission	1. To identify the key clinical research questions relevant to
	musculoskeletal health.
	2. To improve the scientific quality of musculoskeletal research and
	its translation into policy and practice.
	3. To facilitate and endorse clinical research based on scientific
	quality and potential to improve health outcomes.
	4. Advocate for musculoskeletal research support.
	5. Foster collaboration between research groups and stakeholders.
	6. Advance the understanding of research through mentoring and
	education.
Values	Visionary; altruistic (generous, benevolent); scientific integrity;
	transparency; equity; mutual respect; health consumer-centred;
	ethical
One year goals f	or 2015
Structure and	Clear and transparent structure and governance in place in 12
Governance	months
	Caretaker working group in short term
	• Expand working group size and membership to include
	representative from New Zealand and consumer representative
	(skills based)
	Appoint Executive Officer or Manager
	Undertake stakeholder mapping
Define key	Develop policy and processes for how ANZMUSC will:

ANZMUSC	Facilitate high quality research
functions	Link researchers answering same questions
	Multi-site recruitment, contribution, national, international
	collaboration
	 Methodology input, mentorship, peer review
	Define priorities
	• Endorse any high quality trial (not just priority area trial, no
	limitations initially)
	Funding longer term
Funding	 Goal to raise seed funding of \$200,000 – \$250,000
	• Prioritise how this money will be spent if funds become available
	Appoint full- or part-time executive officer/manager early to
	enable us to move forward
Establish and	• Define members and a process for membership including how
expand	relevant registration information will be recorded; easy website
membership	process preferred
	Consider individual, consumer organisation, and other
	membership
	 Nomination and seconder, board has final approval
Plan future	 Next meeting during ACTA Sydney, Oct 7-10, 2015
meeting and	Plan full meeting for April 2016
communication	Communication via anzmusc.org website
strategy	 Summary of meeting for those who could not attend including
	agreed vision, mission and values to be placed on the website
	Consider a funders; stakeholder meeting to discuss ways of
	establishing five year infrastructure support
	Apply for ANZMUSC CRE funding

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Table 2 Objectives of the ANZMUSC NHMRC Centre for Research Excellence (2018-22)

1. Generate new knowledge that leads to improved health outcomes

- Conduct clinical trials that address important evidence gaps
- Establish stakeholder priorities for future ANZMUSC trials
- Develop an innovative multi-attribute tool for ranking research priorities
- 2. Promote effective transfer of research outcomes into health policy and/or practice
- a. Further the science of research translation for musculoskeletal conditions
- Perform implementation trials to evaluate what works to change practice
- Implement the Australian Clinical Care Standards for hip fracture and knee osteoarthritis into routine care
- Develop 'living' systematic reviews and 'living' recommendations for musculoskeletal health
- b. Effectively translate the results of the CRE
- 3. Develop the musculoskeletal health and medical research workforce
- Build a workforce of trained musculoskeletal clinician trialists
- Invest in personnel to coordinate ANZMUSC's functions and research outputs
- Build capacity by recruiting and supporting student, postdoctoral and clinician researchers and providing expert mentoring for their CRE supervisors
- Develop large-scale project management processes to streamline all aspects of the trial process, reduce duplication of effort and embed trials in routine care

4. Facilitate collaboration

- Nurture effective working collaborations and intellectual exchange
- Foster collaborations with other groups in this field of research
- Support integration and cohesiveness of the team
- Develop a web-based consumer research register

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