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Setting an agenda for strengthening the evidence-base for traditional and complementary medicines: Perspectives from an expert forum in Australia

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ABSTRACT

Objectives: To explore the challenges regarding evidence and complementary medicine in Australia and identify potential future directions to develop leadership, action and debate.
Design: Facilitated discussion among a roundtable of experts to identify and consider the relevant issues and potential actions.
Methods: Purposive sampling of 17 expert stakeholders with a variety of experience in the traditional and complementary medicine (T&CM) arena. Thematic analysis of the half-day discussion transcript resulted in a framework for a broad agenda to support the development of appropriate evidence for T&CM.
Results: Five key areas (with sub-themes) were identified, forming the backbone of an agenda-setting framework: focus areas; strategies; actions and outputs; barriers; and drivers of change. 'Focus areas' encapsulated the main themes and informed all key areas, these were: consumer perspectives and needs; hierarchies of evidence; safety of products, practitioners and practices; modernisation of T&CM; regulation and policy; and evidence-based practice. Two recurring themes informed the framework at multiple levels: the complexity and varied understanding of what is 'appropriate evidence' for T&CM; and putting consumers at the centre – to ensure that their needs and safety are prioritised. Lack of resources for undertaking T&CM research necessitates the need to bring together information from multiple sources so that 'totalities of evidence' can be assessed to increase the T&CM evidence-base. Doing so requires reassessment of the relative value of traditional forms of evidence and challenges current linear evidence hierarchies that prioritise clinical trials as the 'gold standard'.
Conclusions: This Australian agenda-setting framework for strengthening T&CM evidence requires an interdisciplinary leadership group (including consumer, clinician, academic and industry representatives) to build consensus, foster collaboration, and generate and disseminate information. Prioritising the perspectives and needs of consumers should be a primary focus in taking the 'strengthening evidence for T&CM' agenda forward.

1. Background

Many people across the world use traditional and complementary medicine (T&CM) products, practitioners and practices, and in some regions, this use is increasing [1,2]. Definitional and methodological issues related to T&CM products and practices prevent clear global comparisons of T&CM use. It is estimated that up to 70% of people in Australia use at least one T&CM modality within a given year [3,4]. Twelve-month prevalence rates reported elsewhere range from 36%–42% in the USA [1], 20%–44% in the UK [1,5], 75% in the Republic of Korea [6], and 76% in Singapore [7]. Reasons for T&CM use vary and include lack of accessibility to or affordability of biomedical services; [8,9]; cultural relevance [10,11]; perceived benefit for treatment of certain conditions [12–14]; a means to reclaim a sense of control in the face of chronic

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illness [15,16]; and increasingly (particularly in developed countries) the belief that T&CM use in addition to biomedicine and other lifestyle factors is beneficial for disease prevention and maintaining or improving health and wellbeing [6,17,18].

Despite the high prevalence of T&CM use, there is some debate regarding the 'evidence-base' for these medicines. The World Health Organization (WHO) has acknowledged that for T&CM to be considered "an integral part of health care, it must be supported by evidence" and that there is a "dearth of research and innovation into the various forms of T&CM" [19]. The generation of evidence and what constitutes 'good evidence' has been a controversial issue, and continues to be, as the market experiences sustained growth. While some commentators state that the same scientific methods and standards used for pharmaceutical medicines must be applied to 'prove' efficacy of T&CM products [20], others argue that because T&CM products are often highly contextualised and complex interventions, different evaluation models are required and many have been developed [21–24].

In November 2015, a roundtable expert forum was co-convened in Australia by NICM (a national integrative medicine research institute based at Western Sydney University) and a membership-based peak body (the Australian Self-Medication Industry [ASMI]). The objective of the forum was to bring together experts in complementary medicine and evidence-based practice to engage in an open conversation around the challenges regarding evidence and complementary medicine, with a view to identify potential future directions to develop leadership, action and debate around the issue. While the forum had a predominantly Australian focus and was initially concerned with natural health products, the issues discussed often had relevance beyond Australia and to T&CM more broadly conceived (including T&CM products, practitioners and practices). This paper summarises the key themes arising from the forum and in doing so outlines an agenda to further discourse, community engagement, action and research in this area.

2. Methods

2.1. Aims & design

A descriptive qualitative design was used to explore the themes arising from an experts' forum toward furthering understanding of how 'evidence' for complementary medicine products is conceptualised, and to develop an agenda to guide how it should be conceptualised and supported going forward into the future.

2.2. Participants

A purposeful sample of academic, industry and consumer participants for the expert complementary medicine evidence forum were identified by NICM and ASMI staff through known academic and industry networks. Twenty-two participants with different disciplinary and institutional backgrounds were invited by email, chosen for their varied knowledge and contributions to the field of T&CM in Australia and elsewhere. Forum participants had mixed expertise in the T&CM arena relating to different T&CM modalities, medicine, nursing or pharmacy, clinical practice, research, education, industry, regulation, policy, and/or consumer advocacy. Seventeen participants attended the forum on 12 November 2015, at the ASMI office in North Sydney, Australia (see Acknowledgements). All but one (USA) attendee was Australian and many had international as well as local T&CM experience. A professional facilitator guided the discussion. Table 1 outlines basic characteristics of participants.

Table 1
Characteristics of forum participants.

Characteristic	n
Age (in years)	
<45	5
45–55	5
>55	7
Gender	
Female	8
Male	9
Background/Representation[a]	
Academic research/education:	14
Healthcare professional: – *T&CM*	10
– *Medicine or allied to medicine*	10
Industry: – *T&CM or pharmaceutical*	4
Consumer or patient advocacy:	2
	N = 17

[a] More than one response allowed.

2.3. Data collection

Prior to the forum, invitees identified and shared journal articles or other information within the group (references available upon request) and considered a set of questions related to T&CM 'evidence', including: What are the evidence gaps and research priorities for Australia? Who is the priority – consumer, practitioner or academic? What needs to be in place to facilitate the generation and utilisation of evidence? What are the challenges and opportunities? And how do we develop a strategy to move forward?

The four-hour forum was audio recorded and professionally transcribed without participant identifiers (as agreed by the group). The de-identified transcript was circulated to all participants for review and validation. The authors were forum participants and were subsequently commissioned by the forum organisers to undertake qualitative analysis of the transcript to provide a full summary of the key findings, themes and concepts arising.

2.4. Data analysis

Data analysis and the creation of conceptual figures and theme maps were facilitated by NVivo11 Pro [25]. Line by line coding was undertaken independently by RC and ML (both experienced qualitative researchers), with focus on high-level themes arising from the transcript. A second round of coding was undertaken by each researcher to produce more nuanced sub-themes. The two coders shared their results, checked for alignment of codes, discussed differences and made some adjustments. While the two coding hierarchies were well aligned, their framing was different. One focused on evidence for complementary medicine practice as a central concept (ML) [26], the other encapsulated the broadest network of ideas related to the question of 'what is appropriate evidence for T&CM' (RC). Rather than amalgamating the two coding trees both were considered to contribute worthwhile perspectives–the latter forms the basis for this paper.

In December 2016, a draft report outlining the key areas and themes arising from the broad coding hierarchy developed by RC was circulated to the forum invitees. Nine provided comments giving rise to editorial changes. The forum report was finalised in March 2017. The results reported below are sourced from that document. Quotes in the results are taken directly from the forum transcript. Identifiers are not associated with the quotes due to the anonymous, de-identified nature of the transcript. While a variety of terms were used by participants when referring to various traditional and complementary medicine practices and products,

the inclusive acronym T&CM is used here for consistency. The themes discussed in this paper arose within a closed forum of experts and do not necessarily represent broad opinion outside the forum.

3. Results

While the aim of the forum was to discuss challenges related to evidence for T&CM products, the forum discussion promptly expanded to incorporate T&CM practitioners and practice. Table 2 summarises the key areas and themes arising, organised into a linked framework that can be used to guide agenda-setting and actions towards strengthening appropriate evidence for T&CM (noting that a T&CM leadership group or other similar entity is needed to operationalise the strategies and coordinate the actions). The remainder of the results section elaborates on these themes. The five key areas into which sub-themes are grouped are as follows:

(1) *Focus Areas:* The six 'focus areas' capture the main broad themes arising. They inform themes 2–6, particularly 'Strategies' and 'Actions and Outputs'.
(2) *Strategies*: The five strategies provide higher-level, longer term strategic actions related to the 'Focus Areas', but are also linked to addressing the 'Barriers' and operationalising the 'Actions and Outputs'.
(3) *Actions and Outputs*: The four themes within this key area are suggested actions to be undertaken in a shorter rather than longer time frame, and are linked to addressing the 'Barriers'.
(4) *Barriers*: The five identified barriers need to be addressed or overcome in order to progress debate and discourse around appropriate evidence for T&CM.
(5) *Drivers of Change*: Nine drivers of change were identified that could be utilised for strategic planning and furthering discourse and debate.

3.1. Focus areas

3.1.1. Consumer perspectives and needs

Consumers should be at the centre of the agenda to ensure that their perspectives and needs are met and their safety always prioritised–taking precedence over a clinical or regulatory focus. As one participant said: "We need to understand consumers, not claim that we understand them, but know that we understand what their needs and demands are". Australia is a multicultural society where people use T&CM for a multitude of cultural and ideological reasons; 'proven' efficacy may not always be a primary motivation for T&CM use. It is important then that the T&CM evidence debate accommodates the information needs of consumers about T&CM products, practitioners and practices. Information for T&CM consumers should be accessible to those who do as well as do not interact with T&CM or other primary healthcare clinicians.

3.1.2. Hierarchies of evidence

There is a subjective element to current hierarchies of scientific evidence that discounts information from observation and experience that may have been gathered over centuries and the cultural relevance of knowledge and practice. For traditional medicine, this can mean discounting thousands of years of observation and knowledge synthesis. The current linear hierarchy of evidence does not value such 'traditional' evidence but asserts randomised controlled trials as the 'gold standard' of evidence. As such, evidence tends to be "labelled good, mediocre, bad or rubbish". The relative value of traditional forms of evidence needs better understanding, and the current hierarchy of evidence challenged.

3.1.3. Safety of products, practitioners and practices

Research around T&CM products and practices tends to focus on efficacy and mechanisms of action. Greater knowledge on safety of T&CM products, practitioners and practices, is needed. Such information should be presented differently for different audiences (e.g. consumers, clinicians and regulators). It was noted by participants that: "if safety is not an issue, efficacy may not be a problem, but if you have something that's not safe, it better be really effective to make it worth the risk." In considering safety, certain questions need to be answered, such as: "What information about safety should be taken into account?"; "How safe is safe enough?"; and "Who makes decisions about safety parameters?". A leadership group should take up these questions. The modernisation of T&CM also impacts on safety (see 3.1.4). Public safety considerations should underlie all other focus areas, strategies and actions related to reshaping debate about T&CM evidence.

3.1.4. Modernisation of T&CM

The nature of T&CM product formulation, manufacture, mode of prescribing and practice has been rapidly changing over decades. The modernisation of traditional medicine, including the manufacture of standardised products and novel formulations that may not have a long tradition of use, has altered what is known about T&CM and the role of traditional sources of evidence or information. Novel formulations are used alongside more traditional products and preparations that have been relatively unchanged over long periods of time. The impact of modernisation on T&CM efficacy, safety, regulation and its relevance to traditional evidence are areas needing focused attention – with clear distinction between truly traditional and newer formulations.

3.1.5. Regulation and policy

Government regulators and policy-makers set the framework within which debate and/or conversation around T&CM evidence occurs. Debates should be framed so that impacts can be made on the regulatory process. Information to inform legal, ethical, social and political considerations is needed alongside consideration of the available 'evidence' on safety and effectiveness. Greater focus is needed on translation of research into policy-relevant information to inform regulation around T&CM use. For example, the acceptable 'safe' amount of a certain vitamin or mineral for general use by the population may be substantially lower than that required to be an effective dose for clinical use. Optimising the safe and effective use of T&CM products for consumers and practitioners is the goal of this focus area.

3.1.6. Evidence-based practice

When generating T&CM evidence clinician and consumer decision-making should be supported enabling clinicians to provide the best course of evidence-based care for their clients, cognisant of consumers' beliefs, needs and circumstances. Such 'evidence-based practice' aligns with the original concept of evidence-based medicine (EBM); that is, integrating individual clinical expertise with the best available external clinical evidence to evaluate the most appropriate course of care for a patient while taking into account the patient's beliefs, needs and circumstance [27,28]. A focus on evidence-based practice can include questioning: what information is important for consumers and clinicians? (and provide that information in an accessible format); how do clinicians make clinical decisions?; how do clinicians and clients draw meaning from information?; and how do clinicians "at the coal-face" decide what information to tell consumers?

Table 2
Framework for developing appropriate evidence for T&CM.

Key Area	Themes	Summary points
1. Focus areas	3.1.1. Consumer perspectives and needs	■ Consider different cultural needs of consumers and understand consumers' perceptions of evidence, their values and needs related to T&CM ■ Be guided by consumers' needs to direct debate on T&CM evidence ■ People access T&CM via different avenues. Not all T&CM consumers consult T&CM clinicians; there is a need to ensure that available information on products (e.g. labelling) and practices is appropriate
	3.1.2. Hierarchies of evidence	■ Re-vision the evidence hierarchy to appropriately include various types of research design best suited to the research question and intervention ■ Consider the 'totality of evidence'
	3.1.3. Safety of products, practitioners & practices	■ How safe is 'safe enough'? Consumer safety is paramount → safety considerations should underlie all debate
	3.1.4. Modernisation of T&CM	■ Understand the impact of modernisation of traditional medicine formulations and practices on T&CM efficacy, safety and relevance of traditional evidence
	3.1.5. Regulation and policy	■ Evidence and other information inform regulation and policy for T&CM ■ Facilitate more effective use of T&CM products and practitioners
	3.1.6. Evidence-based practice	■ Support clinicians to provide the best care for their clients ■ Information to enable informed clinician and consumer decision-making ■ There will never be 'evidence' on which to base every clinical decision
2. Strategies	3.2.1. Foster leadership and collaboration	**Establish a leadership group** that can help to: ■ Build leadership capacity to change the nature of the debate, foster collaboration (including with non-T&CM sectors), inform appropriate T&CM research, and consider incentives for industry to generate and disseminate information & evidence
	3.2.2. Consumer and cultural focus	■ Ensure consumer relevance underlies actions and outcomes ■ Highlight cultural needs relevant to community access to T&CM ■ Utilise the leverage of consumer self-care, increasing patient autonomy and preventative medicine related to T&CM use
	3.2.3. Re-vision concepts and hierarchies of evidence	■ Restore focus on the importance of incorporating clinical experience and patient preferences into the (evidence-based medicine) clinical decision-making process ■ Gather "totalities of evidence" about T&CM and use them to inform debate
	3.2.4. Make new and better use of existing resources	■ Bring attention to and better utilise existing sources of T&CM relevant information and resources for research and dissemination ■ Collaborate to access resources for research (data collection, facilities, funding)
	3.2.5.Educate and operationalise	■ Education of T&CM and non-T&CM providers, academics, researchers, media, consumers, industry and regulators about relevant T&CM evidence and information ■ Operationalise all actions ensuring they move beyond rhetoric
3. Actions & outputs	3.3.1. Reach consensus	■ Identification and definition of the scope of issues of concern ■ Basic definitions, e.g. complementary medicine, 'traditional', patient-centred approach ■ How to move forward to generate change
	3.3.2. Needs assessment and evidence-translation model	■ Find out what consumers want, value and need; the level of consumer awareness about T&CM evidence; and how T&CM practitioner knowledge is valued by consumers
	3.3.3. Research and publish	■ To explore and expand on the issues and clarify debate – including debate around evidence-hierarchies ■ Give attention to consumer meaningful research and appropriate research design
	3.3.4. Develop tools for change	■ *Charter of Consumer Rights* related to T&CM use ■ *Communication Strategy* ■ *Framework for Collaboration, Cooperation and Action* ■ A Consumer's Forum for T&CM
	3.3.5. Communicate and lobby	■ Undertake lobbying to change the nature of the debate about evidence supporting T&CM ■ Draw on the above Action & Output themes to strengthen communication and lobbying
4. Barriers	3.4.1. Epistemological and paradigmatic	■ Attempt to address paradigmatic barriers that make it difficult to move between different systems of medical practice and knowledge
	3.4.2. Lack of definitions	■ Without agreed definitions the scope of the debate cannot be clarified
	3.4.3. Lack of leadership and action	■ Factions within the T&CM arena prevent collegiality and strong leadership. This prevents unity in furthering the debate and completing Actions
	3.4.4. Lack of awareness	■ Lack of engagement, awareness and understanding of available research among T&CM and non-T&CM clinicians and consumers
	3.4.5. Lack of institutional support	■ Lack of mainstream institutional support leading to limited resources (e.g. research funding), education, and some contested regulatory limits on the practice of T&CM

Table 2 (*Continued*)

Key Area	Themes	Summary points
5. Drivers of change	3.5.1. Sociocultural and political	■ Social, cultural and political forces that drive social movements also drive change over time in the T&CM arena. These forces prompt generational shifts that drive change in the T&CM arena in terms of levels of T&CM acceptance
	3.5.2. Patients/consumers	■ T&CM consumers are a great force for driving regulatory change and acceptance of T&CM. Consumers are the interface between the T&CM and conventional medical professions and can influence the conventional medical profession
	3.5.3. Clinicians	■ T&CM clinicians drive the generation of clinical innovation and knowledge derived from clinical experience (e.g. adverse events, novel usage) ■ Student medical clinicians are potentially great drivers of change in T&CM knowledge, acceptance, and use of evidence
	3.5.4. Educators & researchers	■ Researchers drive the generation of T&CM 'evidence' and innovation ■ Educators influence the type of information that is shared and its use and acceptance (particularly among T&CM and 'mainstream' medical, nursing and allied health training)
	3.5.5. Insurers	■ Health insurers can have direct impact on what T&CM interventions and protocols are used by T&CM practitioners through their decisions on what to fund (insurance rebate)
	3.5.6. Regulators	■ Regulators can change the framework within which debate and/or conversation around T&CM evidence occurs
	3.5.7. Legal and ethical obligations	■ Awareness by medical peak bodies and professionals of their medico-legal and ethical obligations of understanding consumer T&CM use and its implications related to duty of care ■ Explicit awareness and comfort with the levels and types of evidence available to inform decision-making (regulatory and clinical)
	3.5.8. Media	■ Influential in shaping debate, but have a tendency to report negative information about T&CM
	3.5.9. Key individuals	■ Influential individuals able to champion or facilitate the development and/or acceptance of T&CM

Numbering is consistent with the sub-headings used in the descriptions of the themes within the manuscript.

3.2. Strategies

3.2.1. Foster leadership and collaboration

A leadership group is needed, comprising "people who (can) change the nature of debate around evidence supporting complementary medicines", to "put some levelness into the public debate", and "build thought-leader capacity". Such a leadership group should be interdisciplinary, build consensus, foster collaboration (including collaboration with non-T&CM sectors), inform the direction and design of appropriate T&CM research, and consider incentives for industry to generate and disseminate more information and evidence.

3.2.2. Consumer and cultural focus

T&CMs can offer culturally appropriate, person-centred care that facilitates wellness and proactivity in healthcare management (self-care). Attention needs to be paid to the steps that support such care. First, finding out what is meaningful for consumers, across cultures; engaging with consumers in pragmatic debate and discussion; and empowering consumers to change the debate (e.g. enabling them to engage with regulators about their T&CM preferences and information needs). Consumers should be partners in determining what relevant evidence is. This knowledge and collaboration can facilitate engagement with regulators about T&CM evidence and information needs, and may help to provide culturally responsible and consumer-valued healthcare.

3.2.3. Re-vision concepts and hierarchies of evidence

Restoration of the original concept of EBM (see 3.1.6), and reconceptualization of hierarchies of evidence through consideration of "totalities of evidence" could provide a strong framework for furthering discussion and debate relevant to T&CM evidence, and to highlight new information and research needs. Linear notions of evidence hierarchies can be challenged by conceptualising non-linear "totalities of evidence" for T&CM, which include traditional and other sources of evidence and research. Such a totality could more fully consider T&CM-relevant information, such as history of use, cultural aspects, quality, safety, efficacy, mechanisms of action, cost-effectiveness, whole-of-practice, and consumer/patient preferences. Such information should draw from a variety of research designs including qualitative, mixed methods, observational, case studies and clinical trials. Appropriate research designs need to generate appropriate and rigorous evidence.

3.2.4. Make new and better use of existing resources

The T&CM research arena is not well resourced relative to some other areas in health care. New and existing collaborative relationships should be cultivated to further T&CM research and evidence generation, to mine underutilised sources of evidence, and to better communicate existing T&CM evidence and information. Data collection and information resources that could be better utilised for T&CM purposes include: traditional herbal monographs; oral histories; health insurers; T&CM product manufacturers; government health departments and health related agencies; and academic and research institutions. Collaborative efforts could include the incorporation of T&CM relevant questions in health-related data collection tools within the mainstream health sector, with those results being made widely available for research and analytic purposes. As one forum participant stated:

> (We need to be) able to engage with the evidence that we currently do have without having to reinvent the wheel entirely; there are still pockets of evidence that are completely overlooked.

3.2.5. Educate and operationalise

Planned strategies, actions and outputs need to educate and move beyond rhetoric to ensure they are operationalised.

Education of T&CM and non-T&CM healthcare providers, academics, researchers, consumers, industry, regulators and the media is important. Education should highlight the sociocultural value of T&CM and its relevance to population health promotion, chronic illness prevention and treatment, consumer empowerment, and consumer proactivity. Education and provision of information to providers and regulators can further foster cross-sectoral communication, collaboration and referral between practitioners, and enable providers to be more informed about available research when it comes to discussing information with patients/clients related to their healthcare decision-making.

3.3. Actions and outputs

3.3.1. Reach consensus

Consensus needs to be reached on the definition of T&CM, as well as the scope of issues of concern. A better definition is needed to accommodate the variety of traditional, complementary and alternative medicines available. Defining what is meant by 'traditional' evidence also should be clarified and communicated to practitioners as well as researchers and policy-makers; so should the meaning of the 'patient-centred approach' and its application in T&CM service delivery. The following forum participant quote captures some of the complexity around these definitional issues:

> How we define evidence has got a lot to do with what's conventional (and) what's unconventional. (. . .) It's not all about what happens at the laboratory or in clinical trials, it is about the actual knowledge that we've got from our previous generations that is a repository of important knowledge that needs to be respected. (. . .) One of the things that we need to also be aware of is that this is a very complex interplay. We know when trying to talk about complementary medicine or other medicines that they range from things that were invented in the laboratory last month to things that human beings have taken since the beginning of recorded history. So it is a very diverse field and the concept of evidence is also very diverse and we're trying to interplay two very complex dimensions together.

3.3.2. Consumer needs assessment and the evidence-translation model

A *consumer needs assessment* is necessary to explore the pragmatic needs of T&CM consumers, their perception of what level or type of information is meaningful and valued (including how it should be conveyed), and opinions about the reliability of sources from which this information is derived. Different cultural uses and needs of T&CM, and any mismatch between currently available product information and consumer information needs should be highlighted. Such an assessment could assist in developing an *evidence-translation model* for providing meaningful information to consumers. Both the needs assessment and translation model could potentially inform the provision of information in clinical practice, as well as policy development for regulators and T&CM peak bodies.

3.3.3. Research and publish

Academic research and writing is needed to clarify ideas around evidence that can later be translated into consumer-friendly terms. Research could examine: how to move beyond linear evidence hierarchies to accommodate 'totalities of evidence' (see 3.2.3); issues around the modernisation of T&CM (3.1.4), including implications for safety, efficacy, research and regulation; the need to identify and test new ways of conducting T&CM research to explore and validate novel research designs or novel application of research; how 'big data' and administrative data might provide a potential evidence source; the value of traditional medicine in a broad, cross-cultural context; consumer accessibility to T&CM information; and complexities inherent in generating T&CM evidence and the dissemination of related information.

3.3.4. Develop tools for change

A leadership group (3.2.1) should work to develop tools to inform the T&CM evidence debate and related policy, such as:

- A *Charter of Consumer Rights* related specifically to T&CM use. This charter would define consumers' rights related to T&CM or other culturally relevant non-mainstream healthcare products, practices and practitioners around access to and use of quality, safe T&CM products.
- *A Communication Strategy*. With a strong focus on articulating consumer information needs, the strategy should outline pathways for communication with regulators and clinicians.
- *A Framework for Collaboration, Cooperation and Action.* This framework would provide a practical guide for undertaking the work outlined above.
- *A Consumer's Forum for T&CM:* The purpose of this forum would be to move beyond sceptical debate by creating a different, more grass-roots conversation and lobby group.

3.3.5. Communicate and lobby

Communication and lobbying are integral to changing the nature of the debate about evidence supporting T&CM. The preceding *Actions and Outputs* should incorporate good communication but they should, in themselves, be tools to strengthen communication and lobbying.

3.4. Barriers

3.4.1. Epistemological and paradigmatic

It was discussed how the epistemologies and ideologies underpinning different systems of medicine create paradigmatic barriers that make it difficult to move between those systems. This can mean that undisputable evidence in support of T&CM might not be sufficient to change the attitudes of those philosophically or ideologically opposed to T&CM. Associated with this is the systemic barrier that T&CM systems of knowledge are embedded within philosophies and cultures often divergent to those associated with many of the institutions of power. This barrier, often unacknowledged, has far-reaching implications and is the most difficult to address – hence it needs to be explicitly incorporated into the agenda. As articulated by one forum participant:

> This is a social battle to try and shift the centre of gravity of power (. . .), it's the people who control the institutions of power and money in society against whom there are these attempts to try and assert the moral entitlement of consumers and patients and so on. (. . .) If it were just a matter of saying 'I'll show you the data' (. . .) they would sit back and be convinced. We wouldn't be having this discussion because the battle would have been over years ago.

3.4.2. Lack of definitions

Remedy is needed for the absence of a sufficient definition of T&CM which prevents explicit scoping and clarification of the conversation or debate around the evidence requirements for T&CM.

3.4.3. Lack of leadership and action

There are factional barriers within the T&CM arena that can undermine a strong sense of collegiality and leadership across the

T&CM sector. It was noted that lack of leadership has led to "a lot of rhetoric" but "very little action in terms of moving forward". Further, a lack of leadership may also lead to people within the T&CM arena feeling that: "we all deal with (issues) by ourselves to certain degrees (. . .) you always kind of feel like you're up against the world".

3.4.4. Lack of awareness

A lack of engagement with, awareness, and understanding of available research evidence among T&CM and non-T&CM clinicians and among consumers is a barrier that can be addressed through evidence-translation, education and communication.

3.4.5. Lack of institutional support

This theme links with the epistemological barriers (3.4.1). When institutional support is lacking, resources for T&CM can be limited (e.g. very limited government funding for T&CM related research), or education curtailed (e.g. medical students not receiving what they perceive to be sufficient T&CM-relevant education). It was perceived that such barriers also might be linked to legal or regulatory limits being placed on the practice of some T&CMs (the example was given of labelling requirements for some T&CM products in Australia listing a dosage that is insufficient for clinical effect).

3.5. Drivers of change

The drivers of change listed in Table 2 can be utilised to facilitate change. The various groups (3.5.1–3.5.9) need to be recognised and approached differently to make best use of their potential to generate change.

4. Discussion

This paper presents an Australian-focused agenda for strengthening the evidence-base for T&CM. It is the outcome of a roundtable discussion of experts who collectively brought together many decades of accumulated knowledge from research, clinical practice and/or teaching experience in the fields of T&CM (Chinese medicine, naturopathy, herbal medicine and others), medicine (including general practice), nursing, pharmacology, social sciences and philosophy. The interweaving of the themes throughout the framework highlights key aspects to consider in setting such an agenda. Integral to the agenda is the importance of keeping central the needs and preferences of the public, and so partnering with consumers to co-design and implement strategies to move forward. The actions, research ideas and questions posed by the forum participants provide a starting point for furthering the T&CM evidence agenda. The next step is the creation of a leadership group of coordinated individuals and organisations to provide stewardship towards identifying appropriate evidence for T&CM and lobbying for recognition.

While the forum participants came together ostensibly to discuss appropriate 'evidence' for T&CM products, appropriate evidence for T&CM practices was discussed with equal importance, indicating perhaps a false dichotomy. Throughout the discussion, safety of T&CM *products* was closely linked to safety of T&CM *practices* and *practitioners*. An aspect of T&CM safety, not widely discussed in the literature, was the impacts of modernisation of traditional T&CM therapies; specifically, when T&CM products are prepared or used in new ways that deviate from accumulated, time-tested knowledge about parameters of safe use [29,30]. The WHO *Traditional Medicine Action Plan for South-East Asia* has highlighted the need to encourage research focusing on the impact of modernised forms of T&CM products, including their processing, formulations and use [31]. Lack of accumulated traditional knowledge and research on the safety and efficacy of such 'modernised' products has safety implications for consumers. It is important that there be greater awareness around the differences between 'modernised' and traditional forms of T&CM. The Food and Drug Administration (FDA) in Thailand registers herbal medicines under four classifications: traditional drugs; modified traditional drugs; modern herbal medicines or phytopharmaceuticals; and new drugs [32]. Each type requires increasing levels of evidence for their safety and efficacy [32]. This is a more nuanced approach than the European Medicines Agency and the Australian Therapeutic Goods Administration (TGA) and more needs to be known about the safety of 'modernised' formulations.

Pharmacovigilance systems (adverse events reporting and responses to them) can be a source of information to increase knowledge about T&CM safety; however, these systems are often deficient in relation to T&CM data capture [33,34] and so are not always be equipped to provide sufficient information to differentiate 'modernised' from 'traditional' T&CM preparations [33,35]. Interactions between T&CM products and pharmaceuticals are also common and poorly understood [36].

Reaching consensus on basic definitions related to T&CM was another identified area for action. Defining T&CM is not straightforward. The commonly used umbrella term 'complementary' and 'alternative' medicine is contested–defining therapies or modalities in relation to their complementarity or alternativeness to biomedicine [37]. The boundaries between 'T&CM' and 'conventional' biomedical practice can be blurred, particularly with the rise of 'integrative' medicine practised by biomedical physicians [38–41], and the extent to which biomedical and social sciences are taught in many T&CM curriculums [42,43]. The terms CAM, complementary medicine, traditional medicine and integrative medicine were all used by the forum participants and sometimes interchangeably. This highlights a lack of agreed terminology, but also the different aspects of traditional, complementary, alternative, and integrative healthcare. In an attempt to develop an operational definition for the Cochrane Collaboration, Wieland and colleagues found it "impossible to capture in a single table suitable for publication" a comprehensive list of terms to describe individual T&CM therapies. They hypothesised that there "will never be universal agreement upon CAM aside from a core set of therapies and that even this agreement will be susceptible to change over time" [44]. In going forward, however, it is important that a leadership group defines the boundaries within which the group can operate, including a theoretical and/or operational definition of T&CM (or of complementary medicine, or complementary and integrative medicine).

It has long been argued that the T&CM arena must develop appropriate, rational and coherent research methods that reflect the complexity of certain products and patient-important outcomes. For example, clinical trial designs and reporting standards used for pharmaceutical medicines may not account for the chemical complexity inherent in many herbal preparations (i.e. formulations that blend multiple herbal medicines each containing many active compounds) and the impact of practice context [23,45–51]. The need for appropriate research evidence goes beyond T&CM products to encompass practices and therapeutic settings [21]. Identifying appropriate research designs for T&CM continues to receive international attention. Global surveys of T&CM researchers acknowledge the need for a broad spectrum of research for T&CM, including unique methodologies to explore context, safety and comparative effectiveness [52–54].

Discussion on appropriate research design for building the evidence-base for T&CM led the forum to consider 're-visioning'

linear hierarchies of evidence to better accommodate high quality evidence from a wider variety of sources and research methodologies – and so accepting 'totalities of evidence' for T&CM [55,56]. Such a 'totality' would bring together information from many sources (historical and modern) to generate greater depth of understanding of T&CM efficacy, safety, acceptability, to provide meaningful information for policy makers, healthcare professionals and consumers.

Greater emphasis on the original notion of EBM [27] provides a bridge across the divide between T&CM and biomedical focused healthcare research – providing that EBM remains true to its original definition where clinicians' decisions are informed by the best available empirical evidence, knowledge derived from clinical experience, and consideration of patient preferences and values.

5. Conclusion

The time is ripe in Australia to establish a leadership group to change the nature of debate around what is appropriate evidence for T&CM and to lead action to advance this area. Clinicians and T&CM consumers should be mobilised to lobby for greater recognition. This paper provides a framework that can be used to guide such work. The framework is broad but encapsulates: focus on consumers; the importance of evidence, regulation and policy; challenges arising from the modernisation of T&CM; and supporting healthcare practitioners and consumers alike who must navigate the complexities of the rapidly growing evidence-base. Keeping the needs and perspectives of consumers central is a key element in going forward and getting political attention. Rather than reliance on linear evidence hierarchies to evaluate T&CM, 'totalities of evidence' provide a way to draw together information from disparate sources so that the knowledge gained might be greater than the sum of its parts.

Ethics approval and consent to participate

Formal ethics approval was not required for the roundtable discussion (the forum). All forum participants recorded their consent for their de-identified contributions to be reported, all were provided opportunity to comment on the draft manuscript, and all provided written consent to be named in the acknowledgements of this paper.

Consent for publication

The authors and forum participants have read the manuscript and provided written consent for publication.

Competing interests

Author JH, is engaged in integrative medicine clinical practice and is an academic researcher at NICM. As a medical research institute, NICM receives research grants and donations from foundations, universities, government agencies, individuals and industry. Sponsors and donors provide untied funding for work to advance the vision and mission of NICM. The project that is the subject of this article was not undertaken as part of a contractual relationship with any organisation or donor. Authors RC and ML have no competing interests to declare.

Authors' contributions

RC and ML undertook data analysis. RC conceptualized and drafted the paper with input from ML and JH. All authors reviewed and revised the manuscript.

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