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Towards consensus: defining and supporting a professional role for pharmacists associated with traditional and complementary medicines – a protocol of implementing an international e-survey

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ABSTRACT

Introduction Traditional and complementary medicines (T&CM) are predominantly self-selected from retail outlets including pharmacies as part of self-care practices. Concerns about the appropriate and safe use of T&CM products raises questions about 'should' and 'how' pharmacists could adopt professional responsibilities. There lacks a consensus about the scope of these responsibilities, or the initiatives required to execute them. The aim of this study is to identify an international set of core responsibilities that support pharmacists' contribution to ensuring the quality and safe use of T&CMs to promote public health.

Methods and analysis An international cross-sectional e-survey of pharmacists representing the six WHO regions will be conducted over a 12-month period. Pharmacists will be invited via representative organisations and professional networks within their respective country. Survey responses to statements about the relevance of T&CM to day-to-day practice; opinions about the bioethical and practice responsibilities; and support required to build their scope of practice associated with T&CM will be collected centrally via the online survey platform Survey Monkey and analysed using the Statistical Package for Social Sciences V.27 software for Windows. Bivariate statistical analysis will be conducted to examine the associations between agreement to statements within each section with key demographic variables, country of practice, pharmacy type, age, gender, qualification and years in practice. Cronbach's alpha will be used to test the internal consistency of items from certain sections of the survey and evince their clarity to respondents of the questionnaire.

Ethics and dissemination Ethics approval has been obtained from the University of Macau (approval number SSHRE21-APP068-ICMS-01). The results of this survey will be used to inform key discussion points in a consensus process and a step towards developing an agreed and defined professional role for pharmacists in T&CMs.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ We will conduct an international web-based, cross-sectional survey of pharmacists using the Checklist for Reporting the Results of Internet E-Surveys and Strengthening the Reporting of Observational Studies in Epidemiology guidelines.
⇒ We have undertaken a comprehensive and iterative process to develop and pilot the survey instrument with pharmacists.
⇒ Dissemination of the survey in different countries over the same time will capture similarities and differences between the sociodemographic contexts.
⇒ Using convenience sampling of pharmacist professional associations and networks may introduce selection bias.
⇒ Use of the same core survey questions translated from English may have compromised some of the cultural nuances specific to a country or region.

INTRODUCTION

Safe and appropriate use of traditional and complementary medicines: a public health matter

The use of traditional and complementary medicines (T&CM) is highly prevalent around the world.[1] Ensuring the safe and appropriate use of T&CM to minimise risks and optimise benefits is an important area of public health that is yet to be fully addressed. While the terms 'traditional medicine (TM)' and 'complementary medicine (CM)' are often used interchangeably or combined, there are fundamental differences between the two.[1] TM is defined as 'the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention,

diagnosis, improvement or treatment of physical and mental illness'.[1] Whereas, CM is described as a broad set of healthcare practices that are not part of a country's own traditional or conventional medicine and are not fully integrated into the dominant healthcare system.[1] The terms TM and CM encompasses products, practices and practitioners.[1] For the purposes of this study, T&CM products will refer to natural products that are used for medicinal purposes including herbal products, nutritional supplements, vitamin and minerals, essential oils and homeopathic products.[2]

T&CM products are an increasingly prevalent component of healthcare and self-care practices across the world. People choose T&CM products for health maintenance as well as disease prevention and treatment, with varying prevalence rates across regions.[1] As new evidence emerges regarding the safety and effectiveness of some T&CM products, knowledge about their contribution to health outcomes across world regions will become clearer. However, many consumers consider T&CM products as 'natural and therefore safe', and thus may not extend the same caution towards their use as they would for prescription medicines.[3] Further, decisions about T&CM products use among people with serious conditions such as cancer maybe uninformed/misinformed.[4] Indeed, there are safety risks related to the quality of products,[5] potential adverse events including drug–herb/nutrient interactions,[6] and delays in initiating known effective treatments, all of which can easily be overlooked.[7] This is particularly the case for special population groups such as children, the elderly and people living with chronic or other complex health issues, among whom the risk of experiencing adverse drug reactions and drug–herb interactions may be increased.[8] Some of these risks are potentially confounded by integrative approaches (the use of T&CM products in conjunction with conventional medicines)[9] and poor interprofessional communication between conventional and complementary medicine practitioners.[10]

Collectively, there is a public health need to harness the potential benefits and minimise risk associated with T&CM products around the world. The evidence base evaluating the use of T&CM products is growing, which can help resolve uncertainty on safety and effectiveness and should be used to guide decisions about their use.[11] The Cochrane Complementary Medicine group critically evaluates and synthesises the evidence originated from meta-analyses and randomised clinical trials about the effectiveness of a range of T&CM products and practices for the treatment of various conditions, and accounts for 10% of Cochrane reviews.[12] Indeed, the research on T&CM herbal ingredients is growing exponentially. It is apparent that identifying large-scale high-quality evidence is challenging due to heterogenous study designs (populations studied, formulations and doses used, lack of detailed reporting) and risk of bias. Therefore, for the average consumer, access to a health professional who can help identify, evaluate and translate the available evidence to inform and guide their decisions about using T&CM products is important.

Pharmacists' role in addressing the concerns about the use of T&CM products

The pharmacist's role in contributing to public health by ensuring the safe and appropriate use of medicines is well established. Discussion regarding broadening the scope of pharmacists' professional practice to include T&CM products began over two decades ago.[5] International and national professional pharmacist organisations also advocate the inclusion of T&CM products into pharmacists' scope of practice. In general, pharmacists recognise the relevance of T&CM products to their daily practice, the needs of consumers and are keen on stepping up their professional role in the delivery of more responsible pharmaceutical services.[13–15] Further, an argument proposing pharmacists provide professional advice in this area should not be limited to those T&CM products accessed only through pharmacies. Indeed, encouraging disclosure about all T&CM products including those purchased through other retail stores and online outlets needs to be considered by pharmacists as part of the pharmaceutical care they provide. Despite this, pharmacists still do not engage and are professionally underperforming in this area.[16] Such observations have been reported in the USA,[15] Australia,[16] China[14] and many other countries.[17]

Lack of an international consensus on pharmacists' responsibilities in T&CM products

No international consensus has been reached about the practicalities and processes required to engage pharmacists in caring for people who use T&CM products. A systematic review published in 2017 identified pharmacists' practical responsibilities most commonly reported in the literature and called for actions to reach a consensus on how pharmacists should be involved in safeguarding the proper use of T&CM.[17] The seven responsibilities proposed were for pharmacists to acknowledge the use of T&CM products in the communities they serve; be knowledgeable about the evidence base for T&CM products; ensure patients are using T&CM products safely; document the use of T&CM products on patient records; report adverse drug reactions associated with T&CM products; educate patients about T&CM products; and communicate with other healthcare professionals about the use of T&CM products.

These findings were raised again in a more recent systematic review[18] that informed the development of a bioethical framework for pharmacists' responsibilities when selling T&CMs.[19] The framework supported and built on the afore-mentioned pharmacists responsibilities to propose that both pharmacists and their staff should be trained in the provision of evidence-based T&CM recommendations; pharmacy staff should know when to refer to a pharmacist about T&CM products; pharmacists should be able to provide T&CM product information for people to make informed decisions; the layout and

business model of the pharmacy should be conducive to consumers receiving T&CM product advice from a pharmacist when purchasing the products; and pharmacists should intervene if the risk of harm is significant. Despite these individual and collective research efforts, a substantial gap remains between the responsibilities and ethical framework that have been proposed in relation to T&CM products and what takes place in day-to-day pharmacy practice.[16 20] This may be related to the fact that internationally and nationally in most countries, the legal and professional expectations associated with this role are still not clearly defined.[13]

Changes to the legal and professional expectations of pharmacists associated with T&CM products is complex and involves multiple stakeholders including professional pharmacy organisations, universities, government, pharmacy owners and pharmacists to develop education and training, build the T&CM evidence base and reliable and accessible T&CM resources and imbed a workplace culture that supports best practice in T&CM.[21] This requires a strategic and coordinated effort driven by pharmacists and their representative organisations around the world towards a consensus that translates the last two decades of research into implementable global practice behaviours that support public health and safety. According to a strategic model developed by Ung *et al*, among other actions, translating a set of responsibilities into practice standards and implementing those standards is critical to improving pharmacists' professional practice associated with T&CM products.[21] As such, a clear description of pharmacist professional involvement in T&CM products serves two main purposes. First, it raises the public's attention about the need for health professional's involvement when making decisions about the use of T&CM products and drives the standardisation of pharmacists' practice behaviours. More importantly, it forms the foundation for developing competency standards that inform learning outcomes in undergraduate and postgraduate pharmacy education. The need for T&CM education in pharmacy training programmes is well established to facilitate competent and confident communications between pharmacists and the public they serve.

AIMS/GOALS

The overarching aim of this international study is to identify a set of core responsibilities that support pharmacists' contribution to ensuring the quality and safe use of T&CM products and promote of public health.

The objectives are (1) to develop, pilot and disseminate a cross-country e-survey through an international collaborative effort via professional associations and representative organisations; and (2) provide an international perspective of pharmacists' opinions about their professional responsibilities associated with T&CMs, and the steps and support required to formalise such a role; and (3) use these perspectives and key points of agreement to inform the next project—a consensus process.

METHODS AND ANALYSIS

A cross-sectional online survey with convenience sampling in each of the participating countries will be employed. This study protocol outlined here is developed in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology guideline[22] and the Checklist for Reporting Results of Internet E-Surveys.[23]

This international collaboration is led by researchers from the Institute of Chinese Medical Sciences, University of Macau and The University of Sydney School of Pharmacy, Faculty of Medicine and Health in New South Wales Australia. A web-based cross-sectional open survey will be disseminated across countries representing pharmacists from the six designated WHO regions: African Region (AFR), Region of the Americas (AMR), South-East Asian Region (SEAR), European Region (EUR), Eastern Mediterranean Region (EMR) and Western Pacific Region (WPR) over a 12-month period. Countries to be surveyed will be recruited via purposive sampling and snowballing. To identify researchers to lead the survey in individual countries, a search of published studies on the topic of pharmacists and T&CM published within the last 5 years will be conducted. Email addresses of the corresponding author/s available in each publication will be used to initiate contact. Authors who respond to the email will be invited to a research team discussion (online) and encouraged to extend the invitation to researchers in the field. To date, the recruitment method for building an international research team has attracted commitment from researchers located across the six designated WHO regions AFR (Cabo Verde and Angola), AMR (the USA and Brazil), SEAR (Thailand and Indonesia), EUR (Croatia, the UK and Portugal), EMR (United Arab Emirates and Lebanon) and the WPR (Australia, China and Malaysia) who have confirmed their participation. The researcher/team based in each country will be responsible for leading the study in their respective country. The link to the e-survey will be open for a maximum of 4 weeks.

Population and recruitment

Pharmacists engaged in a range of practice settings (both in the past and present) including community pharmacy, hospital pharmacy, clinical/consultancy, the pharmaceutical industry, academia and regulatory bodies across the participating countries will be eligible to participate. People who are not pharmacists or pharmacists from outside of the participating countries will not be eligible to participate. No incentives for participation will be offered. The research team within each country will be required to engage with national or local pharmacists' representative organisations and professional networks to recruit participants. In accordance with the size of the pharmacist workforce, which may vary considerably from a few hundred to

several hundred thousand,[24] varying degrees of access to the lists of registered pharmacists and the differences in the organisational structures of pharmacy organisations, a combination of sampling approaches including probability sampling (when the entire pharmacist workforce in the country is reachable), purposive sampling (when only a subset of pharmacist workforce in the country is reachable) and snowball sampling will be employed. The minimum sample size for each country will be targeted to obtain a CI of 95%, with a margin of error 5% for the survey results.

In each country, the local research team member will select the pharmacist professional networks through which to disseminate the link to the survey. In accordance with the ethical requirements of each country, an invitation to participate in the open survey will be circulated via pharmacists' representative organisations within the respective country. The invitation with the survey link will be distributed through professional newsletters, email correspondence, local supporting professional organisation, pharmacist professional networks and/or social media links. The recruitment rate will be calculated by the ratio of people who agreed to participate on the first page of the survey divided by the number who visited the survey but did not agree to participate.

Survey development and pretesting

Following a systematic review of the literature reporting on the topic of pharmacists and T&CM products,[17] the research team has undertaken a comprehensive and iterative process to develop and pilot the survey instrument (with pharmacist coinvestigators). To ensure the face validity of the questionnaire, the initial instrument was first assessed by four researchers experienced in quantitative studies and pharmacy practice (including a full professor, one postdoctoral fellow and two PhD students who specialise in the discipline of medicinal administration and research experiences related to the objectives of this study) through a focus group. They were also asked to evaluate if the statements in the questionnaire would allow reasonable and operational measurements of each key item and to elaborate further on how to improve the validity of the questionnaire design. Based on their feedback, revisions were made to improve the comprehensibility of items. The revised instrument was then pilot tested on a convenience sample of 20 pharmacists in Macau who received their pharmacy training in the USA (n=2), the UK (n=3), Australia (n=3), Portugal (n=2), Mainland China (n=5) and Taiwan (n=5), and had a minimum of 3 years of professional pharmacy practice experience within the community, hospital and/or regulation sectors. Two pharmacists held leadership positions in pharmacist professional organisations. They were asked to specifically evaluate whether the items encapsulated pharmacists practice related to T&CM products. They all agreed that the questions were comprehendible thus confirming the face and content validity of the survey instrument. No removal or addition of the original items was suggested.

The research team member based in each region/country will organise translation of the survey instrument if required, local field testing and any additional ethical review required within that country. Whenever applicable, translation will ensure that the survey is available in the national language of the country and other relevant languages. For survey questionnaires translated from English, a third step is undertaken translating the items back to English to ensure the intent of questions that have not been lost in translation. To finalise the survey instrument structure used in each country, field testing using a print form of the survey to 5–10 individuals will be conducted to have them provide feedback about translations. Three rounds of iteration per country survey are expected to finalise the content. Further field testing in digital form will be conducted with another 5–10 individuals per country to examine errors in skip logic.

Inclusion criteria for the survey include adults (≥18 years of age), currently practising as pharmacist in the participating countries and able to provide online informed consent. A completeness check is embedded via a forced response with all items providing a non-response option 'neutral'. Participants are able to select a back button to allow respondents to review and change their answers. Completion rate will be the ratio of people who finished the survey who agreed to participate, that is, the number of people submitting the last questionnaire page, divided by the number of people who agreed to participate. A setting in Survey Monkey will be activated to prevent users' access to the survey from a single IP address (in countries where this is available) two times. IP addresses will not be used to identify participants' computers and ensure complete privacy. The average time to complete the survey is 9–11 min.

Questionnaire design

The survey instrument starts with a brief overview about the research topic, a link to a participant information statement and a question confirming consent. Overall, the survey consists of 5 sections involving 43 items relevant to T&CM products in pharmacy practice: section 1—participants' sociodemographic characteristics (seven items), section 2—participants' perception about T&CM (five items), section 3—opinions about bioethical responsibilities related to T&CM products (three items), section 4—opinions about practice responsibilities related to T&CM products (15 items) and section 5—the support they need to build their scope of practice related to T&CM products (13 items). The survey ends with an open question to draw participants' additional comments regarding professional pharmacy practice regarding T&CM products. The full survey instrument is included as a supplementary file (insert link here).

In section 1, participants will be asked to confirm their eligibility of being a pharmacist in the first question. Questions about basic demographic characteristics such

as gender and age will follow. In the subsequent five questions, sociodemographic information that has been suggested to have an impact on how pharmacists perceive their professional practice related to T&CM products will be sought. These include education background,[25] practice setting,[14] status of employment[21] and history of T&CM education.[15]

In section 2, the level of agreement to three items capturing pharmacists' perception about T&CM products are sought. Perceptions about evidence, safety and efficacy are thought to influence pharmacists' approach to providing advice area in day-to-day practice.[14] An additional two items will identify what types of T&CM products participants consider should (or should not) be within the scope of their professional practice.

In section 3, the level of agreement to three items designed to capture opinions about a set of proposed bioethical responsibilities,[18] and a framework for pharmacists managing T&CM products are requested.[19]

In section 4, participants will be asked to rate their level of agreement to 15 responsibilities that have been proposed in the earlier literature associated with pharmacists and T&CM products.[17 26 27]

In section 5, level of agreement to 13 items related to the factors thought to enable pharmacists to effectively engage and build their scope of practice related to T&CM products will be sought.[13 20 28] These items correspond to six domains: (1) clarifying pharmacist role related to T&CM products, (2) a need for T&CM related education, (3) fostering workplace support, (4) facilitating more non-biased research of T&CM products, (5) promoting effective interprofessional communication and (6) improving regulation standards of T&CM products.

Level of agreement scores will be obtained by coding the 5-point Likert scale, that is, 1=low level of agreement and 5=high level of agreement.

Data protection and consent

This research study will present no greater than minimal risk to participants. The participants will be allowed to stop the survey at any point of time. No participant names or other identifiers will be collected. While research team members will coordinate the study in each country, and analyse the survey data for their country, decisions about data sharing across countries will be agreed on and data sharing agreements for cross-country analyses will be signed between the research team and the leading research team member in each country.

All survey data will be collected via the author's licensed access to Survey Monkey in Macau. Survey Monkey is an online data capture tool that stores data on secure servers. A survey link specific to each country will be created. The data will be collected centrally via the online survey platform Survey Monkey in accordance with the user agreements licenced to The University of Macau. Participation in the study is voluntary, and the survey completed anonymously. A question at the start of the survey will confirm that participants have read and understood the participation information statement and agree to the use of their responses in the analysis.

Data analysis plan

Individual country anonymous survey data will be provided to the external coinvestigators (research team members) in an Excel spreadsheet once the survey data for their country/region is completed. The metadata (all country/regions survey results) will be held by the CIs (JEH and COLU) and analysed using the Statistical Package for Social Sciences V.27 software for Windows.

This statistical analysis plan focuses on the cross-county comparison component of the analysis. Only survey data that meet the following criteria will be included in the international comparison: completed surveys of at least 200 participants (unless the pharmacist workface is less than 200 in the participating country), human research ethics committee/institutional review board approval from the local authority if required in addition to the University of Macau approval, description of sampling methodology, and local instrument translated whenever applicable, and field tested.

The demographic data of the respondents and the ratings of the item statements will be analysed using descriptive statistics (frequencies, means and SD). In addition to descriptive analysis for responses to sections 2–5, various bivariate statistical procedures will be used to evaluate the association between the ratings of item statements and the demographic variables. The international analysis will use multiple linear regression to examine individual-level and country-level variables associated with primary measurements: pharmacist's opinions about their professional responsibilities associated with T&CMs, and the steps and support required to formalise such a role. This is to identify the respondents' demographic characteristics worth considering when deciding on the strategies that promote the implementation of the practice behaviours. Data from different countries will also be combined to conduct subgroup analyses on the following groups of individuals: age groups, education level, seniority, practice setting and previous education about T&CM. 'A p value of less than 0.05 will be accepted as statistically significant. Data from sections 3–5 of the survey will be placed into an exploratory factor analysis procedure to help identify overarching domains of pharmacists' responsibilities related to T&CM products. Cronbach's alpha will be calculated on the combination of these items to help assess their internal consistency and as a check to help assess the sincerity of the respondent's engagement during the survey process. In lacking a gold standard to measure pharmacists' perceptions, the exploratory factor analysis will help affirm at least some degree of validity as to the construct of pharmacists' responsibilities.

Patient and public involvement

No patient/s were involved in the development of this study protocol.

Ethics and dissemination

The study has been approved by the University of Macau (approval number SSHRE21-APP068-ICMS-01). All potential participants will be provided a participant information statement outlining the background, purpose, and details of the study; how their data will be stored during and after the study; and contact details of the lead investigator. The results of this study will be submitted for publication in peer-reviewed journals and conference proceedings. To ensure a comprehensive insight into each country/region results, both country, and region specific, and a collective report will be reported.

Results will be disseminated in scientific papers and made available to professional audience during professional events. All participating countries will be encouraged to communicate research findings to relevant key stakeholders and to use the findings as a foundation to extend more in-depth research in the country. Based on the collaborative work in this project, all the participating investigators will form a consortium, which will take a lead in developing a universal set of pharmacists' primary responsibilities in T&CMs for academic and professional interests.

IMPLICATIONS OF THIS RESEARCH

Evidence suggests that use of T&CMs by the public all over the world will continue to proliferate.[1] While the benefits and risks of many T&CMs are yet to be fully evaluated, the prevalent use without consistent oversight has not been fully addressed by the public health sector. Pharmacists play an integral role in contributing to public health through their expertise in medicines management. However, T&CMs continue to be self-selected and purchased as 'retail products' rather than medicines and are not routinely integrated into pharmaceutical care and practice. While some isolated measures towards integration have been proposed, there remains no consensus on how to deliver pharmaceutical care in a coordinated, systematic manner.

To date, no research examining pharmacist's role in T&CMs across world regions during a single period has been conducted. It is critical that pharmacist professions' opinions are represented strongly in the development of a consensus process about their professional role in T&CMs. This study is an important step towards ensuring the credibility and applicability of a consensus discussion. The results of this survey will be used to inform key discussion points in a consensus process and a step towards developing an agreed and defined professional role for pharmacists in T&CMs; and the support required for them to enact that role effectively. This will have implications to the quality and safe use of T&CMs and therefore public health.

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