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STARTING FROM SCRATCH –  
PATIENT-REPORTED OUTCOME QUESTIONNAIRES  
& THEIR ROLE IN AN  
INTEGRATIVE MEDICINE PRIMARY CARE  
MINIMUM-DATASET.

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Thesis submitted in fulfilment of the degree of

Doctor of Philosophy

2013

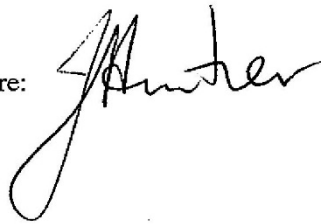


THE UNIVERSITY OF  
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Sydney School of Public Health

## **DECLARATION**

This thesis is submitted to the University of Sydney in fulfillment of the requirement is for the Doctor of Philosophy. The work presented in this thesis is, to the best of my knowledge and belief, original except as acknowledged in the text. I hereby declare that I have not submitted this material, in either full or in part, for a degree at this or any other institution.

Signature: 

Date: 4/4/2013

# **STARTING FROM SCRATCH – PATIENT-REPORTED OUTCOME QUESTIONNAIRES & THEIR ROLE IN AN INTEGRATIVE MEDICINE PRIMARY CARE MINIMUM-DATASET.**

## **ABSTRACT**

### **AIM**

This research explored the use of patient questionnaires for evaluating integrative medicine (IM) clinics in the primary care setting.

### **BACKGROUND**

Integrative medicine (IM) combines traditional, complementary, and alternative medicine with conventional biomedicine. With more clinics in Australia offering IM, it is important to evaluate outcomes.

### **METHODS**

Mixed methods were used. This included a case study of an IM clinic in Sydney, Australia; interviews with 20 patients and 13 staff at the clinic; and a systematic literature review of patient questionnaires.

### **RESULTS**

Challenges for measuring IM outcomes limitations with routine clinical data collection, selecting appropriate questionnaires able to measure the wide range of IM outcomes whilst

minimizing responder burden, patient recruitment and practitioner support. Electronic questionnaires have many advantages. Alternative formats such as paper are still needed. Not all interviewees were interested in cohort results or research and instead wanted to access their individual patient results.

## **DISCUSSION**

The results from the studies were synthesised and a set of recommendations are offered.

## **CONCLUSIONS**

Patient questionnaires could be used to establish a minimum dataset for use in research, health service development, and informing and improving individual patient care. A bottom-up approach that addresses stakeholders' needs for a dataset is essential.

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## GLOSSARY OF TERMS

The term **Traditional, Complementary & Alternative Medicine (TCAM)** is used throughout this thesis in preference to more commonly used terms, because it acknowledges that for many people, including some Indigenous Australians, these therapies are neither complementary nor alternative medicines. Instead, they may be their mainstream conventional medicine and sometimes the only medicine available.

**Traditional, Complementary & Alternative Medicine (TCAM)** covers various traditional and natural therapies. Other commonly used terms that have a similar meaning are **Complementary & Alternative Medicine (CAM)** and **Complementary Medicine (CM)**.

The other terms used in this thesis are listed in alphabetical order.

**Ayurvedic Medicine** refers to the traditional Indian medical practice that appeared during the Vedic period in India.

**Biomedicine** is a clinical practice that draws on the scientific disciplines of chemistry, physics, biology, physiology, statistics, epidemiology etc. In this thesis it is used to differentiate **biomedical** doctors and **biomedical** health services from TCAM practitioners and TCAM health services.

**Evidence-Based Medicine (EBM)** utilizes the best available scientific evidence to inform clinical decisions and healthcare provision.

**General Practitioner (GP)** is a biomedical doctor who provides medical care for people of all ages with both acute and chronic illness in the primary care setting. Preventative medicine and screening for disease are other important roles of the GP. The term **family doctor and family physician** are synonymous terms commonly used in the USA.

**Holistic Health (HH)** has different meanings and uses. For some it is synonymous with TCAM. In this thesis, unless stated otherwise, holistic health refers to the health of the whole person and recognises that a person's health is multifaceted. Theoretically, any style of medicine or intervention can be provided in a holistic way.

**Integrative Medicine (IM)** in this thesis refers to the combination of Western biomedicine with TCAM. **IM practitioners** have biomedical training and training in one or more TCAM therapies. **IM clinics** offer healthcare services provided by various combinations of biomedical, IM and TCAM practitioners.

**Integrative Medicine Minimum Dataset (IM-MDS)** is a dataset that systematically collects an agreed set of longitudinal cohort data from IM clinics, practitioners or patients.

**Naturopathy** refers to traditional natural therapies of European origin. Practitioners are often called **Naturopaths**.

**Patient-Centred Care** addresses the healthcare needs and preferences of patients by establishing a partnership with the patient that enables active participation in the decision-making process and their management.

**Patient-Reported Outcomes (PRO)** are health-related outcomes measured from patients' written or spoken responses to questionnaires.

**Primary Care** describes health services that are the first point of consultation for people in the community. Patients are then referred on to **Secondary Care** and **Tertiary Care** (either in the hospital or community) for more specialised health care.

**Traditional Chinese Medicine (TCM)** originates from China. Similar systems are used across East Asia and more recently have been grouped together under the term **Traditional Oriental Medicine (TOM)**.

**Traditional Medicine** is a broad term referring to therapies originating from a traditional or indigenous culture. This includes traditional Western herbal and naturopathic medicines, traditional Chinese medicine, traditional Oriental medicine, and Ayurvedic medicine.

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## **PUBLICATIONS ARISING FROM THIS THESIS**

Hunter J, Corcoran K, Phelps K, Leeder S. The Challenges of Establishing an Integrative Medicine Primary Care Clinic in Sydney, Australia. *J Altern Complement Med.* 2012;18(11):1008-13. Epub 2012/08/29. doi:10.1089/acm.2011.0392.

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Hunter J, Corcoran K, Leeder S, Phelps K. Is it time to abandon paper? The use of emails and the Internet for health services research - a cost-effectiveness and qualitative study. *J Eval Clin Pract.* 2012. Epub 2012/05/30. doi:10.1111/j.1365-2753.2012.01864.x.

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Hunter J, Corcoran K, Leeder S, Phelps K. Integrative medicine outcomes: What should we measure? *Comp Ther Clin Practice.* 2013;19(1):20-6. doi:10.1016/j.ctcp.2012.10.002.

Hunter J, Leeder S. Patient questionnaires for use in the integrative medicine primary care setting – A systematic literature review. *Eur J Integr Med.* 2013; 5(3):194-216 doi: 10.1016/j.eujim.2013.02.0023

Hunter J, Marshall J, Leeder S, Corcoran K, Phelps K. A positive concept of health - interviews with patients and practitioners in an integrative medicine clinic. *Comp Ther Clin Practice*. 2013; published online 26 August 2013, doi: 10.1016/j.ctcp.2013.07.001

Hunter J. Exploring the prospect of a complementary and integrative medicine database for use in the Australian primary care setting. *Advances in Integrative Medicine*.

2014;1(1):25-31 doi:10.1016/j.aimed.2013.08.001

## **PRESENTATIONS ARISING FROM THIS THESIS**

ABSTRACT: Abstract – Patients’ concept of health that is more than the absence of disease. *Research Presentation Day - Influencing Public Health Policy and Practice through the Next Generation of Researchers*. University of Sydney, Australia, 2012.

ABSTRACT: Motivators for participating in, or supporting observational research. *Research Presentation Day - Influencing Public Health Policy and Practice through the Next Generation of Researchers*. University of Sydney, Australia, 2012.

ABSTRACT: Patients’ concept of health that is more than the absence of disease. *17th International Integrative Medicine Conference: Australian Integrative Medicine Association*. Sydney, Australia, 2012.

ABSTRACT: What is holistic health? Patient and practitioner perspectives. *17th International Integrative Medicine Conference: Australian Integrative Medicine Association*. Sydney, Australia. 2011

ABSTRACT: A systematic literature review of patient reported outcome measurement tools for routine use in primary care integrative medicine: Hunter J, Leeder S, Usherwood T. *5th International Congress on Complementary Medicine Research*. Tromsø, Norway. 2010

ABSTRACT: Systematic literature review of patient reported outcome measurement tools for routine use in primary care integrative medicine. *Research Presentation Day -*

*Influencing Public Health Policy and Practice through the Next Generation of Researchers.* University of Sydney, Australia. 2010

ABSTRACT: Systematic literature review of patient reported outcome measurement tools for routine use in primary care integrative medicine. *16<sup>th</sup> International Integrative Medicine Conference: Australian Integrative Medicine Association.* Noosa, Australia. 2010

## **AUTHOR'S CONTRIBUTION**

I, the author, Jennifer Hunter under the supervision of Professor Stephen Leeder, Menzies Centre for Health Policy, University of Sydney and Professor Timothy Usherwood, Department of General Practice, Sydney Medical School (Westmead), University of Sydney; carried out the work presented in this thesis.

I planned the research; designed the studies; wrote the funding grant applications; obtained ethics approval; supervised the research assistants; collected, managed and analysed the data; interpreted the results; drafted and revised the manuscripts for submission to peer-reviewed journals; and wrote and compiled this thesis.

## **STATEMENT OF CONTRIBUTION FROM CO-AUTHORS**

Professor Stephen Leeder directly supervised the research, providing guidance throughout. He assisted funding applications; provided feedback on study design and ethics approval; and gave editorial input on this thesis and all the papers submitted for publication.

Professor Kerry Phelp assisted with funding applications; provided feedback on study design and analysis of the papers presented in Chapters 4 and 5; and gave editorial input on papers submitted for publication. Katherine Corcoran helped collect and analyse the qualitative data. She gave editorial input on the papers submitted for publication. Jack Marshall helped analyse the qualitative data and gave editorial input on the paper presented in Chapter 7.

Signed co-author declarations forms can be found in Appendix III.

## **ETHICAL CLEARANCE**

Ethics approval was granted from two Human Research Ethic Committees (HREC) for the research presented in Chapters 6 to 10. The University of Sydney HREC was the overseeing committee for the investigators. The Illawara HREC, University of Wollongong was the overseeing committee for the Area Health Service where the clinic was located.

## **PREFACE**

I present this thesis for examination as a ‘thesis by publication’ with chapters containing work published or accepted for publication in peer-review journals. The research draws on my clinical and academic skills in integrative medicine and public health medicine.

In Australia, integrative medicine (IM) refers to the combination of traditional, complementary, and alternative medicine (TCAM) with conventional biomedicine. My interest in TCAM began shortly after graduating as a medical practitioner in 1990.

Throughout my career as a clinician I have studied various TCAM modalities and have integrated TCAM into my clinical practice in primary care. A background in public health medicine and recent work undertaken for the National Institute of Complementary Medicine heightened my awareness of the urgent need for IM health services research in Australia.

I was especially interested in effectiveness research, whole systems research, and the potential use of a minimum dataset that would collect longitudinal data from patients and clinics. The aim would be to measure the wide range of outcomes relevant to IM and to use electronic patient questionnaires that could be linked to routine clinical data and e-health records.

This research was undertaken whilst I was working part-time in an IM primary care clinic in Sydney, Australia. IM health services research is in its infancy, especially in Australia. Only a few case studies of IM clinics are reported in the literature and none were Australian. I decided it was important to undertake a case study of the clinic where I worked and to share this information with the wider IM community. At the same time, I began a

systematic review to identify and appraise patient-reported outcome questionnaires. I had originally thought I would then pilot test a small battery of selected questionnaires with patients in the clinic. However, whilst reviewing the literature, I realised that before a final selection could be made, more information was needed from the patients and practitioners at the clinic about their views on the use of patient questionnaires.

Although my original research interest was to use quantitative methods, mostly qualitative methods were employed. It has been an invaluable learning experience that enabled me to discover firsthand the value of qualitative methods for providing an in-depth understanding on a subject. Given mixed methods and whole systems research are both recommended approaches for IM evaluation, the skills I have acquired in qualitative methodology and mixed method research will be important adjuvant to any quantitative methods I might use in the future.

I am now looking towards building on the research presented in this thesis to establish a minimum dataset for evaluating patient outcomes in integrative medicine.



## CHAPTER 1: INTRODUCTION

The introductory chapter summarises the relevant background information that inspired this research, its aims and objectives, scope and limitations, and the thesis outline.

*'Starting from scratch'* was first coined by sport in the 1800s. Competitors with no handicap in a race had to start from the scratch line. At the beginning of a bout, boxers who met the required standard were *'up to scratch'* and would face each other at the scratch line.

A new competitor in the health industry is emerging – traditional, alternative and complementary medicine (TCAM) and integrative medicine (IM). Sceptics devalue the clinical expertise and traditional knowledge that inform many of these therapeutic approaches. They call upon exponents of TCAM and IM to provide robust scientific evidence that is *'up to scratch'*. Similar to other complex healthcare interventions discussion continues about appropriate methods for evaluating these interventions. Irrespective of the chosen methodology, the systematic collection of patient and health service data, and outcomes will be needed.

Following a case study of an IM primary care clinic in Sydney, Australia, the decision was made to focus the remaining research presented in this thesis on patient questionnaires and their place in a minimum dataset. This necessitated *'starting from scratch'*. Before developing or testing patient questionnaires or using them in a dataset, a systematic approach should be taken to ascertain which questionnaires if any, are most appropriate and strategies to improve support for their use by patients and practitioners.

## 1.1 BACKGROUND

Over the past few decades, traditional, complementary and alternative medicine (TCAM) has become increasingly popular throughout developed countries. Coupled with this is a rise in the number of biomedical practitioners who are either integrating aspects of TCAM into their own clinical practice, or working in multidisciplinary teams with TCAM practitioners; either approach is commonly referred to as Integrative Medicine (IM).

In Australia, the majority of TCAM and IM is practised in the community and primary care setting; the facilities and services are mostly private enterprise with indirect funding from government health rebates and private insurers.<sup>1</sup> The growing demand for IM makes it even more important to systematically evaluate the services. As in all areas of health care delivery, evaluations are needed for the development of high quality services that meet the needs of the individual and the community.

The evaluation of IM services is still in its early days and more research is urgently needed.<sup>2</sup> Only a few IM clinics are reported in the literature and it is challenging to engage clinics to participate in research.<sup>3,4</sup> Most of this research has been undertaken outside of Australia and investigates institutions. Less is known about the private sector and IM primary care services. There are no published evaluations of Australian IM primary care clinics.

Evaluating IM services is challenging, because the interventions and outcomes are complex and context specific.<sup>5-7</sup> TCAM and IM aim to provide holistic, patient-centred care.<sup>3,8</sup> Like much of primary care medicine, the results of randomised control trial with strict inclusion criteria are not always applicable.<sup>9</sup> Comparative effective research, mixed

methods and whole systems research have been proposed as appropriate methodologies for evaluating IM.<sup>9-11</sup>

The National Institute of Complementary Medicine (NICM) in its directions report for IM recommended a “*strategy and process to develop a minimum data set to monitor and evaluate IM clinical practice in Australia*”.<sup>1</sup> This would entail collecting continuous data on IM health service activities and outcomes for IM surveillance and evaluation.

Given that in Australia the majority of IM primary care clinics are owned by private enterprise, for such an endeavour to be successful it would require the support of the IM clinics, practitioners and patients. It is therefore pertinent to consult these stakeholders before attempting to collect longitudinal data from such clinics.

## **1.2 AIMS & OBJECTIVES**

### **Aim**

Explore the use of patient-reported outcome (PRO) questionnaires to collect longitudinal data for measuring outcomes in the IM primary care setting.

### **Objectives**

1. Conduct a systematic literature review to identify and appraise PRO questionnaires for measuring IM outcomes.
2. Undertake a case study of the primary care IM clinic where the PRO questionnaires will be piloted:
  - a. to evaluate the clinic and
  - b. identify any factors for consideration when undertaking research in the clinic.

3. Explore patient and staff views about:
  - a. which outcomes are important for the clinic to measure;
  - b. their conceptual understanding of health that is more than the absence of disease;
  - c. their motivation to answer or encourage patients to answer ongoing PRO questionnaires; and
  - d. logistical and ethical considerations for using paper and Internet questionnaires.
4. Compare response rates and costs of postal and email patient invitations.
5. Synthesise the results to propose how best to use PRO questionnaires to evaluate IM outcomes and their role in an integrative medicine minimum dataset (IM-MDS).

### **1.3 SCOPE & LIMITATIONS**

This research focuses on the use of patient questionnaires for evaluating IM and their place in an IM-MDS. PRO questionnaires have not been tested, nor have they been used to measure patient outcomes.

Evaluating the outcomes of IM is complex and PRO questionnaires on their own are unlikely to be adequate. The use of PRO questionnaires in whole systems research and other mixed methods are mentioned, but not explored in detail. Similarly, other potential data sources are only mentioned.

### **1.4 THESIS OUTLINE**

This thesis begins by summarising the relevant literature, followed by an outline of the research methods. Arising from this work are eight papers that have been published or accepted for publication. Each paper is presented as a chapter and includes its own

background information, a literature review, methods, results, and a discussion. They each address one or more of the research objectives. To avoid duplication, any information presented in the papers is not repeated in detail in the literature review, methods and discussion chapters of this thesis. Each paper has its own list of references. For consistency the other chapters in the thesis end with their own list of references.

**Chapter 1 (Introduction):** presents the background information, rationale for undertaking the research, aims and objectives, scopes and limitations, and the thesis outline.

**Chapter 2 (Literature Review):** summarises the relevant literature pertaining to IM evaluation.

**Chapter 3 (Method):** summarises the methods used and the rationale.

**Chapters 4 & 5 (Papers 1 & 2):** present the findings from a case study of a primary care IM clinic.

**Chapter 6 (Paper 3):** evaluates the use of paper and electronic formats for inviting patients to participate in research, and for answering patient questionnaires.

**Chapter 7 (Paper 4):** presents the reasons patients would answer PRO questionnaires, practitioners and staff would support observational research in the clinic, and the perceived usefulness of patient questionnaires.

**Chapter 8 (Paper 5):** presents patient, practitioner and staff views about measuring holistic health outcomes in an IM clinic.

**Chapter 9 (Paper 6):** presents the concept of health that is more than the absence of disease arising from patient and practitioner interviews.

**Chapter 10 (Paper 7):** reviews the literature on PRO questionnaires to propose a shortlist of tools for use in a dataset.

**Chapter 11 (Paper 8):** proposes a minimum dataset of PRO questionnaires for use in Australian IM clinics.

**Chapter 12 (Discussion & Conclusion):** summarises the overall findings from the research, the implications and limitations, and finishes with a concluding comment.

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cancer care: why do we need it and how do we get started? *Integr Cancer Ther.* Dec

2006;5(4):287-292.



## **CHAPTER 2: LITERATURE REVIEW**

This chapter provides an overview of the relevant literature pertaining to the research topic. The following topics are covered:

1. definitions of IM;
2. IM in Australia;
3. evaluating IM in the primary care setting;
4. patient outcomes in IM;
5. patient reported outcome (PRO) questionnaires;
6. outcome datasets;
7. patient recruitment; and
8. conclusion.

Further reviews of the literature are presented in the subsequent chapters that form part of the published papers.

### **2.1 DEFINITIONS OF INTEGRATIVE MEDICINE**

The term Integrative Medicine (IM) evolved from concepts such as holistic medicine; natural therapies; and traditional, complementary and alternative medicine (TCAM).<sup>1</sup> For the purpose of this thesis, the term integrative medicine is used broadly to refer to any combining of orthodox biomedicine with TCAM. Individual practitioners or multidisciplinary teams of practitioners can provide IM services.

Different definitions for IM are proposed. They range from only using modalities that are evidence-based, to focusing on the importance of delivering holistic, patient centred care. Groups representing IM clinicians tend to use the broadest definitions.

For example, the National Center for Complementary and Alternative Medicine (CAM) that is a subsidiary of the National Institutes of Health (NIH) emphasises evidence in their definition.

*“... mainstream medical therapies and CAM therapies for which there is some high-quality scientific evidence of safety and effectiveness.”<sup>2</sup>*

A definition of IM arising from a systematic review of IM health services focuses on the goals of healthcare delivery and suggests that IM is the:

*“integration of conventional (allopathic) medicine and CAM, involving shared management of the patient, shared patient care, shared practice guidelines, and shared common values and goals to treat the well-being of the whole person.”<sup>3</sup>*

The Consortium of Academic Health Centres for Integrative Medicine in the USA uses the following definition:

*“Integrative Medicine is the practice of medicine that reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence and makes use of all appropriate therapeutic approaches, healthcare professionals and disciplines to achieve optimal health and healing.”<sup>4</sup>*

The Royal Australian College of General Practitioners and the Australasian Integrative Medicine Association joint working party proposes a similar definition to the IM clinicians in the USA:

*“The term Integrative Medicine (IM) refers to the blending of conventional and natural/complementary medicines and/or therapies along with lifestyle interventions and a holistic approach – taking into account the physical, psychological, social and spiritual wellbeing of the person – with the aim of using the most appropriate, safe and evidence-based modality(ies) available.”<sup>5</sup>*

## **2.2 INTEGRATIVE MEDICINE IN AUSTRALIA**

Over the past few decades, TCAM and IM have become increasingly popular.<sup>6</sup>

Suggested reasons include demand from an aging population with more chronic illness; a reduced faith in modern science; the ‘green’ movement; postmodern values; a consumer-driven healthcare system; and the importing of traditional medicines associated with more migration.<sup>7</sup>

Australia is following international trends. Approximately two thirds of Australians use TCAM, mostly to maintain general health.<sup>8,9</sup> Women aged between 25-34 years, higher income earners, and people with higher education levels are more likely to use TCAM.<sup>9</sup> In 2004, Australians spent an estimated AUD\$1.8 billion on TCAM.<sup>9</sup> Consumer demand is thought to be an important driver of TCAM.<sup>10,11</sup> Patients often decide when to seek TCAM healthcare and how this will be integrated with orthodox biomedicine.<sup>12</sup>

Australian general practitioners’ (GPs’) attitudes towards TCAM are changing.<sup>13</sup> Along with the public, GPs are now considering many TCAM therapies to be effective and safe.<sup>14</sup>

A survey of Australian general practitioners (GPs) conducted in 2000, found over 80% had referred patients to a TCAM practitioner.<sup>15</sup> In a 2008 survey, 90% of Australian GPs and virtually all pharmacists had prescribed at least one TCAM in the past 12 months, most commonly vitamins, minerals, fish oil or glucosamine.<sup>16</sup> A third of the GPs and half the pharmacists surveyed stated they practise integrative medicine, which was defined as “a holistic approach to health care that integrates conventional medical care with complementary therapies”.<sup>16</sup>

The exact number and types of IM clinics in Australia are unknown. Internet searches of business directories and personal networking revealed many different settings, models and styles of clinics. The majority of IM clinics in Australia are primary care clinics operating in the private sector. Although these clinics are private businesses, some of the funding for patient services comes from the Australian government through Medicare and from private insurers. Australian IM clinics range from solo or small group practices of GPs (using one or more TCAM therapies) to clinics housing several GPs (with or without TCAM experience) working either in a team or alongside TCAM practitioners. A few hospital based IM services are also in operation in Australia.<sup>17</sup> Very few of these clinics and services have been evaluated.

## **2.3 EVALUATING INTEGRATIVE MEDICINE IN THE PRIMARY CARE**

### **SETTING**

IM is challenging to evaluate because it aims to provide individualised, patient-centred care. IM has multiple outcomes that extend beyond just treating a disease or symptom. Often there is a focus on wellness and health promotion that may impact holistically in a person’s life e.g. physical, cognitive, emotional, spiritual, occupational, social and

environmental.<sup>18</sup> Notwithstanding these challenges, it is important to find ways to evaluate the safety, effectiveness, and social and economic impact of IM.<sup>19</sup>

The gold standard of evidence-based medicine, the randomised control trial (RCT), has limited applications in the IM setting.<sup>20</sup> It evolved with the development of pharmaceuticals and is best applied to measuring the outcomes of interventions that behave like drugs.<sup>21,22</sup> The cluster randomized multicentre trial is a variant of the RCT that can be used to evaluate more complex interventions (e.g. a health promotion program) where contamination of the control group is likely. The need to control for biases by restricting the inclusion criteria of an RCT, often makes it difficult to generalise the results to other clinical settings or patient groups.<sup>23</sup>

The wider medical community is beginning to recognise this limitation of the RCT. In response, comparative effectiveness research (CER) is one attempt to build an evidence base to inform healthcare at the individual and population levels. CER encompasses a broad range of study designs and aims to answer clinically relevant questions that more closely reflect real life (effectiveness).<sup>24</sup> However, there is still a tendency for exponents of the CER to focus on answering narrow questions about a specific outcome and to rank the RCT as the optimum study design.<sup>25</sup> Similar to the RCT, CER will only be useful for evaluating some aspects of IM primary care.

Alternate approaches have been proposed for evaluating IM and other complex healthcare such as primary care, palliative care and rehabilitation. A systematic review identified four sets of guidelines:

1. Complex interventions research (MRC, UK 2000);<sup>26</sup>

2. Whole systems research (International group, 2003);<sup>27,28</sup>
3. CAM systems research (NAFKAM, Norway 2004);<sup>29</sup> and
4. Whole medical systems research (NCCAM, US 2005).<sup>30</sup>

All four documents acknowledged the challenges with assessing complex healthcare and suggested using mixed methodology and multidisciplinary research teams. However, there were different opinions about the research process and aims. Generally, there was consensus that using a reductionist approach of simply adding the sums of the parts cannot provide a picture of the whole; but there was no agreement in terminology or strategy.<sup>31</sup>

A review of the literature on approaches to assessing primary care quality identified a top-down approach in Australia, New Zealand, and the United Kingdom, and a bottom-up approach in Germany and the Netherlands.<sup>32</sup> Common across all countries was Donabedian's framework for evaluating health services that considers the structure, process and outcomes.<sup>33,34</sup> The domains identified in the literature for assessing quality were safety, effectiveness, outcomes of care, patient centred experience, timeliness, access, efficiency, value for money, capacity, equity and health improvement. A multidimensional approach to measuring quality was recommended. The authors emphasised the importance of building a sense of ownership by the primary care providers for any quality assurance activity and directly measuring patient outcomes, rather than relying solely on process indicators as proxy-health outcomes.<sup>32</sup>

## **2.4 PATIENT OUTCOMES IN INTEGRATIVE MEDICINE**

The patient outcomes of a healthcare service should reflect its aims. Patient outcomes may be specific to a disease or intervention, or general. Objective outcomes include clinical examinations and investigation results. Patient questionnaires and interviews are

commonly used to measure subjective outcomes such as symptoms, quality of life, wellbeing and satisfaction.<sup>35,36</sup>

Similar to TCAM, a wide range of outcomes are potentially relevant to IM. In a series of qualitative studies of traditional and biomedical acupuncturists and their patients, two types of outcomes were identified:

1. direct patient effects from the intervention such as changes in symptoms, medication use, wellbeing (energy, strength, relaxation) and self-concept (self-awareness, self-acceptance, self-confidence, self-responsibility, self-help); and
2. patient processes such as the therapeutic relationship and a new holistic understanding.

Although the different outcomes were distinct, they were also interconnected and reflect the underlying philosophy that the “*whole being is greater than the sum of the parts*”.<sup>37,38</sup>

The Canadian Interdisciplinary Network for CAM Research (IN-CAM) surveyed TCAM and IM researchers, practitioners and students, from which 92 different specific TCAM outcomes were identified. The outcomes were grouped into the following domains: context, patient process, holistic, health-related quality of life, spiritual, psychological, physical, social and individualized. Although the process and context of healing are not actual ‘health outcomes’ they were identified as relevant outcomes for TCAM and IM research and therefore important to measure.<sup>39,40</sup>

Along with the outcomes already listed above, Deng et al. extended IM outcomes to encompass community outcomes such as cohesiveness, social costs and environmental impact, and provider outcomes such as role satisfaction. The patient outcomes also

covered health behaviours and lifestyle, financial costs (including self-care and self-funded therapies), opportunity costs, side effects, and occupational productivity.<sup>19</sup>

Such a vast array of potential outcomes from IM will be challenging to measure and confer significant responder and researcher burden. Therefore, it will be important to prioritise those most important to the patients and practitioners of IM clinics.

## **2.5 PATIENT-REPORTED OUTCOME QUESTIONNAIRES**

The use of patient-reported outcomes (PRO) questionnaires has grown considerably over the past twenty years, with thousands of questionnaires now available. A systematic approach must therefore be used to identify and appraise potentially suitable PRO questionnaires for use in the IM primary care setting.

In response to the need for researchers to access appropriate PRO questionnaires for TCAM and IM research, the IN-CAM group established an on-line database listing potentially useful questionnaires.<sup>39</sup> However, the listing of questionnaires in this database appears to have been an ad-hoc process and many of the questionnaires are yet to be tested in IM or TCAM settings.

PRO questionnaire appraisal begins by assessing validity and reliability followed by responsiveness or sensitivity to change, whether the results are clinically meaningful, and appropriateness for a clinical setting or population group. Logistical considerations are also important and include responder and researcher burden, alternative forms of administration, and availability in different languages.<sup>41</sup>



Ideally, questionnaires measuring similar constructs should be compared directly to determine which questionnaires have the most suitable psychometric properties. However, there is a paucity of such studies in the TCAM setting and no comparative studies have been conducted in the IM setting.<sup>42</sup> Instead of using a systematic approach, the process of selecting PRO questionnaires often reflects little more than the researcher's personal preference. This increases the possibility that a chosen questionnaire will be insensitive to change and so lead to false negative results.

Another important consideration when selecting PRO questionnaires for IM research is that some patients use IM for health promotion and disease prevention, rather than to treat disease.<sup>43</sup> Compared to disease management outcomes, considerably less attention has been given to developing PRO questionnaires to measure 'health that is more than the absence of disease'.<sup>44</sup> Most PRO questionnaires were developed for population groups suffering from diseases. Consequently, a well recognised limitation of many popular PRO questionnaires is their ceiling effect, which means they are unable to discriminate differences between healthier individuals and detect changes in their 'health' status.<sup>45</sup> Added to this is a paucity of empirical data about how patients and practitioners conceptualise 'health that is more than the absence of disease'. This knowledge is important for developing and evaluating questionnaires aiming to measure this concept.

## **2.6 OUTCOME DATASETS**

The need to establish an Australian minimum dataset for IM was endorsed by the National Institute of Complementary Medicine (NICM).<sup>17</sup> Datasets collect standardised information over time. Their uses and complexity are increasing as more data are collected electronically by health services.

The UK Clinical Practice Research Datalink (CPRD) is an excellent example of a primary care dataset.<sup>46</sup> It uses the National Health Service (NHS) unique patient identifier to link data extracted from the primary care electronic health records with other surveillance datasets. Its developers claim that the CPRD offers:

*“opportunities for health researchers to draw on the power of large multi-linked observational datasets on a previously unprecedented scale. Access is provided to support clinical innovation, strengthen evidence of effectiveness and improve health outcomes as well as safeguard public health and enable health services research.”*<sup>47</sup>

Many of the potential uses described for the CPRD will necessitate collecting patient reported outcomes (PROs). However, PROs are not routinely measured and specifically funded projects will be needed to assess PROs from smaller patient cohorts. The alternatives are to link primary care data to other information about outcomes such as mortality rates, or to use proxy-outcomes such as process indicators or changes in risk factors.

Neither approach however is likely to be very informative about IM primary care outcomes. Very large numbers are needed to measure changes in the general population for rare outcomes such as mortality and the incidence of many diseases; aside from monitoring very high-risk sub-groups, these rarer outcomes will be too insensitive for evaluating health services. Furthermore, mortality and morbidity rates cannot provide any information about other important IM outcomes such as symptom improvement, functioning, quality of life or the quality of care.

Process indicators that record clinical activity are another alternative to measuring PRO's. Examples include hospital admissions rates, medications prescribed, screening for disease and risk factors, and changes in risk factors. The assumption is that patient outcomes will improve if the appropriate medication is prescribed, screening activities are undertaken, or when risk factor for a disease is reduced. In the IM setting however, process indicators will only provide very limited information about IM outcomes. Collecting data about changes in risk factors is appropriate because it is a reason some patients seek IM care. However, other indicators, such as monitoring prescribing data, are unlikely to be appropriate because many of the therapies used in IM lack adequate evidence to allow any assumptions about patient outcomes to be made. Hospital admission rates would only be suitable for small sub-groups of patients with a high risk of hospital admission. Therefore, although some process indicators may be useful, an IM dataset will need to include data collected directly from patients.

Small batteries of PRO questionnaires aiming to measure various patient outcomes have already been recommended.<sup>48,49</sup> The People Reported Outcomes from Complementary, Alternative & Integrative Medicine (PROCAIM) established a dataset that used PRO questionnaires to measure the longitudinal outcomes of patients attending TCAM clinics at the University of California, Los Angeles.<sup>50</sup> The chosen questionnaires collected information about demographics, symptoms, general health, mood, spirituality/religiosity and life orientation. More recently, PROCAIM pilot tested a different battery of questionnaires in nine generic TCAM clinics across the USA. The dataset was smaller and collected information about demographics, quality of life and pain.<sup>51</sup>

A similar approach to PROCAIM could be used to establish a dataset to measure the broad range of outcomes relevant to IM primary care. This would require careful planning. Stakeholders need to be consulted to determine the purpose and use of a dataset; data requirements, collection, coding and analysis; and discuss ethical considerations. The challenge of recruiting patients, practitioners and clinics to participate must not be underestimated. Unlike the UK, data collection by Australian health services is more ad-hoc, especially in primary care where there are less funding requirements to systematically collect data. Therefore, a bottom-up approach will be needed to successfully develop an IM dataset in Australia.

## **2.7 PATIENT RECRUITMENT**

The difficulties of conducting research in primary care are well recognised. Along with the methodological challenges of determining effectiveness and evaluating complex interventions, substantial barriers include a heavy service commitment and a lack of research culture and capacity.<sup>52,53</sup> IM primary care research is further challenged by less funding, fewer academic leaders and disjointed research networks.

Engaging patients, practitioners and clinics to participate in research is challenging. A wide range of factors is known to affect participation and response rates in medical research. Overall, a lot more attention has been given to understanding what influences and motivates patient participation and the ethical implications of recruiting patients to participate in clinical trials.<sup>54-60</sup> However, participation rates continue to decline for all types of research and more information is needed about what motivates people to participate in observational research.<sup>61</sup>

IM research also faces these challenges. For example, an observational study that used a set of patient questionnaires to measure the longitudinal outcomes of patients attending IM clinics in Canada was unable to recruit enough patients. Subsequent interviews with practitioners at the clinics found the barriers could be categorised into four groups: organizational culture, organizational resources, organizational environment and logistical challenges.<sup>43</sup>

Participation rates and response rates were also a problem for the pilot test of PROCAIM in nine TCAM clinics in the USA. Only 38 of the 80 enrolled patients completed the baseline questionnaires, from which 22 completed the questionnaires three months later. Limited study resources were a reason given by the research team for the low participation.<sup>51</sup>

Given the scarcity of resources for conducting IM research, it is essential to maximise patient and practitioner participation. Therefore, before embarking upon a research program to evaluate IM outcomes it is important to determine what will motivate patients to participate in IM research and practitioners and clinics to support research.

## **2.8 CONCLUSION**

Evaluating IM primary care will continue to become more important as the popularity of this approach to health care grows in Australia. More information is needed to optimise the effectiveness and health care delivery of IM. Given the overlap of IM primary care with TCAM and general primary care, researchers should draw on the knowledge base of these disciplines. However, it is reasonable to expect there will be issues specific to IM research and this requires further clarification.

IM evaluation will need to include patient reported outcomes. These outcomes must not only have clinical relevance to practitioners but also reflect outcomes important to patients. A dataset that uses a battery of patient questionnaires would be one approach to systematically collecting information about patients' experiences with IM. Recruiting and collecting information electronically from patients and linking this to other electronic health data offers exciting opportunities for research. However, before attempting to establish an IM dataset, a lot more information is needed to select appropriate questionnaires; design a suitable dataset; and engage patients, practitioners, clinics and researchers to participate.

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## **CHAPTER 3: METHODS**

This chapter summarises the methods reported in the eight papers that follow. The main purpose of the research presented in this thesis to explore how patient questionnaires might be used in an IM dataset. In answering this question, a systematic approach would be used to obtain contextual information about the IM clinic where the proposed dataset would be used; ascertain which patient questionnaires if any, are most appropriate for use IM primary care setting; and identify strategies to engage patients and practitioners to use questionnaires.

### **3.1 AIM & OBJECTIVES**

#### **Aim**

Explore the use of patient-reported outcome (PRO) questionnaires to collect longitudinal data for measuring outcomes in the IM primary care setting.

#### **Objectives**

1. Conduct a systematic literature review to identify and appraise PRO questionnaires for measuring IM outcomes.
2. Undertake a case study of the primary care IM clinic where the PRO questionnaires will be piloted:
  - a. to evaluate the clinic and
  - b. identify any factors for consideration when undertaking research in the clinic.
3. Explore patient and staff views about:
  - a. which outcomes are important for the clinic to measure;

- b. their conceptual understanding of holistic health that is more than the absence of disease;
  - c. their motivation to answer or encourage patients to answer ongoing PRO questionnaires; and
  - d. logistical and ethical considerations for using paper and Internet questionnaires.
4. Compare response rates and costs of postal and email patient invitations.
5. Synthesise the results to propose how best to use PRO questionnaires to evaluate IM outcomes and their role in an integrative medicine minimum dataset (IM-MDS).

## **3.2 OUTLINE OF METHODOLOGY**

Mixed method was used to gather and analyse data in five parts:

1. a case study of the clinic where the outcomes research would be based;
2. appraisal of patient response rates and the costs of paper versus email invitations;
3. semi-structured interviews with 20 patients, 13 practitioners and the practice manager from the clinic;
4. a systematic literature review to identify and appraise PRO tools and other questionnaires; and
5. in light of these findings, explore the role of patient questionnaires in a minimum dataset for IM primary care.

### **3.3 ETHICS APPROVAL**

Ethics approval was sought from two Human Research Ethic Committees (HREC). Endorsement from the University of Sydney HREC was required because this was the overseeing institution. The South Eastern Sydney and Illawarra Area Health Service (SESIAHS) HREC was approached because the clinic was located in this region. The University of Wollongong HREC was the overseeing body for the SESIAHS.

### **3.4 METHOD USED FOR THE CASE STUDY**

A case study of an Australian IM primary care clinic was undertaken. The purpose was to evaluate the clinic and identify factors that need to be considered when undertaking research in the clinic. Pre-existing data was sourced and mixed method was used to evaluate the clinic.

Debate continues about appropriate methods for evaluating IM healthcare.<sup>1,2</sup> As per the recommendations made by Walter *et al.*,<sup>3</sup> Donabedian's model of *outcomes, process and structure*,<sup>4,5</sup> was used as the foundation for the case study. Similar to other mixed method study designs such as rapid assessment procedures, the qualitative and quantitative methods drew on a wide range of disciplines.<sup>3,6</sup>

For pragmatic reasons only pre-existing data was used for the case study. This meant that limited information would be available about most patient outcomes and many processes. However, an advantage of this approach was that it would allow a rapid assessment of the data currently available in the clinic.



Information was obtained from personal knowledge of the clinic's history to provide information about dates, staffing and services offered. As a practitioner in the clinic I was able to access confidential information about the clinic's finances, the minutes of staff meetings, a staff survey, a patient satisfaction survey and data routinely collected by the clinic for the purposes of administration and clinical record keeping.

The staff survey was conducted shortly after the clinic's third anniversary. It was inspired from the work of Boon et al. who reviewed the different levels of integration in IM that I read whilst writing a review paper about establishing IM clinics in Australia.<sup>7,8</sup> The staff in the clinic were asked to read these two papers and answer an anonymous written questionnaire. The aim of the questionnaire was to systematically document the opinions of practitioners, especially the less vocal ones. It consisted of 27 questions, beginning with a broad open-ended question about the top three issues they felt needed to be addressed, followed by 25 statements with a 5-point response option and prompts for comments. The statements aimed to elicit the practitioners' views on the clinic's provision of patient-centred care, integrative medicine and its success factors. The survey ended with another open-ended question about their vision for the clinic. The results were analysed and a slide presentation with a handout summarising the results were given in a staff meeting for further discussion. The practice manager made notes during the meeting that formed part of the minutes. I also made my own written notes a few hours after the meeting. A copy of the questionnaire and the slide presentation can be found in Appendix I. The handout summarising the results that was given to staff is not presented because it contains confidential and sensitive information about the clinic and its staff.

The results of a patient satisfaction questionnaire were also reviewed (see Appendix I). The questionnaire is commonly used in Australian primary care clinics as part of routine quality assurance; however, no references are provided nor is there any information about its psychometric properties. The questionnaire comprised of 16 statements about various aspects of the services provided by the clinic. There was a 5-point response option from very unsatisfied to very satisfied. It was anonymous and available at the front reception desk for any patient to complete. Prompts to complete the questionnaire by staff were made on an ad-hoc basis. Ninety-three questionnaires were completed by patients attending the clinic in 2010. The administration staff analysed the data and presented a summary of the results in the clinic's accreditation documents.

Descriptive statistics were used to analyse the quantitative data from the staff and patient questionnaires and routine data collected by the clinic. Qualitative data from the staff survey and the minutes from practice meetings were manually coded on paper. Categories and themes were identified using iterative and recursive processes. The synthesis of the quantitative and qualitative data used both inductive and abductive theory building.<sup>9</sup> The practitioner survey was an important qualitative data source. The open-ended questions and the discussion of the results at the subsequent staff meeting helped generate important new themes. The qualitative analysis drew on the quantitative data to provide further contextual information to support thematic generation.

### **3.5 PATIENT RECRUITMENT AND COSTS OF EMAIL VERSUS POSTAL**

#### **INVITATIONS**

Internet access via computers, tablets and mobile telephones is increasing at a rapid rate.

Traditional methods for recruiting patients by post and the use of paper questionnaires may eventually be superseded by electronic formats. Data was therefore collected to appraise response rates, logistics and costs of email verses postal invitations.

The clinic's database had 6154 patients 18 years or older, of which 4315 patients had provided email addresses. Email invitations were sent from the clinic's email address to all these patients. A secure web-marketing service was used that included an unsubscribe function. It was also possible to monitor the number of emails opened and those registered as spam by Hotmail or AOL. The email invitation was personalized with the patient's name. Both the clinic's logo and the University of Sydney logo were included in the body of the email. A female medical director signed the invitation letters. The email header used the word 'research'. Patients were asked to reply to the email or call the clinic if they wanted to participate.

A random sample of one in four patients younger than 60 with no email address (i.e. 270 of 1080) were sent a postal invitation. Irrespective of whether they had provided an email address, all 767 patients older than 59 were sent a postal invitation. The postal invitations also used both the clinic's logo and the University of Sydney logo. They were electronically signed by the same medical director as the email invitations. An option for a paid postal reply was not provided. Patients were asked to contact the clinic in person or via telephone.

The numbers of patients with and without email addresses were compared by sex and age using the Chi squared test and the Chi squared test for independence respectively. The Chi squared test was used to compare the response rates of men and women overall and for postal and email invitations.

Most of the costs were documented. Not recorded was the time it took to undertake tasks such as extracting the email addresses from the clinic's database, setting up a web-mail account, mail-merging, printing and posting invitations.

### **3.6 PATIENT SAMPLING FOR INTERVIEWS**

A stratified, random sampling technique was used to ensure a wide range of patients were selected for interview. The stratification groups were age, sex, case-mix (complex and simple); those with or without an email address; and old and new patients to the clinic.

Patients who only presented with self-limiting illness or for health promotion were defined as simple cases. A patient who presented with multiple health problems or had one severe health problem was defined as a complex case-mix. The clinic had only been in operation for just over four years; consequently an old patient was defined as being registered with the clinic for over a year and having attended the clinic more than once.

Although random sampling techniques are not always needed for qualitative research it is not contraindicated. In this instance 334 patients volunteered but only 20 patients were likely to be needed for an interview. Some stratification groups had only 2 or 3 patients (e.g. males over 70 years of age), whereas others had more than 50. The purpose of the interviews was to identify and describe all the different opinions patients may have rather

than to quantify them. Stratified sampling was used to increase the likelihood that a wide range of patients with different characteristics and points of view were interviewed. Table 1 in the Supplementary document in Chapter 8 details the characteristics of the patients interviewed.

### **3.7 PRACTITIONER AND PRACTICE MANAGER SAMPLING FOR**

#### **INTERVIEWS**

All 13 practitioners were sent emails from the practice manager inviting them to participate. Everyone including the practice manager consented for interview. There were six biomedical doctors. One was a general practitioner with no TCAM training. One only provided specialised nutritional and environmental medicine. The other four were general practitioners providing primary care services integrated with at least one of the following TCAM modalities: nutritional and environmental medicine, traditional oriental medicine, Western naturopathy, energy medicine and Journey Work psychology. The three psychologists interviewed each had different interests. One augmented her practice with hypnotherapy, Reiki and flower essences. Another had a special interest in positive psychology and life coaching. The other specialised in short, solution-focused interventions such as Cognitive Behavioural Therapy. The four other practitioners interviewed were a dietitian who had undertaken conventional biomedical training only and three TCAM practitioners: a traditional Chinese medicine and 5-element practitioner; a practitioner trained in Japanese shiatsu, nutrition and yoga; and a Western trained naturopath and acupuncturist.

The list of practitioners is slightly different to the list presented in the case study (Chapters 4 and 5). This is because some practitioners had already left the clinic, whilst others had joined the clinic in the six month gap between the census date for the case study and the commencement of interviews.

### **3.8 PATIENT, PRACTITIONER AND CLINIC MANAGER INTERVIEWS**

Before selecting and pilot testing patient questionnaires in an IM primary clinic, more information was needed about the factors likely to influence patient participation and practitioner support for research. It was also important to explore what patients and practitioners thought were important for an IM primary care clinic to measure. The need to ask these questions before proceeding with any research in the clinic was highlighted by a study in Canada of IM primary care clinics. The research team was unable to enrol enough patients. One of the reasons cited by many of the staff and practitioners from the clinics was the questionnaires only focused was on disease outcomes and did not measure other relevant outcomes like health promotion. The same study affirmed the importance of considering other logistical and organisational issues that can affect patient participation in and practitioner support for research.<sup>10</sup>

The purpose of the interviews therefore was to canvas patient, practitioner and staff views about the use of patient questionnaires in IM primary care. The interviews were exploratory; there was no predetermined hypothesis. The basic content of the interview was determined from the challenges of measuring IM outcomes and recruiting patients to participate in research that were identified in the literature, coupled with personal knowledge and experience. A semi-structured interview format was chosen to help facilitate an open discussion about the topics and identify the wide range of options likely

to be held by participants. The content and structure was reviewed by senior qualitative researchers at the Menzies Centre for Health Policy, University of Sydney. It was then pilot tested, with the research assistants who would be conducting the interviews, followed by a receptionist at the clinic who was also a patient at the clinic. The methods used were inductive and iterative, so content was modified accordingly as the interviews progressed.

As an introductory question interviewees were asked about their understanding of the term 'holistic health'. They were then shown a list of the different topics covered by various questionnaires. Examples of different types of questionnaires were available if needed for further clarification. The interviewees were then asked to comment on the topics they thought were important for the clinic to measure. Patients were also asked about the personal relevance of the topics now, in the past and potentially in the future. Questions were asked to explore a patient's motivation to answer questionnaires or the practitioner's motivation to encourage their patients to answer questionnaires. When exploring these motivators, questions were asked about the perceived usefulness of questionnaires, responder burden and accessing of individual patient results. Patients were also asked about confidentiality and the use of electronic questionnaire formats. A copy of the interview schedules can be found in Appendix II.

Following preliminary analysis of the first four interviews coupled with the preliminary results of the systematic literature review of PRO questionnaires another topic was added to the interview schedule that aimed to explore interviewees' conceptions of wellness and 'health that is more than the absence of disease'.

Two people were present for each interview; one interviewed whilst the other took notes and ensured that all the questions were discussed. All patients and practitioners gave written consent before their interview. Included in the consent form was the option to nominate in advance their preferred interviewer and to ask the other researcher, who would otherwise be present as a scribe, to leave the interview. Alternative interview locations to attending the clinic were offered to participants. Participants were offered financial reimbursement for travel expenses.

The duration of interviews was 1 to 1.5 hours. All the interviews were electronically recorded for transcription. Immediately following each interview the two researchers discussed the interview, reviewed the notes taken during the interview and made further notes. This began the process of analysis that was inductive and iterative.<sup>9,11</sup> For example, during the preliminary analysis it became apparent that a participant's concept of holistic health often correlated with the topics they thought were important for the clinic to measure. Later interviews then explored this in more detail along with how these views influenced their conception of wellness. At the end of the 20 interviews with patients thematic saturation was reached. Therefore, no further sampling and interviewing of patients was needed.<sup>12</sup> The only exception was the add-on questions about the concept of wellness that only the last 16 patients were asked.

The interview notes, preliminary analysis notes and transcriptions were entered into N-Vivo 9 program for coding, indexing and categorising.<sup>13</sup> This was jointly done by the two interviewers. The data was then independently reviewed in greater detail by the researchers followed by further group discussion where any disagreements in the final interpretation



were resolved. The aim was to identify all possible points of view; therefore, strongly expressed opinions were considered as important as those more commonly held.<sup>12</sup>

At the specific request of the practice manager, so as to maintain the confidentiality of her responses, none of her quotes were presented in the results and only her non-identifiable views were reported. Similarly, the characteristics of the practitioners were generally not reported with the practitioner's quote.

### **3.9 SYSTEMATIC LITERATURE REVIEW OF PATIENT QUESTIONNAIRES**

Shortlists for patient-reported outcome (PRO) questionnaires have previously been proposed for use in IM. However, these lists were not generated systematically and often they had not been tested in the IM primary care setting.<sup>10,14</sup> Therefore, before pilot testing a shortlist of PRO questionnaires in the clinic, a systematic literature review was undertaken to identify potentially suitable questionnaires.

IM outcomes are broad so many types of questionnaires measuring different topics could be relevant. Two Internet databases listing at least 2,000 PRO questionnaires were already known: the IN-CAM database that was designed as a resource for TCAM researchers and the more general PROCAIM database.<sup>15,16</sup> Therefore, rather than conducting multiple in-depth searches of publication databases, a more efficient approach was to begin with an Internet search to identify other PRO databases listing questionnaires. Further searches in the publication database were then conducted. The aim was to identify questionnaires measuring topics important to IM such as wellness and lifestyle questionnaires that were under represented in the Internet questionnaire databases. The search strategy and

appraisal process is outlined in detail in the published paper in chapter 10. The PRISMA guideline for reporting systematic reviews was used.<sup>17,18</sup>

The literature review was commenced at the beginning of the research project; it continued throughout. The final shortlist was also informed by the results from the case study of the clinic and the interviews with patients and staff at the clinic.

### **3.10 FINAL SYNTHESIS OF RESULTS**

The results of the previously described studies were further evaluated using an approach similar to the methodology recommended for systems research in health services and health policy.<sup>19</sup>

Firstly the topic of interest is identified. In this instance it was the challenge of evaluating patient outcomes in the IM primary care setting. After reviewing the literature, including white papers and policy documents, the research question began to focus on the use of PRO questionnaires. Of particular interest was how this data could be collected longitudinally for use in multicentre health services research and its place in an IM minimum dataset. A multidisciplinary approach using mixed methods is recommended to answer these questions and was adopted throughout.

An important part of answering this question was to consider what aspects of the healthcare system and which stakeholders are likely to be affected by the recommendations or conclusions. Since the research team already comprised of experienced public health academics and IM biomedical doctors their perspective was already known to some extent. Therefore, the most important stakeholders to first consult

were patients, managers and the other IM practitioners in the clinic, especially those with less research experience. This was the rationale for spending a considerable amount of time interviewing and analysing the views of patients and staff at the clinic. These results were evaluated in light of the findings from the case study and the systematic review to formulate a final set of recommendations about the use of PRO questionnaires in the IM primary care setting.

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# **CHAPTER 4: THE CHALLENGES OF ESTABLISHING AN INTEGRATIVE MEDICINE PRIMARY CARE CLINIC IN SYDNEY, AUSTRALIA.**

Hunter J, Corcoran K, Phelps K, Leeder S. The Challenges of Establishing an Integrative Medicine Primary Care Clinic in Sydney, Australia. *J Altern Complement Med.* 2012;18(11):1008-13. Epub 2012/08/29. doi:10.1089/acm.2011.0392.

## **FOREWORD**

Prompted by the need for more evaluations of Integrative Medicine (IM) clinics, I undertook a case study of the first four years of an IM primary care clinic. I was working as an IM general medical practitioner at the clinic during that time.

The evaluation drew on Donabedian's principles for assessing health services – structure, process and outcomes. Pre-existing data was collated and analysed using mixed methods.

A secondary aim of the study was to identify any potential challenges to undertaking further research in the clinic.

## **TABLES AND FIGURES**

**Chapter 4 / Table 1:** Distribution of practitioner skill base and competencies at the 4<sup>th</sup> year anniversary

**Chapter 4 / Figure 1:** Number of patients registered with the clinic (May 1, 2006 to April 30, 2010)

**Chapter 4 / Figure 2:** Percentage of the total 4 years of patient consultations per year by practitioner group (May 1, 2006 to April 30, 2010)

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## The Challenges of Establishing an Integrative Medicine Primary Care Clinic in Sydney, Australia

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### Abstract

**Background:** In May 2006, a multidisciplinary community-based integrative medicine (IM) clinic was established in Sydney, Australia. It was designed to offer a wide range of IM services, for primary care and to serve as a referral center.

**Objective:** The aim of this study was to determine which factors were successful and which ones posed challenges for establishing this kind of clinic.

**Method:** A study of the first 4 years of this primary care integrative medicine clinic was undertaken, using mixed methods—both qualitative and quantitative.

**Results:** Consistent with success factors identified in the literature, the clinic had an open-minded culture, credible supporters, suitable facilities, and clinically competent practitioners. Throughout the 4 years of its existence, the clinic strove to create an economically sustainable environment and to develop the service. As time progressed, it became evident that at least half of the practitioners needed to be biomedical doctors for the practice to remain viable. The challenges encountered were creating an economically sustainable clinic, managing high staff and practitioner turnover, finding the right balance between practitioners and services offered, developing an integrative medicine team, and building research capacity to evaluate the clinic and patient outcomes.

**Conclusions:** Although many integrative medicine clinics fail to survive the first few years, after 4 years, this multidisciplinary primary care clinic had succeeded in establishing a viable health care service offering both integrative medicine and conventional, traditional, complementary, and alternative medicine. Finding the right mix of staff members and following up with evaluations to track progress are important.

### Introduction

IN MAY 2006, a multidisciplinary community-based integrative medicine (IM) clinic was established in Sydney, Australia. This clinic set out to offer a wide range of IM services, operating both at the primary care level and as a secondary referral center. After 4 years, the directors were keen to begin evaluating the clinic formally, with this article serving as the first documentation of that evaluation.

Services offering orthodox biomedicine, and traditional, complementary and alternative medicine (TCAM) provided by 1 or more practitioners are often referred to as integrative medicine (IM) clinics. The definition of IM is evolving, and, for many providers and consumers it has supplanted such terms as holistic, natural, complementary, and alternative medicine.<sup>1,2</sup> In this article an *IM clinic* refers to any clinic that offers both conventional biomedicine and TCAM services.

Two kinds of locations for IM clinics are reported in the literature: the hospital and the primary care setting. IM

clinics have adopted service models ranging from those simply housing health care practitioners from different paradigms, through to clinics offering multidisciplinary, integrated, patient-centered care.<sup>2–6</sup> Few IM clinics have been described in the literature and little is known about the Australian setting.<sup>3,7</sup>

Many IM clinics fail to survive beyond the first few years of operation.<sup>8</sup> Evaluations of IM clinics have found similar prerequisites for survival beyond inception funding. These were: an open-minded culture; credible supporters; high competency of practitioners, with the right fit of practitioners and staff; effective communication and trust; suitable physical facilities; an economically sustainable environment; and resources for service development and evaluation.<sup>3,9–12</sup>

Specific to IM primary care clinics, a review of four clinics in the United States, found that, although the practices varied in their philosophies, therapies, and practitioner skills, there were common characteristics that contributed to their success. All four practices had created business models that

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enabled extended consultation time. Most of the biomedical doctors were already trained in TCAM therapies before joining the practice and, if not, they developed an interest in TCAM quickly and began integrating such therapies into their work. As well as offering primary care services, some of the practices also had a specialized consultative role.<sup>13</sup>

## Methods

This study was conducted to describe the 4 four years of a primary care IM clinic and to examine the factors contributing to its success and what challenges were posed.

Debate continues about appropriate methodology for evaluating complex healthcare such as IM<sup>14,15</sup> and the applicability of mixed methods for this purpose.<sup>16</sup> Similar to a proposed evaluation model by Walter et al.,<sup>17</sup> the current investigators returned to Donabedian's model—*structure, process, and outcomes*<sup>18</sup>—as the basis for evaluation.

The methods for data collection proposed by Walter et al.<sup>17</sup> included both qualitative and quantitative approaches drawing on a wide range of disciplines, and were similar to other mixed-method approaches, including rapid-assessment procedures.<sup>19</sup> Based on this, both qualitative and quantitative data from the first 4 years of the clinic were collated and analyzed. Qualitative data were obtained by reviewing the minutes of staff meetings, checking written responses from a staff questionnaire, and incorporating 2 of the current authors' personal knowledge of the clinic's history regarding dates, staffing, services offered, and confidential information, such as the clinic's finances. Quantitative data were obtained from a staff questionnaire, a patient-satisfaction questionnaire, and analysis of data routinely collected for administration and clinical records.

Based on the literature, a staff questionnaire was developed and distributed shortly after the clinic's third anniversary. All practitioners, the medical director, and 1 nonclinical director responded on the written questionnaire anonymously. The aim was to document their opinions, especially the less-vocal ones. The questionnaire consisted of 27 questions, beginning with an exploratory broad open-ended question about top three issues, followed by 25 statements, with a 5-point response option and prompts for comments. The statements were designed as "questions" about the provision of patient-centered care,<sup>9</sup> the IM team, and the success factors for an IM clinic identified from the literature. The results of the questionnaire responses were presented and discussed in a staff meeting shortly after.

As part of quality-assurance requirements for registration as a general practice (GP) clinic, an *ad-hoc* survey of 93 patients who had seen a GP was undertaken. This questionnaire had been recommended by the registration body. The questionnaire had 16 statements with a 5-point response option from "very unsatisfied" to "very satisfied" that were designed to measure patient satisfaction with the services provided by the clinic. There was no evidence that the questionnaire was a tested, standardized tool, but this questionnaire was readily available and locally acceptable.

Qualitative data were manually coded on paper from which categories and themes were identified using iterative and recursive processes.<sup>20</sup> The practitioner questionnaire was an important data source. As well as addressing the topics identified in the literature, the open-ended questions and

discussion about the results at a staff meeting generated new themes. As part of this process, the qualitative analysis drew on the quantitative data to provide further contextual information. Quantitative data were analyzed using descriptive statistics.

## Results

Information was most readily available about the structure, such the building, staff and, apothecaries; and process, such as the business model and the services provided. The only outcome data were obtained from the patient-satisfaction survey.

### Description of the clinic

The clinical director's vision (which was often expressed at staff meetings) was to create a center for excellence in the practice of IM. The clinic used the definition of IM written by The Consortium of Academic Health Centres for Integrative Medicine.<sup>21</sup>

The business model used by the clinic was common for primary care in Australia. Only the managerial staff members were employed by the clinic. A mix of biomedical doctors, and allied-health and natural therapy practitioners subcontracted their services to the clinic, earning money on a fee-for-service basis, with a proportion paid to the clinic to cover operational costs.

Recruitment of practitioners to the clinic aimed to provide a comprehensive skill mix and to meet perceived patient demand. Table 1 lists the 15 practitioners, who were working in the clinic at the fourth-year anniversary, and shows their skill base. Two (2) biomedical doctors, 1 psychologist, and the 1 shiatsu practitioner were male. All practitioners worked part-time.

Aside from a small Chinese herbal apothecary and a small Western herbal apothecary where practitioners mixed individualized formulas, no products were sold directly to patients by the clinic. Instead, patients were given a written prescription to purchase natural therapies from local health food stores and pharmacies.

The majority of patients self-referred to the clinic and could choose to see any practitioner. Often, patients who had complex chronic health problems were unsure about which practitioner to visit first. The receptionists were not trained in medical triage and were instructed in these instances to schedule an initial consultation with a biomedical doctor. Most patients used the clinic as their primary health care practice. A small number of patients, who sometimes were referred by an outside practitioner, used the clinic for specialized IM or TCAM services. The administrative software was not used to record any data about referral patterns.

Most patients paid a fee at the time of the service and claimed a partial refund through their private health insurance or through the government-funded Australian Medicare system. Both public and private health care rebates were small, with out-of-pocket expenses commonly ranging from 50% to 80% of the fees paid by patients. Approximately one sixth (15.8%) of services were billed directly to Australian Medicare or to other insurers with no out-of-pocket cost to the patients. In most cases, this was for services provided by the biomedical doctors.

TABLE 1. DISTRIBUTION OF PRACTITIONER SKILL BASE AND COMPETENCIES AT 4TH YEAR ANNIVERSARY

Practitioner type	Biomedical	Musculoskeletal	Nutrition	Western naturopathy	TOM	Psychology	Energy*
GP <sup>†</sup>	Yes	Yes	Some	Some	Yes	Some	Yes
GP	Yes		Some	Some	Some	Some	
GP	Yes		Some	Some		Some	
GP	Yes	Some				Yes	
GP	Yes		Some				
GP	Yes						
Doctor <sup>‡</sup>	Yes		Yes				
Naturopath		Some	Yes	Yes	Some		
Naturopath			Yes	Yes			Yes
Shiatsu		Yes	Yes		Yes	Some	Yes
Acupuncturist		Yes			Yes	Some	Yes
Psychologist						Yes	
Psychologist						Yes	
Psychologist						Yes	Yes
Dietitian			Yes				

Note: Blank spaces indicate No.

\*Energy medicine includes TOM (*Chi*), homeopathy, flower essences, and Reiki.

<sup>†</sup>GPs providing conventional primary care services +/- TCAM.

<sup>‡</sup>Doctor refers to a biomedical doctor providing specialized environmental and nutritional medicine only.  
TOM, Traditional Oriental Medicine; GP, general practitioner.

Notwithstanding the personal expenses to patients, the demand for the services offered by the clinic continued to grow at a steady pace. After 4 years, 6604 patients were registered with the clinic (Fig. 1). Patient demographics were in keeping with population trends for TCAM use in Australia.<sup>22</sup>

The clinic opened with a larger proportion of allied-health and TCAM practitioners; however, 4 years later, there was an equal number of biomedical doctors. Biomedical doctors were the main income generators for the clinic; they saw the most patients, billed more per consultation, and had shorter consultations. Biomedical doctors provided approximately two thirds of the consultations each year. The median consultation time for biomedical doctors was 30 minutes and for other practitioners, the median consultation time was 1 hour (Fig. 2). In the fourth year, the clinic became financially viable.

The clinic was computerized and used integrated clinical records. Except for highly confidential psychology notes, all practitioners could enter and access all clinical information. The clinical software was the most common software used in

general practice in Australia. Its main limitations for use in an IM setting were that many of the functions were only relevant to the biomedical doctors and the majority of the natural-medicine products had to be entered into the prescribing software so that medications, both pharmaceutical and natural, were listed together. This also meant that the system lacked an automatic function to flag potential drug-herb-nutritional interactions.

The clinic participated in a national accreditation program for primary-care clinics. However, the accreditation body was designed to assess conventional primary care clinics rather than those offering IM, and there were no accreditation bodies in Australia for TCAM or IM clinics. Therefore, aspects of the clinic's activities that were beyond the scope of conventional primary care were not reviewed by the accreditation body.

Ninety-seven (97) patients (56 females and 37 males) who had seen a biomedical doctor completed the satisfaction questionnaire. Virtually all of the patients (94/97) stated that they were "very satisfied" with all 16 aspects of the clinic. Three (3) patients marked the next level down, "satisfied," for a few questions and "very satisfied" for the remainder.

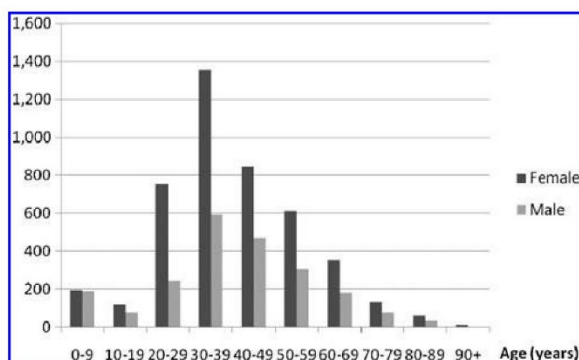


FIG. 1. Number of patients registered with the clinic (May 1, 2006 to April 30, 2010).

### Success factors

Many of the components outlined in the introduction of this article as important for a successful IM clinic were met. Results from the staff questionnaire and observations from clinic meetings showed that there was general agreement among the practitioners of a shared vision, an open-minded culture, credible supporters, suitable facilities, and confidence in the clinical competency of the other practitioners. Generally, practitioners believed that they and the other practitioners provided patient-centered care.

In an effort to create an economically sustainable environment and develop the service, the directors took a pragmatic approach and remained amenable to trying new ideas. The directors explored different marketing strategies and tried various therapies and clinical services. Sound financial

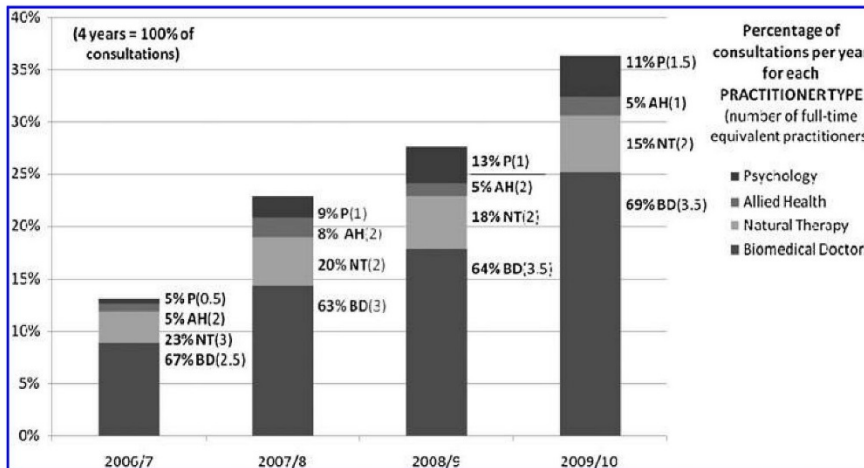


FIG. 2. Percentage of the total 4 years of patient consultations per year by practitioner group (May 1, 2006 to April 30, 2010). *Allied Health* is defined as services provided by non-medical practitioners who are recognized by the Australian Government for Medicare funding and are not a biomedical doctor. The category includes dietitians, exercise physiologists, chiropractors, osteopaths and physiotherapists. *Natural Therapy* includes all other traditional, complementary, and alternative medicine (TCAM) practitioners.

planning was essential for the clinic’s survival, especially factoring in the capacity to run at a loss in the early years to allow time for the business to grow. The financial pressures required strong leadership and commitment from the directors to see the clinic through its toughest times.

**Challenges**

The overriding concern for this clinic was to create a sustainable business while fulfilling the vision of the directors—to create a center for excellence in the practice of IM. This was not without its costs and compromises. The challenges encountered were: managing high staff and practitioner turnover; finding the right balance between biomedical doctors and other practitioners and the services they offered; creating an IM team; and building research capacity.

By the end of the study period, the clinic had employed its fourth practice manager. Typical issues arose that can occur with any employment, particularly in a new business, such as problems with personality, management styles, competency and role overload. The common theme however was that, although the first three managers were experienced practice managers, none of them had experience working in an IM clinic with a variety of practitioner types. This called for new organizational and interpersonal skills, including the ability to respond to a wider and complex range of patient and practitioner needs. Eventually the clinic promoted a receptionist with previous non-health managerial experience, who performed well and was free of preconceptions about clinic management.

Practitioner turnover was also a problem. The clinic opened with 13 practitioners: 5 biomedical doctors; 1 dietitian; 1 exercise physiologist; 1 psychologist; 3 naturopaths, 1 Traditional Chinese Medicine practitioner; and 1 shiatsu practitioner. Over the first 4 years, 20 practitioners came and went, including: 6 biomedical doctors; 3 naturopaths; 3 nutritionists; 3 dietitians; 2 exercise physiologists; 1 physiotherapist; 1 masseuse; and 1 chiropractor. The most common reason for practitioners leaving the clinic was insufficient patient numbers and, therefore, lack of personal income.

It was very difficult for the clinic to find highly skilled practitioners who also had the charisma and drive to build

their own patient bases. Most practitioners had to build their patient bases from scratch. This proved to be slow and difficult. Early on, the clinic tried many different marketing techniques. However, the most successful was word of mouth.

In the case of biomedical doctors, it was hard to find clinicians with adequate IM training and knowledge. Many started in the clinic with open minds but had limited TCAM knowledge. Those who have remained have been active in self-directed learning to expand their skill base in IM.

Regarding allied-health and TCAM practitioners, the biggest challenge was building a sustainable patient base. This, in turn, affected the clinic’s ability to offer a comprehensive range of services, because many practitioner types (especially those offering physically based therapies) left the clinic.

The reasons given by practitioners for why it was difficult to build a patient base were:

1. Not enough referrals from biomedical doctors within and outside the clinic
2. The challenge of establishing a point of difference from biomedical doctors in the clinic who had similar skills
3. Aspects of the business model that removed the pressure on practitioners to pay a service fee irrespective of throughput, and prevented natural therapists from making commissions from selling products and generating return customers by selling elite products that were difficult to find elsewhere.

In response to feedback from patients and staff, the directors tried a variety of approaches to build the business. This included trying different multidisciplinary speciality health programs; and encouraging patients with complex health problems to see a range of practitioners, including joint consultations, in which the practitioners worked together to formulate a management plan. However, there was little or no demand for these services and the comment from some practitioners was that patients had stated they often felt “overserved”.

Forming a strong cohesive team was a challenge. Practitioners commented that team building was constrained by: high turnover of staff and practitioners; little opportunity for formal team building; limited face-to-face contact with other

practitioners (communication between practitioners relied heavily on shared clinical records, electronic correspondence, and corridor conversations); time and financial pressures; and a lack of indepth understanding about what the other practitioners did. Comments from the staff questionnaire indicated that biomedical dominance also affected team building negatively.\*

Although the directors and many practitioners wanted to undertake research, it had yet to become an integral part of the clinic's culture. For example, they used an unpublished patient satisfaction questionnaire and administered it, using no scientific rigor. Another example was the presumption that, in choosing the most popular software used in Australia, data for health services and clinical data would be extracted easily for research purposes; this turned out not to be the case. Both the administration and clinical software had very limited search functions and did not use a standardised coding system.

### Discussion

As the clinic evolved, it became apparent that the business model required that at least half the team be biomedical doctors, because they were the main income generators and an important referral source for the other practitioners. The available data made the current authors unable to explain fully this greater demand for biomedical doctors.

Extended consultation time is a factor commonly cited by users and providers of TCAM and IM as a reason that patients seek this style of care.<sup>13,23</sup> However, this does not explain the greater demand for biomedical doctors in the clinic, because other practitioners generally spent more time with patients. Studies have identified other factors, such as practitioner empathy, holistic care, and a patient-centered approach, as reasons patients seek TCAM and IM.<sup>7,13,23</sup> However, it is unlikely that the biomedical doctors in the clinic were better at providing this style of care compared to the other practitioners.

Another contributor may have been the greater range of services provided by the biomedical doctors. As well as offering selected TCAM/IM services, these practitioners provided biomedical services that the other practitioners were not trained and/or legally permitted to provide. Furthermore, the Australian general practitioner is the gatekeeper to subsidized testing, biomedical specialists and the tertiary-hospital sector.

In keeping with an in-depth review of patients attending three other IM clinics in Sydney, Australia,<sup>7</sup> it is possible that the clinic's patients may perceive that there is "enhanced safety" gained from visiting biomedical doctors. This raises interesting questions about how patients might be reconciling a conservative modern scientific approach with more postmodern ideologies that reject science as the only truth and that are often attributed to the rise in popularity of TCAM.<sup>24</sup>

In Western societies, biomedical doctors are still at the top of the hierarchy in the health care system.<sup>25</sup> The social mindset of patients, receptionists, and practitioners will unwittingly generate a higher demand for biomedical doctors.

Biomedical dominance along with further exploration about the IM team will be discussed in more detail in a second article.\*

Out-of-pocket costs to patients (for consultations with practitioners and natural therapy products) were often considerable. As such, economic theory suggests that the clinic was providing a luxury service. The willingness-to-pay by a growing patient base provided weak evidence to suggest that at least some aspects of health care needs were being met.

Although the directors planned for the clinic to undertake research, capacity was limited. A lack of research culture and difficulties with using Australian clinical software for research purposes was not unique to this clinic.<sup>26,27</sup> Another Australian research group evaluating primary care reported similar frustrations with using the common general practice software packages.<sup>28</sup>

In Australia, coding of symptoms, diseases, or management are not requirements of clinical governance nor of service payment. As such, there is little incentive to build these functions into clinical software in this country. However, even if systematic coding were to become a feature of the clinical software, aside from Traditional Oriental Medicine, as yet there are no internationally agreed coding systems for other TCAM therapies nor for IM.<sup>29</sup>

Regarding the limitations of this study, neither of the questionnaires were standardized tools; therefore, the validity and reliability of the results are unknown. Much of the content of the practitioner questionnaire was in response to the literature rather than arising from discussions with practitioners and patients. However, the large number of open-ended questions provided many opportunities for practitioners to discuss other issues. Nevertheless, indepth interviews would have generated much richer data. The patient sample was likely to be biased because patients filled out the questionnaire on an *ad-hoc* basis (i.e., neither consecutively nor randomly sampled). Therefore, the current authors still have very limited information about the patients' experiences.

### Conclusions

After 4 years, this clinic had succeeded in creating a sustainable business offering a range of IM and TCAM services in a multidisciplinary primary care setting. The challenges were many, often reflecting the tension between high ideals and economic necessity. This affected the development of the IM team and the range of services offered.

The development of IM clinics is still in its early stages. Irrespective of scientific evidence for effectiveness, there is an increasing market demand for this style of medicine and more IM clinics are appearing across the globe. Therefore, it is important to describe and evaluate existing IM clinics to promote understanding regarding their advantages and disadvantages, and the models of health care provided. The use of mixed methods is appropriate for IM health service evaluation.

### Disclosure Statement

Dr. Phelps is the owner and medical director of the clinic. Aside from indirect financial benefit from improving the reputation of the clinic through publishing research, Dr. Phelps has no competing financial interests.

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No competing financial interests exist for the other three authors.

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# **CHAPTER 5: THE INTEGRATIVE MEDICINE TEAM – IS BIOMEDICAL DOMINANCE INEVITABLE?**

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## **FOREWORD**

This paper expands on the information presented in the previous chapter. It compares the IM team and health service models reported in the literature with what was reportedly occurring in the clinic. An important finding that emerged when analysing the data from the case study was the theme of biomedical dominance and its negative impact on developing an integrated team and healthcare model. The paper also provides contextual information about the provision of IM primary care health services in Australia.

## **TABLES AND FIGURES**

**Chapter 5 / Table 1:** Continuum of seven team-oriented health care practices

**Chapter 5 / Figure 1:** Practitioner views about the style of health care they considered to be most commonly practiced in the clinic

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## The Integrative Medicine Team—Is Biomedical Dominance Inevitable?

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### Abstract

**Introduction:** As traditional, complementary, and alternative medicines (TCAM) continue to find their way into mainstream medical practice, questions arise about the future of integrative medicine (IM). Concern has been voiced that the biomedical profession will dominate IM and many of the core principles and philosophies governing the practice of TCAM will be lost.

**Methods:** Using mixed methods, an IM primary care clinic in Sydney, Australia, was compared to the IM models discussed in the literature.

**Results:** Commercial concerns greatly influenced the team's development and the services provided by the practice under study. Questions arose as to whether the clinic was simply incorporating TCAM or truly integrating it. Further analysis of the data revealed evidence of biomedical dominance.

**Conclusions:** Given the current health care system in Australia, it seems likely that the biomedical doctor will continue to occupy a central logistical and leadership role in this clinic's IM team.

### Introduction

IN RESPONSE TO GROWING consumer demand for traditional, complementary, and alternative medicines (TCAM), the biomedical professions are integrating more TCAM in their clinical practices.<sup>1</sup> Professional bodies and researchers have proposed a range of definitions for and approaches to integrative medicine (IM); however, a final definition is likely to emerge and settle only as the practice of IM develops.<sup>1–7</sup>

#### *IM teams and health care models*

Given the diversity of descriptions of IM, it is not surprising that clinics claiming to offer IM also provide health care using different team arrangements and service models.

Boon *et al.*,<sup>8</sup> in discussing team arrangements, proposed a continuum of seven team-oriented health care practices: parallel, consultative, collaborative, coordinated, multidisciplinary, interdisciplinary, and integrative (Table 1). As the team becomes more integrative, there is less reliance upon biomedical models and a greater diversity in healing philosophies; care is patient-centered and holistic; the team becomes more complex and is nonhierarchical, and roles are less defined; and communication with the patient and between practitioners increases, with more consensus-based decision making.

A recent review of IM health care models identified three general approaches to service provision<sup>9</sup>:

1. *Selective incorporation* in which either the biomedical doctor provides selected TCAM therapies or TCAM practitioners provide services under the guidance of the biomedical doctor.
2. *Integrative medicine* in which multidisciplinary teams collaborate to provide a comprehensive range of TCAM services alongside biomedical services.
3. *Patient-centered pluralism* in which patients choose the level of integration and potential disagreements between the different paradigms and philosophies of healing are allowed.

#### *Biomedical dominance*

In all westernized countries, health care services are organized by professional authority, with biomedical doctors commanding the highest rank. To do so, the profession must maintain autonomy, authority, and dominance over health care.<sup>10</sup> A significant body of work in the field of health sociology suggests that "medical dominance" is structurally embedded into society.<sup>11,12</sup> It is supported by the socialization of students training for their professional roles, the competition between professions claiming jurisdiction over

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TABLE 1. CONTINUUM OF SEVEN TEAM-ORIENTED HEALTH CARE PRACTICES<sup>a</sup>

Parallel	Independent practitioners working in the same premises.
Consultative	Expert advice is provided to another practitioner upon request.
Collaborative	Patient information is shared on a case-by-case basis between independent practitioners who are caring for the same patient.
Coordinated	A case manager coordinates communication between the team of practitioners and the patient.
Multidisciplinary	A team leader directs the services provided by the team of practitioners.
Interdisciplinary	The team members, usually through regular face-to-face meetings, jointly make decisions about patient care.
Integrative	Interdisciplinary, nonhierarchical blending of biomedicine and traditional, complementary, and alternative medicines. The patient and practitioners have shared goals and values.

<sup>a</sup>Adapted from Boone *et al.*<sup>8</sup>

specialized knowledge (social closure), the co-option of elements from other professional domains, and the marketing to and acceptance of professional authority by the layperson that is often backed by government legislation and funding.<sup>10,12–15</sup>

There is continuing debate about whether the neoliberal economic reforms of the past few decades have significantly weakened biomedical dominance.<sup>10,13,14</sup> Certainly, the freer capitalistic market has coincided with a rise in patient demand for TCAM, legislative changes legitimizing TCAM, insurance funding for TCAM, and changes in consumer expectations and behavior.<sup>1,10</sup> As part of this process, there is evidence that both the biomedical professions and TCAM practitioners are absorbing elements of each other. However, it is not clear if the motivation is to integrate and find common ground or to promote their own professional legitimacy.<sup>16</sup>

When integrating biomedicine with TCAM, there is the possibility that biomedical doctors will control the process as in other health care services.<sup>17</sup> Although only a small number of studies have been published, biomedical dominance has also been observed in the IM setting.<sup>3,9</sup> There is a tendency for biomedical doctors to control patient care and use biomedical language as the main form of communication between practitioners.<sup>18,19</sup> Research confirms the significant impact biomedical practitioners' attitudes and knowledge of TCAM have on the style of IM practiced and the level of integration.<sup>7,20,21</sup>

The pressure to only include evidence-based TCAM<sup>2,5,22</sup> further demonstrates the tendency of the biomedical profession to incorporate TCAM into orthodox medicine rather than truly integrate the two. A concern raised about the

evidence-based approach to integration is that the biomedical professions are cherry-picking rather than truly integrating the different healing modalities.<sup>17,23</sup>

### Objectives

In response to the research on and debate about what constitutes an IM team and the impact of biomedical dominance, this article presents some of the findings from a case study of an IM clinic.

The results were evaluated in light of the following questions: (1) What model of health care is provided by the clinic by what type of IM team? (2) Are there signs of biomedical dominance?

### Methods

The findings discussed in this article come from a case study of the first 4 years of an IM primary care clinic in Sydney, Australia.<sup>24</sup> A mixed method approach was used to collect and analyze the data. The results and conclusions presented in this article are mostly drawn from a staff questionnaire but also include a review of the minutes taken of staff meetings, the authors' personal knowledge of the clinic's history and background, and other quantitative data routinely collect by the clinic. Although both quantitative and qualitative data were collected, the synthesis of the data was qualitative using both inductive and abductive theory building.<sup>25</sup>

Fourteen practitioners (six biomedical doctors including the medical director, three psychologists, a dietitian, two naturopaths, a traditional Chinese medicine practitioner, and a shiatsu practitioner) and one manager completed an anonymous questionnaire with both quantitative and qualitative questions. The questionnaire was constructed by the first author as part of a team building exercise in the clinic.<sup>24</sup> In the questionnaire, the 15 respondents were asked to read the article by Boon *et al.*<sup>8</sup> and comment about what style of team arrangement they thought the clinic was mostly providing. A description of patient-centered care was also given,<sup>26</sup> which accompanied questions about the provision of patient-centered care. Other questions asked about team building, communication, trust, and interreferrals among practitioners. The review of IM health care models<sup>9</sup> had not been published at this stage, so these models were not specifically discussed. The quantitative and qualitative results of the questionnaire were analyzed and presented at a staff meeting for further discussion. The minutes of this meeting, along with written notes taken during and shortly after the meeting were coded on paper. In an attempt to further explore the issues raised by practitioners, the analysis also drew on the other data collected about the clinic.

The question of whether there were signs of biomedical dominance did not arise until the data analysis began. It was not specifically addressed in the questionnaire, nor was it formally discussed by practitioners in staff meetings. Drawing on principles from Grounded Theory, both the qualitative and quantitative data were re-examined and re-coded using a cyclical iterative and recursive process to generate and test the hypothesis of whether there was biomedical dominance and to explore related issues.<sup>25</sup> Unfortunately, limited resources prevented further in-depth

exploration; for example, with practitioner and patient interviews, or another staff questionnaire.

**Results**

*The IM team and health care model*

All practitioners stated in the questionnaire that they were committed to the concept of working in an IM team. Yet there were considerable differences in opinion about the team as defined by Boon *et al.*<sup>8</sup> (Fig. 1). Despite small numbers, there was no qualitative difference in the responses from the different practitioner groups.

One practitioner wrote:

P1: *I think the team generally works together on a client's health needs mostly by sharing client notes... I do work in a collaborative manner especially on difficult and complicated cases and in this process, it becomes a collaborative/consultative process. This, however, depends on availability of practitioners for a quick face-to-face meeting... [With a biomedical doctor with little IM experience, collaboration was limited whilst the biomedical doctor was] gaining more confidence/understanding in natural therapies and becoming more willing to refer.*

Attempting to define the IM team prompted much discussion about the practice of IM. Practitioners commented in the staff meeting that the clinic also provides conventional primary care and is not a specialized IM clinic. Therefore, not all clinical presentations warrant a team approach and different types of teamwork would be appropriate for different clinical presentations. There was general agreement in the staff meeting that selecting only one of Boon and colleagues' categories to describe the clinic's team had limited usefulness.

Aside from a lack of clinical need for a team approach for all patients attending the clinic, other contributing factors limiting a team approach and its development were

- practitioners not having an in-depth understanding of each other's modalities
- high staff and practitioner turnover rates
- infrequent staff meetings
- lack of interest and incentives for practitioners to meet and discuss cases
- minimal, if any payment for case conferencing

- busy practitioners who were not available for face-to-face conferencing
- practitioners, who all work part-time, not being in the clinic at the same time

Similar to the practitioners' varied opinions about the clinic's team arrangements, the results of the questionnaire found differing views about other important aspects that influence teamwork. Although everyone felt confident with the clinical competency of the other practitioners, their views were mixed when asked about effective communication and cross referrals.

Comments about difficulties with communication among practitioners mostly focused on practical issues such as technical challenges with electronic messaging systems and a lack of face-to-face contact with other practitioners due to the reasons just listed. Consequently, there was a heavy reliance upon the integrated clinical records, instant messaging, emails, and *ad hoc* corridor conversations.

Data were not collected by the clinic to track referral patterns. Management observed that the business model of the clinic required at least half the practitioners to be biomedical doctors.<sup>24</sup> One reason given was that the biomedical doctors were an important referral source for the less busy TCAM and allied-health practitioners. Comments from the staff questionnaire suggested that referrals within the clinic were mostly between the biomedical doctors and the TCAM and allied-health practitioners. The TCAM and allied-health practitioners rarely cross-referred to each other. It was not clear from the data why this was the case; however, the following quote from a TCAM practitioner who also claimed to refer patients to other practitioners conjectured that some practitioners may not have seen any extra benefit in referring and consider their therapeutic system to be holistic and complete.

P2: *There is always going to be an element of believing that one's own practice can engender the cure [for the patient] and outside help [from other practitioners in the clinic] is not necessary.*

Added to this was evidence that not all practitioners were comfortable with the other philosophies of healing and therapies provided by practitioners in the clinic.

P1: *Some practitioners are open-minded and others need [scientific] evidence and are not open about some healing methods.*

Patient preferences played a significant role in the development of the clinic.<sup>24</sup> The directors and practitioners in the clinic trialed different IM services such as implementing specialty health programs in which a group of practitioners worked together as an integrated team and offered joint consultations with more than one practitioner. However, there was little patient demand for these integrated health care services. In some cases, patients even felt overserved and one practitioner commented:

P3: *The problems I encounter include: with some patients, a sense of being referred to too many practitioners.*

The clinic's business model meant that patients rather than practitioners mostly made the final decision about the level of integration. Many patients self-referred and chose which

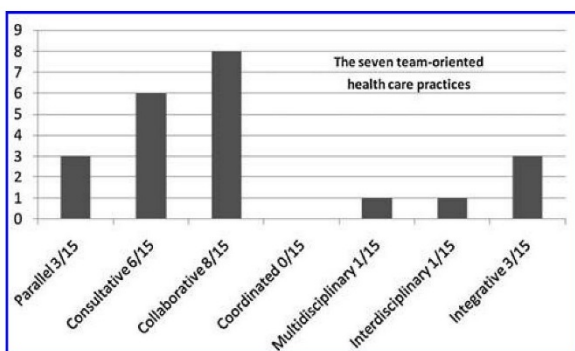


FIG. 1. Practitioner views about the style of health care they considered to be most commonly practiced in the clinic.<sup>8</sup> Some practitioners selected more than one option (*n* = 15).

practitioners to consult. Even if the practitioner recommended a highly integrated team approach, the patient ultimately made the decision.

All the practitioners stated in the questionnaire that they and the other practitioners mostly provided patient-centered care.<sup>26</sup> However, the following comments demonstrate that practitioners did not always understand or use the patient-centered model:

P4: *There are times when a directive approach is needed. The model suggests that the patient can direct their healing needs and process. This [biomedical doctor] can't get the optimum outcome, in that an expert needs to direct the process, i.e. a doctor.*

P5: *For the most part I would say that the patients I have seen who have seen other practitioners at the clinic feel well attended to. Sometimes I have heard a complaint of not being heard and at other times I have felt the practitioner may have been concentrating on a treatment of the symptom or disease rather than the patient's special circumstances.*

#### Biomedical dominance

Although practitioners never raised the issue of biomedical dominance in staff meetings, throughout the questionnaire TCAM and allied-health practitioners alluded to frustration with biomedical dominance of the clinic's health care model:

P5: *I think that the model at the clinic is still very GP [general practice] focused. I think that the GP still dominates the process and operates as the primary health care provider.*

P2: *There is still a sense of hierarchy that does not sit as comfortably with the integrated team model.*

Further to this, there were many signs suggesting biomedical dominance in the clinic:

- the clinic is owned and led by a biomedical doctor
- the clinical governance and accreditation systems are only for the biomedical doctors
- the computer software was designed for biomedical doctors
- clinic meetings uses biomedicine as the default language
- biomedical doctors charge the highest consultation fees
- the financial survival of the clinic requires at least half the practitioners to be biomedical doctors
- biomedical doctors can practice or prescribe various components of other practitioners' modalities without any formal training or accreditation but not *vice versa*
- in shared cases, the final authority for management decisions mostly rests with the biomedical doctor and/or the patient, but rarely with a nonmedical practitioner.

On the last point, while answering the questionnaire, a TCAM practitioner raised the question of accountability within the team.

P7: *Accountability—doctors are medico-legally accountable. Who are the CM practitioners accountable to? The doctors? Themselves? The clinic?*

When the question of accountability was discussed in staff meetings, based on the advice of the practitioners' indemnity

insurers, there was general agreement that the biomedical doctor was medico-legally accountable for the care provided by an IM team, especially if the team included an unregistered health practitioner. At the time of this study, aside from osteopaths and chiropractors, Australian statutory law did not regulate other TCAM practitioners, thus limiting legal recourse by aggrieved patients.

Over the first 4 years of the clinic, it became clear that biomedical doctors have an important role in the economic survival of the clinic.<sup>24</sup> The financial pressures of having to attract biomedical doctors to the clinic meant that management often had to balance the desire for equity across the team with the need to provide extra benefits. For example, biomedical doctors were guaranteed access to the limited parking. This comment from an allied-health practitioner demonstrates the discontent these difficult decisions often generated:

P6: *Well it's not an equal team. The doctors are at the top. You can see this all the way down to who gets a car space—only the doctors.*

#### Discussion

In the evolution of health care services in western countries, TCAM and IM are unusual—patients, as empowered consumers, have mostly driven the demand, often ignoring the advice of the biomedical professions. Demand appears to be growing, and as more biomedical practitioners start to use and integrate TCAM, the definition of IM and the development of IM teams and health care models will continue to evolve.<sup>1</sup> In the case of this clinic, commercial and social pressures strongly influenced its efforts to provide IM and the development of the team.<sup>24</sup>

Rather than imposing a health care model on the team, the directors allowed the clinic to evolve naturally. The advantage of this approach was the clinic was able to respond to market demands and become financially viable. However, having to survive in the real world placed considerable stressors on the IM team that reduced their capacity to develop a truly integrative model.

Questions arose as to whether this clinic had a fully integrated cohesive team or was simply housing practitioners under the one roof with in-house referrals and shared care for some patients. Certainly, there was expressed frustration from some practitioners about the need for a more cohesive equal IM team. There was evidence to suggest the team was fluctuating between the seven team-oriented health care practices described by Boon *et al.*<sup>8</sup> The team's orientation was influenced by the patient's clinical needs and preferences and the practitioners who were involved in the patient's care.

The comments from practitioners about the practice of IM were in line with previous research that observed the level of integration between TCAM practitioners and biomedical doctors correlated with the biomedical doctor's knowledge of TCAM.<sup>20</sup> The comments suggested that the biomedical doctors with training in other medical systems practiced more integratively within the team. It was not clear if all biomedical doctors in the clinic require a minimum level of TCAM knowledge to practice as effective IM team members, and for that matter, if all practitioners need to be well versed in each other's therapeutic approaches and languages.<sup>6</sup>

A lack of experience with integrating different therapeutic paradigms may also help explain the low referrals between the different TCAM and allied-health practitioners.

When considering the clinic's IM health care model, it varied between selective incorporation, integrative medicine, and patient-centered pluralism as outlined in the Introduction.<sup>6</sup> Further in-depth research may find one of the models predominates.

Evidence of biomedical dominance in the clinic was consistent with other research that suggests allied-health and TCAM practitioners would prefer a less hierarchical system.<sup>21</sup> The questionnaire was anonymous and questions about biomedical dominance were not specifically addressed by the questionnaire, nor discussed with practitioners. As such, it was not clear from the data whether the biomedical doctors had a different opinion and if there were any other differences between the practitioner groups. Given the structural embeddedness that helps perpetuate the biomedical dominance of multidisciplinary teams,<sup>11</sup> it is not surprising that the biomedical doctors did not comment and perhaps were unaware of their dominance of the team.

Similar to other research, the tendency that we described of biomedical doctors to dominate the multidisciplinary team appeared to be as a result of both internal factors within the clinic and external factors.<sup>11</sup>

The biomedical doctors were in greatest demand at the clinic<sup>24</sup> and this reinforced their dominant position over both allied-health and TCAM practitioners. There was evidence that common strategies used by professions to safeguard their positions such as social closure and co-optation were at play. For example, the clinic's infrastructure was designed primarily to support the biomedical doctors, biomedicine was the default language used by the practitioners in the clinic, and the biomedical doctors provided some TCAM and allied-health services but not *vice versa*.

Including biomedical doctors in an Australian IM team inherently creates market forces that selectively empower them.<sup>10,11</sup> Australian regulation further enables social closure by excluding TCAM and allied-health practitioners from providing many health care services. Access to pharmaceuticals and investigations in Australia is mostly restricted to services requested by biomedical doctors. The Australian health care system uses the general practitioner as the gatekeeper to other biomedical specialties. Coupled with the lack of communication and established referral patterns between TCAM practitioners and biomedical specialists and hospitals, co-ordination of patient care necessitates the general practitioner taking at the very least a central logistical role in the clinic's team.

Not only did social factors outside the clinic create a market advantage for the biomedical doctors, it also created other pressures that may have contributed towards the imbalance within the team. For example, there was external pressure on biomedical doctors to maintain control of a patient's management for fear of medical negligence or retribution by the medical board if they endorse non-evidence-based therapies or accepted an alternate TCAM diagnosis. To what extent the team is affected by these external pressures requires further exploration. In particular, are the biomedical doctors aware of and willing to relinquish their dominant position, and do the other practitioners want to assume more responsibility and control over their patients' care.

## Conclusions

In establishing an IM clinic, the directors were faced with considerable challenges on all levels that strongly influenced the types of services offered by the clinic and the development of its team. As found in other research, there were signs of biomedical dominance that negatively affected the development of a truly equal, integrative team. However, given the persistent structural embeddedness supporting biomedical dominance, it is unlikely that the clinic will be able to radically change the status quo. For the time being, biomedical doctors will have at the very least, a significant impact on the clinic's health care model and maintain some kind of directing leadership role.

Perhaps of greatest interest should be patients' views and preferences, along with further exploration about the factors driving their choices. Some indication of patient preference was already known simply by watching consumer behavior and from the positive results from a patient satisfaction survey.<sup>24</sup> However, more information is needed about patients' views to determine whether they are seeking a patient-centered pluralistic health service model; what their experiences and outcomes are with different styles of IM; and how these compare with conventional biomedical primary care.

## Author Disclosure Statement

Kerryn Phelps is an owner and medical director of the clinic. Aside from indirect financial benefit from improving the reputation of the clinic through publishing research, Phelps has no competing financial interests. No competing financial interests exist for the other three authors.

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## **CHAPTER 6: IS IT TIME TO ABANDON PAPER? THE USE OF EMAILS AND THE INTERNET FOR HEALTH SERVICES RESEARCH – A COST-EFFECTIVENESS AND QUALITATIVE STUDY.**

Hunter J, Corcoran K, Leeder S, Phelps K. Is it time to abandon paper? The use of emails and the Internet for health services research - a cost-effectiveness and qualitative study. *J Eval Clin Pract.* 2012. Epub 2012/05/30. 'doi':10.1111/j.1365-2753.2012.01864.x.

### **FOREWORD**

This paper presents information about the cost effectiveness of email verses paper invitations sent to patients inviting them to be interviewed. It also presents the findings from the patient interviews about their views on the use of electronic patient questionnaires for health services research.

### **TABLES AND FIGURES**

**Chapter 6 / Table 1:** Factors affecting response rates to questionnaires in clinical trials

**Chapter 6 / Table 2:** Age and gender of patients with and without email addresses

**Chapter 6 / Table 3:** Patient views about Internet questionnaires

**Chapter 6 / Table 4:** Suggestions by patients for reducing responder burden

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## Is it time to abandon paper? The use of emails and the Internet for health services research – a cost-effectiveness and qualitative study

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### Keywords

health services research, Internet, patient participation, primary care, qualitative research, response rate

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### Abstract

**Rationale** A multidisciplinary primary care clinic in Sydney, Australia, was planning to use electronic questionnaires to measure patient-reported outcomes.

**Methods** Semi-structured interviews with 20 patients were undertaken to explore, among other things, practical issues regarding different questionnaire formats. The response rates and costs of email versus postal invitations were also evaluated.

**Results** Compared with postal invitations, email invitations offered a cost-effective and practical alternative, with a greater proportion of patients volunteering for an interview. Assuming the interface is well-designed and user-friendly, many patients were happy to use the Internet to answer questionnaires. Most patients thought alternate formats should also be offered. Patients discussed advantages and disadvantages of the Internet format. Although more younger patients and females had given the clinic an email address; both sexes, and young and old patients, expressed strong preferences for either wanting or not wanting to use the Internet.

**Conclusion** Researchers should consider using email invitations as a cost-effective first-line strategy to recruit patients to participate in health services research. Internet questionnaires are potentially cheaper than paper questionnaires, and the format is acceptable to many patients. However, for the time being, concurrent alternate formats need to be offered to ensure wider acceptability and to maximize response rates.

### Introduction

Patient questionnaires are widely used in health services research. As public access to computers and the Internet increases, traditional questionnaires based on written completion of a paper or interview may be superseded by electronic formats. The potential advantages of Internet questionnaires include reduced costs, the immediacy of results available to both researchers and participants, and the ability to use automatic prompts to help reduce the number of unanswered questions or implausible answers [1–5]. Important disadvantages include the technical and design challenges of creating a modern user-friendly interface and managing web-based datasets [3,6–11].

Appealing as new technology may be, a systematic review by McCluskey and Topping recommends using postal surveys supplemented with other formats for non-responders. Interviews, either face-to-face or telephone, were the recommended alternative.

Internet survey methods were also favoured, although the authors found less evidence to support their use [12]. This advice is not surprising because response rates of less than 20% have been reported by some epidemiological surveys using Internet questionnaires [2]. However, in these instances, the participants were sent paper invitations. Rates tend to be higher when the invitation to complete an Internet questionnaire is sent by email rather than post [13–16].

Given participant's preference for different questionnaire formats, recruitment bias is an important consideration. Under-recruitment of particular groups of people less likely to answer Internet questionnaires will reduce the generalizability of results. Some studies have found biased results associated with different questionnaire formats or location [17–20]. However, other studies did not find any difference [13,14,21–23]. Younger people, men and people with a higher education are more likely to answer Internet questionnaires [6,14,24,25].

Several systematic reviews have evaluated factors influencing recruitment rates, response rates to patient questionnaires and strategies to improve participation for both postal and electronic formats [26–28]. Although most systematic reviews focus on clinical trials, the results are relevant to population surveys and health services research (Table 1).

The psychometric properties of a questionnaire originally designed for pen-and-paper or interview must be re-evaluated when converting it to an electronic format [29,30]. There are an increasing number of publications confirming comparability, mostly with favourable results [30–40]. Another consideration is the comparability of paper versus electronic consent forms. Varnhagen *et al.* found little difference between participants' time to read and recall information from paper and electronic consent forms [41].

## Methodology

Before commencing a research project planning to use Internet questionnaires to measure patient outcomes, in-depth semi-structured interviews were conducted with 20 patients from a multidisciplinary primary care clinic in Sydney, Australia, where the proposed project would be based. The interviews explored a wide range of topics pertaining to patients' views about using questionnaires for evaluating health outcomes. This paper will report our findings about patients' views on questionnaire format, design, responder burden, consent, confidentiality, Internet secu-

rity and spamming. The response rates to, and costs of, email and postal invitations are also presented.

## Ethics approval

The study was approved by two Human Research Ethics Committees (HREC): the University of Sydney HREC and the South Eastern Sydney and Illawarra Area Health Service HREC. All patients gave written informed consent before being interviewed.

## Patient recruitment

Patients 18 years or older, who had attended the clinic, were considered eligible to participate. The aim was to recruit around 20 patients with different characteristics according to age, gender, casemix, old and new patients of the clinic, and those with and without email addresses.

Using a secure web-marketing service, an email invitation was sent from the clinic's email address to all adult patients. The email included an unsubscribe function. A postal invitation was sent to all patients 60 years or older (including those who had been sent an email). To reduce costs, a random sample of one in four patients younger than 60 with no email address were sent a postal invitation.

The invitation was personalized and included both the clinic's logo and the associated university logo. The medical director, who is a female, signed the invitation letters. The email header used the word 'research'. Patients were asked to reply to the email or call the clinic if they wanted to participate. The postal invitations did not provide an option for a paid postal reply, instead patients were asked to contact the clinic via telephone or in person.

**Table 1** Factors affecting response rates to questionnaires in clinical trials

### Postal questionnaires [26–28]

#### Increased response rate:

Financial incentives, recorded delivery, a teaser on the envelope to encourage opening, participant interest in the topic, pre-notification, providing unconditional monetary incentives irrespective of response, shorter questionnaires, enclosing a copy of the questionnaire with follow-up letters, mentioning an obligation to respond, university sponsorship, financial incentives, recorded delivery and participant interest in the topic.

#### Reduced response rate:

Sensitive topics

### Electronic questionnaires [26]

#### Increased response rate:

Including any type of picture in the email invitation, non-monetary incentives, shorter questionnaires, stating that other people had responded, lottery tickets with immediate notification of lottery results, providing survey results, using a white background, personalizing the questionnaire, using a simple header, using a textual instead of a visual presentation of response categories, giving a deadline and participant interest in the topic.

#### Reduced response rate:

Including the word 'survey' in the subject line of the header and using a male as the signature

#### No effect on response rate:

Other header options such as including a topic, or an empty header; using different types of images, offering larger versus smaller incentives.

## Interviews and analysis

Two investigators conducted the semi-structured interviews. Qualitative analysis began immediately after the interview and summary notes were made. After all the interviews were completed, the data were entered and coded using N-Vivo ([http://www.qsrinternational.com/support\\_faqs\\_detail.aspx?view=11](http://www.qsrinternational.com/support_faqs_detail.aspx?view=11)). An inductive approach was used to identify and explore taxonomies, themes and ideas [42,43].

The purpose of the interviews was to identify a broad range of opinions from a wide range of patients rather than quantify their frequency. Thematic saturation of the data was reached following 20 interviews, so no more patients were recruited.

## Results

### Patient characteristics

Of the 6155 patients 18 years or older who had attended the clinic, an email address was available for 4315 (70%) patients. The clinic had more female patients and younger patients, and proportionately more email addresses for both (Table 2).

### Response rates

A letter of invitation was emailed to the 4315 patients with an email address and 810 letters were posted using Australian Mail.

**Table 2** Age and gender of patients with and without email addresses

Age group	Email	No email	Total
18–29	783	247	1030
30–39	1555	425	1980
40–49	957	381	1338
50–59	629	320	949
60–69	315	240	555
70–79	55	134	189
80–89	19	77	96
90+	2	16	18
Male	774	685	1459
Female	3541	1155	4696
Total	4315	1840	6155

The clinic had more email addresses for younger adults ( $\chi^2$  test for independence,  $P < 0.001$ ; 7 d.f.) and women ( $\chi^2$  test;  $P < 0.001$ ; 1 d.f.).

Of the letters posted, 767 were sent to patients 60 years or older and 270 to those younger than 60. The total response rate was 6.2%. The response rate to the postal invitations was much lower at 2.0% compared to 7.4% for all emails sent [ $\chi^2$ ;  $P < 0.001$ ; 1 degree of freedom (d.f.)]. Overall, fewer men (4.7%) compared to women (7.0%) agreed to participate ( $\chi^2$ ;  $P = 0.007$ ; 1 d.f.), with similar proportions of men and women responding to the postal and email invitations ( $\chi^2$ ;  $P = 0.2$ ; 1 d.f.). Other characteristics of the respondents and non-respondents were not compared.

Four weeks after the 4315 email invitations were sent, 33.0% were opened, 47.4% were unopened and 19.5% bounced. Recipients registered six of the opened emails as junk or spam with Hotmail or AOL; 27 clicked the unsubscribe function. Of the 1425 opened emails, 318 (22.3%) volunteered to participate.

The cost of sending the email invitations was \$AUD0.05 per email. This included a one-off setup fee to create an account, a monthly rental fee and a fee based on the number of emails sent. Each postal letter cost \$AUD0.95 to print and post. The cost estimates for both options exclude administration costs such as the time taken for the staff to extract the email addresses from the clinic's database and set up a web-mail account; or mail-merge, print and post invitations.

### Patient interviews: questionnaire format and location

Patients were asked about their preferred format – electronic, paper or interview. Assuming a well-designed user-friendly system, most patients thought the Internet was an acceptable format. However, most thought that alternate formats such as paper or interviews were important for wider acceptability. A preference for electronic formats was neither sex- nor age-related. Both men and women, and young and old patients, either expressed a strong preference for electronic formats and the Internet, or stated they did not want to use them and preferred another format. Table 3 summarizes patients' views on the advantages and disadvantages of Internet questionnaires.

For example, a 35-year-old internet savvy male patient preferred to answer a paper questionnaire at home.

Pa\_14: I'd like to take [the questionnaire] home. I don't like to feel pressured. I need time to read it through and think about it . . .

**Table 3** Patient views about Internet questionnaires

Advantages of internet
1. Targeted, instant feedback of individual results can be provided to respondents.
2. Supportive health information and information about the meaning of the results can be provided to respondents.
3. The Internet is convenient, especially if there is the option to save a partly completed questionnaire to continue answering later.
4. Electronic formats reduce data entry time and researcher burden.
Disadvantages of internet
1. Not all patients are computer literate or savvy which may preclude them from participating or significantly add to responder burden.
2. The Internet can be distracting and this can make completing long questionnaires difficult.
3. Slow download rates, server problems, bad programming or poor design can make the process of answering questionnaires slow and clunky.

Int\_02: So one of the ideas is to use the Internet. Would that work for you?

Pa\_14: Oh OK [pause] so then for me a hard copy is better for me, I get side-tracked on the Internet . . . and I don't know about you, but I'm always forgetting my passwords.

For many, completing questionnaires at home was the preferred option; however, some patients discussed the advantages of completing questionnaires, either paper or Internet, while attending the clinic (Table 3). Completing a questionnaire can be an efficient use of time for patients or a helpful distraction whilst a patient is waiting to see their practitioner or undergoing treatment. One patient commented that whilst attending the clinic:

Pat\_08: 'You are more in the mood; you're in the right head space to answer questions.'

### Patient Interviews: responder burden, frequency and length of questionnaires

It was explained to patients that the clinic was planning to use questionnaires to measure a wide range of health domains and to measure changes in health status over time. The number of questionnaires and questions could be considerable, so patients were asked about responder burden, how it might influence their decision to participate and ways to help reduce responder burden.

The overall impression from the interviews was that most patients would prefer to complete shorter questionnaires more frequently. However, this was not the case for everyone and some had strong contrary views and different preferences for length and frequency.

Pat\_17: I'd want to get it all done at once; otherwise, it is a flow breaker. If it was part of a series of treatments where you said, 'we're going to take some blood, set up the i.v. and you're going to fill this in', it's in the flow. That's OK, I've already scheduled that time to be here.

Pat\_13: You wouldn't want to be receiving them weekly or monthly, perhaps a couple of questionnaires, a couple of times a year. I'd be happy to do that if it only took me five minutes.

**Table 4** Suggestions by patients for reducing responder burden

1. Reduce the length, depth or frequency of questionnaires.
2. Prioritize the importance of the health domains, ask fewer questions for less important areas.
3. Maintain breadth and depth by breaking down a long questionnaire into a series of shorter questionnaires to be sent out over a staggered time interval.
4. Tailor questionnaires to match a patient's health problems or interest, or through the use of screening questions and algorithms.
5. Improve expectation management so respondents know in advance the frequency and length of questionnaires and the duration of the project. For electronic formats, display the progress or the number of questions remaining.
6. Sign-post and group questions into topics or domains.
7. Ensure only essential information is collected, for example do not ask for extra identifying information if it could be accessed through linked patient data.

Pat\_10: I'd be willing to do three hours of questions, but not in one session . . . fortnightly would be fine . . . I tend to leave things to the last minute so probably more often would be better for me.

Pat\_03: I mean I personally don't mind spending time answering questionnaires. When having gone for some Chinese medicine, I had a 20-page document to fill out. I just felt sorry for the practitioner having to read all my answers.

Factors that could influence the patient's acceptance of a longer questionnaire or more frequent questionnaires included the patient's interest in the topic, the intended use of the questionnaires, the expected rate of change of the parameters being measured and accurately informing patients in advance of how much time was involved (expectation management).

Patients thought the use of algorithms was an appropriate way to shorten questionnaires. However, mixed views were expressed about other ways to tailor questionnaires. In particular, some patients advised against allowing participants to choose the topics or domains they are interested in or think are more relevant.

Pat\_13: Some people don't even know their lifestyle's a problem . . . so you've got to check.

However, for others, not only was this type of tailoring a way to reduce questionnaire length, it would help engage them to participate.

Pat\_20: If you gave me a list and there was a range of topics there and you let me chose the topics you could sit me down for ages. But if you tell me what to focus on it might not engage me.

Table 4 summarizes the suggestions patients made for reducing responder burden.

### **Patient interviews: consent, spamming, confidentiality and Internet security**

Obtaining consent was important at all levels of patient engagement, from sending emails to patients to invite them to participate through to how the data will be used and who has access.

Pat\_21: I accept spam as a fact of life, but it annoys me . . . If it was too often, I'd be wondering why do they need all this

data? I assume any of these things should be opt-in, not 'assumed' opt-in. So when the person first comes to the clinic, you should be asked if you are happy to receive a survey. After each time, you're asked again.

Patients were asked at what stage they would feel spammed if the clinic sent emails inviting them to participate or ongoing email prompts to answer questionnaires. Again, there were a wide range of responses. Some patients were not concerned about spam, whereas others were and stated that if emails came too frequently they would ignore them. Some patients commented that because they already receive many emails, they were likely to delete email requests should they come too frequently. Some considered emails every 1–2 weeks acceptable, whereas others thought monthly emails were still too frequent.

All patients anticipated their confidentiality would be maintained. Nevertheless, many commented that people have different preferences for disclosing information, and some drew a distinction between confidential and anonymous data collection. Further to this, some patients wanted all the questionnaires to be anonymous; others wanted the option for some domains or topics to be anonymous; others again were happy for all their results to be used confidentially. A few patients were very reluctant to answer anonymous questionnaires because they wanted their individual results to be sent to their treating practitioner(s). The different preferred levels of disclosure were influenced by the patient's view about how they thought their results should be used, the sensitivity of the topic and the patient's trust in the practitioners and researchers.

Int\_01: Let's say [the questionnaire about a sensitive topic] was on the Internet, how would you feel about answering it anonymously?

Pat\_17: If it was anonymous, I'd think this really isn't going to help me. I wouldn't be bothered. I'm selfish and you'll only attract a certain type. Some people, you know they're going to think this is great for the community, but the individual type won't want to do it . . .

Int\_01: Oh OK then, so from a selfish individual point of view, what types of things would engage you? Why would you want to answer it?

Pat\_17: Well [PAUSE] I'd at least want the results to be fed back to my practitioner; so that you can help customise the facilitation of their, of my wellness program.

Whilst another patient commented:

Pat\_14: If it's anonymous especially, then you can just be super honest about everything . . . I much prefer anonymous. Umm, but I trust you guys, so I'd still tell the truth.

Patients were asked if they had any concerns regarding the security of the data collected, particularly data collected via the Internet. Mostly patients were confident that security issues would be addressed; however, some voiced concerns, especially regarding sensitive information. Some patients said they would look for specific signs before answering a questionnaire on the Internet and were more likely to trust certain Internet servers, whereas others were happy to be given assurance that appropriate security measures were in place.

Pat\_21: If it comes from a credible source like a University, then I'm more likely to do it. Or the clinic I suppose.

Pat\_22: It's a technical question that's beyond my competence. If you spell out in the email, what you're doing and the delicacy of it, I'm generally OK with it.

Regarding the use of the Internet to answer questionnaires, patients were asked about login usernames and passwords. Most patients had experience with logging into a site and using a password, with many stating they were comfortable with this process. Some wanted the option to be able to change their username and/or password. Others wanted alternate options, including anonymous data collection to be available.

## Discussion

Although the total response rate was low, for the purpose of this qualitative study, it was more than adequate because a wide range of patients volunteered and data saturation was reached with the 20 interviews. The invitation strategy was able to provide some preliminary data on the cost effectiveness of postal and email invitations.

Only one-third of the email invitations were opened. Notwithstanding, the total response rates were much higher compared with the postal invitations. This may reflect the minimal effort and expense needed to respond via email. Not including a paid postal option is likely to have reduced response rates to the postal invitations [44].

Nearly half of the emails were unopened. Possible reasons for this include patients providing email addresses they rarely use; ignoring unsolicited e-mails, especially if there is a high volume of daily emails; and using filtering software and heuristics that automatically quarantine emails [44,45]. It is also possible that the use of the word 'research' in the header elicited a negative response similar to including the word 'survey' [26].

Only a small proportion of emails were registered as spam or used the unsubscribe function. This is in keeping with the results from a national survey in Australia that found most people take no action and simply ignore unsolicited emails [45]. Therefore, it cannot be assumed that all the other patients who took no action wanted to be invited nor would like to receive further emails.

Almost one-fifth of emails bounced. Data entry errors would account for some of these, along with patients closing email accounts but not informing the clinic. The clinic was missing an email address for another 30% of the patients. The national average for Australian adults using a personal email address 2 years prior to this project was 72%, so it is probable that some patients did not provide the clinic with an email address [45]. The increasing numbers of older adults in the clinic without an email address is in keeping with national trends. However, no differences were found nationally between men and women, yet the clinic had significantly fewer email addresses for men across all age groups. Given a gender bias with data entry is unlikely, more male patients must have withheld their email address when registering with the clinic. The reasons for this are unknown.

Our findings were consistent with other research, demonstrating that although many patients will answer questionnaires on the Internet, alternate formats should be provided [14–16,46]. Internet response rates for patients who do not have access to the Internet could potentially be increased by providing electronic equipment for patients to answer questionnaires in the clinic [34]. However, if a patient was only halfway through the questionnaire and it was time to see their practitioner, completing the questionnaire might be problematic. Furthermore, technical challenges associated with using an unfamiliar computer could place extra burden on the

administrative staff; there is a risk that equipment might be damaged or stolen; and answering questions on a computer in a public space can bias answers, especially to sensitive topics [18,20].

It was apparent that the clinic would need to find the right balance between the frequency, length, content and style of questionnaires. Although many patients stated they would prefer shorter, more frequent questionnaires, this was not the case for all patients. The different preferences are consistent with other research. Some research has found that patients are more likely to answer shorter questionnaires, be they paper or electronic formats [26,47]. However, a multivariate analysis of email surveys found that survey length alone was not enough to predict response rates [44]. Another factor to consider when choosing questionnaire length is the logistical challenges associated with longer Internet questionnaires [5].

We found that anonymous versus confidential data collection may either positively or negatively influence participation. The difference in patient preference was influenced by their trust in the research team, the sensitivity of the topics and how they thought their results should be used. Anonymous data have more limited use than confidential data and there is an increased risk of multiple responses from the same person, especially if incentives are offered [48]. Therefore, if anonymous Internet questionnaires are used, it is important to utilize methods to identify multiple submissions [48].

## Recommendations

Our study found a wide range of patient preferences, which, in turn, will affect the response rates and acceptability of patient questionnaires. Although it is impossible to please all of the people all of the time, by addressing many of the issues raised by patients, there is the potential to maximum recruitment and retention of participants.

Notwithstanding the problems with email invitations, based on our findings and other research, a time-efficient and cost-effective strategy may be to begin with email invitations, including one or two reminders to non-responders, followed by postal invitations with reminders to the remaining non-responders and those without an email. Pre-notification may improve response rates or response time, and could be used to determine each patient's preferred questionnaire format. Where possible, the invitation or prompt to answer an Internet questionnaire should be emailed with a web-link to the questionnaire rather than sent by post. Ideally, an email invitation should include an image; be personalized and signed by a female; and come from a trustworthy URL. Avoid using the word 'survey' or similar words in the email header. Postal questionnaires must include paid return post.

To reduce response bias and improve the generalizability of results, more than one questionnaire format is needed. Given the advantages of electronic formats, it may be worthwhile to begin by encouraging patients to answer electronic questionnaires and use alternate formats for non-responders. Questionnaire formats and designs should be pilot tested to maximize their acceptability and resolve any logistical issues. The psychometric properties of a questionnaire must be confirmed before using it in an alternate format. To help reduce responder burden, only essential information should be collected.

With increasing acceptability and access to the Internet and ongoing technical advances, the opportunities to use this format to collect patient data will continue to grow and offer the potential for more cost-effective research methods. However, at least for the time being, alternate concurrent formats are required, especially if there is the potential for bias or reduced generalizability of results.

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# **CHAPTER 7: APPEALING TO ALTRUISM IS NOT ENOUGH: MOTIVATORS FOR PARTICIPATING IN HEALTH SERVICES RESEARCH.**

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## **FOREWORD**

This paper was published in two parts: a brief report and an on-line supplementary document.

Compared to the papers presented in other chapters, the supplementary document provides the most detailed information about the patient selection, sampling, consent, interviews and analysis.

An emerging theme from the interviews was the different motivators for participating in or supporting research and how the participant's motivators are linked to their assumptions about the usefulness of questionnaires. The logistical and ethical considerations of using patient reported outcome questionnaires in health services research are discussed.



## **TABLES AND FIGURES**

**Chapter 7 / Table 1 & Chapter 7 (Supplementary) / Table 5:** Potential uses of the results from patient questionnaires

**Chapter 7 (Supplementary) / Table 1:** Patient characteristics

**Chapter 7 (Supplementary) / Table 2:** Potential domains to be covered by different questionnaires

**Chapter 7 (Supplementary) / Table 3:** Interview prompts

**Chapter 7 (Supplementary) / Table 4:** Factors influencing participation in observational research

**Chapter 7 (Supplementary) / Table 6:** De-identified quotes from patients and practitioners

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Appealing to altruism is not enough: motivators for participating in health services

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## APPEALING TO ALTRUISM IS NOT ENOUGH: MOTIVATORS FOR PARTICIPATING IN HEALTH SERVICES RESEARCH

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**ABSTRACT:** THIS PILOT STUDY SOUGHT TO IDENTIFY motivators and barriers to participating in a longitudinal survey; we interviewed patients and practitioners at a multidisciplinary primary care clinic where the proposed project would be based. While altruism motivates participation in medical research, we found that for many potential participants, the opportunity to benefit directly was the primary, and sometimes the only motive to participate or encourage participation in the research project. Patients often wanted direct feedback from their individual results, and they expected to provide consent before the results were forwarded to other parties such as their practitioners. Similarly, some practitioners were more likely to support the project if participation benefited patients directly. Other factors were also identified that influenced the acceptability and perceived risks and benefits of participating. More work is needed to understand these motivators and how patients might benefit directly from participating in health services research, especially when direct medical benefit is not possible.

**KEY WORDS:** research ethics, observational research, health services research, qualitative research, patient participation, research design

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**R**ECRUITING AND RETAINING PATIENTS FOR research is becoming more challenging. Response rates to invitations to participate in all types of research have dramatically declined over the past decade (McCluskey & Topping, 2011; Williams et al., 2008). Low participation and high dropouts can adversely affect the timeline and budget of a project, and reduce the statistical power to detect a finding if the sample size is too small or

if participants have a lower rate of an explanatory variable. Furthermore, low participation can cause recruitment bias if research participants differ from nonparticipants (Eastwood et al., 1996; Marcus & Schutz, 2005; Pagan et al., 2006; Stewart et al., 2009; Trauth et al., 2000), which in turn reduces the validity and generalizability of results (Eastwood et al., 1996; Taylor et al., 2008; Webb et al., 2010). Many factors have been shown to improve response rates to questionnaires and minimize dropouts. Mostly this research has focused on the use of different survey methods; invitation strategies, including incentives; and questionnaire format, design, and content (Edwards et al., 2009; McCluskey & Topping, 2011; Sheehan, 2006).

Researchers state that good, ongoing communication and appealing to altruism are key factors for improving participation in observational research where the risks of participating are low (Levy et al., 2010; Williams et al., 2008). However, there is growing recognition that patients often hope to benefit directly (e.g., through being informed of the individual results) when participating in nontrial research such as genetic epidemiology (Beskow et al., 2011; Hallowell et al., 2010; Ruiz-Canela, Valle-Mansilla, & Sulmasy, 2011). Less is known about motivators to participate in other types of observational research, particularly health services research.

Encouragement from the treating practitioners also affects participation (Fouad et al., 2008; Verhoef et al., 2010). Concerns with the study design and the potential for adverse indirect impact and blame on the doctor-patient relationship were reasons cited by clinicians for not encouraging patients to participate in clinical trials (Amiel et al., 2007; Rendell, Merritt, & Geddes, 2007). Presumptions about the reasons a patient will refuse also influences a practitioner's decision to invite participants (Amiel et al., 2007). The organizational culture, resources, and environment; logistical challenges; and beliefs and attitudes about the value of research were found to influence practitioner support of an observational research project similar to the one proposed here (Verhoef et al., 2010).

Before commencing a longitudinal observational study of patients attending a multidisciplinary primary care clinic in Sydney, Australia, the views of patients and

practitioners were sought to gain insight into their motivation and barriers to participating. The proposed research would require patients repeatedly to answer questionnaires about patient-reported outcomes and other information relevant to health service evaluation, such as patient satisfaction and enablement. This paper briefly presents the findings pertaining to the motivators and barriers of patients answering questionnaires and practitioners encouraging patients to answer questionnaires in the context of longitudinal health studies.

### Method

In-depth face-to-face semi-structured interviews were conducted with 20 patients and 13 staff at a multidisciplinary primary care clinic in Sydney, Australia. The research team consisted of two practitioners from the clinic and two independent academics. Ethics approval was granted from two human research ethic committees (HREC).

The clinic sent an e-mail or postal invitation to 5,082 patients; 334 patients volunteered to be interviewed. To ensure a wide selection of patient characteristics, the volunteers were categorized by age, sex, complex or simple cases, paper or e-mail invitation, and old or new patient. A random selection of patients from these categories was chosen for interview. It was estimated that 20 patients would be enough to reach thematic saturation where no new information is identified. If this was not attained by the end of the initial series of interviews, further sampling and interviews would be undertaken.

All 12 practitioners (except for the first and last authors) and the clinic's practice manager were e-mailed an invitation to be interviewed, and they all consented to participate. The practitioners comprised six doctors, three psychologists, one dietician, and three complementary medicine practitioners.

Written consent was obtained before the interview. The interviews took one hour each. During the first half of the interview, the discussion focused on the relevance of measuring different health-related domains. Interviewees were shown examples of questionnaires. The next 30 minutes were spent discussing patient and practitioner views on perceived uses of questionnaires; whether they were interested in knowing individual patient results and cohort results; the impact of questionnaire design and format on responder burden; and issues around confidentiality. For patients, we explored their motivation to answer ongoing questionnaires; for practitioners, we asked about their motivation to invite and encourage patient participation.

One practitioner and one academic each conducted half the interviews, while the other sat at a distance and took notes. Although the interviews were electronically recorded, due to time restrictions, the decision was made also to use a scribe to enable rapid preliminary analysis of the data immediately following each interview. This helped to identify emerging themes or issues that needed further exploration in the subsequent interviews, and ensured that thematic saturation had been reached by the end of the 20 patient interviews (Ezzy, 2002). It would also be a valuable backup should the recording fail.

Data from the interview notes and transcriptions were entered and coded in QSR NVivo 9 data management program (QSR International Pty. Ltd., 2010). The analysis was an iterative process that used inductive approach to identify and explore taxonomies, themes, and ideas (Bradley, Curry, & Devers, 2007; Ezzy, 2002). The aim of the interviews was to identify all possible points of view and themes rather than quantify the frequency. Therefore, a single comment, especially if the respondent felt strongly about it, was considered equally as important as those held by many participants (Fereday & Muir-Cochrane, 2006).

An online supplementary document (available at <http://dx.doi.org/10.1525/jer.2012.7.3.84>) outlines the HREC approval; presents more information about the sample and patient selection; lists the characteristics of the 20 patients who were interviewed; provides a description about how confidentiality was maintained and consent was obtained; lists the health-related domains and questionnaires shown to interviewees during the first half of the interview, and the prompts often used by the interviewers; and provides more information about the analysis.

### Results

This paper presents the results from the second half of the interview. Mostly, there was little qualitative difference between practitioners and patients, or subgroups. A wide range of opinions was expressed. The main differences reflected the different emphasis of the questions when interviewing patients and practitioners.

The interviews revealed that people would be motivated to participate or support research for many reasons. There was a complex interplay among factors, and patients and practitioners weighed the perceived benefits of patients participating against potential risks and costs.

Interviewees discussed two types of results and their potential uses (Table 1). Individual patient results could be used to benefit the patient completing the

TABLE 1. Potential Uses of the Results from Patient Questionnaires.

<b>Individual patient data could be used to:</b>	
1.	provide feedback to patients who want to monitor their own progress
2.	raise patient awareness about their health
3.	engage the patient in their health care
4.	provide extra information to a patient's practitioners to inform and improve the clinical care of a patient
<b>Cohort data could be used for:</b>	
1.	quality assurance to improve the clinic's service delivery
2.	appraising practitioner performance in the clinic
3.	clinical governance and accreditation purposes
4.	informing clinical guidelines
5.	answering academic research questions

questionnaire. Cohort data could be used for the benefit of the clinic or society. For the most part, a combination of potential benefits was important to interviewees. However, the importance varied, and strong and opposing views were expressed about the value and use of the individual and cohort results.

Patients were more motivated to participate, and practitioners were more likely to encourage participation, if the questionnaires were to be used in a way they considered useful. For example, a few patients stated the only reason they would participate was to benefit directly from the use of their individual results. In contrast, other patients commented that rather than their individual results, they anticipated benefiting from the reporting of cohort data to inform them about their own lifestyle or healthcare choices. For practitioners, their own perception about the usefulness of individual and cohort results influenced the reasons they thought patients would be motivated to participate.

Altruism was a motivator that was expressed either as a desire to support the clinic to improve its service for the benefit of other patients, or to help generate knowledge for the benefit of society. For many of those motivated by altruism—be it for the benefit of the clinic or society—it was secondary to the importance they placed on individual patient benefit. In contrast, some patients and practitioners demonstrated no appreciation of, or interest in, the use of questionnaires for these purposes.

It was apparent from the interviews that researchers must find the right balance among frequency, length, and content (including breadth and depth of questions). The advantages and disadvantages of answering

questionnaires in different locations such as the clinic or at home, along with using different formats such as electronic and paper, were discussed. Obtaining consent and concerns about confidentiality were important to interviewees at all levels of patient engagement. So too were other potential risks from completing questionnaires.

More detailed results and quotes from interviews can be found in the online supplementary document (available at <http://dx.doi.org/10.1525/jer.2012.7.3.84>)

## Discussion

Based on our findings and previous research, emphasizing the social benefits has a base in evidence when promoting research to the general community. Altruism is often assumed to be the primary motivator for participating in observational research, because the risks or participating are low. Furthermore, if the data is sourced from patient questionnaires, then unlike the results from clinical examinations or investigations, answering patient-reported questionnaires theoretically provides no new information to the respondent. Therefore, the results should be less interesting to patients and offer less opportunity for participants to benefit directly from participation.

However, the findings from this study suggest that similar to other types of research, many interviewees anticipated benefit from patients knowing their individual results and this was an important motivator for some potential participants. Ethically, the benefits to patients for participating in research should be maximized and outweigh risks (UNESCO, 2005). This includes benefits “to which the participants attach significance” (NHMRC, 2007). Commonly, participants are provided with a summary of the research findings. However, a meta-analysis of mostly nonmedical surveys found that offering the overall study results did not improve response rates (Cockayne & Torgerson, 2005). Similarly, many of the interviewees were not interested in cohort results. Instead, they wanted to see positive change from the research for the benefit of others and/or they wanted to benefit directly. Those patients who want the opportunity to benefit directly from accessing their individual patient-reported results while participating in health services research should ideally be given this option. This in turn may improve participation rates (Hallowell et al., 2010; McCann, Campbell, & Entwistle, 2010).

Obtaining consent and providing individual results to participants is complex (Cadigan et al., 2011;

Franrenet et al., 2011; Knoppers et al., 2006; Ravitsky & Wilfond, 2006; Shalowitz & Miller, 2008). Similar to other research, participants could be given their results directly from the research team or through a nominated treating practitioner (Cadigan et al., 2011). Notification of results to participants and practitioners must be optional and include the right not to be informed and for their practitioner(s) not to be notified (Knoppers et al., 2006). Further consultation with practitioners is needed to clarify the implications of the extra workload generated from receiving individual patient results and to discuss other logistical, medico-legal, and ethical issues.

An addendum to this discussion can be found in the online supplementary document (available at <http://dx.doi.org/10.1525/jer.2012.7.3.84>).

#### *Limitations of This Study*

There were both advantages and disadvantages to including practitioners in the research team. Practitioner involvement helped allay concern among patients about accessing patient databases in the clinic. It also allowed efficient and accurate coding of the volunteer patients to create a stratified sample; ensured the research was relevant to their health service setting; and improved the level of support for research. Several patients and practitioners also stated their trust in the practitioners in the research team was a reason they volunteered to be interviewed, and one patient only wanted his practitioner to be the interviewer. Three practitioners stated that generally they did not trust research; however, because the practitioners would be driving the projects they would be more supportive than usual.

Including a practitioner in the interview team, however, may have biased our results. Nine of the patients interviewed had consulted this practitioner on at least one occasion and all the practitioners worked alongside the interviewing practitioner. Interviewees may have felt more pressured to say what they thought the practitioner wanted to hear. The presence of two researchers, an interviewer, and a scribe may have compounded this bias. Interviewees would be more likely to respond favorably towards supporting the use of questionnaires. Patients may have understated their desire to benefit personally, and not fully expressed any reluctance they had toward answering repeated questionnaires. Similarly, practitioners may have felt obliged to voice support for the proposed project and been willing to encourage their patients to participate.

Another important limitation of this study was the low response rate of 5%, drawn from one primary care clinic and a small sample of only 20 patients and 13 practitioners. No information was available regarding nonrespondents' reasons for declining to participate. Probably people less motivated by altruism would be less likely to take up the invitation to be interviewed.

Notwithstanding the limitation of the study design, our findings were similar to other research with higher recruitment rates and from different population groups (Fouad et al., 2008; Hallowell et al., 2010; Jerosch-Herold et al., 2011; Kass et al., 1996; Lazovski et al., 2009; McCann et al., 2010; Roberts, Newcomb, & Fost, 1993; Sugarman et al., 1998; Teschke et al., 2010; Trauth et al., 2000). The sample of patients interviewed was broad and thematic saturation was reached. However, a larger sample is more likely to identify validly important differences among patients and practitioners.

Although the staff interviewed were only from one clinic, our results are in line with those from practitioners of three multidisciplinary community-based clinics in Canada (Verhoef et al., 2010). The Canadian study was prompted by low recruitment and retention for an observational survey aiming to measure patient-reported outcomes and confirmed the importance of consulting staff before undertaking research in their clinic. Practitioners and staff working in other types of primary care clinics and hospitals, especially those where research is more common, may hold different views to those interviewed in this study.

#### **Best Practices**

In-depth interviews with patients and practitioners are an effective way to identify factors that influence participation in and support of research. Consultation with stakeholders before commencing a project has the potential to improve recruitment rates and acceptability.

#### **Research Agenda**

This study raises the question about how best to motivate patients to participate in and practitioners to support health services research. It challenges the assumption that patients are disinterested in their individual results from patient-reported questionnaires because theoretically they already know the answers. More research is needed in different clinical settings, with different patients and practitioner groups and larger numbers.

Many of the ethical and logistical issues with returning individual results to participants are relevant to all types

of research, although there are distinct differences between patient-reported results and other results from examinations and investigations that may well apply here.

Health services research poses its own unique challenges. For example, in the clinic where this project was conducted, patient questionnaires were not used routinely, nor are they a predominant feature of health services in Australia. Patients and practitioners would not necessarily presume the questionnaires would be used as part of their routine clinical care. This assumption is supported by discussions in a staff meeting held prior to the interviews. The notion that results from patient-reported questionnaires might also be used as part of routine clinical care was not raised by the research team nor discussed by any of the practitioners. Therefore, in this setting, the interviewees' views about the perceived benefits of individual results are significant. However, once the proposed project is operational, it will be important to assess whether patients and practitioners continue to value the individual results from patient-reported questionnaires. Similarly, accessing individual results may not be an important motivator for participating in or supporting health services research in locations where the use of patient questionnaires is more commonplace.

#### Educational Implications

Given the overall decline in research participation, it is important to find ethical and innovative ways to make research more attractive to participants, particularly those who are motivated by the desire to benefit personally. Direct incentives such as payment or other types of reimbursement will work for some and create their own biases. Others will be more interested in the potential health benefits from accessing their individual results. However, if recruitment only focuses on the direct benefits to participants, then those who are primarily motivated by altruism will be missed. Therefore, when communicating the potential benefits of participating in health services research, it is important to highlight benefits for the individual, clinic or health service, and society.

If a project is based in a health service or clinic, then it is important to appreciate that not all practitioners will have a strong research culture. Similar to patients, practitioners may be more inclined to support participation if there is the potential for their patients to either benefit directly from receiving their individual results or indirectly through improved patient care. Others will be more interested in using cohort results to improve clinical services or

to answer bigger research questions. Consultation with stakeholders is useful in the early design stages, and practitioners who are interested in doing research should be encouraged to join the research team.

Finally, it is important to consider the impact different interviewers, such as researchers and health service staff, can have on the willingness of patients and staff to participate in research, and toward biasing the results.

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#### Authors' Biographical Sketches

**Jennifer Hunter** is General Practitioner at Uclinic, Sydney, where the project was based, and a PhD candidate in Public Health at the Menzies Centre for Health Policy, University of Sydney. Her past experience in health services research meant that Jennifer understood the importance of consulting relevant stakeholders during the design phase of a study.

**Katherine Corcoran** was a research assistant at the Menzies Centre for Health Policy, University of Sydney.

**Stephen Leeder** is Professor of public health and community medicine at the University of Sydney and Director of the Menzies Centre for Health Policy. He has a long history of involvement in public health research, educational development and policy.

**Kerryn Phelps** is General Practitioner and Director of Uclinic at Uclinic, Sydney, where the project was based; Adjunct Professor at the School of General Practice, Faculty of Medicine, University of Sydney; and Professor (Conjoint) at the School of Public Health and Community Medicine, University of New South Wales. This project would not have been possible if not for her commitment to building research capacity in health services research at the grass roots level.

**Online Supplementary Material to J. Hunter, K. Corcoran, S. Leeder, and K. Phelps, “Appealing to Altruism is Not Enough: Motivators for Participating in Health Services Research,” *Journal of Empirical Research on Human Research Ethics*, 7(3), 84–90.**

In-depth face-to-face semi-structured interviews were conducted with 20 patients and 13 practitioners at a multidisciplinary primary care clinic in Sydney, Australia. This was a consultative process. The aim was to identify and explore the factors influencing participation in health services research. It was conducted before starting a research project that would use patient questionnaires to collect longitudinal data on patient-reported outcomes and other health service information.

The results from these interviews are reported in a series of publications. This document provides supplementary information pertaining to a brief report published in the *Journal of Empirical Research on Human Research Ethics (JERHRE)*. The brief report and this supplementary document focus on the findings about the motivators for participating in or supporting health services research and its relationship to the perceived uses and value of patient-reported questionnaires.

### **Additional Information about the Methods**

#### **Ethics**

Ethics approval was granted from two human research ethic committees (HREC). The University of Sydney HREC was the overseeing committee for the investigators. The Illawarra HREC was the overseeing committee for the Area Health Service where the clinic was located.

#### **Sample**

The clinic was in its fifth year of operation when the interviews were conducted. Along with primary care services the clinic specialized in integrating traditional, complementary, and

alternative medicine (TCAM) with orthodox biomedicine. The team consisted of biomedical doctors, psychologists, complementary medicine practitioners, and a dietitian.

A wide range of patients attended the clinic. Some patients used the clinic for standard primary care services, whereas others utilized the more specialized TCAM and integrative medicine services offered by the team. The demographics of patients attending the clinic were similar to the general population who uses TCAM in Australia, with more women aged between 20 and 50 attending the clinic (MacLennan, Myers, & Taylor, 2006). The majority of patients paid an upfront fee for services; this precluded many people on a low income from attending the clinic.

The clinic had 6,154 active patients 18 years or older in its database. The clinic e-mailed an invitation to all patients with an available e-mail address, and paper invitations were posted to all patients older than 60 years of age and 1 in 4 younger adults. 334 patients volunteered to participate. The response rates were 7.4% (319/4315) for e-mail invitations and 2.0% (15/767) for postal invitations.

### **Patient Selection**

The purpose of the qualitative interviews with patients and practitioners was to identify a wide range of commonly held opinions rather than the frequency with which they were held. Patients for interview were selected randomly from the pool of respondents. This prevented the research team from selecting (or not selecting) by preference patients known to them.

To improve the likelihood of identifying the different views potential participants may have, patients who volunteered to be interviewed were categorized by: age, sex, complex or simple case, paper or e-mail invitation, and old or new patient. A complex case was defined as a patient with co-morbidities and/or a severe chronic illness. Given the clinic was only four years old, a new patient was defined as a patient who had attended the clinic less than once or



was registered for less than a year. Sampling patients from both invitation methods, e-mail and post, was important because another aim of the interviews was to explore patients' views about using electronic and paper formats. The clinic did not have reliable data on other important variables such as ethnicity, education, and socioeconomic status, so further stratification was not possible.

**TABLE 1. Patient Characteristics.**

<b>Age (yrs)</b>	<b>Female</b>	<b>Male</b>	<b>Complex</b>	<b>Simple</b>	<b>Postal</b>	<b>E-mail</b>	<b>Old &gt;1yr</b>	<b>New &lt;1yr</b>
<b>18–30</b>	2	1	1F,0M	1F,1M	1F,0M	1F,1M	2F,1M	0
<b>31–45</b>	3	2	2F,1M	1F,1M	1F,0M	2F,2M	2F,1M	1F,1M
<b>46–60</b>	3	4	2F,2M	1F,2M	2F,1M	1F,3M	2F,3M	1F,1M
<b>61–75</b>	2	1	1F,1M	1F,0M	2F,1M	0F,0M	2F,0M	0F,1M
<b>75+</b>	1	1	1F,1M	0	0	1F,1M	1F,1M	0
<b>TOTAL</b>	<b>11</b>	<b>9</b>	<b>7F, 5M</b>	<b>4F, 4M</b>	<b>6F, 2M</b>	<b>5F, 7M</b>	<b>9F, 6M</b>	<b>2F, 3M</b>

<b>Socioeconomic Characteristics of the Patients Interviewed</b>			
<b>Education Status</b>		<b>Occupation</b>	
<b>Tertiary degree</b>	<b>9</b>	<b>Production or transport worker</b>	<b>0</b>
<b>Other qualification</b>	<b>7</b>	<b>Manager or administrator</b>	<b>2</b>
<b>High school only</b>	<b>4</b>	<b>Trade person</b>	<b>3</b>
		<b>Professional</b>	<b>9</b>
		<b>Clerical, sales &amp; service worker</b>	<b>4</b>
		<b>No occupation or training</b>	<b>2</b>

<b>Language Spoken at Home</b>	
<b>English</b>	<b>20</b>
<b>Other</b>	<b>0</b>

N=20 patients; M=male, F= female

### **Maintaining Patient Confidentiality**

As part of the registration process with the clinic, patients provide written consent to be contacted by the clinic for medical, research, or promotional purposes such as newsletters. To honor patient confidentiality, the clinic coordinated and sent the invitations to patients and practitioners.

The electronic clinical records used by the clinic are integrated; this means that all entries made by practitioners are entered into a patient's clinical file in chronological order

and the other practitioners can read the file. Before registering with the clinic, patients are advised that all the practitioners in the clinic will be able to access and read their clinical records for either clinical or research purposes, and written consent is obtained.

Only those patients who volunteered to be interviewed were coded according to the characteristics outlined previously. This required access to their clinical records. Therefore, only the researchers who were also practitioners at the clinic could code the patients. As well as maintaining patient confidentiality, this approach was seen as an efficient use of researcher time. The practitioners were familiar with the clinical software and had the appropriate expertise to categorize patients.

### **Consent for the Interview**

The invitation letter sent by the clinic to patients and practitioners included a participant information document and consent form. All interviewees gave written consent before being interviewed, including permission to record the interview. Half the interviews were conducted by one of the academic researchers and half were conducted by one of the practitioners. Therefore, the consent form also provided the option to select their preferred interviewer. This option was provided because some patients and practitioners may feel uncomfortable being interviewed by a practitioner from the clinic or an academic who is a stranger. All interviewees except for one selected the “no preference” option. One patient wanted his treating doctor to be the interviewer. The same patient stated he did not want the academic to be present as a scribe. Although it was clearly outlined in the participant information document, it was not until the purpose of the interview was restated orally at the beginning of the interview that the patient realized no personal medical information would be discussed. The patient then stated he was comfortable with the academic researcher attending the interview as a scribe.

## Interview Outline

The interviews lasted approximately one hour. In the first half of the interview, interviewees were presented with a list of potential health-related domains. It was explained that the research team was considering using patient-reported questionnaires to measure some or all of these domains. They were also shown examples of questionnaires and it was explained that responses to a questionnaire were usually summarized as a score. Table 2 lists the health-related domains and questionnaires shown to participants.

**TABLE 2. Potential Domains to be Covered by Different Questionnaires.**

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1.	<b>Physical health</b> – physical symptoms, disabilities, and impact on daily living
2.	<b>Mental health</b> – emotions, mood, stress, sleep, and impact on daily living
3.	<b>Coping</b> – with illness and life’s challenges
4.	<b>Spirituality</b> – more than a belief in God or religiousness, it includes a sense of purpose in life and engagement with spiritual activities, feelings of connection beyond mundane reality
5.	<b>Lifestyle</b> – exercise, diet, alcohol, smoking, drugs, work hours, relaxation, sleep
6.	<b>Life satisfaction</b> – with health, life, relationships, friends, family, work, standard of living
7.	<b>Holistic</b> – total well-being of body, mind, and spirit, and other areas such as feeling a part of the community and future security
8.	<b>Attitudes</b> – toward complementary medicine and philosophy of healing
9.	<b>Consultation/clinic</b> – satisfaction, trust in practitioner, quality of consultation
10.	<b>Change in medication and/or supplement use</b>
11.	<b>Individualized</b> – open questions where the patient chooses what the main problems are and then rates whether they are improving

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The next 30 minutes were spent discussing patient and practitioner views on their perceived usefulness of questionnaires; whether they were interested in knowing individual patient results and cohort results; the impact of questionnaire design and format on responder burden; and confidentiality. For patients, we explored their motivation to answer repeated questionnaires; for practitioners, we asked about their motivation to invite and encourage patient participation. Table 3 outlines the prompts often used by the interviewers.

**TABLE 3. Interview Prompts.**

<b>PATIENT INTERVIEWS</b>	
1.	We would like to ask you some questions about the use of questionnaires in general.
2.	What do you think about patient questionnaires?
3.	Can you see any value or use for questionnaires?
4.	Can you see any benefits from answering questionnaires?
5.	What would motivate you to want to answer questionnaires?
6.	Can you see yourself and/or other patients at this clinic completing these questionnaires?
7.	Would you want to know your own results and/or summary results for the clinic?
8.	Would you want your practitioners to be notified of your results?
9.	Would you want the results to be recorded in your computerized clinical notes at the clinic?
10.	Would you be concerned about confidentiality?
11.	What are your views on different questionnaire formats such as paper, internet, and telephone; and the location such as answering questionnaires in the clinic or at home?
12.	If we need to find a balance between asking all the questions that are potentially important (i.e., comprehensive information) and the time it would take to answer them all (i.e., responder burden): Do you think a long questionnaire or many questionnaires is a problem? Can you think of any ways to help reduce responder burden?
13.	Do you have any other questions or comments?
<b>PRACTITIONER INTERVIEWS</b>	
1.	We would like to ask you some questions about the use of questionnaires in general.
2.	What do you think about patient questionnaires?
3.	Can you see any value or use for questionnaires?
4.	Would you want to know the individual patient results and/or summary results?
5.	Would you want the patient's results to be available in their computerized clinical notes?
6.	Would you want to be notified of your patient's results?
7.	Would you be likely to prompt or encourage your patients to complete questionnaires?
8.	Do you think your patients would be interested in completing questionnaires?
9.	What might be the reasons they would not want to complete a questionnaire?
10.	Are there any ways you envisage individual patient results and/or overall results of the practice being useful to your clinical practice?
11.	Would you be concerned about confidentiality?
12.	We will need to find a balance between asking all the questions that are potentially important (i.e., comprehensive information) and the time it would take to answer them all (i.e., responder burden). Can you think of any ways to help reduce responder burden? Or encourage patients to complete the questionnaires?
13.	Do you have any other questions or comments?

## **Analysis**

Immediately following the interview the notes taken during the interview (along with replaying the recording if needed) were reviewed for preliminary analysis. This enabled the immediate exploration of themes such as altruism versus personal benefit that were emerging from the data, and ensured that thematic saturation had been reached by the end of the series of interviews (Ezzy, 2002).

The interviews were electronically recorded for transcription. The data were entered and coded in QSR NVivo-9, a qualitative data management program designed to organize unstructured information such as transcriptions and interview notes (QSR International Pty. Ltd., 2010). Before coding, the two interviewers refamiliarized themselves with the data and then jointly coded the data initially using broad, open codes, followed by more specific coding to describe the different taxonomies and ideas. The researchers then independently reviewed data. This was followed by further discussion until a consensus about the final coding and interpretation was reached. It included categorizing interviewees according to their “uses” and “motivators” to allow cross comparisons. The analysis was an iterative process that used an inductive approach to identify and explore taxonomies, themes, and ideas (Bradley, Curry, & Devers, 2007; Ezzy, 2002).

The aim of the interviews was to identify all possible points of view and themes rather than quantify their frequencies. Therefore, a single comment, especially if the respondent felt strongly about it, was considered equally as important as those held by many interviewees (Fereday & Muir-Cochrane, 2006).

## **Supplementary Results**

The interviewees covered a wide range of factors that would influence their willingness to participate, or encourage patients to participate, in health services research (Table 4).

Disincentives such as the potential costs and risks of participating were balanced against potential benefits. The perceived benefits and motivators correlated with the interviewees' opinions about the usefulness of individual results and cohort results.

**TABLE 4. Factors Influencing Participation in Observational Research.**

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<ol style="list-style-type: none"> <li>1. Invitation strategies – e-mail, postal, telephone, face-to-face, and personalized invitations; and using reputable clinic or university logos and URLs.</li> <li>2. Perceived value of the purpose and use of questionnaires (see Table 3)</li> <li>3. Incentives – e.g., cash payment, discounts, or a prize draw; especially for ongoing surveys or research or those conducted to benefit private enterprise</li> <li>4. Responder burden – e.g., time, effort, and other potential costs to participants</li> <li>5. Trust in the practitioner, clinic, and researchers</li> <li>6. Expectation management – e.g., accurate information about completion times and frequency of questionnaires</li> <li>7. Questions asked – content, appropriateness, sensitivity of the topic, ease of answering</li> <li>8. Options for questionnaire format – paper, electronic/Internet, telephone, face-to-face</li> <li>9. Options for location – private versus a public space such as the clinic</li> <li>10. User-friendly design, and if using the Internet, fast server speed</li> <li>11. Confidentiality and data security issues, especially if electronic/Internet format</li> <li>12. Options for anonymous versus confidential data collection</li> <li>13. Consent – including notification of results to patients and practitioners, and for use of individual results</li> <li>14. Risks associated with negative emotions triggered by answering questions or from patients receiving their individual results</li> <li>15. Logistical, financial, medico-legal, and ethical implications of practitioners receiving their individual patient results</li> <li>16. Reporting the overall results from the research and its impact on change</li> </ol>
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For the most part, a combination of potential benefits was important to interviewees (Table 5: Quote 1 & 2). However, the importance varied and both patients and practitioners expressed strong and opposing views about the value and use of the results from questionnaires (Table 5: Quotes 2–4).

**TABLE 5. Potential Uses of the Results from Patient Questionnaires.**


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Individual patient data could be used to:
<ol style="list-style-type: none"> <li>1. provide feedback to patients who want to monitor their own progress</li> <li>2. raise patient awareness about their health</li> <li>3. engage the patient in their health care</li> <li>4. provide extra information to a patient's practitioners to inform and improve the clinical care of a patient</li> </ol>
Cohort data could be used for:
<ol style="list-style-type: none"> <li>1. quality assurance to improve the clinic's service delivery</li> <li>2. appraising practitioner performance in the clinic</li> <li>3. clinical governance and accreditation purposes</li> <li>4. informing clinical guidelines</li> <li>5. answering academic questions for the benefit of society</li> </ol>

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Although none of the interviewees wanted financial payment, including reimbursement for costs to attend the interview, direct incentives might be an important motivator for some patients, especially for the completion of repeated questionnaires or for research used for private enterprise. The interviewees recognized that financial payment or other incentives such as a discount on the consultation fees may be inappropriate. Instead, they suggested ideas such as a free lottery ticket or discount shopping voucher.

Alternate ways for participants to benefit were frequently discussed, especially the benefits of using individual results. Patients who wanted to know their results anticipated utility from summary scores and information about interpretation. Some patients commented they would use their own results to track their progress or to compare them with population norms. This in turn could help highlight problem areas that otherwise they may not have realized, or help motivate them to attend to these areas even when they already had some awareness. Some patients went as far as to state the only reason they would answer questionnaires was if there was the potential to directly benefit from the use of their individual results (Table 6: Quote 3).

**TABLE 6. De-identified Quotes from Patients and Practitioners.****Quote 1: A patient with mixed motivations to participate**

Int\_02: *“What would motivate you to answer these types of [health-related] questionnaires?”*

Pa\_07: *“Oh, just the help I can give to the clinic overall and to people in general.”*

Int\_02: *“More so than the results you might get for yourself?”*

Pa\_07: *“Oh, look definitely the feedback I get for myself I’d be interested in... I’m into self-motivation and learning more about myself.”*

**Quote 2: A practitioner who thinks questionnaires should be used for many purposes**

Pr\_34: *“I think [patient outcomes] would be a great thing to document. It would actually be a good thing for practitioners to see how they are impacting on peoples’ health... I always wonder what patients think, what else I could do better...”*

In\_01: *“Would you want summary results or individual results?”*

Pr\_34: *“Summary results would be better. I might want to know individual results, but some like you who’s much busier, you probably wouldn’t, it probably would be overwhelming. But I would like to know individual [results], yeah I would be interested...”*

Int\_01: *“Are there any other uses [of the questionnaires] you’d be interested in?”*

Pr\_34: *“Yeah of course, like publishing it in a journal, a paper.”*

**Quote 3: A patient who only values the use of questionnaires for individual benefit**

Pa\_03: *“I don’t see the point in doing it if my practitioner isn’t going to see the results... whatever can be done to help improve [my] outcomes.”*

**Quote 4: A patient who only values the use of questionnaires for academic research**

Int\_01: *“Would you want to know your own results from the questionnaire?”*

Pa\_20: *“No, I don’t think I’d care... What I would want to know is the report. See I find it very comforting, it fills me with confidence to know [my treatment] really ought to be in the mainstream health system.”*

**Quote 5: A cynical practitioner who is motivated to support because of loyalty to the clinic**

Pr\_26: *“I have to be honest; I find it hard to get any enthusiasm whatsoever. I’m a very non-measuring personality style... and I think what do they do with all this data, is it going to make any impact?... and moreover, if a patient’s going to tell me something, it’s a secondhand story once they’ve already filled in a questionnaire before they meet me... I can’t say from the patient’s perspective, they may think it’s terrific... but because I believe in [this clinic] I will do what I have to do to help with measurement.”*

**Quote 6: A practitioner who thought questionnaires were best used for individual patient care suggested practitioners could motivate patients to participate for the same reason**

Pr\_23: *“It may be that the encouragement and enthusiasm from the practitioner to do it will elicit a better response because [the patient] knows the practitioner’s interested. You know: I see you haven’t done the questionnaire, you really must do it because it’s going to help me help you.”*



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**Quote 7: A practitioner who thought questionnaires were best used for research purposes, also thought this was why most patients would participate**

Int\_01: *“How would you encourage patients to participate?”*

Pr\_37: *“A lot of patients are very altruistic... and a lot of people who select our clinic are the sort of people who want the health system to work differently... So you will probably find the most likely reason patients will be involved in this sort of research is to contribute to the research and increase the likelihood that this type of medicine they’ll be able to access in the future.”*

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**Quote 8: A 35-year-old Internet savvy patient preferred paper format to complete at home**

Pa\_14: *“I’d like to take [the questionnaire] home. I don’t like to feel pressured. I need time to read it through and think about it...”*

Int\_02: *“So one of the ideas is to use the Internet. Would that work for you?”*

Pa\_14: *“Oh OK [pause] so then for me a hard copy is better for me, I get side-tracked on the Internet... and I don’t know about you, but I’m always forgetting my passwords.”*

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**Quote 9: A practitioner discussing anonymous versus confidential questionnaires**

Pr\_31: *“I think some people are a bit dubious about what the results are going to be, what they’ll be used for, so I guess it also depends whether it’s anonymous or confidential. And I suppose it depends on what the questionnaire is. Is it a questionnaire that can be anonymous, or do they need my name and why? What will they do with it? ...I know in clinics where they are doing questionnaires on sexual practices, they are always anonymous.”*

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**Quote 10: Concerns raised by a practitioner about receiving individual results**

Int\_2: *“Would you want to be notified of all your patients’ individual results?”*

Pr\_24: *I guess probably not... If you get a form on a patient you saw say nine months ago and you don’t see continuously, there is the obligation to perhaps either act upon it, or what would you do? ... So I would perhaps be more interested to see a summary of patient results, a trend over time... I am interested in my patient’s [individual] results, but I would be more interested when they present.”*

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In contrast, other patients commented that rather than their individual results, they anticipated benefiting from the reporting of cohort data to contextualize their own lifestyle or healthcare choices. The most common reason patients were not interested in knowing their results was because the information was already known to them (Table 6: Quote 4). These patients were more commonly motivated by altruism.

Altruism was a motivator. This was expressed as a desire to support the clinic to improve its service for the benefit of other patients (Table 6: Quote 1). Supporting research for the benefit of society was another reason (Table 6: Quotes 1 & 4). For many of those motivated by altruism, it was nevertheless secondary to the importance they placed on individual patient benefit. Some wanted feedback about the cohort results. However, others

wanted to see outcomes, such as service improvement or changes to health care provision in Australia. Some patients and practitioners demonstrated no appreciation of, or interest in, the use of questionnaires for research purposes (Table 6: Quote 3 & 5).

Practitioners' views about the value and use of questionnaires and surveys influenced how and why they would encourage patient participation. Those who thought an important use of questionnaires was to obtain individual patient results suggested motivating patients by helping them see how they could directly benefit (Table 6: Quote 6). Conversely, the practitioner would suggest appealing to a patient's altruistic nature if the practitioner considered academic research or improving the clinic's services was most important (Table 6: Quote 7).

Irrespective of the practitioner's opinions on the use and benefits of observational research, they were less likely to encourage patient participation if it demanded too much of their own time or they thought it might negatively affect their relationship with the patient.

It was apparent from the interviews that researchers must find the right balance between frequency, length, and content (including breadth and depth of questions). Interviewees acknowledged that people are time poor. Long, in-depth, frequent questionnaires could be off-putting and sometimes overwhelming to patients. However, some thought the burden of answering long or frequent questionnaires might not be an issue. Patients may appreciate a comprehensive approach, and some patients stated they would accept the increased burden because of their loyalty to the clinic or because they trusted the researchers.

Interviewees recognized the growing significance of the Internet. Assuming a well-designed user-friendly system, many were comfortable with using electronic formats. Nevertheless, some patients preferred paper questionnaires or interviews. The reasons cited included poor computer skills, concerns with confidentiality, and the Internet being

distracting. Interestingly, those preferring non-electronic formats included younger patients who were computer literate (Table 6: Quote 8). A patient in her 70s who preferred a paper option commented that her husband who was in his 80s would want only to use the Internet.

Different locations for answering questionnaires were discussed. The advantages cited for answering questionnaires while at the clinic were that patients are in the right frame of mind to answer questions about their health; it could be an efficient use of time or a helpful distraction; and completing questionnaires at home or work may be inappropriate, distracting or other people may be present and read the answers. Conversely, concerns were raised about logistics and maintaining confidentiality if questionnaires are completed in the clinic waiting room; and that some patients will prefer to answer questionnaires away from the clinic on their own time (Table 6: Quote 8).

Obtaining consent was important to interviewees at all levels of patient engagement, from sending e-mails to patients to invite them to participate through to informing them about how the data will be used, who has access to the data, and data-linkage within and outside of the clinic (Table 6: Quote 9). Of those patients motivated by the potential for their results to be used to directly inform and improve their own care, some still specified that they wanted the option each time they completed a questionnaire to provide consent before their results were forwarded to their practitioner and placed in their clinical file.

Both patients and practitioners anticipated that people would have different preferences for disclosing certain information, and a distinction was made between confidential and anonymous information (Table 6: Quote 9). The preferences of patients interviewed ranged from: wanting all information collected to be anonymous; wanting the option for some questions to be anonymous; wanting all results for confidential use; and those not wanting to answer anonymous questionnaires because such data could not then be used to inform practitioners about the patient's health.

Patients expressed mixed views about data-linkage. Some were comfortable with data-linkage within and outside the clinic, while others were adamant they would not consent, especially if results were linked to a national e-health database. The different preferred levels of disclosure were influenced by the sensitivity of the topics and questions, and the patient's trust in the practitioner, clinic, researchers, and others who might have access to their data.

As well as concerns about confidentiality, other potential risks with completing questionnaires were discussed. Simply answering questions on a topic might raise awareness and create negative feelings about a person's health state. Insensitive feedback of individual results to patients may generate distress. Feedback on lifestyle risk factors, for example, may come across as "browbeating." If practitioners were to be given the results of their individual patients, there were concerns about logistical considerations and the implications of their duty of care to discuss clinically relevant results with patients (Table 6: Quote 10).

### **Addendum to the Discussion**

There is a paucity of research on the motivators for participating in, or supporting research and its ethical implication in, observational research when neither a clinical examination nor analysis of human tissue or blood samples is performed. The findings reported in this paper are an important first step in understanding potential benefits and risks that patients and practitioners may ascribe to the results of patient-reported questionnaires that are used in health services research.

Although the type of individual results is different, the three motivators identified in our interviews were similar to those found by a series of interviews with individuals participating in genetic epidemiological research (Hallowell et al., 2010). These were:

- the opportunity for personal therapeutic or nontherapeutic benefits;

- an altruistic desire to help support others with whom the participant has a personal relationship; and
- an altruistic desire to help society by furthering academic knowledge.

The difference between the two studies was that in the case of genetic epidemiology research, participants would be able to benefit directly from accessing genetic information that otherwise was unknown to them; and in this study, participants could benefit directly from knowing their individual results or from improved clinical care if their practitioner was given their individual results. The other difference was that participants in the genetic epidemiology study hoped that other family members and their future generations would benefit from the genetic information, whereas interviewees in this study expressed the desire to support the clinic, the practitioners, and other patients attending the clinic. In both studies, there was a complex interplay between these motivators.

Interviewees also discussed direct incentives as another way to benefit and encourage participation. A meta-analysis of participation in medical research found that small monetary incentives can increase response rates to postal questionnaires (Edwards et al., 2005). Debate continues about the ethics of financial payment. Mostly this debate focuses on clinical trials where it is important to ensure payment does not coerce participants to accept undue risk. Counterarguments in support of payment include that it demonstrates appreciation of participants, and it may help reduce the perception of likely benefit from accessing a new, more efficacious therapy that is being tested in a clinical trial (i.e., the therapeutic misconception) (Breitkopf et al., 2011).

In Australia, aside from the reimbursement of costs such as travel, providing financial payment or other direct incentives for participating in research is not commonplace. In the case of health services research, the majority of primary care clinics are private enterprise and patients may freely move between doctors and clinics. Therefore, before offering direct

incentives to participate in health services research arising from a clinic, it would be important to ensure participants did not feel obliged to continue using the clinic's services if they choose to participate and accept the incentive. Given that direct incentives are not commonly used in Australia, it is not surprising that interviewees mainly focused on other ways patients could benefit from participating.

Similar to the findings of other research, we found that practitioners' opinions about the project biased the reasons they thought patients would choose to participate (Amiel et al., 2007). For example, if the practitioner was more interested in the wider benefits of research for the clinic or society, they would often suggest using this as the way to encourage patients to participate. Similar to patients, some practitioners will not be interested in supporting academic research unless their patients benefit directly. Prior to commencing a research project that involves a clinic or practitioners, it is important to understand the practitioners' views about their perception of the value of research.

If patients are to receive results either directly or indirectly through their practitioner, then further detailed consultation with these practitioners will be needed. Obtaining consent and providing individual results to participants is complex (Cadigan et al., 2011; Franrenet et al., 2011; Knoppers et al., 2006; Ravitsky & Wilfond, 2006; Shalowitz & Miller, 2008). Some observational studies obtain consent to forward results to the treating doctor, rather than directly to the participant (ELSA, 2004/5; FHS, 2011). The potential risks of how these results may be used (e.g., for insurance and medical reports) and the potential costs of further management should also be discussed in advance (FHS, 2011; HSE, 2011). In a Scottish survey, participants who were given the option to receive written feedback for results had mixed views after the fact. Some experienced anxiety and feelings of powerlessness, whereas others used the feedback as a motivator to improve their health (Lorimer et al., 2011).

Concern was voiced by interviewees about the potential risks of patients being directly informed about their results and the importance of providing results in a sensitive and supportive manner. As noted previously, negative results given directly from the research team to participants can cause harm (Lorimer et al., 2011). Although it was not raised during the interviews, there is also the risk that positive results given directly to the participant rather than via their treating practitioner may be falsely reassuring to a patient. The appropriateness of providing results directly to patients will also depend on the type of result and the format. Patients are likely to anticipate being given their results immediately after completion of a questionnaire answered on the Internet. However, it is not clear whether a very poor score on topics such as mental health or quality of life would be helpful or harmful to patients, especially if there was no recall system.

If practitioners were given their patients' individual results, the patient anticipated that either they would be contacted by their practitioner if there was a problem, or any important results would be discussed during the next consultation. Some patients only wanted to be given their results by the research team if their practitioner was not going to receive them. However, debate continues around the circumstances where researchers should contact participants about their individual results. In genetic research, participants are often unclear about the meaningfulness of these results and may presume that the investigators will contact them with important information (Cadigan et al., 2011). In clinical trials, patients participating in research linked to their health services may have difficulty distinguishing between clinically relevant data collected to inform their medical care versus data to be used for research purposes only. This is particularly so if the practitioners are also investigators (Franrenet et al., 2011).

Practitioners have a duty of care to discuss clinically relevant results with patients. Therefore, providing practitioners with their patients' individual results would generate extra

workload for practitioners and management. Practitioners would require training and guidelines for interpreting summary scores of questionnaires and determining clinical relevance. Patient recall systems would be required to ensure appropriate feedback to patients to communicate important incidental findings.

### **Conclusion**

The interviews with patients and practitioners from this clinic raise awareness that similar to other types of research, those participating in or supporting health services research will not all be motivated by altruism and some will be more interested in knowing individual patient results rather than cohort results. More research is needed with different patient groups and in different health care settings and countries.

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#### DEMONSTRATION QUESTIONNAIRES USED FOR CLARIFICATION

1. Arizona Integrative Outcomes Scale (Bell et al., 2004)
  2. Complementary and Integrative Medicine Outcome Scale (Eton et al., 2005)
  3. Personal Wellbeing Index (Lau et al., 2008)
  4. WHO Quality of Life; brief (Australian version) (WHO, 1998)
  5. Medical Outcomes Study (Stewart, Hays, & Ware, 1992)
  6. SF-12v2 Health Survey (Johnson & Coons, 1998)
  7. Europe Quality of Life Scale - EQ-5D (Australian version) (The-EuroQol-Group, 1990)
  8. Assessment of Quality of Life – 8D (Hawthorne, 2009)
  9. Kessler Psychological Distress Scale (Kessler et al., 2002)
  10. Duke-UNC Functional Social Support (Broadhead et al., 1988)
  11. Spiritual Involvement and Beliefs Scale – Version 2 (Hatch et al., 1998)
  12. Health Education Impact Questionnaire (Osborne, Elsworth, & Whitfield, 2007)
  13. Lifestyle Assessment FANTASTIC (Wilson & Ciliska, 1984)
  14. Health-Promoting Lifestyle Profile (Walker, Sechrist, & Pender, 1987)
  15. CAM Belief Inventory (Bishop, Yardley, & Lewith, 2005)
  16. Patient Enablement Index (Howie et al., 1998)
  17. Consultation Quality Index (Howie et al., 2000)
  18. Trust in Physician Scale (Anderson & Dedrick, 1990)
  19. Consultation Satisfaction Questionnaire (Baker, 1990)
  20. Medication Change Questionnaire (Paterson et al., 2003)
  21. Measure Yourself Medical Outcome Profile (Paterson & Britten, 2000)
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## **CHAPTER 8: INTEGRATIVE MEDICINE OUTCOMES: WHAT SHOULD WE MEASURE?**

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### **FOREWORD**

It is important to ensure that questionnaires measure domains relevant to patients and practitioners. This paper presents the results from the interviews with patients and practitioners about which health, health-related and health-services outcomes are important for the clinic to measure.

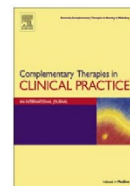
### **TABLES AND FIGURES**

**Chapter 8 / Table 1:** Topics covered by patient-reported health questionnaires

**Chapter 8 / Table 2:** Interview guide used in the first half of the interview

**Chapter 8 / Table 3:** Quotes from the interviews

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## Integrative medicine outcomes: What should we measure?

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### A B S T R A C T

#### Keywords:

Integrative medicine  
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Health services research  
Outcome measurement

The outcomes of Integrative medicine (IM) that combine biomedicine with traditional, complementary and alternative medicine (TCAM) are broad, reflecting the integration. IM is concerned with acute and chronic diseases, holistic approaches, and health promotion and wellness. Before commencing a research program in a primary care IM clinic, stakeholders were interviewed about IM outcomes.

Everyone thought Physical Health and Mental Health were important. Those with a more holistic view of health thought a broader range of topics should be measured. Less important topics were lifestyle; health-related aspects of life satisfaction and quality of life; and healthcare evaluation. However, no one thought these should be excluded. Spirituality was the most contentious. Some commended its inclusion. For others, once religiousness and God were removed, the remaining elements should be relocated to the domains of mental health and life satisfaction.

The results highlight the importance of consulting stakeholders before measuring outcomes.

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### 1. Introduction

Traditional, complementary and alternative medicine (TCAM) and integrative medicine (IM) that combines TCAM with Western biomedicine have joined the landscape of contemporary health services. Various definitions of IM and IM health service models have been described in the literature.<sup>1–9</sup> For the purpose of this paper, a broad definition of IM is used that includes any type of combining of Western biomedicine with TCAM.

Compared to TCAM, there is a paucity of research on IM. It is not clear to what extent the methodologies used to evaluate TCAM outcomes apply to IM. For example, the majority of TCAM research has focused on evaluating the efficacy of various interventions for treating disease. However, practitioner feedback from an outcomes study involving four IM clinics found that one of the reasons for low patient recruitment was that the chosen questionnaires focused on ill-health, whereas many of the patients attending the clinics did so for health promotion and disease prevention.<sup>3</sup>

Debate continues about how best to assess health services such as TCAM and IM, where the interventions and outcomes are complex, ongoing and context-specific.<sup>10–12</sup> IM practitioners commonly use a holistic approach that considers the whole person in their environment and incorporates multiple interventions to synergistically improve health.<sup>13</sup> IM outcomes can be difficult to define and measure because they are wide-reaching, broad and interrelated.<sup>13</sup>

Irrespective of the methodology chosen, the systematic collection of patient-reported outcomes (PRO) with questionnaires is an important evaluation tool. PRO questionnaires aim to measure outcomes that patients are able to perceive and report.<sup>14</sup> They include health and health-related outcomes such as physical, mental, spiritual and social health; quality of life and life satisfaction; lifestyle and risk factors; and information about the context and process of the health intervention.<sup>15–17</sup> Thousands of PRO questionnaires are available. When selecting PROs for health services research, the questionnaire must be well tested; acceptable and relevant to patients, practitioners and the health service; and sensitive to change.<sup>18,19</sup>

Similar to an outcomes project in four IM clinics in Canada,<sup>3</sup> a primary care IM clinic in Sydney, Australia wanted to use PRO questionnaires to measure the longitudinal outcomes of patients attending the clinic. Given the problems with patient participation and staff support in the Canadian study, the first step was to explore patients', practitioners' and the practice manager's opinions about using patient questionnaires to measure outcomes.

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## 2. Methodology

The research questions were: (1) what PROs are important for the clinic to measure; (2) what would motivate patients to answer, and practitioners and the practice manager to encourage patients to answer PRO questionnaires; (3) what are the perceived usefulness of PRO questionnaires in general; and (4) what other logistical issues need to be considered, especially regarding paper versus internet formats? It was anticipated that due to the small sample size, only major qualitative differences between sub-groups of patients and practitioners would be identifiable and a larger, broader sample would be needed to explore in-detail any potential differences. This paper will focus on the results from the first research question. Results from the other questions are presented elsewhere.<sup>20,21</sup>

The setting was a primary care IM clinic based in Sydney, Australia.<sup>22</sup> The clinic had been operational for just over four years. It offered IM services provided by a multi-disciplinary IM team and individual IM practitioners.

Ethics approval was obtained from the University of Sydney Human Research Ethics Committee (HREC) and the South Eastern Sydney and Illawarra Area Health Service HREC. All participants gave written informed consent before being interviewed.

Email and/or postal invitations were sent to the 6154 patients 18 years or older on the clinic's database. 334 patients volunteered from which a stratified, random sample of 20 patients was selected according to age, sex, case-mix (complex and simple), and old and new patients to the clinic using.<sup>23</sup> A complex case-mix was defined as a patient who presented with multiple health problems or had one severe health problem. Simple case-mixes were those who only presented with self-limiting illness or for health promotion. All but two patients had seen at least one biomedical doctor and one allied health practitioner in the clinic. The other two patients had consulted a doctor in the clinic and were using TCAM services outside the clinic.

All 13 practitioners and the practice manager agreed to be interviewed. Of the six biomedical doctors, one was a general practitioner with no TCAM training and one only provided specialised nutritional and environmental medicine. The others were general practitioners providing primary care services integrated with at least one of the following TCAM modalities: nutritional and environmental medicine; traditional oriental medicine; Western naturopathy; energy medicine; and Journey Work psychology. The three psychologists interviewed each had different interests: one augmented her practice with hypnotherapy, reiki and flower essences; another had a special interest in positive psychology and life coaching; the other specialised in short, solution-focused interventions such as Cognitive Behavioural Therapy. The four other practitioners interviewed were a dietitian who had undertaken conventional biomedical training and three TCAM practitioners: a traditional Chinese medicine and 5-element practitioner; a Japanese shiatsu, nutrition and yoga practitioner; and a Western naturopath and acupuncturist.

The face-to-face interviews were all conducted in the clinic. Alternative interview locations such as the participant's home or workplace were offered. Two researchers (one who was also a clinician at the clinic) were present for each interview: one would interview and the other took notes. Patients and practitioners were given the option to select their preferred interviewer, or for only one researcher to be present. If no preference was stated, they were randomly assigned to an interviewer.

The interviews were semi-structured. To introduce the topic, participants were first asked if they had heard the term "holistic health" and to provide a definition. They were then shown a list of ten topics that PRO questionnaires might cover. The list included

**Table 1**

Topics covered by patient-reported health questionnaires.

1.	<b>Physical Health</b> e.g. physical symptoms, disabilities, functional capacity
2.	<b>Mental Health</b> e.g. emotions, mood, stress, sleep, coping, self-concept, functional capacity
3.	<b>Spiritual Health</b> (more than God or religiousness) e.g. spiritual awareness, a sense of purpose in life, self-concept, engagement with spiritual activities
4.	<b>Holistic Health</b> e.g. total health in body, mind and spirit
5.	<b>Lifestyle &amp; Risk factors</b> e.g. exercise, diet, alcohol, smoking, drugs, work, recreation, sleep
6.	<b>Change in Medication</b> e.g. pharmaceuticals, herbs and supplements
7.	<b>Life Satisfaction &amp; Quality of Life</b> e.g. with regard to health, life, relationships, friends, family, work, standard of living, feeling part of the community and future security
8.	<b>Healthcare Attitudes</b> e.g. towards biomedicine, TCAM and IM, philosophy of healing
9.	<b>Consultation/Clinic</b> e.g. satisfaction, trust in practitioner, quality of consultation
10.	<b>Individualised questionnaires</b> e.g. the patient identifies his or her own health concerns and objectives, and rates improvement

health outcomes, proxy-health outcomes (such as known determinants of health), and health service outcomes (Table 1). The list was formulated from our clinical and academic experience, along with a review of the literature and web-based PRO questionnaire databases.<sup>15–17,24–27</sup> A simple list was used instead of alternative schema such as the IN-CAM framework of general to specific outcomes.<sup>15,28</sup> Although conceptually useful for researchers, we found during pilot testing that providing a simple list was more user-friendly. In addition, it was not clear where in the IN-CAM framework proxy-health outcomes such as lifestyle and risk factors should be placed.

The interviews aimed to explore participants' views about which topics were important for the clinic to measure. Patients were also asked about which topics were more relevant to them now compared to the past, and which topics they anticipated to be more important in the future (Table 2). Example questionnaires were available for further prompting or clarification.<sup>29</sup> Approximately 30 min was spent discussing these questions. The remainder of the one-hour interview focused on the perceived usefulness of questionnaires, preferences for questionnaire formats, responder burden, and motivators for participating in, or supporting research.

Inductive and iterative processes were used during the analysis. The interviews were exploratory with no predetermined

**Table 2**

Interview guide used in the first half of the interview.

<i>Patient interview</i>	
(1a)	Are you familiar with the term, holistic health?
(1b)	What do you know about the concept of holistic health?
(1c)	What does holistic health mean to you?
We want to use some questionnaires to measure the health outcomes of patients attending the clinic. We have categorised the questions from these questionnaires into the following topics (see Table 1).	
(2a)	What do you think about answering questions on these areas/topics?
(2b)	Are any or all of these areas/topics important or relevant to you now?
(2c)	Have any or all of these areas/topics been important or relevant in the past?
(2d)	Might any or all of these areas/topics be important or relevant to you in the future?
(2f)	Are any areas/topics missing or underrepresented?
<i>Practitioner/practice manager</i>	
(as above for part 1)	
(2a)	What do you think about measuring these areas/topics?
(2b)	Are any or all of these areas/topics important or relevant to your patients?
(2c)	What about other patients attending this clinic?
(2d)	Are any areas/topics missing or underrepresented?



hypothesis, and immediately following the interviews, the two interviewers reviewed the notes from the interview and began identifying and exploring themes and ideas. This in turn influenced the questioning in subsequent interviews. By the end of the initial series of interviews, thematic saturation of the major themes (where no new information was identified) was reached in both the patient and practitioner groups.<sup>30,31</sup> The interviews were electronically recorded for transcription. The two interviewers jointly used the N-Vivo 9 program to collate, code, index and categorise all the data.<sup>32</sup> The researchers then independently reviewed the data, followed by further group discussion where any disagreements in the final interpretation were resolved. The aim was to summarise the range of opinions rather than quantify responses. Therefore, if an interviewee expressed a very strong opinion, it was considered just as important as more widely held opinions.<sup>33</sup>

### 3. Results

Everyone thought Physical Health and Mental Health were important for the clinic to measure. There was a range of opinions about the importance of the other topics. For some, it was important to measure everything, whereas others prioritised topics. Spiritual Health was the most contentious topic, especially for some patients. Few other qualitative differences between patients and practitioners, between patients with different characteristics, or between the different types of practitioners were identified.

A participant's definition of holistic health often correlated with the topics they thought were important. Their views about the usefulness of questionnaires in general, also influenced participants' opinions about important topics, or the amount and breadth of information needed.

A common definition provided for holistic health was the notion of an indivisible whole person – mind, body and spirit – that included many aspects of a person's life was (Table 3:1 Patient12, Practitioner34 & 37). Not everyone included spiritual aspects in their definition and the term was often used in other contexts. Often participants discussed how to achieve holistic health or talked about integrating TCAM with Western biomedicine (Table 3:2).

Participants who specified all the topics were important often considered health to be holistic or IM healthcare to be all-encompassing, and for an IM practitioner or IM clinic to address the whole person, not just a disease or ailment (Table 3:2). The logical conclusion was that the clinic should make a holistic assessment by measuring all the topics (Table 3:3 Patient18, Practitioner32). Some patients commented that not everyone will realise the importance of measuring all the different topics and their potential influence on each other. A practitioner extended this idea by suggesting that measuring outcomes from all the topics can help increase awareness of the importance of these topics (Table 3:3 Practitioner30).

Conversely, participants were more likely to prioritise topics or recommend removing topics when their notion of holistic health was not all-inclusive, they provide a verbatim definition with no in-depth discussion, or the discussion about holistic healthcare simply meant incorporating TCAM (Table 3:2 & 3:7 Patient05 & 12; Table 3:1 & 3:7 Practitioner34).

Some participants raised the concept of a hierarchy of importance for IM outcomes, Physical Health and Mental Health were often seen as the most important because they were considered to be fundamental aspects of a person's health. These were followed by topics that affect physical and mental health (Table 3:4). Other interviewees prioritised topics that were less likely to be discussed during a consultation or recorded in a patient's clinical records (Table 3:5). A reason not to prioritise Spirituality, Holistic Health, or

Life Satisfaction & Quality of Life was difficulties with defining and measuring these topics (Table 3:6). The main reasons given against prioritising any topics were the importance of a holistic assessment and that people will have different priorities (Table 3:3).

Spiritual Health (and therefore the spirituality component of the Holistic Health topic) generated the strongest remarks for and against its inclusion. Patients gave the following reasons for its exclusion: (1) Spiritual Health had no personal relevance either at all or at the present time; (2) Spiritual Health was outside of the scope of the clinic; (3) if God and religiousness were removed, the remaining topics were covered by Life Satisfaction, Mental Health, and Holistic Health; and (4) Spiritual Health is too difficult to define, measure or answer (Table 3:7). Although none of the practitioners specifically stated that spirituality should be excluded, some thought it should be de-emphasised or assessed less frequently (Table 3:8 Practitioner34). However, other participants, including patients, specifically made a point of commending its inclusion because it was an important aspect of wellbeing and health (Table 3:8).

Some participants questioned whether some aspects of Life Satisfaction & Quality of Life were outside the influence of the clinic and should not be measured (Table 3:9 Practitioner37). However, their views were not as strongly expressed as those who thought Spirituality should be excluded. Conversely, others stated that the Life Satisfaction was an important reason patients attended the clinic (Table 3:9 Practitioner29).

A few participants expressed strong but different opinions about the importance of measuring Healthcare Attitudes towards TCAM and IM. A practitioner questioned its usefulness because patients attending the clinic would be biased towards positive attitudes about TCAM and IM. However, a few patients commented that an important outcome was changes in their attitude since attending the clinic and they anticipated this would be the case for others.

Using questionnaires that were individualised received many positive comments (Table 3:5 Patient09). The reasons given were that it allowed patients to monitor their progress in areas that were important to them; the results could provide extra information about patients' priorities and cover areas missed by closed-ended questions; and it was congruent with the values of an IM clinic that aims to provide patient-centred care. However, a few interviewees were concerned about responder burden with the open-ended questions used with this style of questionnaire.

The topic Change in Medication was thought to be less important by some unless in-depth information about this topic was required, for example, for research purposes (Table 3:10 Patient04). However, one patient commented that it was the most important outcome for him (Table 3:10 Patient05) and one of the psychologists commented that reducing medication use was often a concern for her patients. Another patient commented on the importance of measuring compliance and the reasons for non-compliance (Table 3:10 Patient01).

The discussion about the importance of topics to measure was influenced by the participant's opinions regarding the usefulness of PRO questionnaires. For example, some participants thought questionnaires were best used to inform practitioners about individual patient results. In these instances, long in-depth questionnaires were considered important information-gathering tool that new patients could complete before their first consultation in the clinic. Repeat questionnaires would be shorter, completed in a timely manner to coincide with follow-up appointments, and focus on measuring topics that were relevant to a patient's management goals. Those who thought an important use of questionnaires was to improve service provision often emphasised measuring the topics Healthcare Attitudes and Consultation/Clinic. If academic research was an important reason for using

**Table 3**

Quotes from the interviews.

1. Descriptions of holistic health
  - Patient12:** "The wellbeing of the whole person."
  - Patient09:** "It means physical, mental and spiritual health. [Anything else?] It's life, it's family, it's business."
  - Practitioner34:** "It refers to their physical body, their mental body, their emotional body, their spiritual body."
  - Practitioner37:** "The wording 'holistic' is about considering the whole person and all aspects of that person's wellbeing – physical, emotional and spiritual – in a social and cultural context."
2. Descriptions of holistic healthcare
  - Patient01:** "It's about treating the whole person, not just a single ailment."
  - Patient05:** "Looking at normal prescribed medications as well as alternative medications... to worry about your physical health and mental health, and not just one aspect of your health and the interactions of those."
  - Patient12:** "So looking after my health I start with what I do at home, such as cooking. But also using natural products – to restore, rebalance the system. I use pharmaceuticals if I have to but mostly I've found I don't have to."
  - Patient21:** "it's beyond the usual Western medicine and more about dealing with health issues before they become a major problem... using other things like Eastern or other types of medicines."
  - Practitioner33:** "It's a broad scope approach to any particular issue of a person health and coming from different aspects of psychology, of physical being, of their level of exercise and behaviour, etcetera. So rather than approaching an illness, we approach the person's health in the world."
  - Practitioner29:** "What I love about the holistic health thing is that it de-pathologises. It just looks at different aspects in a different way. So it's not about sickness."
  - Practitioner37:** "I think holistic health is umm in some respects outdated and in other respects an evolving definition of a philosophy of healthcare that involves the physical, emotional and spiritual wellbeing of patients and is ideally patient-centred."
3. Reasons for measuring all the topics and the importance of a holistic assessment
  - Patient18:** "The problem is that you're measuring health and everything influences it and everything matters."
  - Practitioner32:** "I would not feel comfortable saying something is less important – it would be arrogant to do this. Someone might think that their physical problem is the most important, but they're spiritually void... And you can't break it up. It's a holistic thing. You need to connect all the topics. I feel very strongly about that."
  - Practitioner30:** "There are some obvious areas where people are going to come in to see a doctor, like physical health and mental health issues. Umm but they're all important... We as practitioners, we might have different ideas to the patient about what's important, so you can't prioritise... The patient may not want to go there, they may not want to talk about it. That's fine. But at least covering them all, it puts on the table; it might, it raises awareness with the patient that they're all important."
4. A hierarchy of importance reflects the direction of influence of topics on each other
  - Practitioner31:** "Probably some of them I might rate a little bit lower than others. I think Physical Health and the Mental Health are really important, they're the foundations. And then in attempting to address those, you would look at the way people cope with things, and lifestyle things."
  - Patient16:** "Yeah so as well an emphasis on Physical Health and Mental Health, Consultation/Clinic is very important. And again, if you're going to get people to come and do the Life Satisfaction and Holistic things like that, if you're going to try and introduce them to that, then they're going to have to trust you."
  - Practitioner31:** "They're all important. But I guess physical and mental are really important, and then in attempting to address those you would look at the other areas like coping, lifestyle, relaxation, hobbies, relationships, positive attitudes, spiritual (for me not in a religious way) but sense of purpose, what are your goals, what is life?... Often we move onto these areas in more detail once we have addressed the immediate crisis or issue."
5. Topics less likely to be discussed in a consultation or recorded in the clinical notes
  - Patient09:** "I think people will like number 10 [Individualised] because people like things that relate to themselves... I think probably, ironically, the Physical Health is the one that sort of almost matters the least because it is the one you can discuss most, isn't it... Mental Health is important to ask, because it affects so many people, but it's still taboo to talk about it."
  - Practitioner27:** "Our computer reminds us to check their blood pressure, to check their height, check their weight, their cholesterol. Umm, it asks if they're married or divorced. It asks if they've had an operation. So a lot of the physical universe things are recorded, you can get that information without needing to do a questionnaire. So I'd love to know what you find when you asks those other questions."
6. Topics that are difficult to measure
  - Patient22:** "Important to measure? Well topics like happiness and life satisfaction I think. They might be a bit difficult to measure, but they should be outcome goals for a holistic health clinic, because they have such a big influence on our health and longevity"
  - Patient04:** "I think [Spirituality] means something different to different people. So it's kind of such a broad topic that it might be hard to get specific answers from a survey."
  - Patient01:** "I don't think my body, mind and soul have ever been the same. So [for overall Holistic Health] I would probably just pick the middle box. Maybe I had a headache, but was in a good mood. Well you know, it's, it's not always united."
7. Reasons for not measuring spirituality
  - Patient05:** "Spirituality [pause] I suppose you could ask the question and I can tell you to bugger off... I saw a practitioner here who ventured in there, and I was like, no I don't want to go there with you at all. Now I don't know if that was just a stage I was at, but I really feel like that's a bit, for me that's out of [the clinic's] scope. And I can understand why people may find that within your scope. For me personally, no, but I can understand that as a holistic thing, other people would include spirituality."
  - Patient21:** "Being a non-spiritual person myself, it doesn't really have any relevance to me from a health point of view... Things like a 'sense of purpose in life', to me that relates to life satisfaction or my mental state as opposed to a spiritual type thing. The word spiritual has a weird connotation to it."
    - Interviewer:** "If we asked questions from that topic but didn't use the word spiritual, might you feel a bit more comfortable?"
    - Patient21:** "Yeah possibly. If there was any notion of God or religion or whatever, that would put me off..."
    - Interviewer:** "So how would you feel about a question that asked something like: 'rating your total wellbeing, body, mind, and spirit'?"
    - Patient21:** "Umm, I suppose I'd, I'd probably struggle with spirit."
    - Interviewer:** "Would you be able to answer that question, or would you just skip it?"
    - Patient21:** "Umm well if it's in that generic context I'd probably answer it with just thinking about body and mind."
    - Interviewer:** "Would being asked questions about spirituality offend you?"
    - Patient21:** "It wouldn't offend me, but it would probably skew my perception about the organisation asking me those questions. As a consumer, I spend a lot of time finding products that align with my philosophical views on life."
  - Practitioner34:** "Maybe the spirituality one could be concise. Most people are uncomfortable with that... and then maybe not asking certain ones again too soon. Like I mean the spirituality one, that's not going to change very quickly."
8. Reasons for measuring spirituality
  - Patient08:** "I love this one. I love the spirituality as well and underlining to people that's not just about religion. Because I think the sense of purpose, and something to do, someone to love, something to hope for, I think those are critical to people's wellbeing, and those things really do affect your physical health as well as your mental health."
  - Practitioner27:** "Umm I actually love your spirituality topic... Because you know, the healthier a person is spiritually, the better their wellbeing and their overall health is going to be."
9. Reasons for and against measuring Life Satisfaction & Quality of Life
  - Practitioner37:** "I would always include social [health] in lifestyle and it would also go in Life Satisfaction... Well we should probably only measure those areas of Life Satisfaction & Quality of Life that directly relate to health and we can influence... A difficulty for younger people is they often have young children, teenagers, and are caring for older people... Well we can help with tools for coping, but we don't have any social workers here."
  - Practitioner29:** "Patients coming to this clinic are often seeking more than just physical and mental health. They're looking issues around Life Satisfaction, so the questionnaire needs to cover that also."
10. Change in Medication comments

(continued on next page)

Table 3 (continued)

<b>Patient05:</b> "For me – getting off the medication is the biggest thing for me. A glimmer of hope that I am a self-reliant patient and not dependent on the practitioner."
<b>Patient04:</b> "You'd only use this one if you were seeking in depth, detailed information... explain that you're looking for very good quality information." [This patient thought the main use of questionnaires was for research purposes]
<b>Patient01:</b> "It's better to measure outcomes rather than outputs. Like are they taking the oral contraceptive pill or changing their sexual practices, not just the number of prescriptions... and how they're using their prescription and why they are not taking their medication."
11. Unexpected outcomes
<b>Patient04:</b> "Initially I went [for acupuncture] to deal with fertility. So I started going to her and I couldn't believe how quickly I started to feel just better within myself and you know, releasing the energy blocks and that sort of thing. But in the beginning it was a little bit like, you know, for some people it would be a bit like a counselling session. 'Cause she asks a lot of questions about how are you feeling about a lot of different things and sometimes it can be quite emotional, 'cause you've got some kind of energy block somewhere that, you know, and you don't really know it and you don't really think about it, you just don't feel great... I had the time to kind of rejuvenate. I didn't think it would be like that. So I needed to deal with that first. Fertility, I think, will come if I'm feeling good." [This patient was pregnant]"
<b>Practitioner37:</b> "My worry [with shorter questionnaires] would be what could be missed. You know, one of the reasons I think integrative medicine suits me is that you get to tick all the boxes. It's not about short cuts, it's about looking at umm, the whole person, the whole situation. So what would concern me is if there was say something we weren't expecting like, umm, changes in part of their lifestyle factors, then you might actually miss out on something that was quite relevant."

Note: No unique themes or ideas emerged from the interview with the practice manager. Her quotes were excluded to maintain confidentiality.

questionnaires, then the interviewee would suggest that the research question should determine the choice of topics and questionnaires.

Responder burden was discussed because measuring all the topics in detail would require a large number of questions. Interviewees suggested tailoring questionnaires as a way to reduce responder burden. For example, screening questions could be used, or the patient or practitioner could decide whether to skip a questionnaire if it was not relevant. The problem voiced with these approaches was the risk of missing important information, including unexpected outcomes (Table 3:11). Another suggestion was to break up the questionnaire into shorter questionnaires measuring different topics at different times. However, some questioned the validity of this approach because a holistic assessment is best done where all topics are measured at the one time. (Table 3:3 Practitioner32).

Generally, participants thought the list of topics was very comprehensive. However, a few missing or underrepresented topics were identified. Some participants wanted to ensure the questionnaires would cover areas such as: social health, work, sexual health, gambling, health knowledge, specific aspects of diet such as organic and unprocessed food, fatigue, gastrointestinal health, pain, positive attributes of health, and a needs assessment of the services provided by the clinic. One patient reminded us of the importance of using culturally sensitive questionnaires.

#### 4. Discussion

Physical Health and Mental Health are fundamental elements of health and healthcare outcomes, so it was not surprising there was unanimous support for their inclusion. Participants also emphasised the importance of the topics Lifestyle & Risk Factors, Consultation/Clinic and the social health component of Life Satisfaction & Quality of Life because they affect an individual's health and wellbeing.

Similar to other IM clinics,<sup>19</sup> the Lifestyle & Risk Factors topic was an important reason patients attend the clinic, yet they tend to be underrepresented in TCAM outcome questionnaires.<sup>34–37</sup> Although this suggests that IM healthcare outcomes may be broader than TCAM, it may simply reflect the emphasis to date on evaluating the efficacy of TCAM for treating diseases.

Western biomedical PRO questionnaire databases list many of the topics that participants thought were important for the clinic to measure.<sup>16,17,26</sup> However, there are few if any questionnaires measuring concepts such as holistic health, wellness and wellbeing, and the majority of questionnaires are designed to measure changes in populations with disease whereas some patients attending IM clinics are well and seek disease prevention and health promotion.

The topic Spiritual Health, and therefore the spiritual component of Holistic Health, was the most contentious with strong views expressed for and against their inclusion. We were careful to distinguish between religion and spirituality,<sup>38</sup> yet it remained a problem. For some, the issue was with the terminology that in turn would reduce the acceptability of questionnaires using words such as soul, spirit, spirituality and faith.<sup>36</sup> For others, Spiritual Health was considered outside the scope of an IM clinic. In both instances, aside from personal preference, there were no obvious reasons to explain why this was the case, such as patient characteristics, therapeutic choices, or the type of practitioner. The World Health Organisation has been criticised for ignoring Spiritual Health; however, they do recommend healthcare services such as Palliative Care should integrate the "spiritual aspects of patient care".<sup>39–42</sup> Although many cultures consider spirituality to be an inseparable component of health and wellbeing, and healthcare organisations often aim to provide spiritual assessments and pastoral care for patients, similar to our findings, there is tension about whether to include spiritual health and if it is included, what aspect should be emphasised.<sup>38,43,44</sup> Even if spirituality is considered an integral part of health and healthcare, it still may not be suitable as an outcome measure. Research in the field suggests that many aspects of an individual's spiritual health are slow to change, if at all.<sup>45</sup>

Responder burden is an important concern, since hundreds of questions would be needed for a complete thorough measurement. It is not clear how to reconcile tensions between the need to make a comprehensive holistic assessment and minimise responder burden. Simply asking patients to rate their overall holistic health is unlikely to provide meaningful results since patients often find it difficult to reduce their assessment to a "single truth",<sup>46</sup> and multi-domain TCAM and wellbeing/wellness questionnaires although promising, require further testing in the IM setting.<sup>47–49</sup>

Although some interviewees were concerned about the validity of tailoring questionnaires, it may be a necessary compromise. A 'minimum' and an 'optimum' dataset for patient-reported IM outcomes could be created. The minimum dataset would briefly cover all the relevant topics and could be answered in one sitting. The optimum dataset would be all-inclusive and allow for more in-depth questioning about different topics. Using item response theory and computerised adaptive testing, screening questions from the minimum dataset could be used to prompt further questioning, whilst skipping irrelevant questions. The DYNHA SF-36 is a well validated example of this approach. Depending on their answers, responders are asked between 8 and 36 questions.<sup>50</sup>

An obvious way to reduce responder burden is for questionnaires to collect data that cannot be retrieved from other sources such as the patient's electronic clinical records. However, at least in Australia, this poses significant challenges because of ongoing

difficulties with extracting routine clinical data from the primary care software commonly used, and it will be many years before the recently released national personally controlled electronic health records will provide useful data for research purposes.<sup>51,52</sup>

The small sample size from only one clinic limits the generalisability of the results presented in this paper. The transferability of the results into different IM healthcare settings is also limited. A larger sample from different populations, practitioner groups and IM clinics, and more in-depth inquiry into the context that influenced participant's views may have elucidated clearer differences among sub-groups of patients and practitioners. The questions posed to patients were more theoretical so participants often spoke about the topics more generally rather than talking about their own outcomes or their patients' outcomes. The interviewees did not review the sample questionnaires in detail, nor was their in-depth questioning on their personal experiences with IM outcomes. As is the case for TCAM, further work is needed to develop an outcomes taxonomy and assess questionnaires for use in the IM setting.

## 5. Conclusion

This study highlights the complexity of defining PRO outcomes for IM. IM outcomes may be broader than either conventional biomedicine or TCAM alone, reflecting the integration of these different approaches to healthcare. Participants' views were not always aligned about the importance of the proposed topics, especially Spirituality. The interviews highlighted the difficulty in defining and measuring topics such as life satisfaction, quality of life, spirituality and holistic health. There is a real risk of responder burden with measuring so many outcomes, and it is unlikely that even an extensive battery of questionnaires will be able to capture the whole picture. Measuring IM outcomes will require a holistic approach using various types of data, PROs being just one source. Consulting patients and practitioners of IM clinics is important to help ensure that the chosen outcomes and methodology are appropriate.

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### Conflict of interest statement

KP is the medical director at the clinic where the research was conducted; JH, KP work as clinicians at the same clinic. There are no other relationships nor activities that could appear to have influenced the submitted work.

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# **CHAPTER 9: A POSITIVE CONCEPT OF HEALTH - INTERVIEWS WITH PATIENTS AND PRACTITIONERS IN AN INTEGRATIVE MEDICINE CLINIC.**

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## **FOREWORD**

A limitation of many popular questionnaires is their inability to detect changes that are beyond the absence of disease. Following the preliminary analysis of the first eight interviews with four patients and four practitioners, the remaining interviews were extended to explore the interviewees' understanding of this concept. The results of this pilot study are presented in the this paper.

## **TABLES AND FIGURES**

**Chapter 9 / Table 1:** Dimensions of health, wellness and wellbeing

**Chapter 9 / Table 2:** Characteristics of interviewees

**Chapter 9 / Table 3:** Analytical approach

**Chapter 9 / Table 4:** Interview outline

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## A positive concept of health – Interviews with patients and practitioners in an integrative medicine clinic



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### ABSTRACT

#### Keywords:

Complementary and alternative medicine  
Qualitative research  
Wellbeing  
Wellness  
Holistic health

Using the phenomenography method, interviews with patients and practitioners were undertaken to explore their understanding of 'health that is more than the absence of disease'.

The question was challenging and stimulating for all interviewees. A few were unable to conceptualise this positive definition of health, some perceived it as an optimum end-state, whereas others saw it as an ongoing process. Many positive attributes of health and its influencers were identified. The more advanced understandings of this concept were of a holistic, multidimensional, expansive state where the all dimensions of health are interdependent and positively reinforcing.

The results affirmed that wellness is more than psychological wellbeing, 'happiness' and life satisfaction. Optimum physical and cognitive capacities along with spiritual, social and occupational wellness were equally as important. 'Energy and vitality' were sufficiently emphasised by patients and some practitioners to support the inclusion of the principles of vitalism in any discussion about health.

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### 1. Introduction

The World Health Organisation (WHO) first proposed that 'health is more than the absence of disease' in 1946 [1]. This definition has been quoted ad infinitum by the complementary and integrative medicine industry and aligns with the health outcomes they seek to achieve. Measuring these health outcomes however, is challenging because of the paucity of questionnaires validated for this purpose and ongoing debate in clarifying this concept of health [2–6]. Various definitions and models of 'health' have emerged from the disciplines of health and social sciences but much of the literature on this topic is discourse and unsupported by empirical research [6]. Terms such as 'wellness' and 'wellbeing' are commonly used here when referring to 'health that is more than the absence of disease'; they refer to overlapping concepts and are used in various ways by academics, the health industry and laypeople.

'Wellness' models began to emerge from the medical fields in the 1950's and 1960's. Dunn was one of the first to coin the term 'wellness', and emphasised an individual's level of functioning and reaching their full potential [7]. Around the same time, Engel proposed the bio-psycho-social model that aimed to move beyond a biomedical disease focus on health to encompass the importance of an individual's mental health and the social environment [8]. Hettler extended this model to include spiritual and occupational wellness [9]. An environmental model was proposed by Larson who emphasised the importance of an individual's response and adaptation to environmental stressors [10]. Most of these early models of wellness however, focused on an individual's health in the context of healthcare, health-promoting behaviours and levels of functioning [11]. These were duly criticised for failing to adequately address 'wellbeing' [12].

A holistic model of health has gained traction in the literature over the past 20 years, recognising the multidimensional nature of health where all dimensions are interdependent [13–19]. Some models here include a consideration of life satisfaction, living standards, security, and financial wellness [20–23]. These different models use some or all of the eight health dimensions listed in Table 1. The inclusion of spirituality is the most contentious. For example, although spirituality is often considered an integral component of holistic health, WHO publications have tended to

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**Table 1**

Dimensions of health, wellness and wellbeing.

<b>Physical</b>	– fitness, flexibility, strength, agility, and other physical indices such as muscle tone, body mass index, cholesterol level, and blood pressure. Models often focus on health-behaviours and the actions needed to support health, such as self-care, lifestyle and preventative medicine.
<b>Psychological/emotional</b>	– positive attitudes, realistic self-esteem and optimism, awareness of feelings, and resilience.
<b>Intellectual/cognitive</b>	– the ability to learn, be creative, think critically and other higher order cognitive skills.
<b>Spiritual</b>	– a person's values and beliefs, a sense of meaning and purpose in life, inner peace, and an ability to transcend the personal self.
<b>Occupational</b>	– the optimal use of one's skills for meaningful and satisfying activities and work, which may be paid or unpaid. Recreational activities are considered.
<b>Social</b>	– the quality of interpersonal interactions, the giving and receiving of support, and an individual's engagement with their community and environment.
<b>Environmental</b>	– self-mastery and able to manage one's life; or an understanding of the importance of the environment on an individual's health.

exclude the attributes of spirituality from the health-related domains [24,25].

The term 'wellbeing' is commonly used in the social sciences, especially psychology. A distinction is often made between subjective wellbeing (e.g. happiness and life satisfaction) and personal wellbeing (e.g. self-actualisation, functioning at one's full potential and self-mastery) [11,22,26–31]. Similarly, the conceptual framework used by the WHO to describe 'subjective wellbeing' focuses on quality of life and mental health [30]. 'Wellbeing' is also used to describe populations, such as in the Canadian Index of Wellbeing where the concept is extended to include cultural, economic, governance and environmental dimensions [11,32,33].

Empirical data is slowly building about how best to measure health, wellness and wellbeing [4,20,34–36]. Although there are thousands of multidimensional outcome questionnaires aiming to measure various aspects of health and quality of life, most are limited by ceiling effects where a large proportion of the normal population have a maximum score and there is no room for improvement [37]. Questionnaires able to measure the full spectrum of health is important for complementary and integrative medicine because patients engage in healthcare activities to not only treat and prevent disease, but to optimise their holistic health [2,38]. The main limitation of many of the questionnaires developed to measure wellness and wellbeing, is they based upon postulates and technical definitions; the questionnaires arising from these models often fail to measure the multidimensional constructs proposed [6].

More information is needed therefore about laypersons' and healthcare practitioners' understanding of what it means to be healthy. Research exploring people's understanding of these concepts has mostly applied to health behaviour, health promotion (such as screening and preventing disease) and therapeutic interventions, rather than for the development of questionnaires [34]. It was from this requisite that the question, "how would you describe health that is more than the absence of disease," was posed to patients and practitioners from an integrative medicine (IM) clinic [2]. The purpose was to then use the information when evaluating the content validity of wellness and wellbeing questionnaires for use in the clinic.

## 2. Method

The study was nested in a larger qualitative study aiming to explore patient and practitioner views about measuring IM outcomes in the clinic and the use of patient reported outcome

questionnaires [3,39,40]. The research setting was an IM primary care clinic located in Sydney, Australia. The clinic combines conventional biomedicine with traditional, complementary and alternative medicine (TCAM).

Before undertaking the study, ethics approval was obtained from the appropriate university and state health authority human research ethic committees. All fourteen practitioners from the clinic consented to participate. Twenty two patients were selected from a sample of 334 volunteers. Significantly fewer men and older adults volunteered, so a stratified random sampling technique was used to ensure that a wide range of patients was interviewed. Although this approach to patient selection is not a requisite for qualitative studies, there is no reason why it cannot be employed. Twenty patients were available for interview. More detailed information about patient selection and the results from the interviews is reported elsewhere [3,39,40].

From preliminary analysis of the first 8 interviews together with further reviews of the literature, it became apparent that the interviews also needed to specifically explore patients' and practitioners' conceptual understanding of wellness and positive definitions of health. Accordingly, this question was raised at the end of the interviews with the remaining 10 practitioners and 16 patients. Table 2 lists the characteristics of the subset of interviewees who were included in this component of the study. The distribution of patients remained diverse; however, the practitioners not interviewed were two IM biomedical doctors and two of the three TCAM practitioners.

Phenomenography was used as the qualitative methodology to explore the interviewees' conceptual understanding of health that is more than the absence of disease. Phenomenography proposes there is a finite number of ways people will understand a concept or phenomenon. These different conceptions can be mapped to describe the collective understanding of the phenomenon (i.e. the geography). Phenomenography is based on the premise that people interpret their own experiences, building their own understanding and knowledge about a concept that in turn influences their opinions, judgments, explanations, and worldviews. Through phenomenography an accepted social understanding of a concept evolves. The method uses a second tier approach to explore the interviewees' interpretations and understandings of a concept [41–44]. This contrasts with first order approaches such as the phenomenology method used in psychology that is pre-reflective and focuses on describing the interviewee's experience and the essence

**Table 2**

Characteristics of interviewees.

Patients (n = 16)			
<b>Median age</b>	46 years Range 22–76 years	<b>Case mix<sup>a</sup></b>	Simple = 6 Complex = 10
<b>Sex</b>	Male = 7, Female = 9	<b>Language spoken at home</b>	English = 16
<b>Education</b>	Tertiary Degree = 8 Other qualification = 5 Secondary education = 3	<b>Occupation (or previous occupation)</b>	Professional = 7 Manager = 3 Clerical = 4 Trade = 2
Practitioners (n = 10)			
<b>Biomedical doctor</b>	Male = 2, Female = 3	Integrative <sup>b</sup> = 4, Biomedical = 1	
<b>Psychologist</b>	Male = 1, Female = 2	Integrative <sup>b</sup> = 1, Biomedical = 2	
<b>Dietitian</b>	Female = 1	Biomedical = 1	
<b>Traditional Chinese Medicine</b>	Female = 1	TCAM = 1	

<sup>a</sup> Complex case: More than one disease, or one significant major disease (e.g. cancer).

<sup>b</sup> Integrative: The practitioner has training or expertise in both biomedicine and at least one discipline from TCAM.

**Table 3**  
Phenomenography [37–40].**The method involves**

- Exploring individual understandings of the *phenomenon* or *concept* in question to formulate the collective understanding of the phenomenon and formulate a representative model;
- A *model* or *outcome space* is formulated to represent the study group's understanding of the concept

**Glossary****Concept = Phenomenon**

- A concept consists of a finite number of *conceptions*.

**Conceptions = Categories of description**

- Conceptions are the component parts of the concept that are analysed through the internal and external horizons, and the referential and structural elements.
- The internal horizon describes an individual's understanding of their different conceptions.
- The external horizon describes how an individual's understanding relates to the whole concept.
- The referential elements are how the individual's understandings of different conceptions relate and refer to each other as the individual explores and expresses their ideas.
- The structural elements form a diagrammatic schema of the concept.

**Analytical process used**

- Inductive and interpretive approach.
- Data emersion, followed by line coding, and then broader coding of the transcriptions
- Identification and description of the individual's *conceptions/categories of description*.
- Exploration of how the individual's *conceptions* relate to each other, the context from which it emerged, and how their understanding developed as they discussed the *concept*.
- Mapping the whole *concept* by the comparing and combining all the *categories of description*.

**Note:**

- Data saturation for a *category of description/conception* is reached when it is expressed by more than one person, and no new information or ideas emerge from the data.
- An individual rarely expresses all the *conceptions* of the *concept*. Basic characteristics and descriptions are usually clearer. As the person explores the outer boundaries of their understanding, their language often becomes more vague and pre-reflective. Each participant usually expresses more than one *conception*.

of their perception of the phenomenon [45]. Table 3 summarises the phenomenography method used in this study.

Table 4 outlines the questions used in the phenomenographic component of the interviews. Analysis of the interviews began immediately, which influenced the approach to subsequent interviews. The interviews were electronically recorded and transcribed. The first and third authors undertook the early analysis.

**Table 4**

Interview outline.

**Background information given**

Even though in 1946 the World Health Organization stated that 'health is more than just the absence of disease', most patient questionnaires still assess changes in disease states rather than improvements beyond the absence of disease.

**Opening prompt**

How would you describe 'health that is more than just the absence of disease'?

**Further prompts if needed**

What areas or aspects would you see change in a person if they were moving from absence of disease towards a state of optimum health, or of being really well or super-healthy?

Think back to a time in your life when you were really well.

Describe someone you know who is really well.

**Exploring the interviewees conceptual understanding**

Interviewees were encouraged to explain and develop their ideas and thoughts

NOTE: Terms such as 'holistic health', 'wellness', 'wellbeing' and 'quality of life' were avoided unless the interviewee used the term first.

The first and second authors lead the in-depth analysis as per the description given in Table 3.

**3. Results**

The results presented are the main categories of description ("conceptions"). Each was attributed to more than one interviewee. They were not however, always discussed in sufficient detail to ensure that no new information would emerge with more extensive interviewing. Therefore, we are not confident that data saturation was reached.

**3.1. Difficult to describe**

Both patients and practitioners found the questions challenging, and their responses revealed their attitudes about health in general. Patients often drew on their personal experiences with their own health or people they knew, whereas practitioners mostly drew on their clinical training and experience with patients. Rather than describing their understanding of 'health that is more than the absence of disease', it was common for interviewees to default to contrasting 'health with disease', describing what it is like to be unwell or focussing on the causes of health and disease. For some interviewees 'disease' concerned the domains of physical and mental health that were easier to define, whereas 'health' was more nebulous. Some interviewees stated that the question was difficult because a person with good health is less likely to be conscious of their health. A few practitioners commented that achieving wellness is rarely addressed by mainstream Western medicine.

"[Disease], that kind of describes the like the physical side... and I don't think it necessarily describes the whole person... Disease and sickness is just talking about physical health and mental health isn't it, that's it, and that's what can be measured so easily and that's what everybody's measured up to now... The other stuff, people find it hard to measure." [Patient\_01]

"It is a tricky question because we take being healthy for granted." [Patient\_02]

"You don't necessarily know how to define it but you know it when you feel it. And so I think what we're doing with patients is perhaps raising their bar of expectation of how well they can feel... because basically the whole of Western medicine is based on going from unwell to well enough." [Practitioner\_01]

**3.2. Different levels of understanding**

Some interviewees expressed an in-depth, broad and holistic concept of health and wellness whereas others had a more restricted view of health as either physical and mental health, or a conception of health being limited to the absence of disease. For some, the question inspired them to consider the possibility of optimum health as an ideal, a goal, or a continuum of improving health. For many, attaining health, wellness and wellbeing, was an ongoing process where an individual aims to reach their full potential. This conception thus suggests the inclusion of individuals with disabilities, of increasing age, or in palliative care.

"But in terms of disability I mean you look at some people who are for instance in a wheelchair or something, you know, if you looked at their bio-chemistry and their BMI and everything, they could be perfectly healthy." [Practitioner\_02]

"An unrestricted flow in expressing their potential." [Patient\_03]

Some patients with chronic diseases and some practitioners with limited IM or TCAM training, thought the concept of optimum health was an inconceivable, unattainable or unsustainable endpoint. In these instances, they were often more black and white: either a person had a disease (diagnosed or undiagnosed) or they were healthy. They also emphasised the importance of continued expert screening for disease and disease prevention.

*"Are they really healthy or do they think they are?... Have you had a medical in the last year so you know you don't have super high blood pressure, even though you might look good and you might jog every day?... I think you're either healthy or you're not."* [Patient\_04]

*"So somebody who is in optimal [physical] health; who has no psychological issues; who is coping with their bio-psycho social needs, you know, they're not having any relationship or work issues; someone who feels that they belong and has a spiritual belief; someone who has no need at all for any lifestyle intervention. They're fully immunised. I mean I don't know if that person exists in 2010 to be honest with you, and I think all of us probably require some sort of an intervention."* [Practitioner\_03]

### 3.3. Attributes of health

Interviewees identified a wide range of positive attributes of health. These were consistent with the eight dimensions of health listed in Table 1. Mostly these attributes were individually determined and subjective, though some emphasised the importance of objective assessments.

Good physical and mental health and consistent good health were usually considered prerequisites for health. Energy and vitality, a positive attitude, joie de vivre, enablement, freedom to live, motivation, engagement, a sense of purpose, satisfaction with life, and resilience and coping were emphasised.

Although many interviewees had a holistic view of health, only a few discussed the attributes of intellectual and spiritual health. Often spirituality was referred to with clichéd phrases such as 'mind, body and soul/spirit' and little consideration was given to its full meaning. Only a few practitioners demonstrated an in-depth understanding of spiritual wellbeing.

*"So you know, I'm already feeling the difference in my wellbeing from like jumping out of bed in the morning, being awake, being alive, you know feeling that vital energy within me... I think it just happens on all the levels... physical, mental, spiritual – all of those things."* [Patient\_05]

*"Are you being true to who you really are? Are you aware of your soul, spirit, driving force? ...I think that's [health], totally happy and at peace with yourself and doing what it takes to get there."* [Practitioner\_04]

### 3.4. Vitality

Many patients but only a few practitioners, talked about abundant available energy and vitality (especially when waking in the morning) and "a fantastic sense of wellbeing" [Patient\_04].

*"Particularly energy I think, to just be walking around and not necessarily have a specific complaint isn't necessarily the same as being full of energy... [Vitality means] just waking up and getting out of bed and being ready for the day and being able to cope with things. Smiling as you walk down the street."* [Patient\_05]

*"It's jumping out of bed in the morning, being awake, being alive; you know feeling that vital energy within me."* [Patient\_06]

*"So they would say, 'I have more energy, I have more motivation, I wake up in the morning and I'm happy to get out of bed.'" [Practitioner\_05]*

### 3.5. Happiness

A common theme was 'happiness'. Mostly this referred to life satisfaction and positive attitude, though some referred more to emotional joy or spiritual wellbeing.

*"Are you happy with your work, happy with your family life, are you happy with, you know, your relationships? Are you content basically?" [Patient\_01]*

*"It's a sense of peace and happiness inside that's indefinable. It's a sense of the quintessential element that is stillness."* [Practitioner\_04]

### 3.6. Engagement with life

A more expansive and uplifting state of being was often expressed when describing health that is more than the absence of disease. There was a strong focus on a person's health enabling them to engage more fully with living – having aspirations and interests beyond themselves. With sickness, there is a focus on the self and a limited capacity to do things, whereas a person is liberated by having good health and able to develop a sense of purpose beyond just responding to illnesses. The whole experience of being healthy was also described as a natural effortless state – they can just "get on with life" [Patient\_02].

*"For example like a lot of people who are sick don't do anything... But when they start getting well, then they really start becoming aware of what they really want to do."* [Patient\_07]

*"Well it's the quality of your life I suppose. Is my health at a stage where I can do the things that I want to do without being burdened by illness? [he gives examples of physical fitness, positive outlook, stress management, coping, resilience] And, you know, do I do it with direction, do I feel like I'm adding benefit to the world?" [Patient\_08]*

*"Activities of daily living, what they actually manage to do in a day or want to do in a day, motivation, community engagement, social engagement... Travel's quite an important indicator of vitality in old age... My well old patients are usually healthy weight range... an appetite for everything, for spiritual enrichment, for reading, for knowledge."* [Practitioner\_01]

*"Freedom is the word that comes to mind, just freedom to kind of be in a physical body in whichever way you choose to, whether that's freedom to move or freedom to be still ... freedom to participate in ways that bring you love and joy in your life."* [Practitioner\_06]

### 3.7. Maintaining health

Interviewees commonly discussed the importance of a positive attitude, and being proactive and motivated to improve one's health. Patients and psychologists in particular emphasised the importance of resilience and coping. Some interviewees considered sickness and minor, temporary illness to be a natural part of life and not necessarily the same as disease. A healthy person would have the resilience to recover and bounce back from illness or disease. All of the above factors were seen as important in maintaining homeostasis and consistent good health.

*"He had a heart attack a few years ago but not with any of the risk factors. But he then had a full recovery and now he's healthier than"*

before. So that ability to bounce back and be resilient... And he had a strong happy marriage... strong relationships and enjoys his work and his life... He started taking more holidays. He cut- he didn't stop working, but he cut down and let himself say 'no' to work. He started doing different things like Pilates." [Patient\_07]

### 3.8. Influencing factors may also be attributes

Interviewees identified a wide range of factors that positively fed back to influence someone's health. Two patients mentioned the importance of environmental factors on health. Interviewees often talked about influencing factors as if they were attributes; in particular, resilience, coping, motivation, positive attitude and health promoting actions. It was sometimes unclear from the limited data if this reflected an interviewee's difficulty with describing positive attributes of health or whether it reflected a more complex conception of health and wellness that is multidimensional and interdependent.

"I guess wellbeing is also you stop doing things that make you unwell, like that includes smoking, drinking, eating bad foods, stuff like that, but you need the energy to have the motivation to do all of that sort of stuff." [Practitioner\_06]

### 3.9. Conceptual landscape

In summary, the conceptions expressed by the interviewees could be mapped on a continuum of simple through to complex understandings of a state of 'health that is more than the absence of disease'. The simplest conceptions were narrow, limited to physical and mental dimensions of health, or restricted to health being understood only as the absence of disease. At the next level of conceptions, health was more multidimensional and there was a continuum from disease to the absence of disease and then to optimum health. Often however, health was still defined by what it is not or how to achieve it, rather than clearly describing the concept.

The most advanced conception of 'health that is more than the absence of disease' was a liberating and expansive way of being – there were many positive attributes in all the dimensions of health that were more than just the component parts. These positive attributes of health were holistic, interdependent and positively reinforcing. A person with good health was thought to have available resources, optimum functioning and a positive attitude enabling them to maintain their health and live life to its fullest. Being healthy was not a definitive, end-state of perfection. Rather a person's health status should be assessed individually to enable everyone at any stage of life or with disabilities, the possibility of attaining 'health that is more than the absence of disease'.

## 4. Discussion

This study is the first to use phenomenography as the method to explore the concept of 'health that is more than the absence of disease'. Despite data saturation not being attained, a landscape still emerged from this series of interviews representing the different levels of understanding. Many interviewees were inspired by the possibility of optimising health. For some however, their conceptualisation of 'health that is more than the absence of disease' remained limited to 'health as the absence of disease' that is achieved by preventing and treating disease.

A limitation of the study lay in the sample of patients and practitioners interviewed. More interviews with a larger, wider sample-group of patients and practitioners, including laypeople, policy makers and others would be needed to more

comprehensively map the concept across the community. For example, other studies have found that people from higher socio-economic groups are more likely to use positive definitions of health that are multidimensional [34], and consumers of IM and TCAM often use these therapies to promote health, wellness and wellbeing, rather than to treat disease [46]. The sample of patients from this study may therefore have different conceptions compared with other groups of people that do not use TCAM therapies or are from a less affluent area of Australia. Similarly, the sample of practitioners was narrow. Underrepresented groups included TCAM practitioners, allied health practitioners and non-IM doctors. Compared to practitioners with training in TCAM or IM, practitioners with only biomedical training are more likely to use a restricted definition of health such as 'health as the absence of disease' [35].

Notwithstanding the limitations, our results are consistent with much of the research in this field. The different aspects of positive health discussed by the interviewees were mostly in line with the theoretical models and definitions proposed in the literature; that is, health is multidimensional, consisting of interrelated domains [11,17–19,47]; satisfaction ('happiness') in all these areas of a person's life is important [27]; and people have different levels of understanding, including some whose concept may be limited to a biomedical model of health, whereas others may focus on enablement and vitality [4,5,34,36,48].

A notable difference between our findings and many of the models and definitions of health was the theme of 'energy and vitality'. It was a marked indicator that applied to many dimensions of health and wellness and was more than just psychological wellbeing [49,50]. Although Jensen et al. in a meta-analysis of 35 phenomenological studies included vitality as a popular conception of health, vitality was cited as originating from only one paper [5].

Patients, in particular in our study, emphasised 'energy and vitality'. This finding is consistent with another study comparing patients' and non-IM biomedical doctors' views on health [4]. It was surprising however, that the practitioners we interviewed were less inclined to emphasise this theme since fatigue is a common IM presentation, and many of the therapies provided by the clinic use vitalistic concepts [51]. Perhaps though, a sample with more than one traditional medicine practitioner would have resulted in further discussion of 'energy and vitality' as was demonstrated in one larger survey of varied practitioners [36].

Only a subgroup of patients who had chronic diseases and practitioners with little IM or TCAM training that we interviewed conceptualised 'health as the absence of disease' and focused on the importance of professional health care. This finding is consistent with a New York study that interviewed general practitioners (GPs), asthmatic patients and patients with no chronic diseases. GPs in the study were more likely to use a biomedical model that focused on 'health as the absence of disease'; and GPs and patients with asthma were more likely to discuss the importance of professional health care [4].

The multidimensional nature of health was an important finding in a series of interviews with patients and staff from a primary care clinic in Canada. The ability to cope and to function (including optimal functioning) were the two other major themes identified there [52]. These three themes, along with a few less commonly expressed ideas such as health as a continuum and health being limited to the absence of disease, were consistent with our results. Other important themes however, such as 'energy and vitality' and 'happiness' were not mentioned. This may reflect the different emphases of the two interviews or that the Canadian study was based in a primary care clinic that did not offer TCAM services. Improvements in energy, vitality and wellbeing are outcomes commonly reported by TCAM practitioners and their patients [53–58]. The results from

these qualitative studies of TCAM more closely align with the results from our study that identified 'energy and vitality' and 'happiness' to be important themes.

Our findings are also consistent with two interrelated studies that found biomedical, IM and TCAM practitioners all used a wide range of health models as reported in the literature; that is, biomedical, bio-psycho-social, environmental, and holistic models [35,36]. Although the authors acknowledged that the biomedical model of health is limited to the absence of disease [35], they did not disentangle the difference between those broader health models from 'health that is more than the absence of disease'. It is important to note that these two concepts are not synonymous. Our results show that some people whose concept was limited to 'health as the absence of disease' still used broader multidimensional models of health.

The multidimensional nature of health is a difficult concept to untangle. Factor analysis of many wellness and wellbeing questionnaires often do not support the multidimensional models on which the questionnaires are based [6]. The recently developed Self-Assessment of Change questionnaire that was informed by qualitative interviews with TCAM patients rather than a theoretical model, is distinct from many other outcome questionnaires because it does not subdivide the questions into different health domains [59]. Words such as 'energised', 'balanced' and 'whole' that are used in the questionnaire to describe positive experience of health, can be applied to more than one health domain. The results from our study also support a multidimensional concept of wellness in which the different aspects of health are interdependent and holistic [14,18,60]. Energy and vitality, along with other positive attributes such as consistent good health, engagement with life, a sense of purpose and joie de vivre, can apply to more than one dimension. Other factors such as motivation, coping and resilience also applied to more than one dimension, and along with a healthy lifestyle, they were often considered to be both an attribute of good health as well as influencing health. These conceptions align with Antonovsky's 'salutogenic model' of how people maintain health [61], and with many wellness and wellbeing models [13–19,47,62]. Further research is needed therefore to determine whether the failure of some questionnaires to adequately measure these multidimensional, interdependent concepts is a shortcoming of the questionnaire and the analysis or the multidimensional model from which it has arisen.

## 5. Conclusion

Questionnaires able to measure concepts such as wellness and wellbeing are in need of development. Like any questionnaire, they must be informed by empirical research in the field as opposed to theoretical models and opinions of experts. Given the challenges with conceptualising and measuring these concepts, the results from this study provide strong background information for this pursuit.

There is a need to disentangle the difference between holistic, multidimensional models that can be used to describe both disease and health. Compared to disease, concepts such as 'health that is more than the absence of disease', wellness and wellbeing are more nebulous and difficult to define. There is a natural tendency to default to offer contrasting negative definitions and processes for achieving these positive states of health rather than clearly describing the concepts. The terms continue to be used in a variety of ways by various academic disciplines, the health industry and general population. This has yet only served to confound their definitions and their usefulness.

This study then is important to our understanding of 'health that is more than the absence of disease' and opens the following questions for further research:

1. Is there a perfect optimum state of health to attain or is being healthy an ongoing process where an individual aims to reach their full potential? The answer may influence how the concept applies to individuals with disabilities, the aging process, palliative care and people living in different environments.
2. Should 'energy and vitality' be considered a separate dimension of health and if so, does this support the vitalistic concepts common to many of the traditional and energy-based medicines? Can it then be proposed that 'energy and vitality' is an essential component of health and wellness?
3. Can the multidimensional, interdependent nature of health be disentangled enough to reasonably measure wellness with multifactorial questionnaires?
4. Is the topic of 'health that is more than the absence of disease' important in itself as a stimulating and inspiring question?

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## Conflict of interest

KP is the medical director at the clinic where the research was conducted; JH, JM and KP work as clinicians at the same clinic. There are no other relationships nor activities that could appear to have influenced the submitted work.

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# **CHAPTER 10: PATIENT QUESTIONNAIRES FOR USE IN THE INTEGRATIVE MEDICINE PRIMARY CARE SETTING – A SYSTEMATIC LITERATURE REVIEW.**

Hunter J, Leeder S. Patient questionnaires for use in the integrative medicine primary care setting – A systematic literature review. *Eur J Integr Med.* 2013; 5(3):194-216 doi: 10.1016/j.eujim.2013.02.0023

## **FOREWORD**

This systematic literature review was started in 2009 and completed in 2012 following the results from the interviews. A shortlist of potentially relevant patient-reported outcome questionnaires and other patient questionnaires is recommended for further testing in the IM setting.

## **TABLES AND FIGURES**

**Chapter 10 / Table 1:** Search strategies.

**Chapter 10 / Table 2:** Criteria for selecting questionnaires.

**Chapter 10 / Table 3:** Search 1 results: web-based PRO databases and listed questionnaires

**Chapter 10 / Figure 1:** Questionnaire selection and exclusion process

**Chapter 10 / Table 4:** Shortlist of patient-reported questionnaires for integrative medicine primary care

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Review article

## Patient questionnaires for use in the integrative medicine primary care setting—A systematic literature review

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### Abstract

**Introduction:** Increasingly, primary care clinics are offering integrative medicine (IM). These clinics, besides treating illness, emphasise holistic health care, health promotion and enhancing well-being. However, very few such clinics are evaluating their services or patient outcomes.

**Methods:** A systematic review was undertaken to identify, appraise and shortlist the best available patient-reported questionnaires to measure outcomes in IM primary care clinics. As well as patient health outcomes, questionnaires measuring proxy outcomes such as lifestyle risk factors, medication use and health services outcomes were included. The internet and Medline, CINAHL and Allied and Complementary Medicine databases were first searched to identify English web-databases listing potential questionnaires. Publication databases were then searched to identify questionnaires measuring underrepresented topics. Potential questionnaires were evaluated using modified guidelines from the Medical Outcomes Trust.

**Results:** Ten web-based databases were identified that cited over 4000 questionnaires. There was a plethora of mental health and quality-of-life questionnaires from which to choose. However, individualised patient-centred questionnaires along with those measuring wellness, holistic health and health promotion/lifestyle activities were lacking. A final shortlist of 71 questionnaires met the inclusion criteria.

**Conclusions:** The majority of the questionnaires had not been tested in the IM primary care setting. The distribution of scores of many popular questionnaires makes them useless when seeking to differentiate or detect changes and improvement in health and wellbeing in healthier populations. Further evaluation is needed to confirm their suitability.

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**Keywords:** Integrative medicine; Complementary therapies; Primary health care; Outcome assessment (health care); Questionnaires; Systematic review

### Introduction

Integrative medicine (IM) is the combination of traditional, complementary and alternative medicine (TCAM) with orthodox biomedicine [1–3]. As IM services become more commonplace, research is needed to evaluate their effectiveness and quality [4–6]. However, many IM clinics do not use standardised patient reported outcome (PRO) questionnaires as part of their service evaluation [5–7].

IM aims to provide holistic, individualised, and patient-centred care [8–13]. In the primary care setting, IM practitioners and clinics manage acute and chronic illness with a focus on disease prevention and health promotion. Potential outcomes

of TCAM and IM include a wide range of health and health-related domains [14,15]. Debate continues about how best to assess health services when the interventions and outcomes are complex, ongoing and context specific, such as TCAM, IM, palliative care, rehabilitation, and health promotion [16,17]. The systematic collection of PRO with the use of questionnaires is likely to be an important part of the process.

Small batteries of PRO questionnaires have been recommended for TCAM and IM evaluation [18]. However, a criticism of one study using this approach was that these questionnaires failed to measure important IM outcomes such as health promotion and wellness [4]. Another limitation of many existing PRO questionnaires are the observed ceiling effect on the scores when used in the general population (i.e. a many people have a high score) [19]. These questionnaires are therefore unlikely to discriminate changes in healthier patients attending IM clinics.

Interviews with patients and practitioners in an IM primary care clinic confirmed the importance of a holistic assessment.

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Important topics to measure were physical health, mental health, lifestyle and risk factors, changes in medication (including TCAM therapies), attitudes towards healing and TCAM, and health service outcomes (e.g. satisfaction). Most interviewees also considered spiritual health and life satisfaction (including social health) important to measure. However, others thought they were outside the scope of IM. Many thought individualised questionnaires (that use open-ended questions to measure outcomes important to the patient) were useful because they reflect an aim of IM to provide individualised, patient-centred care [14].

A Canadian survey of TCAM researchers, practitioners and students categorised TCAM outcomes into individualised, physical, psychological, social, spiritual, quality of life, holistic measures, context of healing (e.g. attitudes towards healing, patient satisfaction, trust in physician) and process of healing (e.g. readiness to change and experience of transformation) questionnaires [15]. This work informed the framework developed by IN-CAM, a database that lists PRO questionnaires potentially suitable for TCAM research [20].

Thousands of PRO tools are listed on various databases. Outcomes relevant to TCAM are similar but possibly not the same as IM outcomes [14]. Therefore, before commencing an IM research programme to measure PRO, a systematic review was undertaken. The aim was to identify and appraise potential PRO questionnaires and to shortlist the best available questionnaires for use in IM primary care clinics.

## Methods

The search for PRO questionnaires was conducted by the first author and had two parts (Table 1). Where applicable, the PRISMA guidelines for systematic literature reviews were used [21].

### Search 1 – web-based PRO databases and listed questionnaires

Since web-databases already existed listing many PRO questionnaires, the first search began by identifying these databases. Electronic databases were searched for published papers and the Internet was searched for web-based PRO databases (Table 1). From this search, the questionnaires listed on the web-based PRO databases were identified, copied onto a spreadsheet and duplicates were removed. The search carried out in 2009 and updated in 2012.

### Search 2 – under-represented questionnaires

The second search aimed to identify questionnaires measuring topics that were underrepresented on the PRO databases. Papers published about questionnaires were sought by searching electronic databases from which the titles and abstracts were reviewed (Table 1). Manual searches were also conducted using the references listed in key papers and dissertations.

Due to practical reasons, including time restrictions and lack of personnel, we did not systematically count and cross-reference all the references found, or the reasons questionnaires

Table 1  
Search strategies.

Search 1: Web-based pro databases and listed questionnaires

**Electronic databases:** Medline database via PubMed; CINAHL via EBSCOhost and AMED; and Allied and Complementary Medicine via OvidSP

**Date:** 5 October 2009; updated 27 May 2012

**Search terms:** “Complementary Therapies”[Mesh], “Outcome Assessment (Health Care)”[Mesh], “Questionnaires”[Mesh], “Primary Health Care”[Mesh], outcome\*, measure\*, database\*, primary care, patient reported outcome measure\*, primary care outcome measure\*, questionnaire\*, Australian Centre on Quality of Life, PROQOLID, Patient-reported Outcomes and Quality of Life Database, IN-CAM, Chartered Society of Physiotherapy, PROMIS, Patient-Reported Outcome Measurement Information System, PROmeasure, PRO Measure.

**Example of the complete search strategy used on Medline:**

1. “Outcome Assessment (Health Care)”[Mesh] AND “Questionnaires”[Mesh] AND database\*
2. (“Questionnaires”[Mesh]) OR (patient reported outcome measure\*) OR (primary care outcome measure\*) OR (patient reported outcome questionnaire\*) AND database\*
3. (PROQOLID) OR (Patient-reported Outcomes and Quality of Life Database)
4. “Chartered Society of Physiotherapy”
5. (IN-CAM) and database\*
6. (“Australian Centre on Quality of Life”) AND (database\* OR questionnaire\*)
7. (PROMIS) OR (Patient-Reported Outcome Measurement Information System)
8. ((PROmeasure) OR (PRO Measure)) AND database\*
9. ((PROQuestionnaire) OR (PRO Questionnaire)) AND database\*

**Internet:** Google and Yahoo search engines (first 10 pages)

**Date:** 6, 19 and 25 September 2009; updated on 4 and 7 May 2012

**Search terms:** “patient reported outcome”, “patient outcome database”, “patient reported outcome database”, “outcome scales”, “health outcome database”.

**Site search:** All potentially relevant websites were explored including searches for web links to databases and site maps when available.

Search 2: Under represented questionnaires

**Electronic data bases:** MEDLINE database via PubMed; CINAHL via EBSCOhost and AMED; and Allied and Complementary Medicine via OvidSP; PROM Patient-Reported Outcome Measurement [22], National Institute on Alcohol Abuse and Alcoholism [23], National Cancer Institute databases for nutrition and exercise questionnaires [24,25].

**Date:** Database searches July 2010 for alcohol (updated January 2012); January to June 2012 for all other topics.

**Electronic database search terms:** wellness, holistic health, lifestyle, risk factors, smoking, alcohol\*, exercise, physical activity, health education, health promotion, individualized, health risk appraisal, food frequency, diet\*, “Risk Reduction Behavior”[Mesh], “Exercise”[Mesh], “Alcoholic Beverages”[Mesh], “Nutrition Assessment”[Mesh], “Smoking”[Mesh], medication use, medication compliance, patient compliance, (“Questionnaires”[Mesh] OR “Data Collection”[Mesh] AND (“reliab\*” OR “valid\*”))

**Example of the search strategy used on MEDLINE database via PubMed:**

1. (“Questionnaires”[Mesh] OR “Data Collection”[Mesh]) AND (“reliab\*” OR “valid\*”)
2. (holistic health) AND #1
3. (lifestyle) AND #1
4. ((smoking) OR (“Smoking”[Mesh])) AND #1
5. ((health education) OR (health promotion) OR (“Risk Reduction Behavior”[Mesh])) AND #1
6. (individualized) AND #1
7. ((medication use) OR (medication compliance)) AND #1

Table 1 (Continued)

8. (("Nutrition Assessment"[Mesh]) OR (diet*) OR (food frequency)) AND #1 [review papers only]
9. (("Alcoholic Beverages"[Mesh]) OR (alcohol*)) AND #1 [review papers only]
10. (("Exercise"[Mesh]) OR (exercise) OR (physical activity)) AND #1 [review papers only]
<b>Internet:</b> Google and Yahoo search engines, including Google Scholar
<b>Date:</b> July 2010 to June 2012.
<b>Search terms:</b> wellness questionnaire, wellness survey, wellbeing questionnaire, wellbeing survey, holistic health questionnaire, holistic health survey. <i>Questionnaire name.</i>

were excluded. We used published literature reviews and the specialised databases which are listed in Table 1. Search 2 was to confirm that the majority of relevant questionnaires had been identified.

It was difficult to refine the searches on electronic databases for holistic health, wellness, and wellbeing questionnaires because thousands of irrelevant papers were also listed when these search terms were used. Internet searches, including Google scholar helped identify some questionnaires. The best search results were obtained whilst seeking further information about questionnaires already identified. Electronic databases along with the references of these published papers and dissertations were then searched to identify more publications and questionnaires. The process was inductive and iterative, and continued until data saturation was reached where each questionnaire had been identified numerous times and no new questionnaires were found.

### Questionnaire selection

Questionnaires identified in the first search were screened using the information available on the PRO databases. Those surviving the exclusion and inclusion criteria listed in Table 2 were added to a spreadsheet. Further information was then sought from published papers and books, and by correspondence with the authors to confirm the questionnaire met the exclusion and inclusion criteria and for further in-depth appraisal. Questionnaires identified from the second half of the search that met the same inclusion and exclusion criteria were manually also added to the spreadsheet.

### Inclusion and exclusion criteria

Questionnaires were excluded if they were disease-, symptom- or treatment-specific because patients commonly present to IM practitioners with more than one problem. However, questionnaires measuring general mental health were included (but not those measuring only one disease, symptom or psychological construct), along with those measuring general symptoms such as pain, fatigue, gastrointestinal or musculoskeletal symptoms, because these are common presentations in the IM primary care setting [26].

Table 2

Criteria for selecting questionnaires.

Questionnaires excluded	Exceptions to exclusion criteria
<b>Exclusion and inclusion criteria</b>	
<ul style="list-style-type: none"> <li>not patient completed</li> <li>not paper/electronic format</li> <li>non-English only</li> <li>not for all adults 18+ years of age</li> <li>disease, symptom or treatment specific</li> <li>only for use in hospitals or institution</li> <li>not measuring patient attributes</li> <li>not patient completed</li> </ul>	<ul style="list-style-type: none"> <li>general mental health</li> <li>pain, fatigue, gastrointestinal, musculoskeletal</li> <li>health behaviour, risk factors and lifestyle</li> <li>life satisfaction, holistic health, wellness,</li> <li>TCAM or IM use</li> <li>health service outcomes</li> <li>beliefs and attitudes towards TCAM</li> </ul>
<b>Extra criteria used for detailed appraisal<sup>a</sup></b>	
<ul style="list-style-type: none"> <li>adequate referencing</li> <li>questionnaire or detailed description available</li> <li>clear conceptual and measurement model</li> <li>good psychometric properties (e.g. reliability, validity, responsive to change)</li> <li>results are easy to interpret and relevant</li> <li>information available about norms for different population groups</li> <li>wide distribution scores in the general population</li> <li>available in multiple languages</li> <li>alternate forms of administration</li> <li>commonly used and popular</li> </ul>	<ul style="list-style-type: none"> <li>acceptable to stakeholders</li> <li>low responder and administrative burden (ideally &lt;40 items unless measuring multiple topics)</li> <li>designed for and/or used in the TCAM, IM or primary care setting</li> <li>capacity to calculate both clinical and economic outcomes</li> <li>free or low cost</li> <li>excluded if too narrow, e.g. only measures limited aspects of quality of life, mental health spirituality, social health</li> <li>not a health, proxy-health or health service outcome measure</li> </ul>

<sup>a</sup> Adapted from the Scientific Advisory Committee of the Medical Outcomes Trust [26].

Questionnaires measuring lifestyle and risk factors were included as proxy health outcomes because disease prevention and health promotion are also features of IM [4]. The exception was those designed specifically for evaluating the treatment of addictions, because this is a specialised service rather than a service provided by primary care IM clinics.

### Questionnaire appraisal

The aim of the appraisal was to confirm the exclusion and inclusion criteria had been met and to short-list the best available questionnaires able to measure the wide range topics and constructs relevant to IM primary care clinics as outlined in the introduction.

The information sought for each questionnaire included the source (e.g. web databases or second search); name(s) of the questionnaire, abbreviations, and different versions; the topics and constructs measured, measurement information (e.g. format, the number of items, type of data collected, recall time, time to complete, languages); psychometric information (e.g. validity, appropriateness, reliability, responsive to change, interpretability, generalisability); any previous use in TCAM or primary care setting; acceptability to patients and practitioners; cost and copyright considerations, and authors and references. Notes were

also made about any research or review papers comparing different questionnaires. This information was obtained from the data listed on the PRO databases; through literature searches of the electronic databases and the Internet search engines listed in Table 1; by manually searching the references of related papers; and by contacting the authors.

Table 2 outlines the criteria used for the detailed appraisal. The criteria drew on the recommendations from the Scientific Advisory Committee of the UK Medical Outcomes Trust [27]. The Trust proposed eight selection criteria for evaluating PRO questionnaires and these have been used by others [20,28,29]. These are: (1) the conceptual and measurement model; (2) reliability; (3) validity; (4) responsiveness or sensitivity to change; (5) interpretability of results; (6) responder and administrative burden; (7) alternative forms of administration; (8) cultural and language adaptations. We added further criteria. The questionnaires should measure a clinical outcome, a proxy-health outcome, or a health service outcome. Adequate referencing and availability of the questionnaire was essential. Popular, commonly used questionnaires were preferred because if a questionnaire is used more frequently, the psychometric properties become better known. The acceptability of outcome questionnaires to patients, practitioners, and health-services and low responder burden are important to enhance participation rates and to ensure the relevance of the outcomes measured [30,31]. Ideally, the short-listed questionnaires would be designed or validated for use in TCAM or IM, could also be used for economic evaluations, and were free or low cost [15].

## Results

### *Search 1 – web-based PRO databases and listed questionnaires*

Eight general health related web-based databases listing PRO questionnaires were identified in 2009 [20,22,32–38]. PROMIS was included because it lists many questions drawn from multiple questionnaires [39]. Two new databases were identified in 2012, PROMeasure, specialising in electronic questionnaires [40] and a ‘Happiness’ database [41]. Table 3 lists the ten databases.

Combining the questionnaires listed on the databases yielded 3833 questionnaires. Aside from PROMeasure, the other databases all listed questionnaires not on the other sites. The three most important databases were PROQOLID, IN-CAM and AC-QOL. Each listed approximately half of the 478 questionnaires shortlisted for further review and each listed questionnaires unique to that database. Topics well represented by the databases were quality of life (QoL) and mental health. The IN-CAM database was the only one to list TCAM and wellness questionnaires; however, it did not list any questionnaires measuring lifestyle, risk factors, or health education outcomes that were listed on PROQOLID. Fig. 1 is a flow diagram showing the number of questionnaires identified, assessed for eligibility, appraised and finally shortlisted.

Table 3

Search 1 results: web-based PRO databases and listed questionnaires.

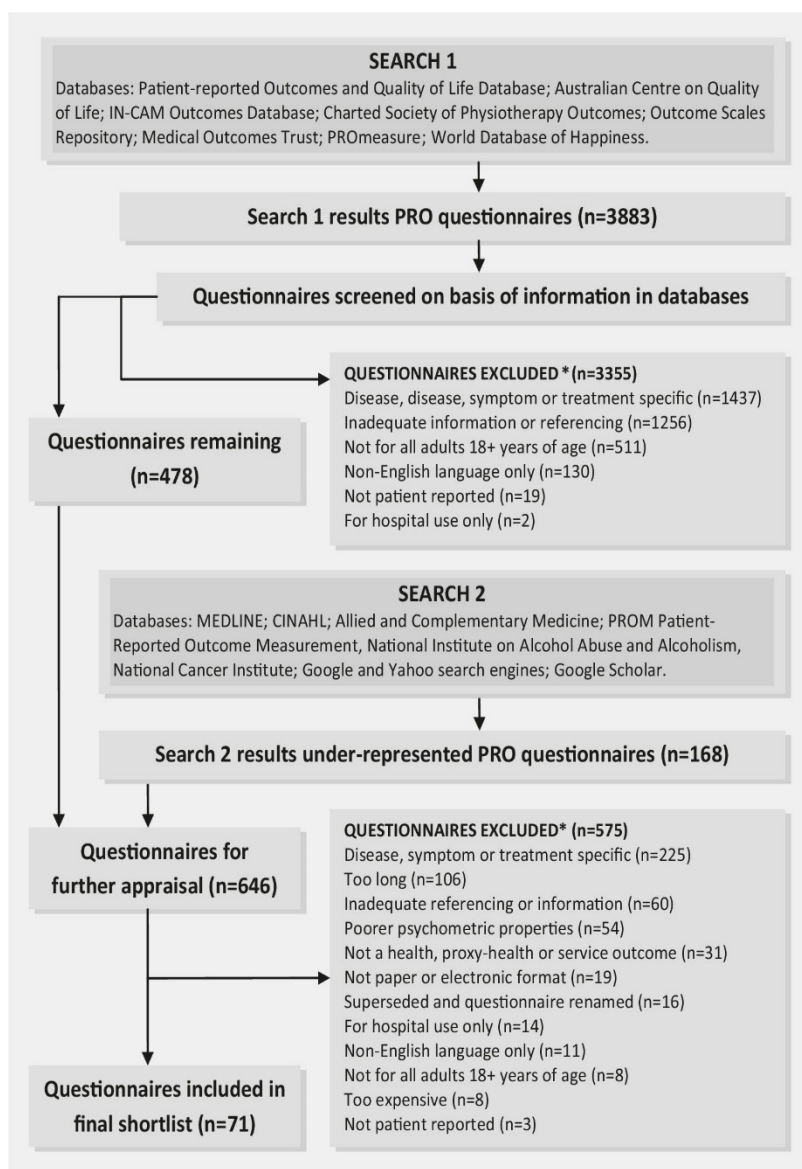
1. Patient-reported Outcomes and Quality of Life Database (PROQOLID) [32,33]	
1114 questionnaires (2009)	Basic searches were by name, author, generic, pathology/disease, or population. Full access to detailed descriptions and use of the advanced search engine require subscription to the site.
1125 questionnaires (2012)	
2. Australian Centre on Quality of Life (AQoL) [34]	
1046 questionnaires (2009 and 2012)	All are briefly described and referenced. Search facilities were basic, by name only.
3. IN-CAM outcomes database [20,37]	
222 questionnaires (2009)	Listed and described in detail measurement tools considered suitable for use in the TCAM setting. Search options were by name, author, domain, description, free text or year.
280 questionnaires (2012)	
4. World Database of Happiness [41]	
1349 questionnaires (2012) (approximately 850 questionnaires were single questions)	Search options were: the kind of happiness, time of happiness, method of assessment, and rating scale.
5. Chartered Society of Physiotherapy Outcomes [35]	
266 questionnaires (2009)	All are briefly described and referenced. Search facilities were basic, by name or free text. The database was only accessible to members in 2012.
6. Outcome Scales Repository [36]	
258 questionnaires (2009 and 2012)	Most tools were disease specific. Search facilities were basic, by domain only. In 2012, the url address had changed, but the content was unchanged.
7. PROMeasure [40]	
37 questionnaires (2009 and 2012)	Verified electronic questionnaires were listed. Search options were by ICD Categories, ICF Categories, PROMIS Categories and free text.
8. Medical Outcomes Trust [38]	
10 generic questionnaires and 9 condition specific questionnaires (2009 and 2012)	The questionnaires were approved by the Scientific Advisory Committee. In 2012, the url address had changed, but the content was unchanged.
9. Patient-Reported Outcome Measurement (PROM) [22]	
Unknown number of questionnaires (2009 and 2012)	The database listed references for PRO questionnaires, often with an abstract, but it did not provide a list of questionnaires. It was not possible to ascertain to what extent the database had been updated in 2012. Search options included keywords for instrument names, topics and types; author; and free text.
10. Patient-Reported Outcome Measurement Information System (PROMIS) [39]	
Unknown number of questionnaires (2012)	This is an item bank of patient reported questions drawn from multiple questionnaires measuring various health domains.

## Search 2 – under-represented questionnaires

## Development of questionnaire categories

Based upon the results from the main searches conducted on the electronic databases and lists created from the manual searches, we estimate that around 3800 papers were reviewed. The search strategy involved many manual searches of references in published papers and dissertations. From this search, 168 questionnaires were added to the questionnaire spreadsheet for further appraisal (Fig. 1).

During the selection and appraisal process, we found the need to develop our own set of categories to describe the topics being measured. Two PRO databases influenced the development of these categories. The PROQOLID database categorised the types of instruments as physical functioning, signs and symptoms, psychological functioning and coping, health related quality of life, social support, patient satisfaction, utility and



\*Often questionnaires were excluded for multiple reasons.  
To prevent duplication, only the first reason was counted.

Fig. 1. Often questionnaires were excluded for multiple reasons. To prevent duplication, only the first reason was counted.

other [33]. The IN-CAM database categorised questionnaires to reflect outcome constructs relevant to TCAM [20]. These were individualised, physical, psychological, spiritual, social, quality of life, holistic, process and context [37]. Neither of these categories were entirely appropriate for our use. PROQOLID did not include IM constructs such as holistic health, and neither PROQOLID nor IN-CAM categorised health promotion and lifestyle/risk factors.

The categories we chose to describe the different topics and constructs measured by the identified questionnaires were: individualised; multidimensional quality of life and holistic health (life satisfaction and general quality of life, health related quality of life, and wellness); physical health (including functioning and symptoms); mental health (mental illness, wellbeing, other); spiritual health; social health; lifestyle, health promotion and risk factors; health services outcomes; and attitudes towards TCAM and health beliefs.

#### *Shortlist of patient questionnaires*

Following in-depth appraisal, a final shortlist of 71 patient questionnaires is proposed (Fig. 1). Forty-three questionnaires came from Search 1, and 27 from Search 2. Table 4 lists the questionnaires, key references and summarises some of the information collected during the appraisal. Information about reliability and validity is presented using a condensed version of the ratings proposed by McDowell that assesses the results of psychometric analysis' and the thoroughness (such as number of studies and sample sizes) [42].

#### *Individualised*

Both IM and TCAM aim to provide patient-centred care. Individualised questionnaires are appropriate because they reflect this approach [19]. Typically, they use open-ended questions to identify outcomes important to the respondent and then rate their severity and impact. Scores are generated that enable changes over time to be measured. The main disadvantages of this approach are that some patients need help to answer the questionnaire, and scoring is only valid for the individual and cannot be used to generate statistical population norms.

Only two individualised questionnaires were identified. MYMOP is recommended because it was developed and validated for primary care and TCAM. MYMOP's main limitation is that it can only measure the outcomes of one health problem, but in the IM setting patients commonly present with multiple problems. To measure the outcomes of each problem would require the use of multiple MYMOP questionnaires, which would increase responder and researcher burden [43,45,46].

The Patient Generated Index aims to measure quality of life. However, even the modified versions are quite complex to administer with a high rate of completed questionnaires having an invalid score. Consequently, some researchers have preferred to use it in an interview format [48–50].

#### *Multidimensional quality of life and holistic health*

Several questionnaires were multidimensional, measuring various aspects of holistic health. These were general health, health-related quality of life (HR-QoL), wellness, and life satisfaction/general QoL.

#### *General health*

The Medical Outcomes Scale (with 116 questions) was included because it is free to use and it measures physical health in the most detail. There are 32 items measuring physical health and fitness, along with 11 items for pain, 9 items for sleep and 11 items for perceived general health. It also measures mental health (38 items), social health (3 items), and activities of daily living (12 items). It is the predecessor of the SF-12, SF-36, MOS Physical Functioning Measure, MOS Mental Health Inventory and MOS Social Support Survey [51]. All which have adequate psychometric properties. Researchers may prefer to use this original tool rather than a battery of smaller questionnaires.

The PROMIS item bank of web-based questions that is currently in development, has the potential to standardise outcome measurement across multiple health domains [39]. However, the focus has remained on chronic disease and it is yet to consider other outcomes relevant to IM such as lifestyle, health promotion and wellness. Furthermore, there is a risk of reduced response rates unless it offers an alternative formats to electronic, such as paper or interview [31].

#### *Wellness*

Eighteen questionnaires were identified that aimed to measure wellness and health beyond the absence of disease. Given the importance of this topic to IM and the paucity of questionnaires, many were shortlisted even though there were major limitations such as length, cost, inadequate information about psychometric data, and when the psychometrics were evaluated the proposed holistic multidimensional model (e.g. physical, emotional, intellectual, spiritual, social, occupational) was not always supported by its factor analysis [57,58,66,222,274]. The exception was the Wellness Evaluation of Lifestyle (5-WEL) that possessed five independent dimensions [54–56]. However, there is a charge for its use, and it was developed and validated for use in positive psychology and life coaching rather than the IM setting. As such, questions about physical and intellectual health are under-represented. Other limitations with existing wellness questionnaires were measurement bias due to the subjective aspects of physical health and defaulting to using proxy outcomes such as health behaviour and lifestyle to assess this domain.

The Perceived Wellness Survey may be the best choice because it is the most evaluated, it is short, there is no charge for its use, and it is available in languages other than English [60,61,63]. However, like most of the other tools aiming to measure this construct, factor analysis fails to support its multidimensional model.

The Arizona Integrative Outcomes Scale is a single-question, visual analogue scale that measures perceived physical, mental, emotional, social and spiritual condition over the past 24 h or 1

Table 4  
Shortlist of patient-reported questionnaires for integrative medicine primary care.

Name	Description	No. items	Reliability <sup>a</sup>	Validity <sup>a</sup>	Sensitive to change <sup>b</sup>	Setting <sup>c</sup>	Comments
<b>Individualised (2)</b>							
Measure Yourself Medical Outcome Profile MYMOP-2, MYMOP-pictorial [43–47]	Identifies problem, rates two symptoms and one activity and change. Also measures change in medication use.	7	Moderate	Good	Yes, very responsive to change	PC, TCAM, CD	Only measures one problem/illness. MYMOP-pictorial uses smiley faces. Guidance recommended for first administration. Paper version very difficult to complete.
Patient Generated Index [48–50]	Individualised rating of quality of life.	18	Moderate	Good	Yes	CD	
<b>Multidimensional quality of life and holistic health (16)</b>							
<b>General health (1)</b>							
Medical Outcomes Study – MOS [51]	HRQoL, physical and mental health, social activities.	116	Moderate	Moderate	Unknown	CD	More information and better psychometrics exist for the questionnaires derived from the MOS.
<b>Wellness (6)</b>							
Arizona Integrative Outcomes Scale [52,53]	Overall physical, mental, emotional, social and spiritual condition.	1 VAS	Poor	Poor	Yes	TCAM	Lacks specificity.
Five Factor Wellness Inventory 5-WEL (or Wellness Evaluation of Lifestyle) [54–56]	5 dimensions – creative, coping, social, essential, and physical self.	73	Moderate	Moderate	Yes	Psychology	Cost for use. Mostly used clinical practice rather than research.
Global Wellness Inventory (or Wellness Inventory) [57–59]	Intellectual, emotional, social, spiritual, physical, and environmental health.	120	Moderate	Moderate	Unknown	Wellness programmes	Cost for use. Mostly used clinical practice rather than research.
Perceived Wellness Survey [60–65]	Social, spiritual, physical, intellectual, emotional and psychological health.	33	Moderate	Moderate	Yes	TCAM	Available in multiple languages and web-base version.
Optimal Living Profile [66]	Intellectual, emotional, social, spiritual, physical, and environmental health	135	Poor	Poor	Unknown	TCAM	Probable cost for use. Reliability and validity are limited by too few studies
Testwell Holistic Lifestyle Questionnaire (or Lifestyle Assessment Questionnaire) [59,67,68]	Physical, emotional, intellectual, spiritual, occupational, self-care, safety.	50 to 100	Moderate	Moderate	High school version no change in intervention programme	Health promotion	Cost for use. Commonly used tool but needs further testing.
<b>Health related quality of life (6)</b>							
Assessment of Quality of Life AQoL/AQoL-4D Basic [69,70]	All 3 assess independent living, physical senses, social, relationships, and psychological; calculates utility score.	15	Good	Good	Yes	PC, CD, surveys	Utility scores use 12 of the 15 questions for AQoL, and all the questions for AQoL-8 and AQoL-2.
AQoL-8 [71]	AQoL-8: is a shorter version of AQoL.	8	Moderate	Moderate	Unknown	PC, CD, surveys	AQoL-8 and AQoL-2 are promising newer tools, but less psychometric data. Use AQoL-2 for mental health problems. Less ceiling effect.

Table 4 (Continued)

Name	Description	No. items	Reliability <sup>a</sup>	Validity <sup>a</sup>	Sensitive to change <sup>b</sup>	Setting <sup>c</sup>	Comments
AQoL-2/AQoL-6D Standard [72,73]	AQoL-2 also measures coping and pain, and more aspects of mental health.	20	Moderate	Moderate	Unknown	PC, CD, surveys	
Complementary and Integrative Medicine Outcome Scale [74,75]	Pain, fatigue, physical, personal control, existential issues, QoL.	29	Poor	Poor	Unknown	PC, TCAM	Reliability and validity are limited by too few studies.
Duke Health Profile [76–80]	General, physical, mental, social and perceived health, and self-esteem.	17	Moderate	Good for mental health	Best for mental health	PC, TCAM, CD, surveys	Has better patient acceptability than SF-36. Component scales lack specificity. Cost to use.
Europe Quality of Life Scale: EQ-5D [45,81–86]	Pain, activities, mobility, self-care; VAS overall health; and utility score.	5 and 1 VAS	Good	Good	Yes, less than other HRQoL tools	PC, TCAM, CD, surveys	Valuation of utility score differs between population groups. Very large ceiling effect, some floor effect.
Outcome in Relation to Impact on Daily Living (Glasgow Homoeopathic Hospital Outcomes Scale) [87,88]	Perceived impact of treatment on 'activities of daily living' and overall 'wellbeing'.	2 or 4	Poor	Poor	Yes	PC, TCAM	Poorly correlated with SF-12 and EQ-5D; high correlation with MYMOP. Reliability and validity are limited by too few studies.
Short Form Health Survey SF-36, SF-36v2, SF-36(DYNHA) [89–96]	General, physical, pain, energy, mental, social, and role functioning. DYNHA – computerised adaptive testing.	36	Good	Good	Yes in some TCAM studies	PC, TCAM, CD, surveys	Cost for SF-36v2 and DYNHA. Caution with component sub-scoring.
SF-12, SF-12v2 [96–98]	Shorter version of SF-36.	12	Good	Good	Yes	PC, CD, surveys	Ceiling effect. Cost for SF-12v2. Overall estimate score has less precision than SF-36. Ceiling effect higher than SF-36, lower than EQ-5D.
SF-6D [82,99–101]	Utility score calculated from six questions used in both SF-36 and SF-12.	6	Good	Good	Yes	PC, CD, surveys	Cost for SF-6D.
<b>Life satisfaction and general quality of life (3)</b>							
Satisfaction with Life Scale [101–104]	Satisfaction with life as a component of subjective wellbeing.	5	Good	Good	Scores change over years	Positive psychology; fibromyalgia	May be insensitive to small changes over short measurement interval.
Personal Wellbeing Index – PWI [105–107]	Satisfaction with eight QoL domains, and overall satisfaction.	9	Good	Good	Unknown	PC, TCAM, surveys	Scores may be too stable over time.
World Health Organisation Quality of Life – brief WHOQoL-BREF [108–114]	General and HRQoL: physical, social psychological and environment.	26	Good	Good	Unknown		Developed from the WHO-QoL 100 item questionnaire.
EUROHIS QOL/WHOQoL-8 [115–117]	Two questions from each of the four domains in WHOQoL-BREF.	8	Good	Good	Unknown	PC, surveys	Less psychometric data available than for WHOQoL-BREF.



Table 4 (Continued)

Name	Description	No. items	Reliability <sup>a</sup>	Validity <sup>a</sup>	Sensitive to change <sup>b</sup>	Setting <sup>c</sup>	Comments
<b>Physical health (8)</b>							
<b>Digestion (1)</b>							
Digestive Health Status Instrument [118,119]	Gastrointestinal (GI) functional symptoms and severity.	34	Good	Good	Yes	PC, CD, surveys	Can be used for screening or outcome for all types of gastrointestinal diseases.
<b>Energy and fatigue (3)</b>							
Fatigue Severity Scale [120,121]	Fatigue severity and impact.	9	Good	Good	Yes	TCAM, CD	Mostly used to assess severe fatigue in CDs.
Lee Fatigue Scale [122–124]	Severity, frequency, pattern and impact or fatigue and energy. All VAS	13	Good	Good	Yes	PC, CD	Longer version is validated for use with sleep apnoea. High researcher burden. Measures both positive and negative constructs.
Multidimensional Fatigue Inventory [125–127]	General, physical and mental fatigue, motivation and activity.	20	Good	Good	Yes	CD, survey	
<b>Pain (4)</b>							
Brief Pain Inventory – short form (Wisconsin Brief Pain Questionnaire) [128–133]	Pain intensity and impact, diagram for location, and open questions for pain management.	15	Good	Moderate	Yes	Acute and chronic pain, surveys	Endorsed by WHO, multiple languages, high responder burden. Longer version has 56 items.
McGill Pain Questionnaire (Short-Form) [132–135]	Description of pain and intensity, diagram for location.	16	Moderate	Moderate	Yes	PC, TCAM, CD	The 5-item Dartmouth pain questionnaire can be used alongside to measure pain impact [136].
Pain Impact Questionnaire – revised [137]	Pain intensity and impact.	6	Moderate	Moderate	Unknown	Acute and chronic pain, surveys	Cost for use. Newly developed tool by Quality-Metrics.
Pain Visual Analogue Scale – VAS [42,133,138,139]	Subjective estimate of pain intensity across a horizontal line.	1	Good	Moderate	Yes, high individual correlation	PC, acute and chronic	Various authors. A Likert-type rating scale may be more appropriate [42].
<b>Mental health (12)</b>							
<b>Illness (4)</b>							
General Health Questionnaire GHQ-12 [140–144]	Outcome and screening tool for non-psychotic mental illness. Positive and negative questions.	12	Good	Good	Yes	PC, TCAM, CD, surveys	Designed for populations with comorbidities.
Hospital Anxiety and Depression Scale [145–151]	Outcome and screening tool for anxiety and depression.	14	Good	Good	Yes	PC, TCAM, CD, surveys	Possible better screening tool than the GHQ-12, MHI-5 and SF-12
Kessler Psychological Distress Scale K10 or CIDI-Short Form [152–155]	Outcome and screening tool for general psychological distress. From SF-36 and MHI-37.	10	Good	Good	Yes	PC, TCAM, CD, surveys	Original rand MHI-37 is a better screening tool than K10 and GHQ-12, greater patient acceptability.
Mental Health Inventory MHI-5 (or Mental Health Component Scale) [156–158]	Outcome and screening tool for general psychological distress. From SF-36 and MHI-37.	5	Moderate	Good	Yes	PC, TCAM, CD, surveys	

Table 4 (Continued)

Name	Description	No. items	Reliability <sup>a</sup>	Validity <sup>a</sup>	Sensitive to change <sup>b</sup>	Setting <sup>c</sup>	Comments
<b>Wellbeing (4)</b> Mental Health Continuum – Short Form [159–162]	Emotional, psychological, and social well-being.	14	Moderate	Good	Unknown	Surveys	Not correlated with questionnaires measuring mental illness.
Warwick-Edinburgh Mental Well-being Scale [163–166]	Positive affect, relationships and functioning.	14	Moderate	Moderate	Unknown	Surveys	Reliability and validity are limited by too few studies.
Orientations to Happiness Questionnaire [167,168]	Pleasure, engagement and meaning orientations, life satisfaction.	18	Poor	Moderate	Unknown	Surveys	Reliability and validity are limited by too few studies.
WHO-5 Well-Being Index (or scale) [169–174]	Positive aspects of mental health.	5	Poor	Poor	Yes	PC, CD, surveys	Contentiously used to screen for depression.
<b>Others (4)</b> Brief Assessment of Sense of Coherence [46,175–178]	Items 12, 14, and 19 from Antonovsky's original SOC-29 questionnaire.	3	Moderate	Poor	Yes	IM, surveys	Other short forms exist, but concerns about the validity of all the soc questionnaires.
General Self-Efficacy Scale [178–181]	Personal agency and coping beliefs	10	Good	Good	Yes	PC, CD, surveys	General not health specific self-efficacy.
Perceived Stress Scale [182–186]	Subjective experience of stress.	10	Good	Good	Yes	TCAM, CD, surveys	Commonly used outcome measure in TCAM research.
Silver Lining Questionnaire SLQ-16 [187–190]	Positive changes in self, personal relationships and life philosophy.	16	Moderate	Moderate	Yes	CD (severe)	Reliability and validity are limited by too few studies.
<b>Spiritual health (4)</b> <b>General (3)</b> Brief Serenity Scale – short [191–193]	Acceptance, Inner Haven and Trust.	22	Moderate	Moderate	Yes	Mindfulness stress reduction	Reliability and validity are limited by too few studies.
Spiritual Involvement and Beliefs Scale [194–196]	Spiritual beliefs and actions.	22	Moderate	Moderate	Unlikely over a few months	PC, TCAM	Definition of spirituality is broad. Reliability/validity limited by too few studies.
Spirituality Index of Well-Being [197,198]	Self efficacy and life scheme.	12	Moderate	Moderate	Unknown	PC, survey	Uses a secular definition of spirituality. Validated across all age groups.
<b>Mindfulness (1)</b> Mindful Attention Awareness Scale [199–204]	Presence of mindful states; attention and awareness.	15	Good	Good	Yes	PC, TCAM, psychology, CD	Available in multiple languages.
<b>Social support (4)</b> Duke-UNC Functional Social Support Questionnaire [205]	Quality and types social support; not quantity.	8	Good	Moderate	Unknown	PC, chronic illness, surveys	Predicted pc use. Poor convergent validity with other measures.
MOS Social Support [206–208]	Five subscales – quantity and quality of social support and interactions.	19	Good	Good	Unknown	Chronic illness, surveys	Available in multiple languages.
Oslo Social Support Scale [209,210]	Perceived social support available in times of crisis.	3	Poor	Moderate	Unknown	Surveys, mental health	Reliability and validity are limited by too few studies.

Table 4 (Continued)

Name	Description	No. items	Reliability <sup>a</sup>	Validity <sup>a</sup>	Sensitive to change <sup>b</sup>	Setting <sup>c</sup>	Comments
Social Support Questionnaire SSQ [211], SSQ-6 [212]	Availability of, and satisfaction with social support.	27	Moderate	Moderate	Unknown	Social support trial, surveys	Reliability and validity are limited by too few studies.
<b>Health promotion and risk factors (15) General (4)</b>							
Lifestyle assessment FANTASTIC [213–218]	Diet, exercise, smoking, alcohol, risk behaviour and mental, social, occupational health.	25	Moderate	Poor	Unknown	PC, TCAM, survey	Consider changing seat-belt to gambling if seat-belt use is compulsory.
Health Education Impact Questionnaire [219]	Evaluation patient education programmes in CD management.	42	Psychometrics not fully evaluated.	Psychometrics not fully evaluated.	Unknown	Health promotion	Has not been used for individual patient outcomes in the clinical setting.
Health-Promoting Lifestyle Profile II [220–224]	Stress management, mental, spiritual, social and occupational health, nutrition, exercise.	52	Moderate	Moderate	Unknown	Health promotion	Available in Spanish and Turkish.
Health and Well-being Assessment [225]	Health, pain, physical activity, diet, sleep, stress, job satisfaction, smoking, alcohol, body mass index.	20	Moderate	Moderate	Unknown	Occupational health	Does not assess substance use, risk taking.
<b>Diet and physical activity (2)</b>							
Rapid Eating and Activity Assessment Questionnaire for Patients REAP [226]	Diet, eating habits, activity/sedentary, and readiness to change.	27	Moderate	Poor	Unknown	PC	Lifestyle questions were not validated against other standardised tools.
Nutrition, Food Safety, and Physical Activity Checklist [227]	Designed to evaluate Nutrition Education Programmes in the USA.	37	Poor	Moderate for diet and activity	Unknown	Nutrition education programmes	For USA population Only diet was validated against a standardised questionnaire. For USA population Consider using without food safety questions.
<b>Diet (4)</b>							
Short Rapid Eating and Activity Assessment Questionnaire for Patients REAP-S [228]	Diet and eating habits.	16	Poor	Poor	Unknown	PC, nutrition programmes	For USA population. Modified for people with low-literacy but tested on medical students.
Food Behaviour Checklist [229–231]	Diet quality and quantity, food security, food expenditure.	39	Moderate	Moderate	Yes	Nutrition education programmes	Appropriate for low literacy. English and Spanish.
Lean eating questionnaire (or Dietary Targets Monitor) [232]	Diet quality and quantity.	28	Moderate	Good for fruit and vegetables and Moderate	Unknown	Surveys	Aims to assess diet targets for National (Scottish) Food and Health Policy
PrimeScreen [233–235]	Diet quality and quantity over the past year.	25	Moderate	Moderate	Yes	PC, surveys	For USA population. Only estimates for surveys.
<b>Physical activity – PA (3)</b>							
Brunei Lifestyle Physical Activity Questionnaire [236]	Amount and intensity of physical activity.	10	Poor	Poor	Unknown	TCAM, PA programmes	Includes yoga as an option. Reliability and validity are limited by too few studies.
Duke Activity Status Index [237–241]	Estimates functional capacity.	12	Good	Good	Yes	CD, surveys	Correlates with peak oxygen uptake.

Table 4 (Continued)

Name	Description	No. items	Reliability <sup>a</sup>	Validity <sup>a</sup>	Sensitive to change <sup>b</sup>	Setting <sup>c</sup>	Comments
<b>International Physical Activity Questionnaire</b> IPAC-S7S IPAC-LUS [242,243]	Duration and intensity of physical activity. IPAC-S7S: past 7 days. IPAC-LUS: a usual week.	27	7	Good	Yes	PC, PA programmes, surveys	Multiple languages and countries.
<b>Alcohol (I)</b> Alcohol Use Disorders Identification Test AUDIT, AUDIT-3 [244,245]	Intake, risk and can screen for alcoholism (AUDIT-3: screen only).	10	3	Good	Yes	PC	Skips questions if no alcohol intake.
<b>Smoking (I)</b> Cigarette Dependence Scale [246–249]	Cigarette intake and dependence.	12	Good	Good	Yes	PC, quit smoking, surveys	Lower dependence scores does not predict smoking abstinence.
<b>Health service outcomes (8)</b> <b>Primary care services (I)</b> General Practice Assessment Questionnaire – Versions 2, 3 and 4 [250,251]	Access, quality and satisfaction with clinic and doctors. Questions from GP Patient Survey [252] and PEI [253,254].	27	Good	Good	Unknown	PC – United Kingdom	Discriminates practice types and patient demographics.
<b>Consultation quality (4)</b> Consultation Quality Index (CQI-2) [253,255]	Continuity of care, empathy, length and patient enablement. Subset of CQI	19	Moderate	Moderate	Unknown	PC	CQI is not as well developed as its subset the PEI. Predictive of other outcomes.
<b>Patient Enablement Index (PEI)</b> [253,254,256]	Trust in treating physician.	7	Good	Good	Unknown	PC, TCAM	
<b>Interpersonal Trust in Physician Scale</b> [257,258]	Trust in Physician Scale TPS	5	Moderate	Moderate	Unknown	PC	Not as well tested or known as the TPS.
<b>Primary Care Assessment Survey – Short Form (PCAS)</b> [261–265]	Perception of doctor's dependability, knowledge, skill, confidentiality. Physician-patient relationship.	11	Good	Good	Unknown	PC	Adjusted one question for the primary care setting. Predictive of other outcomes. Discriminates practice types and patient demographics. Some ceiling effects
<b>Consultation satisfaction (2)</b> Consultation Satisfaction Questionnaire [266,267]	Professional care, depth of relationship and perceived time.	18	Moderate	Moderate	Unknown	PC	For immediate use to assess doctors and other practitioners. Can be used for delayed measurement at home
<b>Medical Interview Satisfaction Scale</b> MISS-21 [268,269]	Relief, communication comfort, rapport, compliance intent.	21	Moderate	Moderate	Unknown	PC	
<b>Medication (I)</b> Medication Change Questionnaire [268,269]	Medication diary for 7 days then repeated. Asks which medication want to take more/less	2 × 7 days	Poor	Poor	Unknown	PC, TCAM	Measures change in both prescription and over the-counter items. High responder burden.

Table 4 (Continued)

Name	Description	No. items	Reliability <sup>a</sup>	Validity <sup>a</sup>	Sensitive to change <sup>b</sup>	Setting <sup>c</sup>	Comments
<b>Attitudes towards TCAM (2)</b>							
CAM Belief Inventory [272]	Beliefs and participation in treatment.	17	Moderate	Moderate	Unknown	TCAM	Provides context about patient characteristics. Only one published study.
Holistic Complementary and Alternative Health Questionnaire [273]	Beliefs about TCAM and holistic health.	11	Moderate	Moderate	Unknown	TCAM, CD	Includes positive dimension of health. Only one published study.

<sup>a</sup> A rating of 'good' means the questionnaire has been tested in many studies conducted by researchers other than the author, and there are acceptable co-efficients and/or other research confirming the different aspects of reliability or validity. A rating of 'poor' means only the authors have tested the questionnaire and the results suggest poor reliability or validity, or they have not been tested. A rating of 'moderate' means the quality of the evidence lies somewhere in between 'good' and 'poor'.

<sup>b</sup> Questionnaires were classified as sensitive to change they had demonstrated the ability to detect real change over time and were therefore more likely to be appropriate as an outcome measure.

<sup>c</sup> PC = primary care; TCAM = traditional, complementary and alternative medicine; IM = integrative medicine; CD = Chronic disease, usually in the hospital or specialist outpatient setting; PA = physical activity.

month [52]. The main criticisms are its inability to distinguish between different aspects of health and that some people find it difficult to summarise their holistic health with a single score [53].

#### Health related quality of life (HRQoL)

There were many HRQoL tools. An important limitation of these questionnaires was ceiling and floor effects [19]. Many of the HRQoL shortlisted can calculate utility scores such as quality-adjusted life years (QALYs) for use in economic evaluations. The AQoL series of questionnaires use the results from all questions, whereas the SF-12 and SF-36 only use six items (called the SF-6). The SF-6, EQ-5D and the shorter versions of the AQoL are more limited by ceiling and floor effects [275].

Other well known HRQoL questionnaires were not short-listed for various reasons. The Health Utilities Index (HUI<sup>®</sup>) is short (15 items), can calculate QALYs, and has a much lower ceiling effect than the other tools shortlisted; however, this is balanced against a higher floor effect in unwell population groups and it incurs a cost [276]. The Dartmouth COOP Charts for Primary Care is also short (9 items) and uses pictures as well as words for the rating scales. However, it was designed as a screening tool for clinicians, rather than an outcome tool for research and it cannot calculate QALYs. Also there are concerns about the reliability of interpretation of the pictures by different cultural groups [42,277]. The Sickness Impact Profile has lower ceiling effects and less floor effects when compared to the SF-36, it covers a wider number of topics, but it is a much longer questionnaire with 136 items [276,278]. The Nottingham Health Profile with 42 yes/no questions cannot calculate QALYs, and its reliability and validity is not as good as some of the other HRQoL questionnaires [42,277].

Two of the HRQoL questionnaires with less rigorous testing, the Complementary and Integrative Medicine Outcome Scale [74,75] and the Outcome in Relation to Impact on Daily Living (ORIDL) [87], were shortlisted because they were the best tools available that have been designed specifically for the TCAM setting. ORIDL has also been validated for use as an outcome tool in primary care.

#### Life satisfaction and general quality of life (QoL)

Three questionnaires were shortlisted that measure aspects of life satisfaction beyond a person's physical and mental health. The Personal Wellbeing Index [105,106] is a short well-validated tool measuring life satisfaction; however, it may not be a suitable outcome measure because individual scores are too stable and tend not to change over time [105,279,280]. The Satisfaction with Life Scale is longer; however, it has been used as an outcome tool [101,281,282]. The WHOQoL-BREF has a sharper focus on health [109,110,112,113,283]. The EUROHIS group recommends a shorter 8-item version of this questionnaire for population surveys [115–117].

#### Physical health

No questionnaires were found that measured general physical health; instead, the majority were designed to measure

physical disability only, which has limited application in the primary care setting. The multidimensional questionnaires covered some aspects of physical health and functioning, in particular the Medical Outcomes Scale previously described [51].

Questionnaires measuring digestion, pain or fatigue were shortlisted if they measured both severity of symptoms and impact on functioning. No questionnaires were found that measured general musculoskeletal health, although there were many questionnaires measuring specific problems such as back pain or knee pain; these were not shortlisted nor were they reviewed in detail. The individualised questionnaire MYMOP and those measuring general pain and HRQoL could be used if the study population included all types of musculoskeletal problems, otherwise a specific outcome tool would be more appropriate [139].

#### *Mental health*

Mental health and psychology questionnaires were well represented in those we examined. Preference was given to questionnaires with less than 20 items.

#### *Illness*

Of those designed to measure mental illness, the most robust of the shortest questionnaires were selected. All four questionnaires have been used in both primary care and TCAM settings to screen for, and measure the outcomes of common non-psychotic mental health problems (such as anxiety and depression) and general mental health distress. The General Health Questionnaire GHQ-12 measures both positive and negative mental health symptoms; however, the majority of research has focused on mental illness and it does not measure other important aspects of positive wellbeing [140–144].

#### *Wellbeing*

Positive psychological wellbeing is another important aspect of mental health [163,164,167,169,284]. However, it may not be a simple continuum from negative to positive mental health. Questionnaires measuring psychological wellbeing often fail to demonstrate a strong inverse correlation with questionnaires measuring mental illness [159]. This may reflect the overlap of aspects of subjective wellbeing with other domains such as life satisfaction and social health [159], along with the importance of measuring other psychological constructs such as self-concept, sense of coherence and coping [160,285]. Therefore, questionnaires measuring psychological wellbeing should be used alongside those measuring mental illness [46,159,161].

#### *Others*

Paterson et al. found an important set of outcomes from acupuncture identified by patients was self-concept (e.g. self-awareness, self-acceptance, self-confidence, self-responsibility, self-help) [286]. The Silver Lining Questionnaire was included because it measures the positive impact of illness in a person's life, such as changes in self-concept [188,189].

The Perceived Stress Scale was included because it is a well-recognised outcome measure that also has demonstrated predictive validity for a person developing a physical or mental illness independent to negative life events and mental health [182,183,186]. Similarly, coping and resilience can predict and influence health outcomes. This construct is assessed in the multidimensional tools the 5-WEL questionnaire [54–56] and the Assessment of Quality of Life-2 [72,73]. Alternatives are the General Self-Efficacy Scale and the Brief Assessment of Sense of Coherence (not shortlisted), or the Spirituality Index of Well-Being listed in the spirituality section in Table 4 [175,179,197,198].

#### *Spiritual health*

Spirituality questionnaires are mostly used to measure attributes that may predict health outcomes. Nineteen questionnaires measuring spirituality were identified. Most were excluded because they only measured one aspect of spirituality such as religiousness or life-meaning, or were restrictive because they used the word God. Poor psychometric properties were a problem with many of the questionnaires. Most of the questionnaires drew on Christian theology and their transcultural application may be limited [287]. Of those selected, the psychometric properties were adequate; however, there were too few studies to allow a higher rating in Table 4.

Questionnaires measuring mindfulness were given extra attention because mindfulness-based interventions such as the practice of meditation are used in TCAM. Aside from mindfulness, none of the spirituality questionnaires have been used to measure outcomes and it is not clear how quickly, if at all, many aspects of spirituality change [194].

#### *Social support*

The social health of a person includes consideration of social adjustment, social roles, and social support given and received. Social support is a predictor of health and health service use and health outcomes [42]. However, it is not clear whether existing questionnaires can also be used as outcome measures. For this reason, only short questionnaires were shortlisted. QoL and some mental health questionnaires measure aspects of social health. Dedicated short social health questionnaires are in need of further development and testing [42] and none of the questionnaires shortlisted were comprehensive measures of social health.

#### *Health promotion and risk factors*

Lifestyle and risk factors such as exercise, nutrition, alcohol, tobacco, drugs and leisure activities, are proxy health outcomes because they are predictive of, rather than directly measuring health and disease. The main challenges with these types of questionnaires are that most are designed for epidemiology interview surveys rather than outcome measures; many lack proper validation of their psychometrics; and there are measurement

errors with self-reported behaviour especially with the use of short self-completed questionnaires [288,289].

#### *General*

Few questionnaires measured lifestyle and multiple risk factors. The FANTASTIC Lifestyle Assessment questionnaire [213–217,290] and the Health and Well-being assessment [225] were shortlisted because they were short. However, neither had been validated against other questionnaires. The Health-Promoting Lifestyle Profile II had better psychometrics. However, it was all positively worded, there were no questions on smoking or alcohol, and the nutritional questions were based on the classic food pyramid that does not allow for specialised prescribed diets as may be the case in IM [221–223]. The HPLP-II is recommended for measuring health-promoting lifestyle behaviours. It measures many (but not all) of the attributes measured in the multidimensional wellness tools. The Health Education Impact Questionnaire also assesses some lifestyle factors along with various other topics relevant to health education and self management programmes for chronic disease [219].

#### *Diet and physical activity*

A handful of combination questionnaires were identified that measured diet, dietary habits, and physical activity. Most of the questionnaires focused on nutrition. The two shortlisted were with reservations because aside from limited reliability and validity, all the nutrition questionnaires identified are likely to have limited application in the IM setting.

#### *Diet*

The most common types of nutritional questionnaires identified were Food frequency questionnaires (FFQ) and 24-h diet recalls (usually with repeated measurements). Both aim to collect detailed information (mostly for use in epidemiology) and demonstrate reasonably comparable results [291,292]. However, these were excluded because they have a high responder burden and are only valid for a specific country or culture. Some, albeit, crudely assessed nutritional supplement intake, but none measured the intake of different types of ‘health-foods’ and ‘super-foods’.

A few brief diet questionnaires were shortlisted. Mostly they were checklists designed to measure adherence to a nutritional guideline or nutritional programme, or for use as a screening tool. Aside from the challenges with the reliability and validity of dietary checklists, their application may prove limited in the IM setting because practitioners commonly prescribe individually determined diets that may conflict with national healthy-eating guidelines.

#### *Physical activity*

Two versions of the well known International Physical Activity Questionnaire (IPAC) were shortlisted [242,243]. However, the IPAC may not be responsiveness to change [243]; it is not appropriate for inactive patients such as those with Chronic Fatigue Syndrome and Fibromyalgia that are common IM presentations [293,294]; and the IPAC-S7S overestimates physical activity [295]. The Duke Activity Status Index (DASI)

may be a more suitable outcome measure for unwell patients [237]. The Brunel lifestyle physical activity questionnaire looks promising as an outcome tool and includes relevant activities for IM such as yoga, but requires more testing to confirm reliability, validity, and suitability as an IM outcome tool [236].

#### *Alcohol*

The Alcohol Use Disorders Identification Test (AUDIT) was shortlisted because it is very short and the only alcohol questionnaire validated as both a screening and outcome tool for use in the primary care setting [296–298].

#### *Smoking*

Of the five most commonly used questionnaires to measure cigarette consumption and dependence [246], the Cigarette Dependence Scale is recommended because it was the shortest with good psychometric properties [247–249].

#### *Health service outcomes*

All the questionnaires evaluating health services (such as satisfaction with the service and treating practitioner, perceived consultation quality, patient enablement, and physician trust) were designed for biomedical, rather than TCAM or IM services. Only the Patient Enablement Instrument that is a subset of the Consultation Quality Index (CQI) [253,255] had been used in both primary care and TCAM settings [253,256,299]. These along with other studies show that the CQI is weakly associated with patient outcomes. It is related to, but not the same as patient satisfaction. The authors propose an alternate to Donabedian’s subdivision of effectiveness into technical and interpersonal effectiveness. They suggest clinical effectiveness should replace technical effectiveness, and emphasise the importance of measuring interpersonal effectiveness because it is an aim of patient-centred care [300].

The only PRO questionnaires identified for use in economic evaluations were the HRQoL tools. Medication use and patient compliance are health-services outcomes that can affect health outcomes and health service costs. Measurement of medication use is problematic especially when it includes over-the-counter medication, herbs and supplements. The questionnaires are time consuming, conferring a high burden on both responders and researchers, and there is a paucity of standardised tools [301]. Only one such tool was shortlisted because it was developed for TCAM and IM use. However, it is still in its early development phase [270,271]. Rather than measuring use, another approach is to measure compliance with prescribed medications and other advice given by practitioners. Numerous questionnaires have been written for this purpose. Few however meets all the criteria needed such as low responder burden, established reliability, information about the reasons for compliance and non-compliance, and responsiveness to change [302]. Furthermore the majority, including a recently developed tool for primary care, were interviews [303].

### Attitudes towards TCAM and health beliefs

One questionnaire measuring attitudes towards TCAM was shortlisted, along with a questionnaire that assesses laypersons' definitions of health [272,304]. These questionnaires have only been used in population surveys and provide contextual information about patients. It is unknown if these scores would change once a patient was exposed to TCAM or IM services.

### Discussion

There were a number of limitations with this review. The Internet searches cannot be replicated because search engines results vary according to location and date. The search strategy may not have identified all suitable questionnaires. A wider search of publication databases such as EMBASE, PsycINFO, ScienceDirect and the Cochrane Library, and a literature search of electronic publication databases for every topic may have identified more questionnaires. Only one researcher undertook the majority of the searching and appraisal and the second search was not systematically documented. This increases the likelihood of errors and selection bias. Notwithstanding these limitations, we are confident that the search strategies and appraisal methods used were thorough and identified the majority of relevant PRO databases and questionnaires.

The need to measure such a broad range of health, health-related, and health service outcomes poses significant challenges to IM researchers. Over 4000 questionnaires were identified but few were established as appropriate for general use in the IM primary care clinics. The PRO questionnaires shortlisted in Table 4 were the best available questionnaires for measuring the different aspects of patient reported outcomes. The shortlist however, was not intended to be definitive, but rather identify a broad range of questionnaires that might be appropriate. None of the questionnaires met all the criteria outlined in the second part of Table 2: extra criteria used for detailed appraisal; each had strengths and limitations, and require ongoing evaluation to ascertain their suitability and psychometric properties in the IM primary care setting. The competition was much higher for common topics such as HRQoL and mental health where more rigorously tested questionnaires were available. We decided to include less robust questionnaires in underrepresented topics because it raises awareness about their existence and the need for further development and evaluation.

None of the questionnaires measured all the outcomes that are relevant to IM, and few had a score distribution able to discriminate change across the full spectrum of disease and health. Therefore, a battery of questions will most likely be needed to comprehensively measure the PRO outcomes of IM primary care clinics. Simply combining some of the questionnaires from each topic in the shortlist may still miss important areas whilst duplicating measurement in others. Another approach would be to build on the work underway by PROMIS [39], where the best individual questions and groups of questions from the shortlisted questionnaires are combined and tested to generate a comprehensive, multidimensional measurement tool. Innovative methods, including the use of algorithms and dynamic

computerised adaptive testing could help minimise responder burden [95].

### Conclusion

This systematic review is the first of its kind to identify and shortlist patient reported outcome questionnaires that may be suitable for general use in IM primary care clinics. A lot more research is required to determine how best to use PRO questionnaires to measure IM outcomes and the practical applications of mixed methods and whole system research that are recommended for evaluating complex healthcare such as IM.

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### Conflict of interest

The authors have no conflicts of interest to declare.

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# **CHAPTER 11: EXPLORING THE PROSPECT OF A COMPLEMENTARY AND INTEGRATIVE MEDICINE DATABASE FOR USE IN THE AUSTRALIAN PRIMARY CARE SETTING.**

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## **FOREWORD**

This last paper synthesises the findings from the previous chapters to discuss how patient-reported outcome questionnaires could be used in an IM minimum dataset for measuring patient outcomes in the IM primary care setting.

## **TABLES AND FIGURES**

**Chapter 11 / Table 1:** Examples of the types of data for an integrative medicine minimum dataset

**Chapter 11 / Table 2:** SWOT analysis of an Australian CIM-MDS

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## Exploring the prospect of a complementary and integrative medicine database for use in the Australian primary care setting



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### ABSTRACT

**Background:** A minimum dataset (MDS) has the potential for many uses in the complementary and integrative medicine (CIM) setting. Methods such as comparative effectiveness (CER) are conducted in real-life clinical settings using data sourced from clinical records and patient reported outcomes (PROs), which is then collated into a MDS of high quality to provide information both immediately and over time. Other uses of a CIM-MDS include surveillance and monitoring CIM use.

**Method:** Strategies for establishing a CIM-MDS in Australia were explored. The focus was data sources, especially the role of PROs. The findings drew on a body of research that included a case study of an IM primary care clinic; interviews with patients, practitioners, and staff from the clinic and a systematic literature review of patient questionnaires for use in the IM setting.

**Results:** Aside from basic information, automated data extraction of clinical data from Australian CIM clinics is very limited. A small battery of patient (and possibly practitioner) questionnaires may be the best way to begin obtaining data. Patient and practitioners may well seek benefits other than contributing to research from the exercise of data collection, such as accessing individual patient results to track outcomes and inform clinical care. The format of the questionnaires matters as well. Although electronic formats are acceptable to many patients, paper questionnaires are still preferable to some.

**Discussion:** A bottom-up approach that involves all stakeholders and builds on other national and international initiatives is recommended for developing a CIM-MDS. The final choice of data for a CIM-MDS will be informed by its intended uses. The lack of any standardised nomenclature for CIM coding is an important obstacle to building a robust dataset; however, in establishing a CIM-MDS there is the opportunity to collect data that could help inform a CIM coding system.

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### What is already known about the topic

- Health services and researchers use minimum datasets for surveillance and research.
- Health service dataset and national data networks are proposed for use in comparative effectiveness research.
- Most of the data relevant to CIM are not included in sufficient detail in existing or proposed datasets for CIM research.
- A bottom-up approach that involves all stakeholders is recommended when building such a dataset.

### What this paper adds

- CIM would benefit from establishing a minimum dataset, both in Australia and internationally.

- Newer methodological and analytical approaches could address some of the complexities of evaluating CIM.
- A dataset that predominantly uses patient reported outcomes questionnaires is recommended for the Australian setting.
- The challenges of creating a CIM minimum dataset in the Australian primary care are discussed.

### 1. Background

The National Institute of Complementary Medicine, Australia recommended the development of a complementary and integrative medicine minimum dataset (CIM-MDS) [1]. This paper draws on a body of work undertaken in response to the recommendation [2–8]. CIM is an evolving term, for the purposes of this paper it is used broadly and refers to traditional, complementary and alternative medicine used in isolation or integrated with Western biomedicine.

A minimum dataset (MDS) is an agreed core set of data. Generally, these data are then collected in a standardised way from

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one or many sources and over time. Common uses of a MDS by healthcare-related organisations encompass research, surveillance, health service monitoring, and evaluating clinical outcomes and quality of healthcare [9]. A recent CIM example was the use of healthcare registries in Sweden that compared mortality and drug prescription patterns of patients using anthroposophic integrative care and conventional care for pain and stress disorders [10].

The uses and complexity of datasets are increasing as more data are collected electronically. However, many datasets are still to reach their full potential for evaluating clinical outcomes and effectiveness and most do not measure many of the outcomes relevant to CIM [4,11]. For example, in the UK, the Clinical Practice Research Datalink extracts data from the primary care electronic health records (EHR) for linkage with other surveillance datasets [12]. The stated aim is to “support clinical innovation, strengthen evidence of effectiveness and improve health outcomes as well as safeguard public health and enable health services research” [13]. Patient reported outcomes that are important outcomes for CIM are not routinely collected, which will limit its usefulness in CIM effectiveness research. Furthermore, many CIM healthcare activities are not recorded.

The Patient Centered Outcomes Research Institute in the USA has recently set out to support clinical effectiveness research by establishing a national research network with the aim of linking data from health services and other sources, including patient advocacy groups [14]. Given the focus will by necessity remain on linking data that is relevant to the dominant biomedical health services, for the foreseeable future, it is unlikely the research network will collect data that can answer many of the CIM effectiveness research questions.

In Australia, the majority of primary care physicians and hospitals use EHRs [15]. However, the precise number is not known and there is no information available for CM practitioners. Similar to the UK and USA, data collection by Australian health services remains ad-hoc and uncoordinated, especially in primary care where there are less funding requirements to systematically collect and code data [15,16]. In 2012, the Australian Government launched the national personally controlled e-health records system. Deciding what data to include, who will enter and maintain the data, who will have access to the data and data security stand as serious operational questions [17]. SNOMED CT [18] is the coding system that will be used to standardise data collection from primary and secondary care health services, but it does not code for many CIM activities.

Patient generated datasets are increasingly perceived as an important source of health data. An example is the website ‘Patients-like-me’ that is a forum where people enter data about their demographics, health profile, treatments and outcomes. Members can share personal experiences with others who have the same diagnosis, track their personal data over time and review longitudinal aggregate data [19]. A novel use of the data was an algorithm matched case-control effectiveness study investigating the outcomes of an off-label use of a prescription medication [20]. The dataset aims to collect detailed information about the use of pharmaceutical medications and biomedical interventions. This is achieved by providing drop down menus that enable patients to easily enter this data. In contrast, the majority of CIM therapies and interventions must be manually entered. The website has also started using standardised PRO questionnaires that patients use to track their progress and compare themselves to others.

The potential applications of a purpose built CIM-MDS include monitoring CIM use, safety and acceptability and evaluating CIM outcomes. A CIM-MDS could also help reduce the costs of research projects and promote multi-centre research. Observational studies that use longitudinal data will obviously benefit from the use of a CIM-MDS that could include quasi-experimental designs such as

comparative studies of matched pairs sourced from the longitudinal data [21]. The observational data could also be used to flag potentially effective therapeutic approaches for further evaluation using more rigorous study designs and identify potential safety issues.

Evaluating CIM is challenging because the interventions and outcomes are complex, broad and context-specific [22]. Mixed methods, comparative effectiveness research, observational outcomes research and whole systems research are recommended CIM methods [21,23–26]. All of these approaches would benefit from accessing data collected through a CIM-MDS.

Comparative effectiveness research (CER) is enjoying new popularity, especially in the US where a wide range of experimental study designs are proposed. CER based in primary care practice has also been recommended for CIM research [27]. The clinically integrated randomised trial is an example of the CER approach that aims both to measure effectiveness and enhance the generalisability of the results [28]. It uses data already collected by a health service dataset. No extra information is collected from the participating patients, so any PROs must be collected as a part of routine clinical care. This method helps to ensure that the experience of treatment allocation and observation for those in the trial and for their treating practitioners are similar to those not participating in the trial. The main inclusion criteria are the practitioner is uncertain about which therapy would be best for their patient and there is no preference for one therapy over another. A therapy is then randomly allocated to the pre-consented patient. Ideally, the patient and practitioner are blinded. IM would be well suited to this approach to research because often there are a variety of management options from which practitioners can choose and limited information about their comparative effectiveness.

Large datasets offer other possibilities for data analysis that are congruent with the philosophy of CIM. Advances in computing power and inferential statistics have the potential to analyse the complexity of CIM in a much more holistic way that is individualised, patient-centred and multidimensional. Multilevel analysis (MLA) can be used to explore how the different levels of patient, therapies, practitioners, clinical settings, and social and geographical circumstances interact to influence patient outcomes. MLA reduces the risk of generating misleading results from statistical and conceptual errors that can occur when data from different levels are analysed on the same level [29]. Aickins proposes similar statistical methods for use in CIM comparative research that aim to deal with the statistical challenges of analysing consecutive measurements and multiple outcome variables. Called Participant-Centered Analysis, these methods can be used to analyse within-patient data to provide valid information about individual patient outcomes [30].

The intended uses of CIM-MDS will govern the types of data needed. If CER was an intended use of the CIM-MDS, then the data collected would need to include some information about patient demographics and medical history, the therapies and services used by patients, and objective and subjective patient outcomes. For multilevel analysis, contextual information about practitioners, health services and geographic location would be needed. Example of the types of data that could be collected by a CIM-MDS for research purposes is presented in Table 1.

Patient data could come directly from patients answering questionnaires and indirectly from health services EHRs, personal e-health records and practitioner questionnaires. Patient and practitioner questionnaires could also be used to obtain data about participating practitioners and clinics. Geographical, social and health information could be sourced from health and social service agencies and even private health insurers; it could include census data, population surveys and information about health services.

**Table 1**  
Examples of the types of data for an integrative medicine minimum dataset.

<b>Patient demographics</b>		
Unique identifier code/s	Sex	Current occupation
Home address	Marital status/household	Annual Income
Date of Birth	Ethnicity	Education
<b>Patient medical history</b>		
Current problem list/diagnosis	Allergies/adverse reactions	Lifestyle and risk factors
History of current problems	Past history	
<b>Patient management</b>		
Disease therapies	Practitioner types and dates of consultations	Costs to patient, healthcare services and third parties
Wellness therapies	Other self-care activities	
Medications (including TCAM)		
<b>Patient outcomes</b>		
Illness and wellness outcomes	Objective outcomes from practitioner evaluation, clinical examination, investigation results	Subjective patient reported outcomes from patient questionnaires
Multiple dimensions/holistic health outcomes		
<b>Practitioner characteristics</b>		
Practitioner demographics, training, expertise, years of clinical experience	Therapeutic techniques used Specialty interests Attitudes about healing and health services	Patient feedback e.g. trust in physician, consultation quality
<b>Clinic and health service characteristics</b>		
Location	Practitioners and description of IM team	Patient feedback e.g. satisfaction with services
Business structure	Services provided, speciality interests	
Years in operation		
<b>Geographical and social characteristics</b>		
Socioeconomic	Urban, suburban, rural	Health, health service & social policies
Healthcare services	Industry, pollution	
Wellbeing index [13]	Environment, weather	

Similar to the Canadian Index of Wellbeing, a population index of wellbeing could be generated to summarise geographical and social characteristics [31].

It is worth noting however that CIM in Australia and internationally is mostly practiced in the private healthcare setting, with little or no funding from health insurers. Therefore, support from the users and providers of CIM will be essential for establishing and maintaining a CIM-MDS. Along with determining the purpose of the dataset and thus the data to be collected by a CIM-MDS, it will be important to find ways for participating patients, practitioners and clinics to directly benefit.

## 2. Method

Given the potential opportunities and challenges with collecting meaningful data for use in a CIM-MDS, a body of research was undertaken to begin exploring these issues. Human research ethics approval was obtained from the relevant committees before undertaking the research. The methods and results are reported in detail elsewhere [2–8]. The purpose of this paper is to apply the findings from this research to the question of establishing a CIM-MDS in Australia.

An approach similar to the methodology recommended for systems research in health services and health policy was used [32]. First, the topic of interest was identified, which in this instance was how best to proceed with establishing a CIM-MDS in Australia. This was followed by a review of the literature, including white papers and policy documents.

A case study of an IM primary care clinic in Sydney, Australia where data for a CIM-MDS might be sourced was then conducted [5,7]. Relevant to establishing a CIM-MDS, the case study reviewed the quality of the electronic health records and technical issues for data extraction. Preliminary results of the case study were in line with the previously reported limitations of data extraction from Australian primary care clinics [15]. The decision was then made to focus on other data sources for the dataset, in particular, patient reported outcomes (PROs).

Semi-structured interviews were then conducted to explore patient and staff views about outcomes important for an IM clinic to measure; their concept of wellness that is more than the absence of disease; their motivation to answer or encourage patients to

answer ongoing PRO questionnaires; and logistical and ethical considerations for using paper versus electronic questionnaires [2,4,6,8]. Information was also gathered to compare the response rates, logistics and costs of postal and email patient invitations [6]. The feasibility of sourcing and using the other types of data listed in Table 1 were not explored.

A systematic literature review was also undertaken to identify and appraise potentially suitable patient questionnaires [3]. A few of the questionnaires shortlisted from the literature review had been used as examples for patients and practitioners to refer to during the interviews. However, no further evaluation was done to assess the suitability of many of the shortlisted questionnaires in the CIM primary care setting and their potential role in a CIM-MDS.

## 3. Results

The following is a summary of the results from this body of research that are directly relevant to the question of establishing an Australian CIM-MDS and the role of PRO questionnaires.

### 3.1. Potential data sources for a CIM-MDS

*CIM clinic data sources.* A crucial early result was the significant limitations with automated data extraction from the EHRs in the clinic [5]. Only basic information such as patient demographics and the number of consultations and with whom, could be reliably extracted. Less reliable data included information about biomedical diagnosis and past history; height, weight, blood pressure; and prescribed pharmaceuticals. Regarding over-the-counter medications (including herbs and nutritional supplements), much of the data was missing if the product was self-prescribed, or often it was entered in the free text rather than the medication list. Other clinical information was either unreliable due to inconsistencies in data entry, or unable to be extracted using automated data queries. Coding for items such as the reason for consultation, diagnosis and medical history was inconsistent and there were many non-standardised entries, especially for CIM activities. Therefore, if detailed information is to be collected from CIM clinics such as this, mostly it would need to be manually extracted and coded.

Other important findings from the case study and subsequent interviews with the practitioners that might negatively impact on

establishing a CIM-MDS were conditional support that assumed minimum interruption to clinical activities from collecting data, a lack of research culture, discontent with the reductionist scientific approach, undertones of dissatisfaction with medical dominance and scepticism that positive results from CIM research will impact healthcare policy [7,8].

*Patient data sources.* An alternative to clinical records is to collect data about inputs and outcomes directly from patients. Results from the semi-structured interviews found that only some patients would be willing to provide data solely for the purpose of research or to improve service provision in the clinic [8]. Many wanted to benefit from accessing their individual results so they would be able to monitor and track personal outcomes. Others saw value in providing the treating practitioners with their individual results to help improve clinical care. This was also seen as an efficient way to collect large amounts of background information before a patient's first consultation with a practitioner and to monitor progress.

Similar to the patients interviewed, many of the practitioners were also interested in the clinical utility of knowing their individual patient results [8]. Some practitioners stated they were already using mental health PRO questionnaires to confirm a clinical diagnosis, measure severity and monitor treatment outcomes. Concerns were raised however about the logistical, ethical and medico-legal implications of accessing individual patient results [4,8].

The format of the patient questionnaires was considered important and would also affect uptake. Many patients stated they would prefer electronic formats and email invitations were found to be a cost effective first line strategy for communicating with patients [6]. However, email addresses were missing for a third of the adult patients registered with the clinic, in particular males and older patients. Some patients from both younger and older age groups stated that they preferred to answer paper questionnaires. Also, there was a high risk of being perceived as 'spamming' patients with frequent requests to answer questionnaires. Patients expected any electronic questionnaires to be user friendly with a slick design that is compatible with multiple electronic devices.

### 3.2. Potential patient questionnaires for use in a CIM-MDS

*Patient and practitioner views.* When asked about the types of outcomes a CIM clinic should evaluate, many patients and practitioners thought all the health and health-related domains were important to measure [4]. However, some felt very strongly that topics such as spirituality and to a lesser extent life-satisfaction should be excluded from measurement because for example, they were outside the scope of a CIM clinic or it was not included in their definition of health. Conversely, others thought these domains were essential to measure and helped differentiate CIM healthcare outcomes from the mainstream biomedical services.

Conflicting views were also expressed about the validity of reducing responder burden by dividing the domains and staggering the questionnaires to be answered at different times. Some commended the idea as a practical way to reduce responder burden. Others thought it would prevent a holistic assessment that should be made based on all information at one time. Patient views varied widely in regard to acceptable length and frequency of questionnaires and whether they preferred open or closed and anonymous or confidential questions.

*Literature review.* A systematic literature review of patient reported outcome (PRO) questionnaires was undertaken to identify valid and useful questionnaires that measured disease and wellness outcomes; proxy-health outcomes such as lifestyle,

risk factors, disease prevention and health promotion activities; and health service quality [3]. The results of the interviews were used to inform the final selection process [2,4]. Pre-existing PRO databases were first searched, followed by individual searches for under-represented topics that were relevant to CIM. Over 4000 PRO questionnaires were identified, from which 71 were recommended for further testing in the CIM setting.

## 4. Discussion

The results from the summary of earlier research presented in this paper offer insights about data collection options for an Australian CIM-MDS. Given the significant limitations of extracting data from CIM clinics and practitioners, the recommendation is to begin building a dataset that sources data directly from patients and includes standardised questionnaires measuring PROs. PROs are important because they are congruent with the patient-centred philosophy of CIM; they are able to measure a broad range of holistic health outcomes, including quality of life; and they are now considered the gold standard for common presentations in CIM such as pain and fatigue symptoms and digestive and musculoskeletal problems. Furthermore, both the patients and practitioners interviewed saw various benefits from patients answering standardised PRO questionnaires. Developing an electronic platform to measure PROs will be challenging and for the time being, to help maximise participation rates, paper questionnaires should be offered as an alternative. Table 2 presents an outline of a SWOT analysis that appraises the strengths, weaknesses, opportunities and threats of establishing a CIM-MDS in Australia. A bottom-up approach is recommended to help engage patients, practitioners, clinics and researchers to support the development of a CIM-MDS.

The intended uses of the dataset and the logistics of collecting the data will dictate the content of the CIM-MDS. For example, less data is required for relatively simple activities such as a CIM-MDS that measures basic CIM use and severe adverse reactions. If however, an aim of the dataset is for effectiveness research comparing different therapeutic interventions, then a lot more information about patient characteristics, their CIM management and health outcomes would be needed. In this instance, much of the data, including the results of patient reported outcomes (PROs), would need to be routinely collected and entered into the patient's clinical records. For such an endeavour to be sustainable, the data will also need to be clinically useful.

If data cannot be readily obtained from CIM practitioners and clinics about inputs and outcomes, then a patient questionnaire would need to be tailor-made to obtain information about their demographics and medical history. Irrespective of whether clinical data can be collected from CIM practitioners and clinics, standardised questionnaires are the only way to measure PROs. Potential PRO questionnaires need to be tested to ascertain their psychometric properties in the CIM primary care setting, their responsiveness to change as an outcome measure and the clinical relevance of the results. Simply choosing PRO questionnaires that are already known to the researchers or in common use, runs the risk of generating false negative results because the questionnaires may be unable to measure relevant changes in health status in the CIM population group under study [33].

As was highlighted by the interviews with patients and practitioners, it will be challenging to find ways to minimise responder burden whilst making an in-depth, holistic assessment. In some instances it may be possible to use screening questions. For example, before administering a comprehensive pain questionnaire, a screening question could be used to determine if the patient is experiencing pain. Results from the patient interviews highlighted that some patients will appreciate a detailed approach

**Table 2**  
SWOT analysis of an Australian CIM-MDS.

Strengths	Weaknesses
<ul style="list-style-type: none"> <li>• A large proportion of Australians use CIM and there are many IM and CM practitioners and clinics.</li> <li>• The relatively small population makes widespread involvement of providers and users of CIM logistically feasible.</li> <li>• Many CIM practitioners have national registration, others can be contacted via CIM organisations.</li> <li>• Herbs and supplements are listed as therapeutic goods on a national database.</li> <li>• Personally controlled e-Health records are being implemented in Australia.</li> <li>• Most public hospitals and primary care clinics use EHR.</li> <li>• There are excellent public health research skills in Australia and growing capacity and funding for CIM research.</li> <li>• A CIM-MDS could be useful to CIM patients, practitioners, academics, health service providers and policy makers.</li> <li>• A bottom-up approach that is patient-centred is congruent with the development and philosophy of CIM.</li> </ul>	<ul style="list-style-type: none"> <li>• CIM research continues to remain relatively underfunded in Australia.</li> <li>• An Australian CIM research group is yet to take the lead on developing a CIM-MDS.</li> <li>• There is poor co-ordination and communication between the different CIM professional and academic groups.</li> <li>• A lot of data will have to be purposively collected from CIM users and providers.</li> <li>• Its success is dependent on bottom-up support from CIM users, practitioners and clinics, which may conflict with any top-down initiatives and funding.</li> <li>• Collecting, standardising and harmonizing data will be very difficult and challenging across the different CIM sectors.</li> <li>• There is no standardised coding for CIM.</li> <li>• Much CIM activity cannot be tracked through Medicare and private health insurance data.</li> <li>• Building websites to collect data electronically is costly, time consuming and requires considerable expertise. So too is collecting data using paper questionnaires.</li> </ul>
Opportunities	Threats
<ul style="list-style-type: none"> <li>• There is national support from the National Institute of Complementary Medicine to establish a CIM-MDS in Australia.</li> <li>• It would be the first national database to systematically collect longitudinal data specifically focusing on CIM use and outcomes.</li> <li>• Its proposal is timely, which may create more support and funding opportunities.</li> <li>• It would provide important data for CIM outcomes research and a platform for more cost-effective CIM research in Australia.</li> <li>• CIM professional groups could use the data to help build their much needed Australian evidence base.</li> <li>• There is the opportunity for cross discipline, multicenter national and international collaborations.</li> </ul>	<ul style="list-style-type: none"> <li>• Priorities and interest of funding bodies may remain focused on mainstream biomedical data and research.</li> <li>• Methodologies for observational effectiveness research are still being developed and are yet to be accepted by much of the mainstream scientific and medical community, as legitimate alternatives to RCTs</li> <li>• Copyright and other legal issues regarding data ownership, data collection methods and confidentiality may hamper the CIM-MDS development and sustainability.</li> <li>• The ever changing technological landscape creates perpetual challenges for developing acceptable, high-tech user interfaces from which to collect and harmonise data.</li> </ul>

and accept the extra responder burden. These patients could be recruited to answer longer sets of questions that could be used to create a shorter questionnaire where the absolute minimum number of questions are asked whilst still maintaining the overall validity, reliability and usefulness of the dataset [34].

The chosen PRO questionnaires should complement those already in use by other CIM datasets such as The People Reported Outcomes from Complementary, Alternative and Integrative Medicine (PROCAIM) and the recently registered observational multicentre study in the USA, Patients Receiving Integrative Medicine Interventions Effectiveness Registry (PRIMER) [35–37].

Both patients and practitioners expressed a range of views about the potential utility of individual patient results and cohort results from PRO questionnaires. This question however was hypothetical and will need to be re-examined in the real-life setting. If individual results from PRO questionnaires are to be forwarded to the patient's treating practitioners, then this information should be clinically meaningful. The logistic and medico-legal implications of providing individual results to patients and practitioners requires further consideration and consultation with relevant stakeholders.

Postal invitations and paper questionnaire formats should be used as an alternative to electronic formats to optimise patient participation. However, uptake of electronic questionnaires might be improved if they provide extra utility to participants compared to the paper format. For example, a CIM-MDS website could provide immediate feedback of results, compare these results with the aggregate results from other participants or population norms and offer the opportunity to chat and share experiences anonymously with other like-minded people. The latter also offers interesting ways to collect and analyse qualitative data from the patient perspective [38].

A potentially viable alternate that was not explored, is for practitioners and clinics actively and purposively to provide data about themselves, their patients and clinical activities. For example, consultation data could be obtained using a similar approach to the Australian BEACH study that uses a one-page data extraction form. General medical practitioners complete the form for 100 consecutive consultations [39]. Contextual information about practitioners for use in multi-level analysis, could be obtained from questionnaires such as the Integrative Medicine Attitude Questionnaire [40] or a questionnaire measuring a practitioner's patient-centredness [41].

Finally, regardless of the chosen data sources and content, the issue of coding CIM requires urgent attention. Standardised coding is needed to enhance the comparability of data collection and presentation [9]. The World Health Organisations (WHO) Family of International Classifications includes work to standardise the terminologies used in traditional medicine in the Western Pacific region (TRM) [42,43]. However, there are many other CIM terminologies and concepts (including wellness) that are not adequately covered by any existing coding systems.

Coding CIM will require careful consideration and research. Svensson-Ranallo et al. propose "a bottom-up, multi-modal approach" to developing the content and coding for a MDS. This involves reviewing both the literature to ensure the dataset is comprehensive and patients' medical records to identify other clinical constructs and terminology that may not be reported in the literature [9]. The next step is to harmonise the data from different sources and create codes for different terminology used to describe similar concepts. Experts are involved and consulted throughout the process. Methodologies such as focus groups and the Delphi technique can be used to facilitate and formally document the process. It should build on preceding research such as the European Delphi process used to identify a core list of CIM

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## **CHAPTER 12: DISCUSSION & CONCLUSION**

This chapter offers an appraisal and discussion of aspects of the research that were not presented in the discussion sections of the published papers. The chapter concludes with recommendations for the use PRO questionnaires when evaluating IM primary care in Australia.

### **12.1 INTRODUCTION**

It is hoped that the work presented in this thesis will be used to inform future research in the field of IM primary care and help ensure that the evidence supporting its use is *up to scratch*. Many of the challenges with conducting IM primary care research are the same as with any health services research, hence the publication of some of the papers from this thesis in mainstream health rather than TCAM and IM journals.

As demonstrated in this thesis, mixed method is appropriate for health services research. By taking an holistic, multidisciplinary approach new insights were gained about the wide range of factors that need to be considered when using PRO questionnaires to evaluate IM primary care. The main disadvantage of this approach was that each factor was not always thoroughly investigated.

The research presented in this thesis splits into three parts each using different methods. It includes a case study of an IM primary care clinic, interviews with patients and practitioners in the clinic and a systematic literature review. The results yielded much data that was further allocated to seven papers for publication. The final paper (Chapter 11)

aimed to synthesise the research to form a set of recommendations for establishing an IM minimum dataset (IM-MDS) in Australia.

Rather than presenting this research as a thesis by publication, the other option was to use the standard classical format for a scientific thesis with only one literature review, methods, results and discussion. However, given the research covered a wide range of topics and used different methodologies, the decision was made to present the papers as individual chapters. This enabled the results pertaining to each topic to be reported and discussed in a logical and cohesive manner.

## **12.2 APPRAISAL & DISCUSSION OF THE CASE STUDY**

This case study was reported in the first paper to be published in a peer review journal about an Australian IM primary care clinic. The use of Donabedian's model for health service evaluation<sup>1</sup> ensured that even with limited data the *structure, process and outcome* were considered.

The results from the quantitative and qualitative data blended well. Many of the conclusions drawn from the analysis would not have been possible if only one method had been used. For example, although the first author had written and analysed the staff questionnaire and the second author was already familiar with the results, until they were reviewed in the context of the other data available about the clinic, neither had fully appreciated there was an issue with biomedical dominance in the clinic. The quantitative data affirmed that for the clinic to be financially viable, the IM team needed a large proportion of biomedical doctors. The qualitative data provided insights into why this



might be so and the tensions that biomedical dominance was generating within the IM team.

For pragmatic reasons, only pre-existing data were used. Purposively-collected quantitative data, for example, about referral patterns within and from outside the clinic, would have been useful to provide more information about the IM team and how patients and practitioners are using the IM primary care services. Interviews with the practitioners and patients from the clinic could have further explored biomedical dominance; why there was greater patient demand for biomedical doctors; the style of medicine practitioners are aiming to provide and patients are seeking; and to what extent this was being achieved by working in, or attending, the clinic.

Another potential limitation of the case study was that the main investigators were also biomedical doctors working in the clinic. The potential for bias was high, especially regarding the interpretation of results from the staff questionnaire and results that may have borne negatively upon the clinic. However, this makes it more likely for example, that *biomedical dominance* was understated rather than overstated. Advantages of including these investigators included the ability to access confidential information such as financial data and clinical records; and unwritten information about the history of the clinic and its surrounding geography was already known.

The case study provided the opportunity to review the clinic before undertaking a research program. In doing so, many factors relevant to ensuring the success of a research program were identified. Of note were the limitations identified with data extraction from the clinic's electronic health records; appreciating that like many primary care and TCAM

clinics, the majority of the staff and practitioners had little experience with participating in research; and the importance of using a bottom-up approach to ensure wide practitioner support.

Consultation with practitioners was pertinent, because any discontent with medical dominance in the clinic may adversely affect practitioner support for further research proposed in this thesis. That this thesis focuses on the use PRO questionnaires to evaluate the clinic to some extent reflects the structural embeddedness of biomedical dominance by the researchers<sup>2</sup> and the preferred *evidence-based medicine* methods that favour clinical trials and quantitative data over qualitative methods. In choosing this approach, practitioners in the clinic who are less indoctrinated by modern scientific methods for generating evidence may feel further marginalised. Deng et al. reiterate this point in their discussion on the context and priorities for IM research. The authors emphasise the importance of measuring outcomes relevant to IM and involving patients and practitioners to tailor and develop research models that reflect the philosophies of IM and the style of medicine practiced.<sup>3</sup>

### **12.3 APPRAISAL OF PATIENT & PRACTITIONER INTERVIEWS**

Although the response rate of patients volunteering for an interview was low, there were more than enough people to use a stratified random sampling technique. This method was used to ensure that a diverse range of patients were selected for interview. Further sampling and interviewing of patients was planned if data saturation was not reached after the first round of interviews. However, aside from the last set of questions about their conceptions of health that is more than the absence of disease, all the key points were discussed by more than one person and no new themes had emerged following the last 16

interviews with patients. Regarding this last part of the interview, although data saturation was not reached, further interviewing was not done because it was an exploratory question that was added on as a pilot study. Nevertheless, the data arising from this pilot study was rich enough to warrant its publication.

Many topics were covered in the interviews. To some extent this limited the time that could be spent on each question, particularly the last question about the concept of 'health that is more than the absence of disease'. The format of the semi-structured interview was designed to allow the sequence of the questions and topics to be changed. This enabled the conversation to flow naturally and provided the opportunity for the interviewee to talk more about a particular question or topic that was important to him or her. The presence of a second interviewer was invaluable to this end because it helped to ensure that all the topics were discussed by the end of the interview. It also meant that an iterative analysis could begin immediately following each interview, which in turn influenced the subsequent interviews.

Although none of the interviewees objected to the presence of a second researcher, some may have felt obliged as a result of the second interviewer's presence to express support for the proposed research. For example, when an interviewee did express scepticism about research or the use of patient questionnaires it was often said apologetically. Consequently it is reasonable to assume that the presence of a second interviewer may have biased some of the results.

## **12.4 THE USE OF ELECTRONIC FORMATS**

Some patients, both young and old, expressed a strong preference in the interviews for paper questionnaire. For the time being, if maximum participation is important, paper-based formats should not be abandoned. The use of electronic questionnaires will continue to grow. The PROMeasure<sup>4</sup> database that lists verified electronic questionnaires and the PROMIS<sup>5</sup> item bank of PRO questions that uses computerised adaptive testing for electronic use, will be important resources to this end.

Electronic formats pose their own unique challenges.<sup>6-13</sup> Of growing importance in the last few years is the rapid uptake of computer tablets and smart phones. This will add to the technical challenges of providing electronic questionnaires that can be easily answered on multiple devices with different operating systems.

In a multicentre pilot study of IM clinics, where only electronic PRO questionnaires were administered, the authors suggested the poor response rate was due to limited study resources.<sup>14</sup> However, the findings from this series of interviews and other research in the field, suggests that only offering an electronic format may have contributed to suboptimal participation.<sup>15-19</sup> The research group has recently registered a larger study with the U.S. National Institutes of Health Clinical Trials using a similar longitudinal observational cohort study design. They have continued to only offer an electronic format and are now drawing most of their questions from the PROMIS item bank.<sup>20</sup> Before any further IM research is undertaken in Australia, it will be important to review the participation rates and appropriateness of the outcome measures used in this study.

## **12.5 REPORTING INDIVIDUAL PATIENT RESULTS**

Along with selecting acceptable formats for the invitations and questionnaires, the intended use of the questionnaires will also influence support for and participation in the research. The results from this series of interviews confirmed that similar to genetic epidemiology research and clinical trials,<sup>21,22</sup> some participants will be motivated to participate if they can benefit directly from accessing their individual results. Similarly, not all practitioners will encourage their patients to participate for research purposes only. Some will be more concerned with using their patients' individual results to inform clinical care.

The logistical, medico-legal and ethical considerations about how best to provide patients and practitioners with individual patient results were not explored in detail. However, it was clear from the interviews that consent should be obtained at each sitting before the results are forwarded on to their treating practitioners. Some epidemiological surveys are beginning to provide individual results to participants and a variety of protocols have been employed.<sup>23-27</sup> The implications of providing patients and practitioners with individual PRO results are complex and will need to be addressed through wide consultation before proceeding to apply them

## **12.6 INTEGRATIVE MEDICINE PRIMARY CARE OUTCOMES**

There is little point however, in optimising patient participation if the questionnaires are not appropriate to the clinical setting. It was for this reason that a lot of the time was dedicated to reviewing the literature and listening to the views of patients and practitioners in the clinic about measuring IM outcomes.

One factor that influenced an interviewee's opinions about which domains were important for an IM clinic to measure, was his or her preconceptions of the term 'holistic health'.

Words such as holistic and holism are often used in association with TCAM and IM.<sup>28-30</sup>

It was for this reason the concept was introduced as a warm-up question. The question also ended up offering useful insight about the interviewee's preconceptions of disease, health and healing. This was further elucidated when he or she were asked about which health domains an IM clinic should be expected to address and his or her conceptual understanding of health that is greater than the absence of disease.

From this series of questions, whether or not to include spirituality in IM outcome measurement was emphasised. The interviewees expressed different definitions of the term 'spirituality' and not everyone included it in their definition of holistic health. Even when spirituality was included in the interviewees' definition of holistic health, strong and opposing views were still expressed about whether IM practitioners should attend to the spiritual needs of their patients and whether spirituality should be included in IM outcome measurement.

These findings mirror the different conceptual understandings that people from different cultures have about the relationship of spirituality to health, the wider debate about whether spirituality is an aspect of health and the ongoing discussions about the role of healthcare organisations to assess and provide spiritual care.<sup>31-37</sup> Positive associations have been observed between a person's religiousness and spirituality and their health. However, the reasons are not fully understood. For example, belonging to a religious group may bring positive health benefits from better social support. Religious or spiritual beliefs may

enhance emotional resilience and coping or increase life satisfaction.<sup>38-43</sup> However, there may be esoteric aspects that cannot be explained by changes in mental health, social support or life satisfaction. Esoteric concepts such as Qui and Prana are features of Oriental medicine and philosophies. This energy or life force is considered to be inextricably linked with an individual's physical, emotional and cognitive health and the practice of these styles of medicine. Other traditional cultures also view spirituality as an integral part of a person's health.<sup>33</sup> The power of prayer to effect changes in health continues to be investigated by more industrialised cultures; although without convincing evidence to date.<sup>44</sup> The implications for IM evaluation of whether spirituality is an integral part of health warrants further research and discussion.

Notwithstanding the different opinions expressed about spirituality and holistic health, there was consensus that a wide range of topics and health domains were important for an IM clinic to address and therefore measure. There is a high risk that in attempting to measure performance across so many domains there will be unacceptable responder. Widely disparate views were expressed in the interviews about what constitutes an acceptable number of questions and the preferred frequency of questionnaires. This raises the question of how to engage those who are willing only to answer brief infrequent questionnaires, whilst satisfying those who consider a more detailed approach to be necessary. One solution might be to first engage those willing to accept greater responder burden to answer a large number of questions. These results could then be used to develop robust shorter sets of questionnaires and generate algorithms for computerised adaptive modelling.

## **12.7 FINDING APPROPRIATE PATIENT QUESTIONNAIRES**

Identifying and appraising PRO questionnaires was painstakingly laborious. The final shortlist presents a broad range of questionnaires covering topics relevant to IM primary care. The methodology had limitations, in particular using only one reviewer and relying on pre-existing PRO databases and the accuracy of their content.

The shortlist was not intended as definitive and it is likely that some potentially appropriate questionnaires were missed or excluded from the final shortlist. For example, the recently-registered observational study of nine IM clinics in the USA is using the questionnaire called the Patient Activation Measure (PAM).<sup>20,45</sup> The questionnaire aims to assess changes in skills, knowledge, beliefs, and motivations of patients as they become more or less 'active' in their own healthcare. Although well tested and published, the questionnaire was not listed on any of the web-based PRO databases, nor was it found using the search strategies.

The results from the interviews helped ensure that the shortlisted questionnaires covered the relevant domains when evaluating IM primary care. They were also used when evaluating the content validity of the questionnaires. Adding the final question about conceptions of health that is more than the absence of disease was particularly useful for evaluating the content validity of the wellness questionnaires.

The results of this literature review could be used to expand the two key databases listing PRO questionnaires – PROQOLID and IN-CAM. Both failed to list many of the questionnaires relevant to IM. The IN-CAM database of questionnaires designed specifically for the TCAM research community did not include health promotion, lifestyle



and risk factors.<sup>46</sup> PROQOLID emphasises quality of life questionnaires, yet it did not list any questionnaires designed to measure positive notions of health beyond the absence of disease.<sup>47</sup>

## **12.8 CONCEPTUALISING WELLNESS**

Although the question about an interviewee's notion of health that is more than the absence of disease was an addendum after the interviewing had commenced, it was often the most engaging and interesting aspect of the interviews and their analysis. The paucity of research on this topic requires urgent attention. Positive aspects of health and wellness are difficult for many people to conceptualise, but until this concept is elucidated within the wider community, it will be difficult to establish effective *health* interventions and policies and the focus will remain on the treatment of disease and disease prevention.

## **12.9 RESEARCH SUMMARY**

Based on the findings presented in this thesis, an integrative medicine minimum dataset is recommended for systematically collecting data about IM primary care outcomes in Australia. Given the challenges facing data collection for research purposes in IM primary care, the recommendation is to start collecting data directly from patients using questionnaires rather than to trying to extract reliable, useful data directly from IM primary care clinics. The obvious advantage to this approach is the data generated would be immediately useful for IM outcomes research. It could also generate cohort and individual patient data that clinics, practitioners and patients could use for other purposes.

The research presented in this thesis provided contextual information about an IM clinic where such a dataset might be used, systematically selected potentially appropriate patient questionnaires and identified ways to engage patients and practitioners to use questionnaires belonging to a longitudinal dataset. Many other areas however were not addressed or require further in-depth exploration.

When undertaking research in IM primary care, the following points should be taken into consideration.

1. A lack of research capacity in IM primary care clinics may negatively impact on support for the project. It is important to ensure that the staff and practitioners understand the research protocol and adequate resources are available to provide extra logistical support should it be needed.
2. Potential distrust by IM and TCAM practitioners of the academic research process, including scepticism that significant results will be translated in to real changes in healthcare practice and policy, may also limit support. Clear strategies for disseminating the findings to the wider community must be developed and communicated to participating staff and practitioners.
3. Not all practitioners will be motivated to support research for altruistic reasons such as improving academic knowledge for the benefit of society. Some practitioners will want to benefit directly by using summary cohort data to inform and improve their own clinical practice and the clinic's services. Others will be more interested in accessing their patients' individual results to inform clinical care.
4. Points 1, 2 and 3 affirm the importance of taking a bottom-up approach when developing a research program in an IM clinic. Simply obtaining support from the

directors of the clinic may not be enough to ensure practitioner support, especially if there are undertones of dissatisfaction with medical dominance within the clinic. Involving practitioners early on in the project's development may help improve a sense of ownership and support for the project and can help ensure the chosen methods are appropriate.

5. Data from the clinic's software and medical records should be pilot tested before incorporating them into any research design.
6. Both electronic and postal formats for invitations and surveys are needed to optimise patient participation in research. Electronic methods of communication are potentially more time efficient and cost effective; however, other methods such as postal, face-to-face or telephone should be used for non-responders.
7. To help improve patient response rates, the acceptability of electronic questionnaires and to minimise responder burden, study designs should refer to the specific information summarised in Chapter 6: Tables 1, 3, and 4; and Chapter 7 (Supplementary document) Tables 4 and 5.
8. The recruitment strategies and study design need to address the three types of motivators for participating in or supporting research. Both individual and cohort results should be available. This strategy will provide the opportunity for individual patients and practitioners, participating clinics and the wider community to benefit from the results.
9. Incorporating PRO questionnaires into routine clinical care has many potential advantages:
  - i. individual patient results can be used for patient feedback and to improve clinical care;

- ii. patients with unusual or exceptional outcomes can be flagged for case studies;
  - iii. the outcomes of different practitioners, therapies, and clinics can be compared;
  - iv. it can be used for comparative effectiveness research because it more closely reflects real life; and
  - v. it can help reduce the marginal costs of research.
10. Ongoing consultation with participating clinics, practitioners and patients is needed if the results of patient questionnaires are to be incorporated into routine clinical practice. Careful attention must be given to the logistical, medico-legal and ethical implications of patients and practitioners accessing individual patient results.
11. The content, length and frequency of questionnaires will also affect response rates and acceptability. Ideally, study designs intending to use PRO questionnaires for IM evaluation should find ways to address the different preferences that potential participants are likely to have.
12. A broad range of health, health-related and health-services outcomes are relevant to IM primary care. A balance must be found between the need to make a comprehensive holistic assessment and minimising responder burden.
13. A holistic assessment should be done in such a way as not to marginalise those who consider spirituality in particular, but also other domains such as life satisfaction, to be inappropriate content for evaluating IM primary care.
14. Many of the questionnaires shortlisted in Chapter 10 require further testing in the IM primary care setting before recommending their use. This includes confirming compatibility between paper and electronic formats of questionnaires.

15. More work is needed to clarify the concept of health that is more than the absence of disease and to establish valid measurements of health and wellness outcomes.
16. Along with patient-reported outcomes, patient data could also include results from clinical examinations, anthropometric tests and pathology reports. Which data to include and data extraction requires further exploration.
17. Questionnaires designed to measure quasi-health outcomes such as risk factors, lifestyle and natural therapy use are needed for the IM setting.
18. A minimum dataset is a useful way to standardise data collection across IM primary care clinics and support multicentre collaborative research.
19. Given the challenges with extracting data from IM clinics for research purposes, a pragmatic way to begin collecting longitudinal data for use in a minimum dataset would be to engage patients to answer PRO questionnaires. These data could be used immediately for much-needed research.
20. The dataset could be expanded over time to electronically link this data with other relevant data from clinical records, practitioners and other on-line wellness applications.
21. Ideally the development of a dataset should be done through international collaboration and potentially build on the work already underway in the USA with the PROCAIM projects.<sup>14,48</sup> Valuable lessons can also be learnt from the ongoing success of patient generated websites such as Patients-Like-Me<sup>49</sup> and other health and wellness sites.
22. Consultation with all stakeholders is necessary at every stage of the process to ensure the successful collection of data from PRO questionnaires; determine its relevance to routine clinical care and research; and the logistics for linking this data with other data sources.

23. The next steps are:

- i. to pilot test the shortlisted patient questionnaires in both paper and electronic formats and evaluate their acceptability, psychometric properties and clinical relevance.
- ii. identify and compare the minimum dataset requirements of different stakeholders – patients, clinicians, clinics and researchers.
- iii. undertake an indepth inquiry into the logistics, ethics, governance of an IM-MDS and its linkage with other data sources.

## **12.10 FINAL CONCLUDING REMARKS**

There is an urgent need to evaluate IM outcomes in the primary care setting. Effectiveness research and observational study designs will often be more appropriate than the standard randomised controlled trials that is typically used to evaluate the efficacy of specific interventions. Questionnaires measuring patient-reported outcomes can provide useful data about the many outcomes relevant to integrative medicine. It offers the opportunity to collect longitudinal data that can be used for multiple purposes and thus meet the needs of patients, practitioners, health services, the wider academic community and health policy makers.

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# APPENDIX I: CASE STUDY: STAFF QUESTIONNAIRE

## STAFF QUESTIONNAIRE



## Team Questionnaire

The purpose of this anonymous questionnaire is for all of us to have an opportunity to stop and think about Uclinic and voice your opinions about the practice of Integrative Medicine.

The responses will be presented along with further discussion at the next clinic meeting on Tuesday 25 November.

Before answering the questionnaire please read the attached article written by Dr Jennifer Hunter: “Establishing an Integrative Practice” and Boon et al: “From Parallel practice to Integrative Health Care”

You can fill this form out by hand or type it in Word and then print it at put it in

**DrJen’s Pigeon Hole or fax: 93407570**

### References

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(The questionnaire layout has been condensed to save paper)

1. Please write about the top 3 issues you would like to see addressed.

2. When considering your own clinical practice, do you use a patient centered model of care? (see diagram p24 Hunter)

Always --- Often --- Sometimes --- Ocassionally --- Never

Comments:

3. When considering your Uclinic colleagues, do they use a patient centered model of care? (see diagram p24 Hunter)

Always --- Often --- Sometimes --- Ocassionally --- Never

Comments:

4. When considering the patient's experience at Uclinic, do you think they experience a patient centered model of care? (see diagram p24 Hunter)

Always --- Often --- Sometimes --- Ocassionally --- Never

Comments:

5. What type of healthcare is most commonly practiced at Uclinic? (see Boon Table 1 and Figure 1 for definitions)

1. Parallel    2. Consultative    3. Collaborative    4. Coordinated

5. Multidisciplinary    6. Interdisciplinary    7. Integrative

Comments:

6. Uclinic has strong effective leadership.

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

7. Uclinic's CEO and administrators are open-minded.

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

8. The staff and practitioners at Uclinic are open-minded.

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

9. The practitioners at Uclinic provide highly competent mainstream medicine services.

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

10. The practitioners at Uclinic provide highly competent complementary medicine services.

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

11. Uclinic has exactly the right fit of practitioners. – circle or delete

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

12. Uclinic has exactly the right fit of administrative staff. – circle or delete

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

13. Uclinic has effective communication channels between practitioners. – circle or delete

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

14. Uclinic facilitates effective cross-referrals between practitioners. – circle or delete

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

15. Uclinic facilitates effective team building between practitioners.

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

16. There is a lot of trust between Uclinic practitioners.

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

17. The physical environment of Uclinic is appropriate.

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

18. Uclinic is matching the unique needs of its community.

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

19. Uclinic is matching market needs in the community. – circle or delete

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

20. I am clear about Uclinic’s Mission Statement and Objectives. – circle or delete

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

21. Uclinic has effective branding and marketing. – circle or delete

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

22. Administrators, practitioners and staff all share a united vision. – circle or delete

Strongly Disagree --- Disagree --- Neutral --- Agree --- Strongly Agree

Comments:

23. What is your vision for Uclinic?

Finally, is there anything else you would like to add?

*THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE.*



## SLIDE PRESENTATION OF RESULTS FOR DISCUSSION IN STAFF MEETING

### INTRODUCTION

#### Establishing an Integrative Practice

- Published Journal Complementary Medicine
- Peer Reviewed?
- Reviewed literature
- How does this compare to what Uclinic is doing?
- What do the practitioners and administrators at Uclinic think we are doing?
- Created a questionnaire based on the key points

#### What is an Integrative Medicine?

The term Integrative Medicine (IM) is often loosely used to describe some sort of bringing together of biomedicine and TCAM.

“The practice of medicine that reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, healthcare professionals and disciplines to achieve optimal health and healing”

Consortium of Academic Health Centers for Integrative Medicine

## What is an IM clinic?

- More than just housing different therapies & practitioners under the one roof
- Boon's continuum of 7 styles of Health Care Practice.
- Tendency for orthodox medicine to dominate
- When doctors also use TCAM then there is more integration and sharing control of patient's care
- Who should be in charge? The patient or the practitioner? If it's the practitioner then which one?

## Success factors for IM clinics

- Open-mindedness of administrators and an open-minded culture within the institution /clinic
- Credible "champions" to conceive, advocate and manifest the IM clinic
- High competency of TCAM and biomedical health care practitioners
- Finding the right fit of practitioners and staff
- Effective communication and trust between practitioners
- Appropriate physical space to house the clinic
- Economically sustainable environment
- Ability to match the unique needs of the community and market

## Purpose of questionnaire

- Find out what everyone really thinks (anonymously)
- Encourage everyone to consider what an Integrative Medicine clinic is, are we practicing it, do we want to be practicing it, what else do we need to do?
- The results to be used to generate further discussion and positive action within Uclinic.
- Compare results to a repeat questionnaire in a year.

### METHOD

## Content of questionnaire?

- Directly relates to key issues in the literature (mostly from health sociologists)
- Combination open ended and Likert Scaled questions.
- Short length - 24 questions
  
- **TIME LINE:** November / December 2008
- **RESPONSE:** 15 people; 2 managers, 13 practitioner

## **RESULTS**

### **Q1. Please write about the top 3 issues you would like to see addressed.**

- General comments: good, overall quite happy
- Building: air-conditioning, herbal dispensary
- Administration: training & support reception
- Team building: improve integration of practitioners
- Patient management: resolution of conflicts, medico-legal accountability, case conferences, treatment protocols, gaps service provision

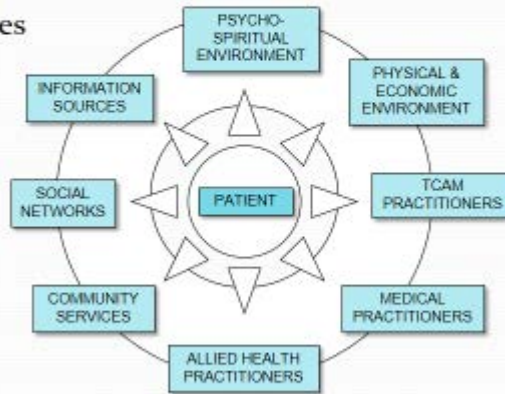
### **Q1. Please write about the top 3 issues you would like to see addressed (CONT).**

- Customer service: follow-up, patient satisfaction
- Marketing & Vision: publicize vision statement, tools for practitioner's marketing and building their practice, clear strategy for the future.
- Business: financial and business model? Commission on products.

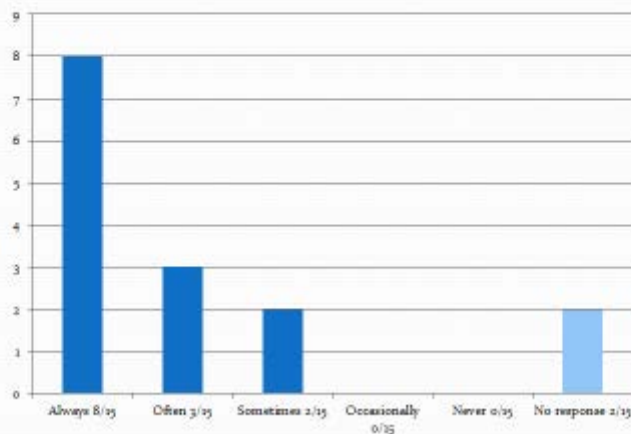
## Q2. When considering your own clinical practice, do you use a patient centered model of care?

Patient-centred encompasses bio-psycho-socio-spiritual dimensions

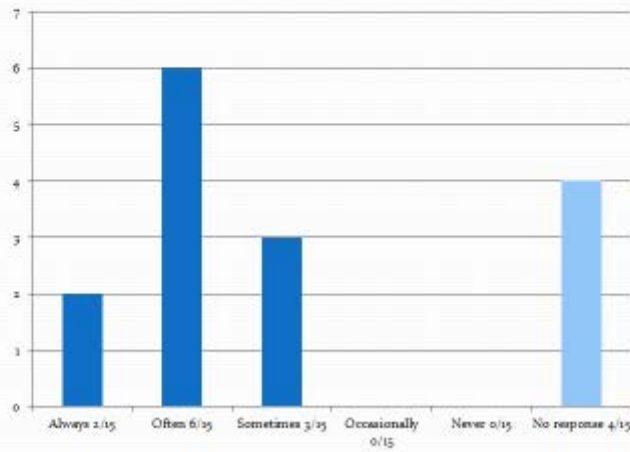
Focuses on the patient, their access to resources, helps them reach self-defined goals for health and wellbeing.



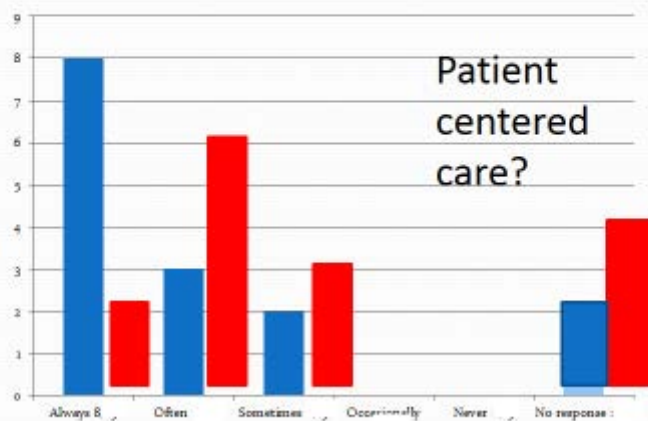
## Q2. When considering your own clinical practice, do you use a patient centered model of care?



Q3. When considering your Uclinic colleagues', do they use a patient centered model of care?



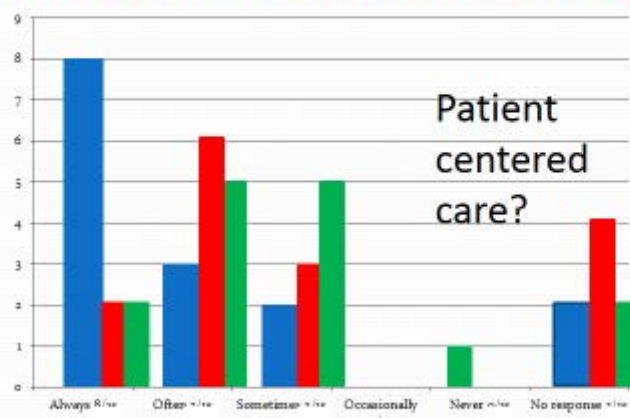
My practice compared with how I think other's practice



## Comments – Q1 & 2

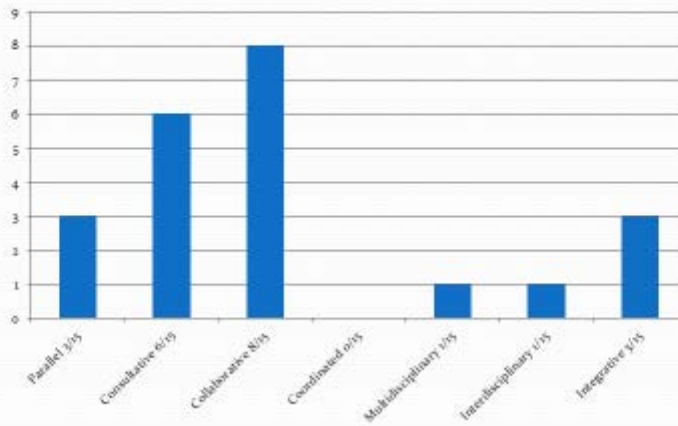
- The patient centre care model is in alignment with the philosophy taught and now practiced.
- Is patient centered care always appropriate?
- Why is there a discrepancy between how we view our own practice verses other practitioners?
  - Big egos?
  - Unfamiliar with other practitioners?
  - Poorly constructed question?

### My practice compared with how I think other's practice and what patient's experience



Are we now doubting if patients experience what we intend to practice?

### Q5) What type of healthcare is most commonly practiced at Uclinic?

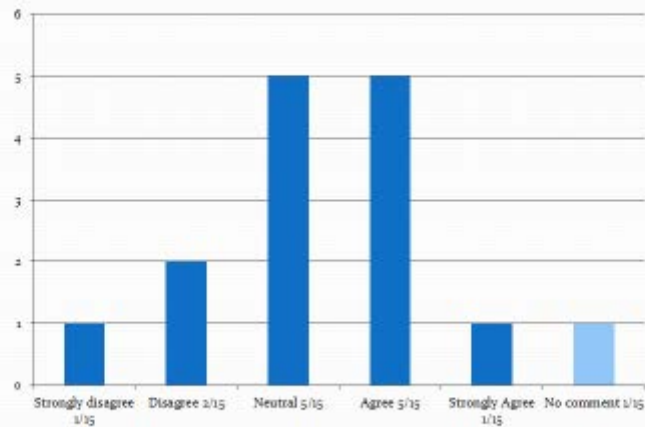


### Healthcare practice at Uclinic?

- What style of healthcare do you practice?  
When & why?
- What style/s of healthcare does Uclinic aim for?
- Is there a one size fits all IM approach?
- Are all the styles appropriate and if so when?
- Is this a question we want to formally explore?



## Q6) UClinic has strong effective leadership



3

5

6

## “Leadership comes in many forms”

- Is it one person or many?
- What is the vision?
- Where are we being lead?
- How can Uclinic’s leadership be more effective?

## Next 4 questions +ve agreement

Q7) Uclinic's CEO and administrators are open-minded

Q8) The staff and practitioners at UClinic are open-minded.

Q9) The practitioners at UClinic provide highly competent mainstream medicine services.

Q10) The practitioners at UClinic provide highly competent complementary medicine services.

## MIXED VIEWS NEXT QUESTIONS

Q11) UClinic has exactly the right fit of practitioners.

- "we are getting there"
- Gaps in service provision

Q12) UClinic has exactly the right fit of administrative staff.

- Concern over high turnover rate
- Seems better now

## MIXED VIEWS NEXT QUESTIONS

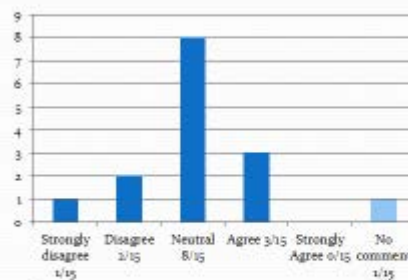
Q13) Uclinic has effective communication channels between practitioners.

- Shared records - “We still all tend to practice in isolation, and see what others are doing by way of notes.”
- Emails, MSM, case conferences.
- Challenges of practitioners working different days

Q12) Uclinic facilitates effective cross-referrals between practitioners.

- 2 disagreed, 3 neutral, but 7 negative comments?
- Room for improvement especially if intend to practice integrative medicine.

Q15) Uclinic facilitates effective team building between practitioners.



### Suggestions:

- Staff / Practitioners meetings
- Case presentations and discussion
- Workshops
- Less focus on doctor's needs and perspectives

## Next 2 questions +ve agreement

Q16) There is a lot of trust between UClinic practitioners.

- We trust each other even though we don't think others are as good at providing patient centered care ;)

Q17) The physical environment of UClinic is appropriate.

- Room temperature control; OHS in dispensary; atmosphere of sterility vs warmth

## 18) UClinic is matching the unique needs of its community.

- Who is the community we are serving?
- Not just the local demographic?
- What are the needs of the community?

“I think we are ahead of our time. The patients who seek us out are looking for what we provide. I think the community needs our model of health care but they don't know it yet.”

### 19) UClinic is matching market needs in the community.

- “Matching market needs in 'a' community - not necessarily the local.”
- “I think the unique selling point at Uclinic is the exceptional skills of the practitioners”
- “If we were (matching market needs), we'd be busier.”
- “There are groups of people in the community who want a special type of health care, and we appeal to that group. Others want a quick cheap or “free” service and it is currently not possible for us to match that market need.”

### MIXED VIEWS NEXT QUESTIONS

Q20) I am clear about UClinic’s Mission Statement and Objectives.

“Do we have one? Where is it?”

Q21) UClinic has effective branding and marketing.

What works? Word of mouth? Effort and money?

Q22) Administrators, practitioners and staff all share a united vision.

The results speak for themselves  
“everyone is not on the same page”

## Q23 What is your vision for UClinic?

aka Mission Statement

Quite a few comments - please see report

### DISCUSSION

## Questions to consider?

- Uclinic's Mission Statement / Vision
- What type of healthcare do we want to provide
- What is the best fit of practitioners & staff
- Build teamwork, communication, confidence
- Create healthy business
- Who is this for? Us? The patients? Both?

## **APPENDIX II: INTERVIEW SCHEDULES**

### **PATIENT INTERVIEW PROMPTS**

#### **DEFINING HOLISTIC HEALTH**

##### **Questions:**

Are you familiar with the term holistic health?

What does holistic health mean to you?

#### **MEASURING HOLISTIC HEALTH**

##### **Context:**

We want to use some questionnaires to measure the holistic health of Uclinic patients.

We found over 2000 patient questionnaires and shortlisted 30 or so of the best. There was no one perfect questionnaire and none of them measures everything. Therefore, we would need to choose from a selection of them to cover all the areas of holistic health.

We have categorised the questions from these questionnaires into the following topics / areas:

(show examples of shortlisted questionnaire for prompts and clarification)

1. Physical health –physical symptoms, disabilities and impact on daily living.
2. Mental health – emotions, mood, stress, sleep and impact on daily living
3. Coping with illness and life's challenges
4. Spirituality – more than a belief in God or religiousness, it includes a sense of purpose in life and engagement with spiritual activities, feelings of connection beyond mundane reality.

5. Lifestyle – exercise, diet, alcohol, smoking, drugs, work hours, relaxation, sleep.
6. Life satisfaction – with health, life, relationships, friends, family, work, standard of living.
7. Holistic –total wellbeing of body, mind and spirit, and other areas such as feeling part of the community and future security.
8. Attitudes towards complementary medicine and philosophy of healing
9. Consultation/clinic – satisfaction, trust in practitioner, quality of consultation
10. Individualised – open questions where the patient chooses what the main problems are and then rates whether they are improving.
11. Change in Medication and/or Supplement Use

**Questions:**

What do you think about answering questions on these areas /topics?

Are any or all of these areas /topics relevant to you now?

Have they been relevant in the past?

Might they be relevant to you in the future?

What about for other patients attending Uclinic?

Where there any important areas /topics that was missing or underrepresented in the shortlist?

**SCOPE OF IM CLINIC**

**Context / Question:**

Measuring holistic health is a very broad concept. Do you think it is reasonable to expect that an integrative medicine clinic or holistic health practitioners should be able to help patients improve all the different aspects of holistic health?



## **RESPONDER BURDEN**

### **Context / Question:**

If we accept that we would need to find a balance between asking all the questions that are important (i.e. comprehensive information) and the time it would take to answer them all (i.e. responder burden), which areas /topics do you think are the most important and least important to measure?

### **Question:**

Can you think of any ways to help reduce the time spent answering questionnaires?

### **Prompt:**

What about: reducing the number of questions or topics, can you think of any ways to help reduce responder burden?

Or: Different questionnaires sent at different times?

Or: Use skip questions to only ask more detailed questions about a topic if the initial screening questions identify a problem.

Any other ideas?

## **OPINIONS ABOUT QUESTIONNAIRES**

We would now like to ask you some questions about the use of questionnaires in general.

### **Questions:**

Can you see any value or use for questionnaires?

What would motivate you to want to answer questionnaires?

Can you see any personal benefit from answering questionnaires?

Can you see yourself and/or other patients at Uclinic completing these questionnaires?

Would you want to know the results?

Would you want your practitioners to be notified of your results?

Would you want the results to be recorded in your computerised clinical notes at Uclinic?

## **USING THE INTERNET TO ANSWER QUESTIONNAIRES**

### **Context:**

We are particularly interested in using the Internet. Imagine if after agreeing to participate, you would be sent email prompts to go on-line and log in to answer one or more questionnaires.

### **Questions:**

Would you feel comfortable doing something like this?

Would you be concerned about confidentiality?

Would you be concerned about being spammed or sent too many emails?

Would you be concerned about computer errors or technical difficulties?

Are any other questions or comments you may have?

## **WELLNESS QUESTIONS**

### **Context:**

25yrs ago the WHO said health is more than just the absence of disease and sickness. Most of the questionnaires are designed to measure changes in health from very sick to no disease. Few aim to measure this concept of health that is more than the absence of disease.

### **Questions:**

How would you describe health that is beyond just the absence of disease?

What does it mean to you?

### **Prompt:**

Think about someone you know that is really healthy.

What characteristics would a person have, what areas or aspects would you see change in a person if they were moving from 'no disease' to 'really well and really healthy'?

What types of questions might we need to ask people to measure this concept in a questionnaire?

## **PRACTITIONER INTERVIEW PROMPTS**

### **DEFINING HOLISTIC HEALTH**

#### **Questions:**

Are you familiar with the term holistic health?

What does holistic health mean to you?

### **MEASURING HOLISTIC HEALTH**

#### **Context:**

We want to use some questionnaires to measure the holistic health of Uclinic patients.

We found over 2000 patient questionnaires and shortlisted 30 or so of the best. There was no one perfect questionnaire and none of them measures everything. Therefore, we would need to choose from a selection of them to cover all the areas of holistic health.

We have categorised the questions from these questionnaires into the following topics / areas:

(show examples of shortlisted questionnaire for prompts and clarification)

1. Physical health –physical symptoms, disabilities and impact on daily living.
2. Mental health – emotions, mood, stress, sleep and impact on daily living
3. Coping with illness and life's challenges
4. Spirituality – more than a belief in God or religiousness, it includes a sense of purpose in life and engagement with spiritual activities, feelings of connection beyond mundane reality.
5. Lifestyle – exercise, diet, alcohol, smoking, drugs, work hours, relaxation, sleep.

6. Life satisfaction – with health, life, relationships, friends, family, work, standard of living.
7. Holistic –total wellbeing of body, mind and spirit, and other areas such as feeling part of the community and future security.
8. Attitudes towards complementary medicine and philosophy of healing
9. Consultation/clinic – satisfaction, trust in practitioner, quality of consultation
10. Individualised – open questions where the patient chooses what the main problems are and then rates whether they are improving.
11. Change in Medication and/or Supplement Use

What do you think about measuring these areas /topics?

Are there any important areas /topics relevant to your patients that are missing or underrepresented in the shortlist?

## **SCOPE OF IM CLINIC**

### **Context / Question:**

Measuring holistic health is a very broad concept. Do you think it is reasonable to expect that an integrative medicine clinic or holistic health practitioners should be able to help patients improve all the different aspects of holistic health?

## **RESPONDER BURDEN**

### **Context / Question:**

If we accept that we would need to find a balance between asking all the questions that are important (i.e. comprehensive information) and the time it would take to answer them all

(i.e. responder burden), which areas /topics do you think are the most important and least important to measure?

**Question:**

Can you think of any ways to help reduce the time spent answering questionnaires?

**Prompt:**

What about: reducing the number of questions or topics, can you think of any ways to help reduce responder burden?

Or: Different questionnaires sent at different times?

Or: Use skip questions to only ask more detailed questions about a topic if the initial screening questions identify a problem.

Any other ideas?

**OPINIONS ABOUT QUESTIONNAIRES**

We would now like to ask you some questions about the use of questionnaires in general.

**Questions:**

What do you think about the use of patient questionnaires?

Can you see any value or use for questionnaires?

Would you want to know the individual patient results and/or summary results?

Would you want the patient's results to be available in their computerised clinical notes?

Would you want to be notified of your patient's results?

Would you be likely to prompt or encourage your patients to complete questionnaires?

Do you think your Uclinic patients would be interested in completing questionnaires?

What might be the reasons they would not want to complete a questionnaire?

Are there any ways you envisage individual patient results and/or overall results of the practice being useful to your clinical practice?

Are any other questions or comments you may have?

## **WELLNESS QUESTIONS**

### **Context:**

25yrs ago the WHO said health is more than just the absence of disease and sickness. Most of the questionnaires are designed to measure changes in health from very sick to no disease. Few aim to measure this concept of health that is more than the absence of disease.

### **Questions:**

How would you describe health that is beyond just the absence of disease?

What does it mean to you?

### **Prompt:**

Think about someone you know or a patient that is really healthy.

What characteristics would a person have, what areas or aspects would you see change in a person if they were moving from 'no disease' to 'really well and really healthy'?

What types of questions might we need to ask people to measure this concept in a questionnaire?

## APPENDIX III: LETTERS OF ACCEPTANCE FOR PUBLICATION

Hunter J, Corcoran K, Phelps K, Leeder S. The Challenges of Establishing an Integrative Medicine Primary Care Clinic in Sydney, Australia. J Altern Complement Med. 2012;18(11):1008-13. Epub 2012/08/29. doi:10.1089/acm.2011.0392.

18-Nov-2011

Dear Dr. Hunter:

We are pleased to accept your manuscript entitled "The challenges of establishing an integrative medicine primary care clinic in Sydney, Australia - a case study." for publication in Journal of Alternative and Complementary Medicine. Your paper is tentatively scheduled for publication in our September 2012 issue.

Please be sure to cite this article to ensure maximum exposure of your work.

You will receive page proofs electronically approximately one month prior to publication from Jason Schappert ([jschappert@liebertpub.com](mailto:jschappert@liebertpub.com)) and may receive additional correspondence related to production from Ms. Billie Spaight ([BSpaight@liebertpub.com](mailto:BSpaight@liebertpub.com)). Please add these as well as [MCanning@liebertpub.com](mailto:MCanning@liebertpub.com) and [RGordon@liebertpub.com](mailto:RGordon@liebertpub.com) to your address book so correspondence from them is not caught in your spam filter.

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Thank you for your contribution. On behalf of the Editors of Journal of Alternative and Complementary Medicine, we look forward to your continued contributions to the Journal.

Sincerely,

Barbara Perrin

Journal of Alternative and Complementary Medicine Editorial Office [JACM-editorial@sbcglobal.net](mailto:JACM-editorial@sbcglobal.net)

Hunter J, Corcoran K, Phelps K, Leeder S. The integrative medicine team - is biomedical dominance inevitable? J Altern Complement Med. 2012;18(12):1127-32. Epub 2012/12/04. doi:10.1089/acm.2011.0393.

16-Dec-2011

Dear Dr. Hunter:

We are pleased to accept your manuscript entitled "The integrative medicine team - is medical dominance inevitable?" for publication in Journal of Alternative and Complementary Medicine. Your paper is tentatively scheduled for publication in our November 2012 issue.

Please be sure to cite this article to ensure maximum exposure of your work.

You will receive page proofs electronically approximately one month prior to publication from Jason Schappert ([jschappert@liebertpub.com](mailto:jschappert@liebertpub.com)) and may receive additional correspondence related to production from Ms. Billie Spaight ([BSpaight@liebertpub.com](mailto:BSpaight@liebertpub.com)). Please add these as well as [MCanning@liebertpub.com](mailto:MCanning@liebertpub.com) and [RGordon@liebertpub.com](mailto:RGordon@liebertpub.com) to your address book so correspondence from them is not caught in your spam filter.

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Thank you for your contribution. On behalf of the Editors of Journal of Alternative and Complementary Medicine, we look forward to your continued contributions to the Journal.

Sincerely,

Barbara Perrin

Journal of Alternative and Complementary Medicine Editorial Office [JACM-editorial@sbcglobal.net](mailto:JACM-editorial@sbcglobal.net)

Hunter J, Corcoran K, Leeder S, Phelps K. Is it time to abandon paper? The use of emails and the Internet for health services research - a cost-effectiveness and qualitative study. J Eval Clin Pract. 2012. Epub 2012/05/30. doi:10.1111/j.1365-2753.2012.01864.x.

5 March 2012

Dr. Jennifer Hunter  
Menzies Centre for Health Policy, School of Public Health University of Sydney  
Sidney, Australia

Dear Dr. Hunter,

‘Is it time to abandon paper? The use of emails and the Internet for health services research – a cost effectiveness and qualitative study’

Thank you for your submission to the Journal of Evaluation in Clinical Practice.

Very fortuitously, your paper arrived just in time to be considered this morning by the Commissions Review Group which normally exercises the peer review function for invited works but which we also employ, where time allows, in the fast-tracking of unsolicited manuscripts as a journal efficiency measure.

I am pleased to tell you that the Group had no criticism of your paper and on the basis of its advice I am happy to confirm acceptance of your article for publication in the Journal of Evaluation in Clinical Practice.

Where papers extend beyond 7 proofed pages, JECP will levy a charge of £60 GBP per extra page. You would then have the following options:

- Remove/edit content from your proof in order to make it 7pp or less.
- Pay excess page charges when the article is published in an issue of the journal.

The JECP offers an OnlineOpen service to authors. Please visit

<https://onlinelibrary.wiley.com/onlineOpenOrder> for further details.

With kind regards

Yours sincerely

Professor Andrew Miles  
Professor of Clinical Epidemiology and Social Medicine/  
Editor-in-Chief, Journal of Evaluation in Clinical Practice

Hunter J, Corcoran K, Leeder S, Phelps K. Appealing to altruism is not enough: motivators for participating in health services research. *J Empir Res Hum Res Ethics*. 2012;7(3):84-90. doi:10.1525/jer.2012.7.3.86.**From:** Joan Sieber [<mailto:joan.sieber@sbcglobal.net>]

**Sent:** Monday, 14 May 2012 6:54 AM

**To:** [drjenniferhunter@yahoo.com.au](mailto:drjenniferhunter@yahoo.com.au)

**Subject:** Appealing to Altruism is Not Enough: Motivators for Participating in Health Services Research

Dear Dr. Hunter,

Thank you for your manuscript: *Appealing to Altruism is Not Enough: Motivators for Participating in Health Services Research*. You have undertaken to study a very important topic, and started on a path that I hope you and others continue to pursue. As detailed below, your research design is too flawed for the paper to be treated as a full report, but what you have done provides a valuable foundation for others to build upon.

I would be happy to publish a brief report, based on your paper, that provides a useful foundation for further research. The idea of a brief report is to introduce your topic, stating that you have done pilot research that can form a basis for further study. You have quite an excellent introduction (literature review) which can largely remain. Your results should be reported very briefly in the text of your paper, and the discussion and research agenda should be mostly taken up with discussion of the limitations of your pilot study, why further research would be important to do, and how further research on this topic might be conducted – the research agenda. Your meaty results, however biased they might be, are nevertheless important to outline very briefly in the article, and to include in more extensive form, in a supplementary online document.

A brief report should be just that -- brief. I am deliberately not providing a word limit because I want you to develop your brief report with the idea of making it as brief as possible without omitting detail that will make the paper inviting and engaging, but putting as much of the detail as feasible in the supplementary online document, which persons wishing to build on your data might access.

I hope that you decide to revise your paper to be a brief report or research agenda, with an accompanying supplementary online document. Please let me know your plans. If you think you could complete such a revision by May 25, it is possible that your brief report could be published in the July issue of JERHRE.

Again, thank you for your paper. I hope you will revise it into a brief report.

Best wishes,

Joan

Joan E. Sieber, PhD, Editor-in-Chief

*Journal of Empirical Research on Human Research Ethics (JERHRE)*

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[joan.sieber@csueastbay.edu](mailto:joan.sieber@csueastbay.edu)

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Hunter J, Corcoran K, Leeder S, Phelps K. Integrative medicine outcomes: What should we measure? *Comp Ther Clin Practice*. 2013;19(1):20-6. doi:10.1016/j.ctcp.2012.10.002.

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Sent: Thursday, 11 October 2012 12:26 AM  
To: [drjenniferhunter@yahoo.com.au](mailto:drjenniferhunter@yahoo.com.au)  
Subject: Your Submission

Ms. Ref. No.: CTCP-D-12-00072R1  
Title: Integrative medicine outcomes: what should we measure?  
Complementary Therapies in Clinical Practice

Dear Dr. Hunter,

I am pleased to inform you that your paper "Integrative medicine outcomes: what should we measure?" has been accepted for publication in *Complementary Therapies in Clinical Practice*.

Below are comments from the editor and reviewers.

Thank you for submitting your work to *Complementary Therapies in Clinical Practice*.

Yours sincerely,

Denise RankinBox  
Editor in Chief  
*Complementary Therapies in Clinical Practice*

Comments from the editors and reviewers:  
This paper is much improved and amendments and clarifications are accepted.

Hunter J, Leeder S. Patient questionnaires for use in the integrative medicine primary care setting – A systematic literature review. Eur J Integr Med. 2013; 5(3):194-216 doi: 10.1016/j.eujim.2013.02.0023

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Editorial Office EUJIM  
Sent: Friday, 1 February 2013 10:42 PM  
To: [drjenniferhunter@yahoo.com.au](mailto:drjenniferhunter@yahoo.com.au)  
Subject: Your Submission

Ms. Ref. No.: EUJIM-D-12-00199R3  
Title: Patient questionnaires for use in the integrative medicine primary care setting - a systematic literature review.  
European Journal of Integrative Medicine

Dear Dr. Jennifer Hunter,

I am pleased to inform you that your paper "Patient questionnaires for use in the integrative medicine primary care setting - a systematic literature review." has been accepted for publication in European Journal of Integrative Medicine.

Below are comments from the editor and reviewers.

Thank you for submitting your work to European Journal of Integrative Medicine.

Yours sincerely,

Prof. Nicola Robinson, PhD  
Editor-in-Chief  
European Journal of Integrative Medicine

Comments from the editors and reviewers:

IF 2010 = 1.200 ranking 13/20 in category Complementary and Integrative Medicine  
(c) Thomson Reuters Journal Citation Reports Science Edition (2010)



Hunter J, Marshall J, Leeder S, Corcoran K, Phelps K. A positive concept of health - interviews with patients and practitioners in an integrative medicine clinic. *Comp Ther Clin Practice*. 2013; published online 26 August 2013, doi: 10.1016/j.ctcp.2013.07.001

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[DRankinBox@compuserve.com](mailto:DRankinBox@compuserve.com)

Sent: Saturday, 20 July 2013 2:59 AM

To: [drjenniferhunter@yahoo.com.au](mailto:drjenniferhunter@yahoo.com.au)

Subject: Your Submission

Ms. Ref. No.: CTCP-D-13-00033R1

Title: A positive concept of health - interviews with patients and practitioners in an integrative medicine clinic.  
Complementary Therapies in Clinical Practice

Dear Dr Hunter,

I am pleased to inform you that your revised paper "A positive concept of health - interviews with patients and practitioners in an integrative medicine clinic." has been accepted for publication in *Complementary Therapies in Clinical Practice*.

We note that you have annotated the manuscript on line. This should not be an issue for the typesetters, however if there are any queries, they will contact you shortly. You will receive a proof copy for final checking. Please read this carefully in case any errors have occurred during the typesetting process.

When your paper is published on ScienceDirect, you want to make sure it gets the attention it deserves. To help you get your message across, Elsevier has developed a new, free service called AudioSlides: brief, webcast-style presentations that are shown (publicly available) next to your published article. This format gives you the opportunity to explain your research in your own words and attract interest. You will receive an invitation email to create an AudioSlides presentation shortly. For more information and examples, please visit <http://www.elsevier.com/audioslides>.

Thank you for submitting your work to *Complementary Therapies in Clinical Practice*.

Yours sincerely,

Denise Rankin-Box  
Editor in Chief  
*Complementary Therapies in Clinical Practice*

Comments from the editors and reviewers:

Thank you for amending the manuscript and for your considered changes.

Hunter J. Exploring the prospect of a complementary and integrative medicine database for use in the Australian primary care setting. *Advances in Integrative Medicine*.

2014;1(1):25-31 doi:10.1016/j.aimed.2013.08.001

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Advances in Integrative Medicine  
Sent: Wednesday, 14 August 2013 2:04 PM  
To: [drjenniferhunter@yahoo.com.au](mailto:drjenniferhunter@yahoo.com.au)  
Subject: Your Submission - AIMED-D-13-00003R2

Ms. Ref. No.: AIMED-D-13-00003R2  
Title: Exploring the prospect of a complementary and integrative medicine database for use in the Australian primary care setting.  
*Advances in Integrative Medicine*

Dear Dr. Jennifer Hunter,

I am pleased to inform you that your paper "Exploring the prospect of a complementary and integrative medicine database for use in the Australian primary care setting." has been accepted for publication in *Advances in Integrative Medicine*.

Below are comments from the editor and reviewers.

Thank you for submitting your work to *Advances in Integrative Medicine*.

Yours sincerely,

Adrienne Chai  
Editorial Office  
*Advances in Integrative Medicine*

Comments from the editor:

I believe that this submission has addressed the reviewer's comments appropriately and should be accepted for publication.

## STATEMENT OF CONTRIBUTION FROM CO-AUTHORS

*PROFESSOR STEPHEN LEEDER*

I, Professor Stephen Leeder, confirm my contribution towards this thesis and the published papers arising from this thesis was as follows. I directly supervised Jennifer Hunter's research, providing guidance throughout. I assisted with funding applications; provided feedback on the study design and human research ethic applications; and gave editorial input on this thesis and the papers I co-authored for publication.

Signature: 

Date: 3/4/13

*PROFESSOR KERRYN PHELPS*

I, Professor Kerryn Phelps, confirm my contribution towards this thesis and the published papers arising from this thesis was as follows. I assisted Jennifer Hunter with the National Institute of Complementary Medicine funding application; provided feedback on study design and analysis of the case study; and gave editorial input on the papers I co-authored for publication.

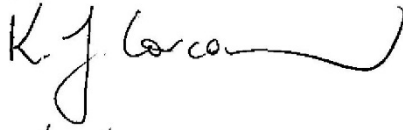
Signature: 

Date: 4/4/13

*KATHERINE CORCORAN*

I, Katherine Corcoran, confirm my contribution towards this thesis and the published papers arising from this thesis was as follows. I assistend Jennifer Hunter with developing the interview schedule and collecting and analysing the qualitative data. I gave editorial input on the papers I co-athored for publication.

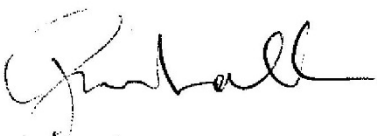
Signature:

Date:   
3/4/2013

*JACK MARSHALL*

I, Jack Marshall, confirm my contribution towards this thesis and the published papers arising from this thesis was as follows. I assistend Jennifer Hunter with the phenomenographical analysis of the qualitative data and gave editorial input on the paper I co-athored for publication.

Signature:

Date:   
3/4/2013