Complementary Medicines in Hospitals: a Focus on Surgical Patients and Safety

by

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December

2006

A thesis submitted in fulfilment of the requirements for the degree of
Doctor of Philosophy
School of Health Sciences
RMIT University
Victoria
Australia
Preface

DECLARATION

I certify that the work described in this thesis was carried out by the author alone within the School of Health Sciences, RMIT University under the supervision of Professor Marc Cohen. This thesis has not been submitted for a degree at any other university, in whole or in part. Full acknowledgement has been made where the work of others is cited or used and any editorial work by a third party has been acknowledged.

Lesley Anne Braun
18/12/06
ACKNOWLEDGEMENTS

I would like to thank the Director of Surgery at Cabrini Hospital Mr Gil Shardey, Director of Surgery at Frankston Hospital A/Prof Colin Russell, Director of Anaesthesia at the Alfred Hospital A/Prof Paul Myles, Director of Anaesthesia at the Austin Hospital A/Prof Larry McNicol, Director of Anaesthesia at Frankston Hospital Dr Terry Loughnan, Director of Pharmacy at Frankston Hospital Skim Lam, Director of Pharmacy at the Alfred Hospital John Barned, Director of Pharmacy at the Austin Hospital Kent Garrett, Director of Pharmacy at Cabrini Hospital Amanda Footit, and Director of Clinical Practice Improvement at Frankston Hospital Dr Gary Braun for participating in this research project, helping to improve the research design, encouraging staff participation in the surveys and data collection which was undertaken in their respective departments. I am grateful to the Director of Nursing Prof Sandra Legg at Cabrini Hospital and the Director of Clinical Practice Improvement at Frankston Hospital for providing staff to undertake data collection amongst surgical patients at their respective hospitals. Sarah Davison should also be acknowledged for help with data entry and Julie Sharp for data collection at Frankston Hospital.

I am also grateful to Mr Gil Shardey (secretary of the Australasian Society of Cardiac and Thoracic Surgeons) and Dr Michael Ben Meir for sharing their ideas. They both gave willingly of their time and were very informative on hospital practice issues. Thank you also, to the hospital doctors, pharmacists and surgical patients from the participating hospitals who took the time to complete the questionnaire.

In particular I would like to thank Professor Marc Cohen for encouraging me to undertake this research, providing guidance and motivation through to the completion of my dissertation and making the research process more enjoyable than I had anticipated. This project would not have been done and I would not be writing this dissertation if it were not for him.

Finally, my deepest gratitude is to my husband Gary for providing help and support on many levels during the last three years. From a professional perspective, his
advice, encouragement and critical appraisal of the research, lecture presentations, abstracts and dissertation drafts has been invaluable. From a practical perspective, his support within Frankston Hospital enabled the data collection process to be undertaken smoothly and excellent response rates to be achieved. From a personal perspective, his encouragement and belief in my ability to undertake and complete this work and make an important contribution towards improving patient wellbeing and safety has made a world of difference. His love and patience have seen me through.
Communications and publications during the period of candidature

*Those marked with an asterisk arose directly from conducting the research

Books


Book chapters


**Dictionary contributions**

Peer-reviewed journal articles


**Other journal articles**


Peer-reviewed conference proceedings

#This sign has been placed next to the citation where the accepted abstract was also delivered as an oral presentation.

Ref Type: Conference Abstract

Ref Type: Conference Abstract

Ref Type: Conference Abstract

Ref Type: Conference Abstract

63. *# Braun, L, Cohen, M, and Braun, G. Perceptions and Knowledge of Complementary Medicines within Hospital - Is Patient Safety Compromised?
RMIT School of Health Sciences. 2006. Melbourne, RMIT School of Health Sciences. 20-7-2006.
Ref Type: Conference Abstract

Ref Type: Conference Abstract

Ref Type: Conference Abstract

Ref Type: Conference Abstract

Ref Type: Conference Abstract

Other conference abstracts

# This sign has been placed next to the citation where the accepted abstract was also delivered as an oral presentation.

Ref Type: Abstract


Ref Type: Abstract

Guidelines


Published research posters


Conferences

2006

1. Braun, L. An Evidence Based look at popular Complementary Medicines for Use in Cardiovascular Disease. 12th International Holistic Health Conference, Queenstown, New Zealand; August 3-6, 2006

2. Braun, L. An Evidence Based review of Complementary Medicines Used for Menopause and Premenstrual Syndrome. Brisbane Women’s Health Update and Education Day, Brisbane, Australia July 22

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3. Braun, L. Drug-herb interactions. Pharmacy CE exhibition, (Reed exhibitions) Sydney, Australia; May 29

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2003

Invited lectures

2006
a. Braun, L. Pharmaceutical Society of Australia Continuing Education Series, South Australia; Full day workshop on - An Evidence Based Review of Complementary Medicines, Interactions and Safety
b. Braun, L. Pharmaceutical Society of Australia Continuing Education Series, Victoria; series of invited lectures on - An Evidence Based Review of Five Complementary Medicines, Interactions and Safety
c. Braun, L. An Evidence Based Review of Five Complementary Medicines, Interactions and Safety; Monash University Pharmacy College, Parkville; Final year undergraduate students
d. Braun, L. Drug-Herb Interactions. Monash University Pharmacy College, Parkville; Final year undergraduate students
e. Braun, L. An Evidence Based Review of Complementary Medicines, Interactions and Safety. Monash University Faculty of Medicine, Clayton; Second year undergraduate students
f. Braun, L. Drug-Herb Interactions and Complementary Medicines Safety, Monash University Faculty of Medicine, Clayton; Second year undergraduate students

2005
a. Braun, L. Eight invited lectures on - An Evidence Based Review of Five Complementary Medicines, Interactions and Safety; Pharmaceutical Society of Australia Continuing Education Series, Victoria
b. Braun, L. An Evidence Based Review of Five Complementary Medicines, Interactions and Safety; Monash University Pharmacy College; Final year undergraduate students
c. Braun, L. Drug-Herb Interactions; Monash University Pharmacy College; Final year undergraduate students
d. Braun, L. An Evidence Based Review of Two Complementary Medicines, Interactions and Safety; Monash University Faculty of Medicine; Second year undergraduate students
e. Braun, L. Drug-Herb Interactions and Complementary Medicines Safety. Monash University Faculty of Medicine; Second year undergraduate students
f. Braun, L. An Evidence Based Review of Five Complementary Medicines, Interactions and Safety; RMIT, School of Health Sciences, Chiropractic

g. Braun, L. An Evidence Based Review of Complementary Medicines, Interactions and Safety; Pharmaceutical Society of Australia Continuing Education Series, South Australia.

h. Braun, L. Complementary Medicines safety in pregnancy, surgery and drug interactions. Royal Women’s Hospital, Pharmacy Department

i. Braun, L. Drug-Herb Interactions. Mildura Base Hospital; Victorian Medical Post-graduate foundation

j. Braun, L. Drug-Herb Interactions. Stawell Base Hospital; Victorian Medical Post-graduate foundation

k. Braun, L. Drug-Herb Interactions. Traralgon Base Hospital; Victorian Medical Post-graduate foundation

l. Braun, L. An Evidence Based Review of Five Complementary Medicines, Interactions and Safety. Northern Division of General Practitioners, Melbourne; May 8

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2003

a. Braun, L. Pharmaceutical Society of Australia Continuing Education Series, Victoria; series of invited lectures on - An Evidence Based Review of Five Complementary Medicines, Interactions and Safety
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ABSTRACT

Aim
This study aimed to determine how CMs used by surgical patients are managed in the hospital system by doctors and pharmacists and what patient and practitioner influences affect this management.

Research design and method
Five systematic reviews were conducted to investigate the peer-reviewed literature for information about Australians use of CM; overseas and Australian doctors and CM; surgical patients use of CM and safety information about CMs in surgery as a basis to design and conduct three surveys. Surveys of hospital doctors, pharmacists and surgical patients were used to obtain measurement of people’s attitudes, perceptions, behaviours and usage of CMs. For healthcare practitioners, knowledge of complementary medicines (CMs), past training, current practice and interest in future practice of complementary therapies (CTs) and education was also investigated.

Results
Approximately 50% of surgical patients reported taking CMs in the 2 weeks prior to surgery and approximately 50% of these patients intended to continue use in hospital. The most commonly used CMs were: fish oil supplements, multivitamins, vitamin C and glucosamine supplements as well as some CMs considered to potentially increase bleeding risk or induce drug interactions. It was not uncommon for CMs to be used at the same time as prescription medicines.

Most surgical patients in general self-prescribe their CMs or have them recommended by family and friends whereas medical practitioners were the main prescribers to cardiac surgery patients. Nearly 60% of patients using CMs in the 2 weeks prior to admission did not tell hospital staff about use. The main reason for non-disclosure was not being asked about use whereas fear of a negative response was rarely a concern. The most common sources of information surgery patients refer to were GPs, pharmacists and health food stores. Hospital doctors and pharmacists did not routinely refer to information sources about CMs safety.
The majority of doctors and pharmacists did not routinely ask patients about CMs, or record usage information. They had little training and knowledge of the evidence of commonly used CMs and lacked confidence in dealing with CMs-related issues. Their attitude to CMs is moderately negative and many are wary of safety, efficacy and cost-effectiveness issues. The majority of practitioners considered some CTs as potentially useful, particularly acupuncture, massage and meditation whereas the medicinal CTs and chiropractic were considered potentially harmful. Most practitioners were interested in future education about CMs and CTs and some would consider practising CTs. Personal usage of CTs was low although there was substantial interest in receiving future treatment.

**Conclusion**

Despite many strategically orientated initiatives developed in Australia to promote evidence based medicine (EBM) and quality use of medicines (QUM), it appears that CMs have been largely ignored and overlooked in the practice of Medicine and Pharmacy within the hospital system. Furthermore, it appears that in regards to CMs a ‘don’t ask, don’t tell, don’t know’ culture exists within hospitals and that evidence based patient-centred care and concordance is not being achieved and potentially patient safety and wellbeing is being compromised.
Abbreviations and definitions

In this paper the term ‘complementary medicine’ or CM will be used instead of ‘complementary and alternative medicine’ or ‘CAM’ based on evidence that in practice it is generally used as an adjunct to conventional care and not as an alternative by patients.

Complementary therapies (CTs) is an umbrella term which will be used here to refer to the 5 key categories of treatment considered CM by the above definition in Australia.

- Mind-body practices e.g. meditation
- Medicinal treatments e.g. herbal medicine
- Manual treatments e.g. chiropractic, massage
- Bioenergetic treatments e.g. acupuncture
- Philosophical systems e.g. Ayurveda

Complementary medicines (CMs) or complementary medicine product: is defined as herbal medicines, nutritional and food supplements and homeopathic remedies available over-the-counter (OTC) from pharmacies, supermarkets, health food stores, through mail order companies, the internet and from practitioner and medical clinics.

Herbal medicines: refers to plant based medicines used for the prevention and treatment of disease. They may be presented in a variety of dose forms such as tablets
and capsules, liquids, powders or teas. In this report, common names of herbal medicines will generally be used.

**Nutritional supplements:** refers to products containing essential nutrients (vitamins and/or minerals) or organic compounds essential for health and maintaining body functions e.g. a multivitamin tablet.

**Food supplements:** refers to products which increase total dietary intake but are not conventional foods. These products may contain concentrated food extracts, for example soy, colostrum or whey protein, probiotics and sometimes contain additional vitamins, minerals, phytochemicals, amino acids, enzymes or herbs.

**Surgical patients:** refers to people who have been admitted to hospital to undergo a surgical procedure.

**Higher education** : refers to education of tertiary level and higher

**Higher income** : refers to an annual income of $Au 100,000 or higher

**Prevalence of CMs use** : The proportion of surveyed volunteers who used CM within the specified time period.

**Predictors of use** : The characteristics of people using the specified medicines or therapies.
Abbreviations

ADR – Adverse Drug Reaction
ADRAC - Adverse Drug Reactions Advisory Committee
AHA – Alternative Health Approach
CHD – Coronary Heart Disease
CMs – Complementary Medicines (refers to medicinal products only)
CTs – Complementary Therapies (refers to medicinal and non-medicinal approaches)
CVD – Cardiovascular Disease
CYP – Cytochrome
EBM – Evidence Based Medicine
EBPC – Evidence Based Patient Care
GMP – Good Manufacturing Practice
GP – General Practitioner
IM – Integrative Medicine
LFTS – Liver Function Tests
MI – Myocardial Infarction
NHMRC – National Health and Medical Research Council
OTC – Over The Counter
PCC – Patient Centred Care
P-gp – P glycoprotein
QUM – Quality Use of Medicines
TGA – Therapeutic Goods Administration
Overview of thesis

This research is a study of surgical inpatient’s attitudes, perceptions, use and behaviours regarding CMs. It is also a study of hospital doctors and pharmacists’ attitudes, perceptions, practices and knowledge of CM, with a focus on medication safety. The findings of this research will have implications for public health, the hospital system, health education and clinical practice.

A literature review of relevant information and research into CM, surgical patients, medical practitioners, pharmacists and safety is presented in Chapter One within four sections. This begins with Section A and a discussion of the introductory and background concepts relevant to this thesis. Section B presents information about the general population’s usage, attitudes, and perceptions about CM, with a systematic review of Australian studies. A second systematic review is presented of studies conducted overseas of medical practitioners and a third of Australian medical practitioners and their beliefs, referral patterns, knowledge, training and use of CM. Finally, a literature review of overseas and Australian studies of pharmacists and their beliefs, referral patterns, knowledge, training and use of CM is included. In section C, a systematic review of published studies regarding surgical patients use and attitudes to CM is included, with additional information about cardiac surgery patients. A review of the safety of OTC CMs will be presented in section D with a focus on drug interactions and safety issues of significance to surgery. This includes a systematic review of the published literature regarding CMs in surgery and presents a discussion of the limitation of the available information.

Chapter two will describe the patient and practitioner surveys research design, methodology and ethical issues. Research results and statistical analysis will be presented in Chapter three. A discussion of the survey results will be presented in Chapter four as six sections. The first three sections will discuss results from the three practitioner surveys, the next two sections will discuss the two patient survey results and the final section will provide a general discussion which integrates information obtained from all studies and further discusses the emerging themes. Chapter five
will present a summary of the research findings and conclusions. Recommendations to improve current practice and patient safety are also included in this chapter.
Chapter One

Section A
Introductory Concepts

A.1.0 Introduction

This section briefly illustrates some of the underlying concepts referred to in this thesis. It describes various definitions of complementary and alternative medicine and explores its evolution from the early 1990’s to current times. A discussion of evidence based medicine and its evolution to include a more patient centred focus is also explored with a focus on its relevance in CM. The section concludes with a discussion about the importance of investigating complementary medicines and their use in hospitals.
**A.2.0 What is Complementary and Alternative Medicine (CAM)?**

Defining the term ‘complementary and alternative medicine’ is a difficult task as no one definition is accepted globally. In part, this is due to the multidimensionality of the concept. In some cases, CAM has been defined by what it is not, rather than what it is and definitions fail to acknowledge the relative nature of the concept. In most cases, the definition is also based on comparisons with orthodox medicine. It is interesting to observe the rapid shift in terminology which has occurred over the last decade in response to the changes in attitudes and perceptions about CAM. Commonly cited definitions of CAM are provided in Table 1.
<table>
<thead>
<tr>
<th>Definition</th>
<th>Year of publication</th>
<th>Reference to interventions</th>
<th>Reference to healthcare systems</th>
<th>Reference to culture</th>
<th>Reference to time</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘interventions neither taught widely in medical schools nor generally available in US hospitals”</td>
<td>1993</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>‘Complementary and alternative medicine (CAM) is a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being’;</td>
<td>1997</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>‘a broad set of health care practises that are not readily integrated into the dominant health care model, because they pose challenges to diverse and societal beliefs and practices (cultural, scientific, medical and educational)”</td>
<td>1998</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>‘a group of therapeutic and diagnostic disciplines that exist largely outside the institutions where conventional healthcare is taught and provided” (4)</td>
<td>1999</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>‘Complementary and alternative medicine (CAM) is a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying</td>
<td>1999</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
theories and beliefs, other than those
intrinsic to the politically dominant
health system of a particular society or
culture in a given historical period. CAM
includes all such practices and ideas
self-defined by their users as preventing
or treating illness or promoting health
and well-being. Boundaries within CAM
and between the CAM domain and that
of the dominant system are not always
sharp or fixed.'

(4)

'diagnosis, treatment and/or prevention
which complements mainstream
medicine by contributing to a common
whole, satisfying a demand not met by
orthodoxy, or diversifying the
conceptual framework of medicine' (5)

Eisenberg et al offered their definition of ‘alternative medical therapies’ in 1993 as part of a survey they conducted of the general population (6). It is a functional definition that limits CAM to interventions only and makes no reference to the various paradigms it encompasses. This definition can now be considered obsolete in Europe and some countries such as the United States and Canada where many medical schools have begun to teach students CAM modalities and some hospitals offer CAM therapies.

The 1990’s were a period of accelerated growth and interest in the use of CAM therapies. They were characterised by more tolerance and willingness to co-operate by the medical establishment, largely as a result of growing patient demand for and substantial expenditure on CAM. As surveys indicated that CAM was being used alongside conventional medicine instead of as a true alternative, the term ‘alternative medicine’ started to appear too limited. By 1997, the Office of Alternative Medicine in the United States was renamed the National Center for Complementary and Alternative Medicine (NCCAM) which underscored this shift in emphasis (7).

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During this period, the National Institute of Health offered a much broader definition of CAM which acknowledged that CAM refers to more than treatment interventions but also includes various philosophical paradigms. It also acknowledged that the term CAM is relative to the setting of its use. As such, a treatment considered as CAM when practised within a specific time and culture may not be considered a CAM treatment when practised elsewhere or at a different time. Whilst being a much more comprehensive definition, it still does not provide a clear method of differentiating CAM practices from mainstream healthcare as it relies on the subjectivity of the individual. The definition currently used by the Cochrane Collaboration is essentially the same as the one developed by the NIH however it goes further by acknowledging the flexibility of what defines CAM.

In the British Medical Journal, Zollman and Vickers defined CAM in a similar way to Eisenberg et al however they also included diagnostic methods which are different to mainstream methods thereby acknowledging that CAM also refer to health systems, not just treatments (4).

The later definition developed by Ernst et al from the U.K. introduces the concept of CAM as being an adjunct to mainstream medicine as distinct from it being an alternative approach. This introduces the concept of ‘integrative medicine’ whereby both CAM and mainstream medicine are used together and is indicative of the changing usage patterns and attitudes to CAM.

As seen by these different definitions, the boundary between CAM and mainstream medicine is a fluid one and has been shifting over time as a result of societies move towards medical pluralism. There are numerous examples of where the line between CAM and conventional is already blurred such as:

- Acupuncture for pain control
- Stress management for anxiety
- Dietary manipulation for coronary heart disease
- Massage as practised in rehabilitation medicine
A.2.1 Integrative medicine (IM)

The term ‘integrative (or, sometimes, integrated) medicine’ describes a relatively recent development in CM. The NCCAM has defined integrative medicine as: health care that “combines mainstream medical therapies and CAM therapies for which there is some high-quality scientific evidence of safety and effectiveness.”(8). The integration of CM with conventional healthcare may provide an opportunity to enhance health and healing by emphasizing the importance of the patient-practitioner relationship, healthy diet and lifestyle approaches, psychological wellbeing and disease prevention strategies.

Three levels of integration have been defined by the WHO to describe the extent of CM integration into pre-existing health care systems (9). These are: tolerant, inclusive and integrative situations. A tolerant situation is said to occur when the dominant conventional healthcare system is autocratic and CM may be practiced in parallel but is not officially recognised. An inclusive situation arises when CM is recognised but not fully integrated into delivery of healthcare. An integrative situation is when CM is officially recognised and incorporated into all aspects of health care, such as national medicines policies, utilisation in hospitals and reimbursed under insurance schemes, e.g. in China.

It has further been suggested that integration occurs on two levels: the individual patient and at a broader policy level (10). Surveys have consistently shown that Australians use CM, often as an adjunct to conventional care suggesting that integration is already happening at an individual patient level (11-13;14;15;16). At a broader level, the Royal Australian College of General Practitioners (RACGP) and the Australian Medical Association (AMA) have released position statements about CM in the last few years which promote the adoption of ‘complementary medicine with high levels of scientific evidence and demonstrating safety and efficacy’ (17). The RACGP position statement goes onto state that such medicine should be ‘used as part of any high quality medical practice’(18). It also stated ‘evidence based aspects of complementary medicine are part of the repertoire of patient care in mainstream medical practice’. In contrast, the Pharmaceutical
Society of Australia’s position statement about CM has remained unchanged since 1997 and makes no mention of promoting the integration of evidence based CMs into practice (19). It does state that ‘the provision of complementary medicines is at the discretion of individual pharmacists who must exercise their professional judgement. However, pharmacists involved in the supply of such products have the same obligation to provide information and advice, consistent with consumer needs, as they do with registered prescription and proprietary medicines’.

Several theories have been put forward to explain the rise of integrative medicine. Parusnikova suggests that integration is motivated by a cognitive interest in CAM due to research suggesting particular therapies have merits and possibly by a need to control the CAM movement through a strategy based on incorporation and subordination and also to utilize its money-making potential (20). Some CAM practitioners are concerned that CAM might be “co-opted” by conventional medicine through the integrative process (21) whereas others view integrative medicine as a component of the patient-centered care movement.

In spite of the debate regarding the definition of CAM, this thesis will use the term complementary medicine or CM. CM encompasses various therapies, healing systems and medicinal treatments. This thesis will use the term complementary medicines (CMs) to refer to the ingested medicines only: herbal medicines, nutritional and food supplements and homeopathic remedies. These are medicinal products which are generally bought over-the-counter (OTC) in retail stores, over the internet and from health care clinics. Further details about definitions used in this thesis are presented in the glossary and abbreviations section.
A.3.0 Key principles in the practice of medicine and pharmacy

A.3.1 Evidence based medicine (EBM)

Evidence Based Medicine (EBM) is a tool widely used to evaluate health care information and act as a means to select and incorporate health care research into the practice of patient care. It is based on universally appealing ethical and clinical ideals in that it helps patients and doctors to make better informed choices. One well accepted definition is:

‘Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients’ (22)

The philosophical underpinnings of the EBM movement are more than a century old however the term was coined and its explicit incorporation into medical education and clinical practice has become widespread only in the past two decades. During this time, it appears that EBM has become widely accepted as the cornerstone of good clinical practice.

In 1979 and again in 1983, a document published by the US Congressional Office of Technology Assessment claimed that ‘it has been estimated that only 10-20% of all procedures currently used in medical practice have been shown to be efficacious by controlled trial’ (23). In other words, 80-90% of medical practice was not supported by scientific research evidence. This claim was based on a 1963 paper which had assessed the prescribing habits of 19 family doctors in a northern British town over a 2 week period (24). Little about these surveys was actually relevant to the general practice of medicine and is even less relevant today however, it did create much debate and lead to further enquiry.

The concept of EBM originated in Canada by a team of clinical epidemiologists over the next decade. In the 1970’s and 80’s, David Sackett and Walter Spitzer at McMasters University in Canada took up the challenge of determining and clarifying the theme of ‘effectiveness’ in medicine. Spitzer chaired a Task Force which
reviewed the primary evidence for preventative interventions in primary care and graded the evidence which was used to show that a treatment did more good than harm. Sackett organized a series of seminars on Health Care evaluation to highlight the usefulness of referring to randomised clinical studies when making decisions.

Sackett and colleagues also promoted the idea that epidemiological principles should be used to incorporate the latest evidence produced by these reviews into the core of physician training and medical practice. Although this group first expanded on the concept in a textbook published in 1985 entitled “Clinical Epidemiology” it was not until the early 1990’s that the phrase ‘evidence based medicine’ was being widely used and the new paradigm took root (25).

In 1992, Sackett and colleagues referred to the crucial importance of clinical skills and the roles of both patients' needs and non-randomised evidence in an early paper on evidence based medicine (26). They also stated that many aspects of clinical medicine cannot, or will not, ever be adequately tested however information derived from clinical experience and intuition can be misleading and clinicians are urged to be cautious when interpreting such information. Despite this, randomised controlled trials and systematic reviews have assumed pre-eminence as the gold standards and placed at the top of the hierarchy of evidence in EBM in the belief that they are least likely to provide 'misleading' information about the effect of an intervention (27).

Increasingly, the limitations of this approach are being recognised and addressed in the literature. These encompass both philosophical and practical problems associated with its use resulting in a slow evolving process which is transforming EBM from its original form (28-31).

Dracup and Bryan-Brown suggest three main deficiencies of EBM (28). First, the evidence on which decisions are based is developed from clinical trials with highly homogeneous samples, under controlled conditions and therefore not always generalisable to the individual patient and their particular circumstance. Second, evidence-based medicine is disease-oriented or based on protocols and not designed to answer the question, "What is the best treatment or procedure for this patient at this
particular time?" Lastly, evidence is unavailable for many of the questions that arise during the course of clinical practice.

Buetow and Kenealy suggest that there are six dimensions on which medicine is based: scientific evidence, theoretic evidence, practical evidence, expert evidence, judicial evidence and ethics-based evidence (30). When medicine focuses solely on scientific evidence, as is largely the case with EBM, it loses the ability to inform and defend judgements and decisions using additional insights from outside science. Buetow et al further make the observation that compared with earlier formulations of EBM, newer versions have started to emerge which acknowledge that research evidence alone is an inadequate guide to action and clinical expertise is the 'central', integrative force in clinical decision making (32). One of the key steps required to allow EBM to progress further is the redefinition of what constitutes evidence.

A.3.1.1 EBM and CM

CM practitioners and conventional medical practitioners share the similar goal of providing optimal health care to their patients. EBM is of relevance to all healthcare information, including information about CM. It is also of relevance to all healthcare interventions, regardless of their origins, including CM treatments.

Already numerous randomised controlled studies (RCTs), systematic reviews and meta-analyses have been published in the peer-reviewed literature. One review identified a total of 20,209 articles published about CM during the period 1997-2002, representing 0.7% of the total number of MEDLINE-listed articles (33). Thirty percent were published in journals with an impact factor over 1.000 and 6.9% over 5.000. Overall, 12.9% of published articles were randomised controlled studies and clinical trials and 0.5% were meta-analyses. According to a 2004 review, over 5800 CM randomised controlled trials have been identified and made available through the central Cochrane Library (34), making CM one of the better represented specialties on the database.
Whilst this is encouraging, one of the most important issues regarding EBM and CM relates to the definition of evidence. EBM continues to give precedence to information derived from RCTs, as evidenced by the hierarchy of evidence supplied by the National Health and Medical Research Council (NHMRC), however this methodology is not always adequate or possible when investigating CM.

One problem of special relevance in CM is that RCTs do not necessarily reflect ‘real world’ practice. Some CM therapies such as naturopathy, homeopathy or Traditional Chinese Medicine rely on individual diagnosis and individualised treatments and can comprise of multiple ingredient medicines and/or diet and lifestyle advice. The randomised controlled trial format relies on standardised treatments and although inclusion and exclusion criteria are used, they make little allowance for individual factors such as biological and social differences. As such, RCTs which isolate a multi-modality practice to one or two standardised treatments will fail to represent the practice as it is truly conducted.

Other aspects of CM practice which are difficult to assess by RCT are those for which it is difficult to develop an adequate placebo, such as massage. Additionally, validated measures do not exist for assessing some outcomes, such as changes in Qi. There are also studies which are unlikely to be performed due to ethical considerations such as safety studies in pregnancy and lactation. As such, other methodologies are required which are considered valid by the research community and given appropriate recognition in the EBM hierarchy of evidence.

Unlike the contemporary practice of Western medicine, some CM practices have been conducted for many generations giving rise to a wealth of information often called ‘traditional evidence’. This information source is based on the tenets of good clinical practice – careful observation and knowledge of the patient, the treatment and the response. This method of data collection constitutes a different form of evidence which has the advantage of real world applicability although it may lack subjectivity. Whilst traditional information is still widely used to guide clinical practice, particularly in the absence of other forms of evidence, it is not recognised as a valid form of evidence according to the NHMRC.
One last observation that requires discussion is the relative lack of funding opportunities for the conduct of clinical trials in CM, in comparison to pharmaceutical research. Unlike the investigation of pharmaceutical drugs, CM therapies and medicines are rarely patentable and therefore provide manufacturers and suppliers with little incentive to fund expensive clinical studies. The short-fall can be made up by other potential funding sources such as government funding or philanthropic donations however these are highly competitive and rarely earmarked for CM research (35). Until adequate funding becomes consistently available, there will remain a relative shortage of world-class RCTs in CM in comparison to pharmaceutical research.

**A.3.1.2 EBM implementation in Australia**

A 2005 study of 244 Australian physicians found that they clearly endorse the principles of EBM, have a good understanding of EBM technical terms and would endorse evidence-based health policy however studies show that patterns of care in relation to particular clinical conditions vary considerably from evidence-based 'best practice'(36). In order to change this situation, several strategically orientated initiatives have been developed to promote EBM in Australia. These include the Australasian Cochrane Collaboration, handbooks and projects either developed or funded by the NHMRC, and new centres such as the National Institute of Clinical Studies, Effective Healthcare Australia, the Australian Centre for Evidence Based Clinical Practice and the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S)(36).

Quality improvement (QI) has also received much attention and national leadership is being provided by numerous bodies such as the Australian Council for Safety and Quality in Health Care (now usually called the Safety and Quality Council). Another major Australian initiative was the development of The National Strategy for the Quality Use of Medicine (QUM) as part of the National Medicines Policy in 1999. The goal of the QUM strategy is to optimize the use of medicines to improve health outcomes. The safe and appropriate use of CMs falls within its scope however there is little information available about how this is achieved.
A.3.1.3 The challenge of implementing EBM in clinical practice

New research is being continually generated and published in an effort to improve clinical practice and our understanding of health and disease, disease diagnosis and treatment. Ideally, as new research becomes available, it will be evaluated, disseminated and ultimately influence clinical practice. However, major difficulties arise in introducing these innovations into routine practice and one of the most consistent findings in the international literature is the gap between evidence and practice (37).

In practice, there are many barriers which slow down or even prevent this process from occurring (38):

1. Lack of access to the evidence
2. Organisational barriers
3. Ineffectual continuing education programs
4. Low patient adherence to treatments

Lack of time and opportunity to become familiar with the relevant new evidence is another factor offered by Grol and Grimshaw as it has been estimated that general internists would need to read 20 articles a day all year round to maintain present knowledge (37). The availability of systematic reviews and guidelines reduces the need for doctors and pharmacists to read original studies however it is still difficult to keep up with such syntheses.

A study of U.K. general practitioners found that the process of applying clinical evidence was influenced by the personal and professional experiences of the practitioner, their relationship with the patient and patient experiences (39). A study of 400 Australian nurses which investigated their beliefs about barriers to evidence implementation identified lack of support from others to use the research and the anticipated outcomes of using research as additional factors (40): Norman further suggests that not understanding the evidence, not believing the evidence and not knowing how to use it are also barriers (41).
Australian GPs are pleased about the move towards using EBM however had concerns about the motives behind evidence based guidelines and whether they were based on effectiveness or cost-effectiveness or a political agenda (42). As a result, reluctance to use EBM may be motivated by uncertainty about the genuineness of the authors. Furthermore, some GPs considered previous experience of greater importance in clinical practice than external research evidence, a similar finding to Freeman and Sweeney (39).

Although EBM encourages the use of primary research studies and systematic reviews to inform clinical decisions, several surveys have suggested that most medical practitioners still rely heavily on the opinion of colleagues or consultants when making these decisions (43-45). Mayer and Piterman identified that if GPs found evidence conflicted with their own prior beliefs, they would talk with colleagues about the evidence for psychological support and affirmation (46).

A review of the literature reveals that barriers to the adoption of evidence into clinical practice are continuously being investigated in healthcare however CM specifically has not been investigated leaving much unknown about the barriers preventing the integration of ‘proven’ CM interventions into hospital practice.

**A.3.2 Shared decision making and patient focussed models**

Shared decision making is the term used to describe the process of two way information giving (medical and personal) between the clinician and the patient concerning all the options available, with a final decision being made jointly between both clinician and patient. It replaces the paternalistic approach and empowers the patient to become an active and equal partner in their own health care.

**A.3.2.1 Patient centred care (PCC)**

Patient-centred care (PCC) is a phrase originally coined by Balint in 1969 to express the belief that each patient “has to be understood as a unique human being” (47). A broad definition of PCC employed today is “care that is closely congruent with and
responsive to patients’ wants, needs, and preferences” (48). Three elements are considered important in PCC: communication, partnerships and a focus on health promotion and healthy lifestyles which goes beyond focussing on a specific condition (49). Systematic reviews show that patient-centred care results in increased adherence to management protocols, reduced morbidity and improved quality of life for patients (50). As a result, patient-centeredness has been promoted extensively in the literature and is now considered by many to be the standard for quality interpersonal care and both good clinical and moral practice (51).

In order for PCC to be effective, the patient must want to be actively involved in their own care. A review of quantitative studies demonstrated that demographic factors affecting patients’ preferences for taking a more active role in decision making are: younger and better educated patients, and women (52). Interestingly these are the same characteristics shared by typical users of CM (14;53).

**A.3.2.2 Evidence based patient choice (EBPC)**

The theory of ‘evidence based patient choice’ (EBPC) brings together two important modern movements in western health care, namely evidence-based medicine (EBM), and patient-centred care (PCC). The integration of EBM and PCC means providing patients with evidence based information in a way that facilitates their ability to make choices about their health care (54). It also means practitioners must consider their understanding of the patient and their values when defining the clinical question used as a starting point in EBM, thereby producing information that is relevant to the patient (55).

**A.3.2.3 Concordance**

The model of concordance was introduced by the Royal Pharmaceutical Society in 1997 as a more patient centred approach between medication prescribers (including pharmacists) and patients than had existed previously. The terms "non-compliance" or "non-adherence" had been widely used prior to this time and could be seen to suggest an unequal, paternalistic relationship.
Concordance aims to achieve the best possible use of medicines and is reached between medication prescriber and patient through negotiation until a therapeutic alliance is achieved (56). It requires the healthcare practitioner to recognise the primacy of the patient’s decision in taking medicines. Patients are encouraged to ask questions and express concerns about the medication prescribed to them and communicate their preferences for treatments and decision making. The prescriber provides evidence based information together with their relevant clinical experiences. The negotiation necessitates compromise on both sides until a mutually acceptable decision is reached. In situations where the patient defers a decision, the prescriber then makes it for the patient, whilst taking into account the individual factors present.

Australian pharmacists are supportive of the principles of concordance and believe that establishing a “therapeutic alliance” is a high priority in the consultation between pharmacists and their patients (57). Furthermore, they believe that pharmacists should respect patients’ beliefs and coping strategies, provide opportunities for patients to communicate their thoughts and be involved in negotiating about their treatment.

Overall, there are four common elements present in the shared decision making models: partnership, communication (including negotiation), information giving, and agreement. In all models, the health care professional (whether medical practitioner or pharmacist) and the patient are viewed as equals in terms of information transfer and decision making.

In order for these models to be effective and successful, both parties must be motivated to develop a therapeutic alliance, have adequate communication skills, be able to access, understand and assess the evidence and be able to compromise to reach a mutually acceptable goal. If either party is unable or unwilling to engage in these steps then an equal partnership has failed to be achieved.
Chapter One

Section B
CTs and the general community, medical practitioners and pharmacists

B.1.0 Introduction

This chapter is a literature review of relevant information and research about CM. It explores what is currently known about the use of CMs and CTs by the general population starting with overseas trends and then focussing on the Australian public. Information is next presented about medical practitioners and pharmacists and their beliefs and attitudes, referral patterns, personal usage, practice and knowledge of CM. This is included because the public demand for CM means these health professionals are coming into contact with CM users or patients enquiring about use and it is their task to provide healthcare advice. Overseas trends are reported for both groups followed by a focus on Australian studies.

This chapter also presents three systematic reviews of the international peer-reviewed literature. The first systematic review evaluates information available about the Australian public and their use of CM. The second systematic review evaluates information regarding overseas medical practitioners and CM and the third evaluates information about Australian medical practitioners and CM. In addition, reviews of overseas and Australian pharmacists and their attitudes, perceptions, training, knowledge and use of CM are also presented.
The decision to undertake multiple systematic reviews of the literature was made as this is a valuable process which reduces bias and enables limitations and gaps in the current knowledge base to be more easily identified.

**B.2.0 Overseas trends in the use of CM**

Unfortunately, the lack of consensus regarding a definition as to what is or what is not to be included in the category of CM has unquestionably complicated efforts to document, in a consistent fashion, the prevalence and patterns of CM use. Results are often confounded by a lack of distinction between CM products, CM practitioners and CM therapies (which may or may not require a CM practitioner). A lack of consistency between surveys as to how many therapies should be included and which type of therapies further complicates the issue. In some instances, respondents have not been provided with a definition of CM thereby relying on their own subjective definition (58). This can lead to misinterpretation and inaccuracies such as when the use of a pharmaceutical medicinal agent is interpreted as a CM product by respondents.

Despite this, it is apparent that the use of CM is widespread in Australia, the United States, United Kingdom, Canada and Europe (4;11;13-15;59-65). Global statistics have established that at least half the individuals living in the industrial world are using CM with a trend towards the use of ingestive therapies such as nutrient supplementation and herbal medicine, and manual therapies such as massage and chiropractic (66).

In the United States, Eisenberg et al identified that 47.3% of all Americans had visited a CM practitioner with an estimated 427 million consultations to CM practitioners in 1990 increasing to 629 million in 1997(60). More recently, a national analysis of CM use in the United States based on 31,044 interviews identified 62% of the surveyed population as having used some form of CM therapy in the previous 12 months (67;68). This figure includes those people who used ‘prayer for one’s own health’. 
When prayer is excluded from the analysis, CM usage within the last 12 months is reduced to 36%. Barnes et al report that the ten most commonly used CM therapies during the previous 12 months were: use of prayer specifically for one's own health (43.0%), prayer by others for one's own health (24.4%), natural products (18.9%), deep breathing exercises (11.6%), participation in prayer group for one's own health (9.6%), meditation (7.6%), chiropractic care (7.5%), yoga (5.1%), massage (5.0%), and diet-based therapies (3.5%).

A large survey of 17626 Canadian residents aged over 15 years estimated that 15% had used some form of CM therapy in the previous 12 months with use most prevalent amongst women, people aged 45-64 years and those with higher income (69). It also identified chiropractic as the most popular CM therapy.

In Europe, it has been estimated that between 20-50% of the population are using CM therapies, a figure which differs between countries and is influenced by whether CM therapies are located in the national health systems or not, methodological variations in data collection and the definitions employed to describe ‘alternative’ therapies (70). In France, homeopathy is one of the most popular CM therapies and was used by 16% of the population in 1982, 29% in 1987 and 36% in 1992(71). In Germany, herbal medicines and homeopathy are used by 95% of doctors because they are taught as part of conventional medical training and therefore widely used.

The use of CM is also prevalent in the United Kingdom. In 1993, a survey of use of CM found that 33% of the population had used some form of CM therapy and that 10% had consulted a CM practitioner in the previous year (72). In 2001, a population-based survey of English adults (n=5010) identified over 28% as using CM during the previous year, and nearly half having used CM at some stage in their lives (73). A study of residents from North East Scotland, compared usage habits and attitudes to CM from 1993 (n=341) to 1999 (n=432) (74). Over this period, use of CM increased from 29% to 41%, with a statistically significant increase in the use of aromatherapy, acupuncture and reflexology. Surveys of patients with chronic and difficult to manage diseases (e.g. cancer, HIV infection, multiple sclerosis, psoriasis, and rheumatological conditions) suggest usage is higher amongst these populations. Osteopathy,
chiropractic, homoeopathy, acupuncture, and herbalism are among the most popular CM therapies in the United Kingdom.

The 2002/03 New Zealand Health Survey \( (n = 12\,000) \) indicated that approximately 24% of adults had visited a CM practitioner over the 12-month study period (75). Massage therapists, chiropractors, osteopaths, homeopaths or naturopaths were the most commonly consulted CM practitioners.

**B.2.1 Description of people who use CM**

Several general variables have been identified as having a relationship to complementary medicine supplement use. These are race or ethnicity, age, education, income, and lifestyle variables such as drinking, smoking, and exercising (76). The use of CM amongst specific patient populations has also been investigated with a higher level of use observed amongst people with chronic conditions.

A study with a sample of over 30,000 American women found 33.5% used CM with use increasing with increasing age, peaking at 45–54 years old (77).

There is evidence that people with more health conditions and poorer health are also more likely to use CM therapies and CMs (78-83). For instance, a survey of cancer patients conducted in 14 European countries \( (n=956) \) revealed that CM is popular amongst this group with 35.9% using some form of CM (range between countries 14.8% to 73.1%) (84). Herbal medicine was the most commonly used CM therapy and its use tripled from the time before diagnosis to the time after diagnosis with cancer. Other examples include patients with glaucoma (81), Parkinson’s disease (78), headache syndromes (82), chronic heart failure (83) and rheumatological conditions (80).
B.2.2 Reasons for the popularity of CM

A wide variety of reasons for the use of CM and its prevailing popularity have been reported in the literature. Some of these have been described as positive motivations such as the pursuit for wellness (85), an interest in health promotion and disease prevention (1;60;86), a preference for holistic and ‘natural’ approaches to health care(86), the perceived safety and effectiveness of CM and that it is generally pleasant and non-invasive(87). Numerous studies have shown that CM is typically used as an adjunct to conventional medical care (11-13;60;86;88;89). According to Eisenberg et al, 79% of respondents who used CM and visited conventional doctors perceived the combination to be superior than when either was used alone(90).

A U.S. based national survey by Astin reported that a holistic philosophy of life and interest in alternative lifestyles, a life changing experience which altered their world view and interest in self care as major factors predisposing people to use CM (86). Other studies have produced similar findings (91-94).

There are also negative motivations which may explain its use such as dissatisfaction with conventional medical care. Although some evidence supports this view (95-97) other studies have failed to identify disenchantment as a major reason for CM use (86;90;91). When dissatisfaction with conventional medicine was identified, this related to dissatisfaction with the quality of medical care (96), failure for conventional treatments to provide adequate outcomes (98;99), concerns about safety and toxicity of conventional treatments (100;101), increased relative cost of conventional care (95), and perceived barriers to obtaining conventional care (96). Post-modern values such as rejection of authority and ‘the establishment’ have also been attributed to the increased popularity of CM (102).
B.2.3 What resources are being used by the general population for CM information?

In today’s age, healthcare practitioners are no longer the main providers of healthcare information and advice. The public can access and be exposed to health information in a variety of ways such as the lay and medical media, family and friends, work colleagues, shop staff, marketing material from manufacturers, books and the Internet. Considering that many people self-select their CMs and do not discuss use with a healthcare professional (CM or conventional), it appears that many find these sources of information or referral sufficient on which to make a decision.

Despite their important role in healthcare, relatively little information is available about the public’s use of medical practitioners and pharmacists as sources of CM information and what they think of the information provided. Studies investigating the reasons why patients using CM do not disclose use to their medical physician provide some insight into this issue.

Eisenberg et al identified that only 39.8% of CM users disclosed their use to physicians in 1990, and in 1997 this figure was 38.5% suggesting disclosure had remained poor (60). Similar findings have been reported in numerous other studies with one review of 12 studies involving patients attending medical clinics identifying non-disclosure rates of 23–72% (103). Of the 12 studies analysed, cancer patients were assessed in four studies, patients with other conditions were assessed in three, three studies involved general clinic patients and one study was a general population study. The wide variations in findings can be attributed to different study designs, patient populations, and definitions and types of CM.

In all 12 studies, the same three themes were consistently reported by patients as reasons for lack of disclosure (104). Most commonly, these were: concern about eliciting a negative response from the physician followed by the patient's perception that the medical practitioner did not need to know about CM use because they are ignorant of CM and unable to contribute useful information and lack of physician enquiry about use.
B.3.0 Trends in the use of CM in Australia

The first major study reported in the peer-reviewed literature about the use of CMs by Australians was conducted by MacLennan et al in 1993 (63). The survey identified that 48.5% of adult South Australians had used at least one non-medically prescribed CM product (excluding calcium, iron and prescribed vitamins) in the previous 12 months. People using CMs were more likely to be peri-menopausal females, better educated, have a higher alcohol intake, be of normal weight and more likely to be employed than non-users. The study has been replicated twice since then showing that CMs and CTs remain popular amongst the general population and there use is generally increasing (13;14).

A systematic review is presented of Australian population studies in order to provide further details about current usage.
B.3.1 Systematic review of CTs use by the Australian general population

B.3.1.1 Aim:
The main aim was to determine the prevalence and patterns of CM use by the general population in Australia. Secondary aims were to investigate whether people using CMs and/or CTs report use to physicians, their reasons for use, and perceptions about CMs and/or CTs and sources of advice regarding CM.

B.3.1.2 Methods:
A search was performed using the following databases for all years available through until October, 2006: Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE, ScienceDirect, Proquest. Search terms used included, but were not limited to:

- ‘complementary medicine’ AND ‘Australia’
- ‘alternative medicine’ AND ‘Australia’
- ‘holistic medicine AND ‘Australia’
- ‘integrative medicine’ AND ‘Australia’
- ‘CAM’ AND ‘Australia’
- ‘CM’ AND ‘Australia’
- ‘herbal medicine’ AND ‘Australia’
- ‘natural therapies’ AND ‘Australia’
- ‘naturopathy’ AND ‘Australia’

A search was also conducted whereby the word ‘medicine’ was replaced by the word ‘therapy’ and then ‘therapies’.

Articles identified in this manner were searched to ascertain relevance to this systematic review. The reference lists of articles considered suitable for inclusion were also searched to identify additional relevant studies which have not been identified by the previous search strategy. Articles were considered eligible if they were population based surveys, presented in English, published in the peer-reviewed literature and described research conducted with the general population living in Australia. Studies were also considered eligible if presented at a prominent Australian
conference. A full-length copy of the study by Kermode et al was unable to be located and was not included in this review.

**B.3.1.3 Results:**

**B.3.1.3.1 Description of studies**

Thirteen articles met the inclusion criteria which described data obtained from eleven different studies. One article described data obtained nationally from patients attending chiropractic clinics (105), three described data from surveys conducted with residents of South Australia (13;14;63), three described surveys of people with cancer (12;58;106) and one described a survey of people with HIV (107). Two articles used the same data obtained from the Australian Longitudinal Study on Women's Health (11;12) and two other articles used the same data obtained from a national population based survey of older Australians aged over 65 years (108;109). One conference presentation met inclusion criteria in which results from a national population based survey conducted by telephone were presented (15). Seven articles reported response rates which were above 60%. A summary of results from relevant articles is presented in Table 1.
Table 1. Australian surveys estimating prevalence of CM usage

<table>
<thead>
<tr>
<th>Year of publication</th>
<th>First author</th>
<th>Number of respondents and special features of population examined</th>
<th>Mode of data collection</th>
<th>Response rate (as presented by the papers authors)</th>
<th>Estimated prevalence of CMs and CTs use</th>
<th>Specific CMs used by studied population (if reported)</th>
<th>Other findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1996</td>
<td>MacLennan et al</td>
<td>N=3004 persons aged 15 or older living in South Australia</td>
<td>Data collected by personal interviews in 1993</td>
<td>73%</td>
<td>48.5% had used at least one non-medically prescribed CM product (excluding calcium, iron and prescribed vitamins) in the previous 12 months</td>
<td>37.6% vitamins, 9.9% herbal medicines, 9.2% minerals, 7.8% evening primrose supplements, 4.4% homeopathic remedies, 3.5% aromatherapy oils, 3.0% ginseng, 1.8% Chinese medicines, 1.3% PMTese, 0.1% Esten, 3.6% others</td>
<td>CM users were more likely to be perimenopausal females, better educated, have a higher alcohol intake, be of normal weight and more likely to be employed than non-users. 20.3% of respondents had visited at least one alternative practitioner, most commonly chiropractors (15%). The users of alternative practitioners were more likely to be younger, live in the country and be overweight. Women were more likely to consult naturopaths, iridologists, and reflexologists than men.</td>
</tr>
<tr>
<td>1998</td>
<td>Kermode et al</td>
<td>N= 645 residents of the North Coast of New South Wales</td>
<td>Telephone survey</td>
<td>unknown</td>
<td>up to 50% visited a complementary health practitioner each year</td>
<td>unknown</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>De Viseer et al</td>
<td>n= 925 men and women living with HIV/AIDS in Australia</td>
<td>Cross-sectional survey of convenience</td>
<td>Not reported</td>
<td>56% of respondents used alternative therapies 46% nutritional supplements 24% massage</td>
<td>Attitudes toward both allopathic and alternative therapies were positive.</td>
<td></td>
</tr>
</tbody>
</table>
sample – data collection conducted in 1997

2002  MacLennan et al (13)  N=3027 persons aged 15 years or older living in South Australia  Data collected by personal interviews in 2000  70.4%

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Herbal medicines</td>
<td>21%</td>
</tr>
<tr>
<td>Meditation</td>
<td>20%</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>10%</td>
</tr>
<tr>
<td>Traditional Chinese medicine</td>
<td>7%</td>
</tr>
<tr>
<td>Exercise</td>
<td>3%</td>
</tr>
<tr>
<td>Yoga</td>
<td>2%</td>
</tr>
<tr>
<td>Reiki</td>
<td>1%</td>
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</table>

The choice of allopathic and/or alternative therapies was related to disease progression. Choice of therapy was also related to attitudes toward allopathic and alternative therapies. Many users of alternative therapies believe that such therapies can alleviate the side effects of antiretroviral drugs.

52.1% had used at least one non-medically prescribed alternative medicine (excluding calcium, iron, and prescribed vitamins) in the previous 12 months.

23.3% of respondents had visited at least one CM practitioner with increasing use of acupuncturists, reflexologists, aromatherapists, and herbal therapists.

36.4% used vitamins
15.3% aromatherapy oils
13.4% herbal medicines
10.6% minerals
8.0% evening primrose oil
4.9% other
4.3% homeopathic remedies
3.2% Chinese medicines
1.6% menopause products

People using CMs more likely to be female, better educated, have a higher income, and be employed. Since 1993, females using significantly more herbal medicines, ginseng, Chinese medicines, aromatherapy oils. Many self-prescribed. Among users, 57.2% did not tell their doctor. Most thought alternative medicines were safe but thought they were, or should be, subject to the same standards as prescribed medicines. Among respondents, 92.9% wished product information to be of standard and content similar to those supplied with pharmaceuticals.
<table>
<thead>
<tr>
<th>Year of publication</th>
<th>Author/s</th>
<th>Number of respondents and special features of population examined</th>
<th>Mode of data collection</th>
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<th>Specific CMs used by studied population (if reported)</th>
<th>Other findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>Adams et al (11)</td>
<td>N=41,817 Research conducted as part of the Australian Longitudinal Study on Women's Health</td>
<td>Survey</td>
<td>98%</td>
<td>28% women aged 45-50 years had consulted a CM practitioner in the previous 12 months</td>
<td>CM users are more likely to live in non-urban areas, report poorer health, have more symptoms and illness than non-users and are higher users of health care services than non users</td>
<td></td>
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<tr>
<td>2003</td>
<td>Sibbritt et al (58)</td>
<td>N= 9375 Australian women aged 73-78. with cancer Data collected from survey conducted in 1999</td>
<td>Data collected from survey conducted in 1999</td>
<td>Not reported</td>
<td>For all cancers combined, 14.5% of women with cancer consulted a CM practitioner. This percentage varied depending on the type of cancer: skin (15.0%), breast (11.5), bowel (8.8%), and other (16.5%).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td>Jamison JR (105)</td>
<td>N= 758 Convenience sampling of patients attending 21 chiropractic clinics in 5 states and the ACT Data were collected using a questionnaire</td>
<td>Data were collected using a questionnaire</td>
<td>Not reported</td>
<td>40% took vitamins</td>
<td>Chiropractors were only occasionally informed about the medication practices of their patients.</td>
<td></td>
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<tr>
<td>Year of publication</td>
<td>Author/s</td>
<td>Number of respondents and special features of population examined</td>
<td>Mode of data collection</td>
<td>Response rate (as presented by the papers authors)</td>
<td>Estimated prevalence of CMs and CTs use</td>
<td>Specific CMs used by studied population (if reported)</td>
<td>Other findings</td>
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<td>2004</td>
<td>Brownie and Rolfe (108)</td>
<td>N= 1263 randomly selected older Australians (&gt; 65 years) randomly selected from the 2000 Australian Electoral Commission roll. All states and territories were proportionally represented in the sample.</td>
<td>Self administered postal survey</td>
<td>62%</td>
<td>43% reported using some form of supplement at the time of the survey (n=548): 52% of females and 35% of males.</td>
<td>26% Vitamin C 17% multivitamin/mineral 17% fish oils 16% vitamin E 13% calcium ( +/- vitamin D) 11% garlic 9% vitamin B (single or mixed) 7% single vitamin 6% zinc 5% ginkgo biloba</td>
<td>Supplement users were more likely to report arthritis, osteoporosis, experience more symptoms consume more medication than non-supplement users. In contrast, there was a reduced likelihood of taking a supplement for those with hypertension, by those using blood pressure medication and heart tablets.</td>
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<tr>
<td>2005</td>
<td>Adams et al (12)</td>
<td>N= 11,202 women aged 50-55years * Research was conducted as part of the Australian Longitudinal Study on Women's Health</td>
<td>Data collected from survey conducted in 2001</td>
<td>99.5%</td>
<td>For all cancers combined, 15.7% of women with cancer consulted a naturopath/herbalist, while 10.9% of women without cancer consulted a naturopath/herbalist.</td>
<td>Not reported</td>
<td>Mid-aged women with cancer were found to be more likely to consult a naturopath/herbalist than mid-aged women without cancer. Naturopathy/herbalism consultations appear to be</td>
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</table>
The percentage of naturopath/herbalist consultations varied depending on the type of cancer presents: breast cancer (17.4%), bowel cancer (22.2%) and other cancer (14.8%) are higher than for women with cervical cancer (6.3%).

2005 Girgis et al (106) N= 1492 cancer patients attending nine major public cancer treatment centers in New South Wales, Australia

Survey 65%

For all cancers, 17.1% of patients were using at least one CT. Herbal treatments and naturopathy are the most popular (constituting over 30% of all CM use recorded).

Not reported

The two main demographic characteristics of CM users were gender and age, where females were more likely to use CM than males and that CM use declined as age increased. Time since diagnosis was identified as the only significant clinical predictor of CM use, where CM use increased with time until 5 years since diagnosis.
<table>
<thead>
<tr>
<th>Year of publication</th>
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<th>Number of respondents and special features of population examined</th>
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<tr>
<td>2006</td>
<td>Brownie (109)</td>
<td>N= 1263 randomly selected older Australians (&gt; 65 years) randomly selected from the 2000 Australian Electoral Commission roll. All states and territories were proportionally represented in the sample.</td>
<td>Self administered postal survey</td>
<td>62%</td>
<td>43% reported using some form of supplement at the time of the survey (n=548): 52% of females and 35% of males.</td>
<td>Supplements used by &lt;5% were: St Johns wort, valerian, St Mary’s thistle, Echinacea, Brahmi, Saw palmetto, Ginseng</td>
<td>Supplement use was significantly associated with gender (female) and chronic musculoskeletal ailments such as arthritis, osteoporosis and generalised back or neck problems. The most common potential drug-supplement interaction was between calcium supplements and antihypertensives.</td>
</tr>
<tr>
<td>2006</td>
<td>MacLennan et al (14)</td>
<td>N=3015 South Australian respondents over the age of 15 years</td>
<td>Data collected by personal interviews in 2004</td>
<td>71.7%</td>
<td>52.2% had used at least one non-medically prescribed alternative medicine (excluding calcium, iron, and prescribed vitamins) in the previous 12 months</td>
<td>39.2% vitamins 20.6% herbal medicines 13.6% minerals 11.2% aromatherapy oils 3.8% soy products 2.3% traditional Chinese medicines 2.2% homeopathics 6.1% other</td>
<td>Greatest use for women 25-34 yrs, higher income and education. CMs used mostly to maintain health. CM users had lower quality-of-life scores than non-users. Among CM users, 49.7% used conventional medicines on same day and 53.2% did not report use of CMs to doctor. About 50% assumed CMs independently tested by government agency; of these, 74.8% believed they were tested for quality &amp; safety, 21.8% for claims, 17.9% for efficacy.</td>
</tr>
<tr>
<td>Year of publication</td>
<td>Author/s</td>
<td>Number of respondents and special features of population examined</td>
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<tr>
<td>2006</td>
<td>Xue et al (15)</td>
<td>N=1067 national population-based study</td>
<td>Computer assisted telephone survey</td>
<td>Not reported</td>
<td>Nationally, 68.9% used at least one CT and/or visited a CM practitioner in the previous 12 months</td>
<td>CTs used by &gt;10% of the sample were: Clinical nutrition (45.8%) Massage (27.2%) Meditation (17.2%) Western herbalism (16.3%) Aromatherapy (16.1%) Chiropractic (16.1%) Yoga (12.0%)</td>
<td>Use of CTs was higher in females, people with higher education, higher income, who ranked their health as fair–poor, were aged 18-34 years and employed.</td>
</tr>
</tbody>
</table>
B.3.1.3.2. Methodological concerns

As is the case with studies conducted overseas, it is difficult to make accurate comparisons between studies because there is a lack of consistency between definitions being used to describe CMs and CTs. For example, MacLennan et al described the prevalence of CMs use and excluded medically prescribed products whereas Jamieson included all CMs, regardless of the prescriber(13;14;63;105). Sibbritt et al asked participants about their use of ‘alternative health practitioners’ without defining what this meant thereby leaving the interpretation open to the individual whereas Adams asked specifically about herbal medicine practitioners and naturopaths and excluded the use of herbal therapy and naturopathic products and remedies purchased over the counter, self-administered, and provided by conventional practitioners (12;58). Additionally, investigators asked about use of CMs or CTs over varying time frames. For example, Xue et al asked about use of CMs and CTs over the previous 12 months whereas Brownie and Rolfe asked participants about their use at the specific time of the survey (15;108) thereby making it difficult to make relevant comparisons.

B.3.1.3.3. Usage trends

Overall, the data collected indicates that the use of CMs and CTs is prevalent amongst the general population, of all ages, regardless of gender and also used by people with various health conditions such as cancer and HIV-AIDs (11-15;58;105-109).

Studies of the general population indicate usage is between 40% (105) and 52% (14) for CMs. Consistently, surveys report that women are more likely to use CM therapies and treatments than men (13;14;63;106;109) and people who use CMs have higher income and higher education (13;14;63). There is also some evidence that people living in non-urban areas (11;63), with poorer health (11) or lower quality of life scores (14) are more likely to use CMs or see a CM practitioner.

Vitamins are the most popular type of CMs used (13;14;63;107;108) however the use of herbal medicine has been increasing steadily. In particular, women’s use of herbal
medicines significantly increased from 16.6% in 2000 to 24.9% in 2004 (P<0.01) according to surveys conducted in South Australia (14).

The percentage of people visiting a CM practitioner has also been steadily increasing in recent years. MacLennan et al report that in 1993, use was estimated as 20.3% of the population (63), rising to 23.3% in 2000 (13) and further increasing to 26.5% in 2004 (14). These studies appear to have under-estimated use nationally as results from a national population study reported that 44.1% had consulted a CM practitioner in the previous 12 months (15).

Xue et al reported on a combined result for the use CMs and CTs indicating that 68.9% of Australians had used at least one CT and/or visited a CM practitioner in the previous 12 months (15). Use was highest in New South Wales where it was estimated that 72.1% of the population had used CTs and/or visited a CM practitioner, and lowest in South Australia where the estimate was 60.8%.

Data from the Australian Longitudinal Study on Women's Health indicate that 19% of women aged 18-23 years had consulted with a CM practitioner in the previous 12 months, 28% women aged 45-50 years and 15% of women aged 70-75 years (11) however usage is lower for women with cancer and ranges from 14.5% (58) to 15.7% (12). More specifically, Adams et al reported that middle aged women with cancer were more likely to visit a naturopath or herbalist than women of the same age without cancer (12). Girgis et al identified that the time since diagnosis was the only significant clinical predictor of CM therapy use by people with cancer, where CM use increased with time until 5 years since diagnosis (106). In regards to people with HIV-AIDs, de Visser et al identified that the choice of conventional and/or complementary therapies was related to disease progression (107).

It is difficult to compare usage figures between older Australians with the general population because the survey by Brownie and Rolfe asked participants about their use of CMs at the time of the study whereas the larger general population studies by Xue et al and MacLennan et al asked about use in the previous 12 months (13-15;108). It is however possible to conclude that use of CMs is lower amongst older
males than older females. Overall, older Australians using CMs are more likely to have musculoskeletal conditions, osteoporosis, report more symptoms and use more medicines than people who do not use CMs (108).

**B.3.1.3.4 What is actually being used?**

A variety of nutritional and food supplements and herbal medicines are being used by Australians however it is difficult to determine exactly what these substances are because most studies group CMs into broad categories such as clinical nutrition, herbal medicines, vitamins or minerals. As a result, information about the use of specific ingredients is limited.

The most detail is provided by Brownie and Rolfe which name actual CMs being taken by their sample population, which comprised of older Australians (108). According to this study, the most commonly used CMs were (starting with most popular): vitamin C, multivitamins, fish oil supplements, vitamin E, calcium supplements, garlic, vitamin B, single vitamins (not specified), zinc and ginkgo biloba.

Xue et al report on the use of specific CTs in their recent national population based survey (15). The five most commonly used CTs used by the sample were (starting with most popular): clinical nutrition, massage, meditation, western herbalism and aromatherapy. MacLennan’s surveys of South Australians report that in 2000, vitamin therapy, aromatherapy, herbal medicine, mineral therapy and homeopathy were the 5 most commonly used CTs. In 2002 this changed slightly and was : vitamin therapy, herbal medicine, mineral therapy, aromatherapy and traditional Chinese medicine.

A workforce survey of the practice of Western herbalism and naturopathy in Australia confirmed that these practices make up a sizeable component of the Australian healthcare sector (111). It was estimated that approximately 1.9 million consultations are conducted annually generating an annual turnover of approximately $AUD 85 million for consultations only. The report also identified that most people are not
referred to naturopaths or herbalists by other health care professionals but are referred by word of mouth.

**B.3.1.3.5 Patient disclosure to physicians**

Although six studies have indicated that people use CM as and adjunct to conventional medicine (11-14;107;108), only two studies reported whether medical physicians are told about this use. Both indicate that people using CMs do not routinely tell physicians about use (13;14). No studies have reported on any investigation into the reasons for non-disclosure. According to Jamison, chiropractors are not always aware of their patient’s use of medication (105) suggesting the problem of non-disclosure may not be confined to medical practitioners.

**B.3.1.3.6 Sources of advice and information**

One study reported that the main sources of advice people receive about CMs are: self (28%), family/friends (26%), medical doctor (21.2%), media (15.1%), health food store (14%), CM practitioner (13.4%), chemist (9.7%) (13). It is not clear whether these are also considered sources of information about CMs and CTs.

**B.3.1.3.7 Reasons for use**

Two studies reported people’s reasons for using CM. The earlier study found people reported using CM in general: to prevent disease (34.6%), to cure sickness (17.8%), both reasons (31.3%) or they didn’t know (16.3%) (13). More recently, a study reported that the majority of people using CMs did so to maintain general health (70%) (14).

**B.3.1.3.8 Perceptions about CM**

Overall, most people (65%) are aware that CMs can be potentially unsafe according to one study (13). Perceptions about how CMs are regulated are varied. One study
reported that most people thought CMs were, or should be, subject to the same standards as prescribed medicines and a later study reported that some people assumed CMs were independently tested by a government agency for quality and safety, the claims made and for efficacy (13;14).

Many people with HIV-AIDs using CTs believed they can alleviate the side effects of antiretroviral drugs (107). Additionally, a positive attitude to both allopathic and CM therapies were reported for this population.

**B.3.1.3.9 Limitations of the review**

The main limitation of this review relates to the heterogeneity of the included studies which reduced the ability of the review to compare results and summarise key trends. Whilst every effort was made to locate relevant studies, it is possible that others exist which were not identified using the search strategy.
B.4.0 Medical practitioners and CM

The widespread public use of CM means that medical practitioners are likely to be coming into increasingly frequent contact with CM users or patients enquiring about use. As a reflection of this, an increasing number of studies have been conducted to investigate physicians’ attitudes, perceptions, usage, training, referral and knowledge of CM.

B.4.1 Overseas and Australian trends for medical physicians

A 1995 meta-analysis of 12 studies found that in general, physicians viewed complementary medicine as moderately effective, with younger physicians more optimistic about these therapies than their older counterparts(112). Zollman and Vickers reported that medical doctors also regarded CM as scientifically unproven and are concerned about ensuring the best choice of treatment for their patients (113). Common concerns include risk of delayed diagnosis, cessation of effective treatments, adverse effects and drug interactions, conflicting advice and treatments. Astin et al analysed data from 19 surveys conducted between 1982 and 1995 of mainstream medical practitioners and identified similar and additional concerns amongst physicians who oppose its use: concerns that CM practitioners do not have sufficient knowledge to diagnose disease, CM lacks evidence of efficacy and CM may be harmful either directly by inducing adverse events or indirectly by delaying use of other treatments (114).

There has been relatively little investigation of medical practitioners in Australia and their perceptions, attitudes, use and referral to CTs.

A systematic review of the literature regarding overseas medical physicians is presented in B.4.2 and a systematic review of the literature regarding Australian medical practitioners is presented in B.4.3.
**B.4.2 Systematic review of overseas medical practitioners and CM**

**B.4.2.1 Aim:**
The primary aim was to review the literature on medical practitioner’s attitudes, beliefs, and knowledge of CMs. Secondary aims were to review the literature on medical practitioner’s personal usage of CM, confidence in dealing with CM-related issues, frequency of asking patients about CMs use, information seeking behaviour and sources of information used for CMs queries, referral patterns to CM and interest in CM training.

**B.4.2.2. Methods:**
A search was performed using the following databases for all years available through until October, 2006: Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE, ScienceDirect, Proquest. Search terms used included, but were not limited to:

- ‘Complementary medicine’ and ‘physician’
- ‘Alternative medicine’ and ‘physician’
- ‘Holistic medicine’ and ‘physician’
- ‘Natural medicine’ and ‘physician’
- ‘Herbal medicine’ and ‘physician’
- ‘Unconventional medicine’ and ‘physician’
- ‘Natural therapies’ and ‘physician’
- ‘Naturopathy’ and ‘physician’

Additional searches were conducted whereby the word ‘physician’ was replaced by the word ‘doctor’ and the word ‘medicine’ was replaced with the word ‘therapies’ and then ‘therapy’.

Articles identified in this manner were searched to ascertain relevance to this systematic review. The reference lists of articles considered suitable for inclusion were also searched to identify additional relevant studies which have not been identified by the previous search strategy. Articles were considered eligible if they...
were published in English, available in the peer-reviewed literature and presented research conducted with the medical practitioners residing outside Australia. Articles published prior to 2000 were excluded because the survey data were deemed too old to be of relevance to current practice.

**B.4.2.3 Results:**

**B.4.2.3.1 Description of studies**

Eighteen studies were identified and deemed relevant to this systematic review (16;115-130). Fourteen studies involved GPs, one oncologists, one medical physicians (excluding GPs), one academics at a teaching hospital, one gastroenterologists and five contained a mixed sample which included participants who were not medical practitioners. Eight studies were conducted in the United States, six in the U.K. and one in each of the following countries: Canada, Germany, Israel, Norway and Italy. Seven studies had a response rate above 60% and three failed to report a response rate. A summary of the key findings relevant to this review are presented in **Table 3**.
Table 3. Studies published from 2000 about physician’s attitudes, beliefs, training, knowledge, referral patterns and practice of CM.

<table>
<thead>
<tr>
<th>Author/s</th>
<th>Year of publication</th>
<th>Country where survey conducted</th>
<th>Sample size</th>
<th>Description of respondents</th>
<th>Response rate</th>
<th>Beliefs and attitudes to CM</th>
<th>Use of CM – personal use and practise of</th>
<th>Referral patterns to CM</th>
<th>Training, knowledge and information</th>
<th>Other relevant information</th>
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</thead>
<tbody>
<tr>
<td>Chen et al (131)</td>
<td>2000</td>
<td>U.S.</td>
<td>N=44</td>
<td>family practice physicians</td>
<td>36.4%</td>
<td>Not reported</td>
<td>Beyond simply referring patients to</td>
<td>The overall referral rate to</td>
<td>Knowledge and training desires were highest for homeopathy and acupuncture</td>
<td>Less than 50% of the physicians who made suggestions and/or referrals did so based on patients' symptoms or when they believed the patients would benefit from the treatments; most physicians made suggestions and/or referrals when they had no other choice, such as when they saw no improvement under conventional treatments.</td>
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<td>from the Cincinnati, Ohio</td>
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<td>alternative practitioners, there were 7 (15.9%) physicians who practiced certain types of alternative treatments, which included massage, herbal medicine, acupuncture, reflexology, chiropractic, homeopathy, hypnosis, and Qigong.</td>
<td>during the past year of this study was 61.4%</td>
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<tr>
<td>Perry and Dowrick</td>
<td>2000</td>
<td>U.K.</td>
<td>N=131</td>
<td>General practitioners</td>
<td>52%</td>
<td></td>
<td>18% regularly used some form of CT in their practice, mainly homeopathy and acupuncture</td>
<td>During the previous week 56.5% of respondents had been involved in complementary medical activity with their</td>
<td>A minority were confident discussing CTs with patients</td>
<td>They were most</td>
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<td>(132)</td>
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<tr>
<td>Study</td>
<td>Year</td>
<td>Country</td>
<td>Sample Size</td>
<td>CM Usage by Physicians</td>
<td>CM Recommendation by Physicians</td>
<td>CM Knowledge Needs</td>
<td>CM Comfort Level</td>
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<td>Corbin and Shapiro (16)</td>
<td>2000</td>
<td>U.S.</td>
<td>N=302</td>
<td>43%</td>
<td>24% had personally used CM.</td>
<td>84% thought they needed to learn more about CM to adequately address patient concerns.</td>
<td>76% of physicians reported having patients using CM; 59% had been asked about specific CM treatments; few physicians felt comfortable discussing CM with patients.</td>
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<td>Author/s</td>
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<td>Lewith et al (117)</td>
<td>2001 U.K.</td>
<td>n = 2,875</td>
<td></td>
<td>All Members and Fellows of the Royal College of Physicians (GPs excluded from data analysis)</td>
<td>23%</td>
<td>Attitudes to CM were generally positive, particularly among those in palliative care, rehabilitation, nuclear medicine, and genito-urinary medicine</td>
<td>32% of respondents practised CM themselves</td>
<td>41% referred patients to CM</td>
<td>Acupuncture, aromatherapy and manipulative medicine (osteopathy and chiropractic) were the most commonly practised CM therapies</td>
<td>CM is used by physicians more frequently in private as compared to NHS practice. Of those who referred patients, 78% referred between 0-3 patients per month</td>
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<tr>
<td>Thomas et al (133)</td>
<td>2001 U.K.</td>
<td>N = 964</td>
<td></td>
<td>General practitioners</td>
<td>78.6%</td>
<td>39.5% of GP partnerships provided access to some form of CM therapy for their NHS patients.</td>
<td>24.6% of partnerships had made NHS referrals for CM therapies</td>
<td>Acupuncture and homeopathy were the most commonly available therapies at GP clinics</td>
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<td>Author/s Year of publication</td>
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<td>Silverstein and Spiegel (125)</td>
<td>U.S.</td>
<td>N=165</td>
<td>Students and faculty of the State University of New York, Health Science Center at Brooklyn</td>
<td>85%</td>
<td>Age and training were negatively correlated in a statistically significant manner with the likelihood of a physician prescribing CMs</td>
<td>Although many physicians asked their patients about their use of alternative remedies, most do not check the remedies in a reference text.</td>
<td>Over 50% had referred a patient for biofeedback or chiropractic Biofeedback, chiropractic most commonly referred to CTs Associate staff, female staff, &gt;50% would like to offer acupuncture, biofeedback, chiropractic care, hydrotherapy, nutritional supplements, or massage to patients in the future</td>
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<tr>
<td>Rooney et al (124)</td>
<td>U.S.</td>
<td>79%</td>
<td>Survey of all medical and associate staff.</td>
<td>55% reported using 1 or more of 18 therapies for themselves. Over 25% of providers used nutritional supplements, herbal medicines, or hydrotherapy with a patient.</td>
<td>Over 50% had referred a patient for biofeedback or chiropractic Biofeedback, chiropractic most commonly referred to CTs Associate staff, female staff, &gt;50% would like to offer acupuncture, biofeedback, chiropractic care, hydrotherapy, nutritional supplements, or massage to patients in the future</td>
<td>Age and training were negatively correlated in a statistically significant manner with asking patients specifically about CMs and checking the side effects and drug interactions of in a reference text.</td>
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</table>

Chapter ONE Section B – Use of CTs by the general population, physicians and pharmacists
primary care providers, and those who had personally used CM therapies were more likely to have referred or wish to offer these therapies in the future.
<table>
<thead>
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<th>Author/s</th>
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<tbody>
<tr>
<td>Rosenbaum et al (134)</td>
<td>2002</td>
<td>U.S.</td>
<td>N=213</td>
<td>Academic physicians at a large teaching hospital</td>
<td>44%</td>
<td>Biofeedback (15%), meditation (15%) considered most useful CTs; least useful were homeopathy (55%), healing touch (41%), herbal medicine (33%), chiropractic (28%), Ayurvedic (20%); Overall 10% thought none were useful.</td>
<td>33% had personally used CM</td>
<td>Those with most knowledge were most likely to consider CM useful and recommend it</td>
<td>Those who had personally used CM were most likely to have more knowledge of CM</td>
<td>40% thought &lt;10% of patients used CM</td>
</tr>
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Those who personally used CM most likely to consider it useful and estimated higher patient use than others.

77% had recommended at least 1 of the CM therapies listed.

Most commonly 57% biofeedback
41% massage
40% meditation
36% chiropractic
* biofeedback, massage and meditation were available at the institute

46% thought CM education should be required on the medical curriculum and 82% thought it should be elective
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<th>Author/s</th>
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<th>Sample size</th>
<th>Description of respondents</th>
<th>Respon se rate</th>
<th>Beliefs and attitudes to CM</th>
<th>Use of CM – personal use and practise of</th>
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<th>Training, knowledge and information</th>
<th>Other relevant information</th>
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<tr>
<td>Kaczorowski et al (135)</td>
<td>2002</td>
<td>Canada</td>
<td>837 questionnaires were distributed and 417 completed questionnaires (49.8%) were returned. The sampling frame of eligible participants consisted of 229 family physicians and 608 specialists. All family physicians and specialists with a practice address in Hamilton, Ontario, Canada.</td>
<td>Overall response rate 50.2% 50.2% (115/229) for family physicians and 49.7% (302/608) for specialists</td>
<td>Concerns identified: lack of regulation (69.6%), credentials of CM providers (60%), knowledge level of consumers about therapies (52.3%), knowledge level of physicians about therapies (46.5%), lack of formal communication between CM providers and physicians (45.8%). GPs were significantly more concerned about general use of therapies for maintaining health, lack of regulation, credentials of complementary therapists, knowledge level.</td>
<td>The chief reason for consulting or referring patients to CM providers was “Patient request,” and this ranged from 6.1% for homeopathy to 29.4% for acupuncture. Very few selected from the other options such as: belief in holistic treatment, knowing CM providers, no response to conventional therapy, no harm could result from therapy, or personal experience with services.</td>
<td>Both family physicians and specialists indicated that their primary learning needs were to increase knowledge of: (1) scientific principles underlying complementary therapies (ranging from 21.2% for homeopathy to 34.9% for megavitamins); (2) evidence related to efficacy (ranging from 33.3% for homeopathy to 53.3% for herbal medicine); and (3) potential interactions between conventional and complementary medicine (ranging from 14.5% for chiropractic to 46.0% for herbal medicine). Desired educational formats for receiving information on Half of respondents (50.3%) reported that they “Very often” (15.1%) to “Often” (35.2%) ask their patients about the use of complementary therapies and specialists were significantly more likely to do so than general practitioners. The vast majority of physicians reported that complementary providers “Almost never” (29.0%) or “Never” (56.5%) consult with them about their patients.</td>
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of consumer
about
complementary
therapies and
knowledge level
of physicians
about
complementary
therapies than
specialists

knowledge of
complementary
services (ranging
from 9.4% for
chiropractic to
31.1%
naturopathy), no
therapeutic value
(ranging from
7.0% for
acupuncture to
23.9% for
naturopathy),
belief therapy
may be harmful
(ranging from
1.7% for
acupuncture to
22.7% for
homeopathy) and
cost of therapy to
patients (ranging
from 11.1% for
acupuncture to
27.2% for
naturopathy).

complementary
therapies varied
considerably with
continuing medical
education (34.7%)
and workshops
(23.6%) as the
most popular.

frequently than
their general
practitioner
colleagues.

79
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<th>Author/s</th>
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<th>Training, knowledge and information</th>
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<tr>
<td>Schmidt et al (136)</td>
<td>2002</td>
<td>U.K. and Germany</td>
<td>N= 97 in U.K. N=99 in Germany</td>
<td>General practitioners in U.K. and Germany</td>
<td>68%</td>
<td>Overall GPs attitude toward CM was more positive for German GPs compared to British GPs, although not statistically significant.</td>
<td>A significantly higher number of German GPs reported having practised as a CM practitioner before (n=30) and having personally used CM themselves (n=31) compared to British GPs. This was specifically the case for acupuncture. 8% of British respondents claimed to practise or have practised chiropractic treatment, 5% acupuncture treatment, 5% homeopathic treatment and 3% osteopathy.</td>
<td>British GPs reported higher levels of referrals to CM practitioners than German GPs. The most popular CTs that UK GPs referred their patients to were chiropractic treatment (79%), acupuncture (67%) and osteopathy (66%). German GPs referred their patients mainly to acupuncture treatment (82%), chiropractic treatment (73%) and herbal medicine (28%). Significantly more British GPs referred patients to Alexander technique, aromatherapy, homeopathy and osteopathy.</td>
<td>Most GPs, irrespective of country, were concerned about the lack of scientific evidence about CM. British GPs were also highly concerned about lack of knowledge about its indications and the lack of availability on the NHS. German GPs expressed that many practitioners are prejudiced against CAM and that generally there is less patient feedback on alternative methods.</td>
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would be useful for include stress, headache and depression. However, considerably less British GPs would prescribe CM for headaches and more British GPs would prescribe CM for stroke, HIV/AIDS and ME (post-viral fatigue syndrome) compared to German GPs.

<table>
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<tr>
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<th>had personally used chiropractic treatment before, 2% acupuncture and 2% homeopathy.</th>
<th>11% of German GPs had personally used acupuncture before, 7% chiropractic and 5% homeopathy</th>
<th>GPs referred their patients to herbal medicine and naturopathy.</th>
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<tr>
<td>Author/s Year of publication</td>
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<td>Nass et al (137) 2002 U.S.</td>
<td>Questionnaires mailed to 1000 randomly selected gastroenterologists</td>
<td>Not reported</td>
<td>Respondents that had received continuing medical education on CM therapies were more likely to use CM therapies themselves (39.8% vs 23.4%), recommend CM therapies to their patients (50.5% vs 27.0%).</td>
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<td>Author/s</td>
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<tr>
<td>Kemper et al (138)</td>
<td>2003</td>
<td>U.S.</td>
<td>N= 537</td>
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</table>

79% thought herbs and dietary supplements may have some benefit

34% stated ‘I’m sceptical’ 9% thought most benefits are due to placebo

27% ‘I’m concerned that patients may be harmed by them’

74% ‘my colleagues are poorly trained to answer questions about them’

CMs used were:

- 59% multivitamins
- 48% calcium
- 36% vitamin E
- 30% vitamin C
- 19% vitamin B complex or individual B vitamin
- 17% echinacea
- 12% chamomile
- 12% soy
- 11% magnesium

77% used herbs and natural supplements personally (not including multivitamins)

The average score on the knowledge test was 10/20 overall

Most respondents knew the most common clinical uses for echinacea and St Johns wort

Key deficits were in knowledge of adverse effects
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<tr>
<td>Giveon et al (121)</td>
<td>2003</td>
<td>Israel</td>
<td>N=150 completed the survey</td>
<td>Primary care physicians attending a weekly routine continuing medical education program at the Department of Family Medicine, Tel Aviv University.</td>
<td>91%</td>
<td>51% of physicians claimed that herbal remedies have no or only mild side effects, and 63% claimed that they have no or only mild interactions with conventional drugs. Seventy-three percent of physicians took no or little interest in complementary medicine, and 75% in herbal medicine.</td>
<td>31% practiced some kind of complementary medicine.</td>
<td>25% did not refer patients for complementary medicine and 69% did so occasionally</td>
<td>25% had some training in complementary medicine</td>
<td>68% estimated up to 15% of their patients use CM; 53% that up to 15% of their patients use herbal remedies; 50% that 10% of their patients report use of herbal remedies; and 52% that 10% of their patients consult them about herbal drug use. 58% of physicians always or often asked their patients about CM use, and 60% usually asked their patients about herbal use. GPs with no knowledge of herbs asked significantly less often than those with substantial knowledge. GPs who were satisfied when...</td>
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their patients discussed CM with them tended to inquire about its use significantly more often than those who were indifferent or felt bad (angry, worried, sad).

Those who never referred patients for CTs on their own initiative queried patients significantly less often about use than GPs who often referred.

Physicians with a low estimate of patient use of CM had a significantly lower tendency to ask about its use and a significantly lower estimate of the percentage of patients who disclose use of CM.

No relationship between percentage of physicians who questioned patients about use...
of CM or personally practiced CM, physician age, gender, place of graduation, number of years in practice, or qualifications in CM.
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<tr>
<td>Thomas et al (127)</td>
<td>2003</td>
<td>U.K.</td>
<td>the proportion of practices making NHS referrals remained unchanged since the 2001 survey</td>
<td>the proportion of practices making NHS referrals remained unchanged since the 2001 survey</td>
<td>one in two practices in England now offer their patients some access to CM</td>
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<td>Van haselen et al (128)</td>
<td>2004</td>
<td>U.K.</td>
<td>Responses were obtained from 149 GPs and 24 nurses and 32 other primary care team members</td>
<td>40%</td>
<td>83% of respondents had previously referred (or influenced referral) for CM treatments</td>
<td>Acupuncture and homoeopathy were the therapies for which patients were most frequently referred, followed by manual therapies</td>
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<th>Training, Knowledge and Information</th>
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<tbody>
<tr>
<td>Milden and Stokols (118)</td>
<td>2004</td>
<td>U.S.</td>
<td>N=51</td>
<td>California physicians</td>
<td>26%</td>
<td>Physicians who had been in practice the longest (and were therefore presumably older) expressed the most opposition to CM. Both their lack of CM training, as well as the length of time they had been influenced by the institutional norms that historically have resisted CM, may explain their opposition. Gender was neither significantly correlated with nor predictive of positive CM beliefs, attitudes, or behaviours.</td>
<td>Physicians' use or recommendations of CM in their practices are limited by concerns about medical professional norms, yet are positively associated with their use of computer technology for self-education and communication with peers.</td>
<td>61% do not feel sufficiently knowledgeable about CM safety or efficacy, and 81% would like to receive more education on CM modalities.</td>
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<td>Risberg et al (139) 2004</td>
<td>Norway</td>
<td>N=828</td>
<td>Norwegian oncologists, nurses, clerks and therapeutic radiographers</td>
<td>Total response rate was 61%. The following response rates were attained : 108/156 oncologists (69%); 242/414 nurses (58%); 103/164 therapeutic radiographers (63%) and 49/94 clerks (52%). In seven cases, Females showed a significantly more positive view towards CM than males (33% versus 14%). No significant differences according to age group. By contrast, approximately one-third of nurses, 32% of therapeutic radiographers and 55% of clerks reported more positive views</td>
<td>In regards to CM more participants, including physicians, expressed positive attitudes.</td>
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the occupation was not given. with few describing themselves as negative.

Again, females were more positive than males (79% versus 53%). Physicians were less positive than nurses, clerks and therapeutic radiographers.

However, more physicians had a positive attitude and fewer were negative to complementary treatments (13%) than to alternative treatments (81%).
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<tbody>
<tr>
<td>Cocconi et al (116)</td>
<td>2006</td>
<td>Italy</td>
<td>N= 1734</td>
<td>Physicians belonging to the province of Parma</td>
<td>66%</td>
<td>53% thought unconventional medicine (UM) had some efficacy</td>
<td>92% did not practice unconventional medicine (UM).</td>
<td></td>
<td>A large majority of the UM practitioners (77%) had been trained to practice UM by means of formal educational courses; the other 23% said that they were self-educated.</td>
<td>76% reported that patients wanted unconventional therapies</td>
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<td>Of the 143 physicians who declared that they practice any type of UM on their patients, only 8% practice UM alone; the remaining 92% provide UM together with conventional medicine.</td>
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<td>Some 41% of physicians practising UM declared that they subscribe to one or more UM journals and 36% that they belonged to at least one UM society.</td>
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<td>Fifty percent of the physicians practicing UM on their patients stated that they prescribed UM medications.</td>
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<td>Eighty-two percent treated conditions of the musculoskeletal system, 32% psychological or somatic disorders, 28% headaches and 18% allergic conditions or digestive disorders. A smaller proportion treated female endocrine or genital disorders,</td>
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<td>Homeopathy was the most widely practiced discipline (44%), followed by acupuncture (34%), herbal therapy (29%) and manipulative treatments (20%). Of the different manipulative treatments mentioned</td>
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in the questionnaire, most physicians declared that they practiced applied kinesiology and a minority chiropractic or osteopathy. Less than 20% but more than 10% of the UM practitioners reported practicing homotoxicology, posturology and traditional Chinese medicine.
B.4.2.3.2 Methodological concerns

Similar methodological concerns arose during the conduct of this systematic review as experienced in the previous systematic review of the Australian general population use of CMs.

Studies exploring physicians and CM are frequently compromised by poor response rates. Eight studies in the review had a response rate of less than 60%, or did not report a response rate thereby reducing the generalisability of their results. Low response rates can also mean these surveys are skewed towards respondents who have strong opinions, either positive or negative, about CM. Five studies pooled data from different populations besides medical practitioners thereby making it difficult to determine the relevance of the findings. To account for this, their findings were not included in the following discussion unless a separate result was reported for medical practitioners or otherwise indicated. In some instances, reporting was unclear about whether ‘use’ of CM refers to personal use for physicians own health or the practise of CM for patients health which would lead to an inaccurate conclusion. As is the case so often with studies investigating CM, there is a lack of consistency between definitions being used to describe CM. Additionally, some studies failed to make the distinction between referral to CM treatments (which may or may not have required a CM practitioner) or specific type of CM practitioner and time frames for referral differed. The methods used to assess attitudes to CM were highly variable and not always clearly reported, further complicating their interpretation and comparison.

B.4.2.3.3 Personal use of CM

Physician’s personal use of CM affects their likelihood of patient referral, attitudes and perceptions of CM and correspondingly, the advice given to patients (140).

The data generally indicate that in the United States, 24% of GPs have used CM (16), up to 39.8% of gastroenterologists (141) and 33% of academic physicians at a teaching hospital (142). The CTs most commonly used were: massage, meditation, herbal medicine, chiropractic, acupuncture and biofeedback. One study identified that
if physicians had received training about CM, they were more likely to personally use it (141). A similar result was obtained by Rosenbaum et al who found that personal use of CM was associated with greater self-reported knowledge of CM and a higher estimate of patient use (143).

One study of GPs in the U.K. identified personal use of CM. Results indicate that 6% of GPs personally used chiropractic, 2% acupuncture, 2% homeopathy (144). A study of German GPs found usage was higher amongst this group than U.K. based GPs and 11% of German GPs had personally used acupuncture, 7% chiropractic and 5% homeopathy (145).

A comparison between medical practitioners based in the U.S. compared with those in the E.U. shows that homeopathy is less frequently used by U.S. physicians whereas acupuncture and chiropractic is used in both regions.

**B.4.2.3.4 Practice of CM**

In regards to the practice of CTs, 15.9% of U.S. GPs reported practising at least one CT, most commonly massage, herbal medicine, acupuncture, reflexology, chiropractic, homeopathy, hypnosis and QiGong (in order from highest to lowest) (131). Although these results provide some useful information, they should be interpreted cautiously as they come from a small sample. Perry et al reported that 18% of GPs in the UK practice a CT, mostly homeopathy and acupuncture (146) whereas 32% of a sample of physicians (excluding GPs) reported practising a CT, mostly acupuncture, aromatherapy and manipulative therapies (117). In the U.K. CM is practiced by physicians more frequently in private as compared to NHS practice (117). A greater percentage of GPs in Israel practice a CT than in the U.K. or U.S., with Giveon et al estimating this as 31% (121). More German GPs practice CTs than U.K. GPs, with 19% reporting having worked using acupuncture, 11% with chiropractic, 6% with homeopathy, 3% with osteopathy (147). Few Italian GPs practised a CT, and of those that did, homeopathy, acupuncture and herbal medicine were most popular (116).
B.4.2.3.5 Referral patterns

In the United Kingdom, 41% of physicians (excluding GPs) referred patients to CTs, most commonly acupuncture, aromatherapy and manipulative therapies with therapies referred to being similar to those being practiced by the sample (117). According to Rosenbaum et al, 77% of academic physicians at a U.S. teaching institute reported having referred patients to CTs, most commonly biofeedback, massage, meditation and chiropractic and physicians with greater self-reported knowledge of CM were more likely to refer patients to CM (148). It must be noted that the institute where the study was conducted offered these services which is likely to have influenced the results. Two studies of GPs in the U.S. reported that referral to CTs ranges from 48%-61% (16;131). Corbin et al reported that referral was most strongly associated with personal use of CM (16). A survey of gastroenterologists in the U.S. identified that having received continuing medical education about CM increased the likelihood of patient referral (141).

British GPs reported higher levels of referrals to CM practitioners than German GPs (149). The most popular CM therapies that U.K. GPs referred their patients to were chiropractic treatment (79%), acupuncture (67%) and osteopathy (66%) (150). German GPs referred their patients mainly to acupuncture treatment (82%), chiropractic treatment (73%) and herbal medicine (28%) (151). A comparison between the two groups revealed that significantly more British GPs referred patients to Alexander technique, aromatherapy, homeopathy and osteopathy than German GPs. Significantly more German GPs referred their patients to herbal medicine and naturopathy(152).

Of all the surveys reviewed, two identified reasons for referral to CM. These included: patient request (128;135) evidence supporting use (128), if other treatments had failed (128;131).
B.4.2.3.6 Training, knowledge and information sources

Overall, most GPs in the U.S. reported wanting more education about CM. This ranged from 81% (118) to 84% (16). Milden and Stokols reported that 61% of GPs did not feel sufficiently knowledgeable about CM efficacy and safety (118). Nearly half (46%) of academic physicians at a U.S. institute thought CM education should be on the medical curriculum and 82% thought it should be offered as an elective subject (153). In the U.K. 87% of physicians (excluding GPs) using CM themselves, or as part of their clinical team's commitment, had not had any CM training (117). In regards to U.K. GPs, 21% had received training with one or more CT, mostly homeopathy, acupuncture and hypnotherapy (154) and 40% would like to receive training in the same three modalities (155).

Limited information is available about the resources used by medical practitioners for information about CM. One study of U.S. gastroenterologists reported that 76% obtained information about CM from medical journals, 57% the media, 48.1% continuing medical education, 22.4% the internet, or other sources (15.9%) (141).

B.4.2.3.7 Asking patients about CM

The data available demonstrate that physicians do not routinely ask patients about use of CM. Approximately half the respondents in the Canadian- and Israeli-based studies reported asking their patients about CM use (121;135). Kaczorowski reported that Canadian medical specialists were significantly more likely to ask patients than GPs (135). Giveon et al explored this behaviour in greater depth and found that several variables were associated with the frequency of asking patients about CM use (121). These were: physician’s knowledge about CM, estimation of patient use and attitudes to CM. The physicians least likely to ask patients reported no knowledge about CM, a low estimate of patient CM or a negative or indifferent attitude to CM. No information was specifically reported about physicians in the U.K. or U.S. in this regard.
**B.4.2.3.8 Confidence**

The confidence of U.S. or Canadian based physicians in dealing with CM-related issues was not reported in any study located. One study of U.K. GPs investigated this issue and reported that a minority were confident discussing CM with patients (156). The CTs they were most confident discussing were: acupuncture and homeopathy.

**B.4.2.3.9 Attitudes and beliefs**

Varying levels of interest and acceptance of CM by physicians has been demonstrated in the reviewed studies with results generally indicating a growing curiosity about specific CTs. According to Schmidt et al, the overall attitude of U.K. and German GPs toward CM was positive with a slightly more positive attitude expressed by the German GPs (157). Similarly, U.K. physicians (excluding GPs) expressed a generally positive attitude to CM, particularly among those in palliative care, rehabilitation, nuclear medicine, and genito-urinary medicine (117).

In regards to specific CTs, acupuncture, osteopathy and chiropractic were the most highly regarded by U.K. GPs in terms of effectiveness whereas homeopathy and hypnotherapy received a mixed reaction and medical herbalism, aromatherapy and reflexology were viewed more sceptically (158).

Little support for aromatherapy, magnetic field therapy, naturopathic medicine, or ethnic healing methods was reported for a sample of medical staff and associate workers in the U.S.(124). U.S. academic physicians thought biofeedback and meditation were the most useful CTs whereas homeopathy, healing touch, herbal medicine, chiropractic, Ayurvedic medicine was considered the least useful (120). Overall 10% of this sample thought none of the CM therapies were useful. Having greater knowledge of CM or personal use was associated with a more favourable attitude about the usefulness of CM (120).

Physicians also have several concerns about CM. British and German GPs are concerned about the lack of scientific evidence about CM. British GPs were also
highly concerned about lack of knowledge about its indications and the lack of availability on the N.H.S. (159). German GPs were also concerned that many practitioners are prejudiced against CM (160). In another survey, UK GPs expressed uncertainty about the theoretical validity of CTs with 50% considering acupuncture had a valid basis, compared with only 23% for homeopathy and 8% for reflexology (161).

Canadian physicians had numerous concerns about CM which included (starting with the most prevalent): lack of regulation, credentials of CM providers, the knowledge level of consumers about CTs, the knowledge level of physicians about CTs and lack of formal communication between CM and medical practitioners (135). GPs were significantly more concerned about general use of therapies for maintaining health, lack of regulation, credentials of complementary therapists, knowledge level of consumer about complementary therapies and knowledge level of physicians about complementary therapies than specialists (135).

In regards to their perceptions about the safety of CTs, 70% of British GPs thought it is safe to prescribe CM to patients, 22% thought that it was not safe which was similar to German GPs of which 76% said it is safe to prescribe CM and 19% thought it was not safe (162). Fifty one percent of primary care physicians in Israel claimed that herbal medicines had no or only mild side effects, and 63% claimed that they had no or only mild interactions with conventional drugs (121).

4.2.3.3.10 Limitations of this review

Similar to the previous systematic review, the main limitation of this review relates to the heterogeneity of the included studies which reduced the ability of the review to compare results and summarise key trends. Whilst every effort was made to locate relevant studies, it is possible that others exist which were not identified using the search strategy.
B.4.3. Systematic review of Australian medical practitioners and CM

B.4.3.1 Aim:
The primary aim was to review the literature on Australian medical practitioner’s attitudes, beliefs, and knowledge of CMs. Secondary aims were to review the literature on medical practitioner’s personal usage of CM, confidence in dealing with CM-related issues, frequency of asking patients about CMs use, information seeking behaviour and sources of information used for CMs queries, referral patterns to CM and interest in CM training.

B.4.3.2 Methods:
A search was performed using the following databases for all years available through until October, 2006: Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE, ScienceDirect, Proquest. Search terms used included, but were not limited to:

- ‘Australia’ and ‘complementary medicine’ and ‘physician’
- ‘Australia’ and ‘alternative medicine’ and ‘physician’
- ‘Australia’ and ‘holistic medicine’ and ‘physician’
- ‘Australia’ and ‘natural medicine’ and ‘physician’
- ‘Australia’ and ‘unconventional medicine’ and ‘physician’
- ‘Australia’ and ‘natural therapies’ and ‘physician’
- ‘Australia’ and ‘naturopathy’ and ‘physician’

Additional searches were conducted whereby the word ‘physician’ was replaced by the word ‘doctor’ and the word ‘medicine’ was replaced with the word ‘therapies’ and then ‘therapy’.

Articles identified in this manner were searched to ascertain relevance to this systematic review. The reference lists of articles considered suitable for inclusion were also searched to identify additional relevant studies which have not been identified by the previous search strategy. Articles were considered eligible if they were published in English, available in the peer-reviewed literature and presented
research conducted with the medical practitioners residing within Australia. Articles published prior to 2000 were excluded because the survey data were deemed too old to be of relevance to current practice.

**B.4.3.3 Results:**

**B.4.3.3.1 Description of studies**

Four studies were located of which three studies had a response rate above 60% (163-165). Three studies were conducted with general practitioners (163;165;166), one with radiation oncologists and medical oncologists (167) and one was a national study of general practitioners (166). No studies of other hospital doctors were located. A summary of key findings from the studies reviewed is presented in Table 4.
### Table 4. Australian medical practitioners and CM

<table>
<thead>
<tr>
<th>Author/s</th>
<th>Year of publication</th>
<th>Sample size</th>
<th>Description of respondents and setting</th>
<th>Response rate</th>
<th>Beliefs and attitudes to CM</th>
<th>Use of CM – personal use and practise of</th>
<th>Referral patterns to CM</th>
<th>Training, knowledge and information</th>
<th>Other relevant information</th>
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</thead>
<tbody>
<tr>
<td>Pirotta et al.</td>
<td>2000</td>
<td>N=488</td>
<td>GPs in Victoria</td>
<td>64%</td>
<td>Nearly half had considered using CM</td>
<td>93% had referred at least once in the previous year</td>
<td>Acupuncture and hypnosis were most popular</td>
<td>At least 80% of GPs reported that they knew something of acupuncture, hypnosis, meditation and chiropractic; about half knew something of herbal medicine, naturopathy and vitamin and mineral therapy; while 60%-70% had only heard of osteopathy, homoeopathy, spiritual healing, reflexology and aromatherapy.</td>
<td>GPs underestimate their patients' use of complementary therapies.</td>
</tr>
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</table>

Most respondents (93%) agreed that there should be some education on complementary therapies in core medical undergraduate.
GPs have trained in various therapies—meditation (34%), acupuncture (23%), vitamin and mineral therapy (23%), hypnosis (20%), herbal medicine (12%), chiropractic (8%), naturopathy (6%), homoeopathy (5%), spiritual healing (5%), osteopathy (4%), aromatherapy (4%), and reflexology (2%) curricula.
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<tr>
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<th>Other relevant information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easthope et al (163) 2000</td>
<td>N=290</td>
<td>GPs in Tasmania</td>
<td>62%</td>
<td></td>
<td>66% had referred patients to complementary therapies in the last year and 55% to non-medically trained CM practitioners</td>
<td>Acupuncture, hypnotherapy and Feldenkreis were most popular</td>
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<tr>
<td>Newell and Sanson-Fisher (168) 2000</td>
<td>N= 161</td>
<td>Oncologists in Australia: 60 radiation oncologists, 64 medical oncologists and 37 who could not be classified</td>
<td>61%</td>
<td>CTs most likely to be considered helpful: meditation, acupuncture and hypnotherapy.</td>
<td></td>
<td>Oncologists reported knowing most about acupuncture, antioxidant therapy and meditation and least about cellular therapy, magnetotherapy and psychic surgery</td>
<td>Perceptions of patients’ use of most therapies varied widely, with herbal therapies, antioxidant therapy and meditation considered the most commonly used</td>
<td></td>
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</table>
therapies helpful for patients being treated both palliatively and curatively.

Acupuncture considered helpful, especially for palliative patients.

Many therapies considered more likely to help palliative patients and, conversely, more harmful for curative patients.

Less familiar, more physical or invasive therapies dominated those considered likely to be harmful.
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<tr>
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<th>Training, knowledge and information</th>
<th>Other relevant information</th>
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<tbody>
<tr>
<td>Cohen et al</td>
<td>2005 N=636</td>
<td>GPs in Australia</td>
<td></td>
<td>33.2%</td>
<td>&gt;66% thought the following CM therapies were effective and &gt;80% thought they were safe: acupuncture, massage, meditation, yoga, hypnosis</td>
<td>40% had personally used nutritional, herbal or other supplements in the previous 4 weeks</td>
<td>GP's most frequently referred to massage, meditation yoga and acupuncture</td>
<td>GP's who were self-taught or had attended introductory workshops : 23% meditation, 18% vitamins/mineral therapy, 12% yoga, 11% herbal medicine, 11% acupuncture</td>
<td>12% had a diploma or certificate in acupuncture</td>
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<td>(169)</td>
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</table>
B.4.3.3.2 Methodological concerns

Whilst three out of four studies had a response rate above 60%, the largest study of had a response rate of 33%, thereby reducing the generalisability of the results. The low response rate can also mean the results are skewed towards respondents who have strong opinions, either positive or negative, about CM.

B.4.3.3.3 Attitudes and beliefs

Two studies evaluated physician’s attitudes and beliefs about CTs. Cohen et al reported that greater than 66% of GPs thought the following CTs were effective and over 80% thought they were safe: acupuncture, massage, meditation, yoga, hypnosis. The CTs considered to have low effectiveness and low harm potential were: spiritual healing, aromatherapy, reflexology (166).

A survey of oncologists demonstrated they considered meditation, acupuncture and hypnotherapy as helpful whereas CTs considered harmful were coffee enemas, psychic surgery, Iscador therapy and diet therapies (170). When asked about these perceptions in regards to palliative or curative use, oncologists tended to consider the psychosocial therapies helpful for patients being treated both palliatively and curatively and acupuncture was also considered helpful, especially for palliative patients. Many therapies were considered more likely to help palliative patients and, conversely, more harmful for curative patients. The less familiar, more physical or invasive therapies dominated those considered likely to be harmful.

B.4.3.3.4 Personal use of CTs

Only one study evaluated physicians personal use of CTs and demonstrated that 40% of GPs had personally used nutritional, herbal or other supplements in the 4 weeks prior to the survey and the common CMs used were (from highest): multivitamins, vitamins C, B, E, glucosamine, fish oils, zinc, folic acid, iron, antioxidants, selenium, garlic, evening primrose oil (166). Previously, a survey indicated that nearly half of GPs surveyed had considered using CM (165).
**B.4.3.3.5 Referral patterns**

Pirotta et al reported that 93% of GPs had referred patients at least once in the previous year to CTs with acupuncture and hypnosis being the most popular referrals (165). The same year, another study demonstrated that GP referral to CTs in the previous year was far less, only 66% and 55% had referred patients to non-medically trained CM practitioners. Acupuncture, hypnotherapy and Feldenkrais were the most popular referral choices (163). Five years later, the most frequent GP referrals to CTs were reported as massage, meditation, yoga and acupuncture (166).

**B.4.3.3.6 Training, knowledge and information sources**

GPs have trained in various CTs, specifically: meditation (34%), acupuncture (23%), vitamin and mineral therapy (23%), hypnosis (20%), herbal medicine (12%), chiropractic (8%), naturopathy (6%), homoeopathy (5%), spiritual healing (5%), osteopathy (4%), aroma-therapy (4%), and reflexology (2%)(165). A later survey found that 12% of GPs had a formal diploma or certificate in acupuncture and more that 20% expressed interest in attending an introductory workshop on meditation, massage, hypnosis, yoga, herbal medicine (166).

At least 80% of GPs reported that they knew something of acupuncture, hypnosis, meditation and chiropractic; about half knew something of herbal medicine, naturopathy and vitamin and mineral therapy; while 60% -70% had only heard of osteopathy, homoeopathy, spiritual healing, reflexology and aromatherapy (165). Similarly, oncologists reported knowing most about acupuncture and meditation. They also reported knowing the least about cellular therapy, magnetotherapy and psychic surgery (164). None of these studies evaluated participant’s actual knowledge about CTs.

Most GPs (93%) agreed that there should be some education on complementary therapies in core medical undergraduate curricula (165). No studies were located that investigated physicians information seeking behaviours, resources used for information about CM or actual knowledge about commonly used CMs.
B.4.3.3.7 Asking patients about use of CM

No studies were located which investigated the methods or frequency of communication with patients about CM or the reasons for non-communication.

B.4.3.3.8 Limitations

The main limitation of this review relates to the heterogeneity of the included studies which reduced the ability of the review to compare results and summarise key trends. Whilst every effort was made to locate relevant studies, it is possible that others exist which were not identified using the search strategy. It is also apparent that most investigation has been conducted with GPs thereby limiting the generalisability of these results to hospital doctors.
B.5.0 Pharmacists and CM

The three major functions of the pharmacist are: identifying potential and actual drug related problems, resolving actual drug-related problems and preventing potential drug-related problems (171). This requires knowledge of the available evidence regarding the drug, knowledge of the patient and their disease and communication with the patient and other health care professionals.

Within the hospital setting, clinical pharmacists interact with patients on daily ward rounds, conduct medication reviews and counselling sessions, liaise with medical teams to advise on appropriate use of medicine and provide drug information for nurses, doctors and other pharmacists. Drug information pharmacists investigate and advise on the more difficult drug related queries and are available to provide information to patients and all hospital health care staff.Dispensing pharmacists must also be aware of and advise on the safe and appropriate use of medicines.

With the widespread interest and use of CM, pharmacists are likely to be coming into contact with people interested in using or already using CMs. As a reflection of this, recent surveys have indicated that most pharmacists consider it important to have knowledge about CM or herbal medicine and be able to provide information to patients (172;173).

B.5.1 Review of the literature

In order to identify what information has been published in the international peer-reviewed literature about pharmacist’s attitudes, beliefs, personal usage, personal practice, referral patterns, training or knowledge of CM, a search was undertaken of the databases Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE, ScienceDirect and Proquest. Articles were considered for this review if studies were conducted with either community or hospital pharmacists and available in English. Relevant articles were identified by searching the databases for all years available through to October, 2006. \textbf{Table 5} lists relevant studies of overseas and Australia-based pharmacists.
<table>
<thead>
<tr>
<th>Year of publication</th>
<th>First author</th>
<th>Country where survey conducted</th>
<th>Sample size</th>
<th>Description of respondents and setting</th>
<th>Response rate</th>
<th>Beliefs and attitudes to CM</th>
<th>Use of CM – personal use and practice of</th>
<th>Referral patterns to CM</th>
<th>Training, knowledge and information</th>
<th>Other relevant information</th>
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<tbody>
<tr>
<td>1990</td>
<td>Nelson MV et al (174;175)</td>
<td>U.S and U.K.</td>
<td>U.S. n=197</td>
<td>Random sample of hospital and community pharmacists</td>
<td>U.S. 19.7%, U.K. 63.0%</td>
<td>Acupuncture was the Alternative Health Approach (AHA) felt to be most useful by the majority of pharmacists, both in the U.S. (83.8%) and in Britain (91.0%). The most utilized AHAs were osteopathy (21.8%) and chiropractic (19.3%) by U.S. pharmacists and homeopathy (10.1%) and herbal medicine (6.0%) by British pharmacists.</td>
<td>Osteopathy (38.6%) and chiropractic (33.5%) most often referrals by U.S. pharmacists, whereas homeopathy (14.7%) and osteopathy (14.5%) most often referrals by British pharmacists.</td>
<td>More than 50% of U.S. and British pharmacists had ‘never heard of’ or ‘only heard of’ about half of the 21 AHAs assessed.</td>
<td>Differences exist in the perceived knowledge, perception of usefulness, referrals, and utilization of AHAs between U.S. and British pharmacists.</td>
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</table>
or other.

About 40% of the U.S.A. community pharmacists recommended multivitamins more than five times a week compared to 28.6% of U.K. community pharmacists. Anaemia (48.6%), dieting (44.8%), alcoholism (42.3%), pregnancy (40.0%), and fatigue (36.8%) were the five most common reasons for pharmacists to recommend vitamins and minerals.

A large number of pharmacists placed the non-specific symptoms of fatigue and stress in the five most common reasons.
<table>
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<tbody>
<tr>
<td>1999</td>
<td>Bouldin et al (176)</td>
<td>U.S.</td>
<td>N=512</td>
<td>Community pharmacists - geographically stratified random sample of community pharmacies in the United States</td>
<td>26.3%</td>
<td>Pharmacists generally did not believe herbal products are well standardized, or are well accepted by the Food and Drug Administration or the National Association of Boards of Pharmacy.</td>
<td>96% of respondents indicated that they did not feel that they had enough information regarding potential interactions involving herbal products</td>
<td>Approximately 73% of pharmacists responding indicated that their pharmacy carried commercially-prepared herbal products</td>
<td>Pharmacists' attitudes toward herbals do not reflect much confidence in these products. Some caution may be the result of informational bias, as pharmacists do not possess sufficient information on herbals.</td>
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<td>Year of publication</td>
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<td>1999</td>
<td>Rickert et al (177)</td>
<td>U.S.</td>
<td>N=18</td>
<td>Metropolitan St Louis area</td>
<td>60%</td>
<td>Opinion as to the value of herbal medicine:</td>
<td></td>
<td></td>
<td>Sources of information:</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>(n=6 hospital, 5 managed care, 5 independent, 2 chain pharmacies)</td>
<td></td>
<td></td>
<td>Very valuable(n=4), somewhat valuable(4), don’t work/sceptical(3), none(2), very marketable(2), need FDA regulation and standardisation(2)</td>
<td></td>
<td></td>
<td>22%(4)</td>
<td></td>
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<tr>
<td>2000</td>
<td>Chang et al (178)</td>
<td>U.S</td>
<td>N=164</td>
<td>(68.0% practiced in a community pharmacy; 4.1% hospitals; 5.2% academia)</td>
<td>76%</td>
<td>Whether site sold herbal medicines or not had no impact on attitudinal items.</td>
<td></td>
<td></td>
<td>Those with prior education or access to herbal information at work more likely to agree that providing herbal information was a pharmacists professional responsibility.</td>
<td>45.1% had previous continuing education on herbal medicines; the average score on the herbal knowledge test was 6.3 (maximum score of 15).</td>
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Chapter ONE Section B – Use of CTs by the general population, physicians and pharmacists
<table>
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<tbody>
<tr>
<td>2001</td>
<td>Howard et al (179)</td>
<td>U.S.</td>
<td>N=70</td>
<td>Not reported</td>
<td></td>
<td>A majority (52.9%) reported taking dietary supplements including echinacea, zinc, and chromium picolinate.</td>
<td>Fewer than half of pharmacists stated they have recommended a dietary supplement to a patient.</td>
<td>Pharmacists stated the top information sources were: published clinical trials, allopathic health care providers, alternative medicine practitioners, and word of mouth. The Internet was an important source for recommendations although not for personal use. More than 90% rates the ability to view reference citations and computerized alerts on drug-dietary supplement interactions “very important” or “important”. Interest was high in accessing computerized monographs.</td>
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<td>Year of publication</td>
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<tr>
<td>2003</td>
<td>Dolder et al (180)</td>
<td>U.S. postal survey</td>
<td>Pharmacists registered in California</td>
<td>22%</td>
<td>63% reported patients regularly asked them about CMs</td>
<td>37% personally used CMs regularly</td>
<td>Most frequently recommended CMs: echinacea, ginkgo, glucosamine, chondroitin, melatonin, saw palmetto, soy, St John’s wort, valerian, vitamin E, zinc</td>
<td>Most frequently recommended CMs: echinacea, ginkgo, glucosamine, chondroitin, melatonin, saw palmetto, soy, St John’s wort, valerian, vitamin E, zinc</td>
<td>79% had received training, attended educational seminars, or examined literature chiefly focussed on CMs</td>
<td></td>
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</table>

* definition of alternative medications was ‘any product, including herbal medicines, vitamins, minerals and natural products that may be purchased at a health food store, pharmacy, supermarket or alternative health store/magazine for the purpose of self-treatment’. This did not include multivitamins, calcium, iron and vitamin D which are typically prescribed by medical practitioners.
Chapter ONE Section B – Use of CTs by the general population, physicians and pharmacists

2003 Clauson et al (181) U.S. N=534 Pharcists licensed and maintained a residence in Missouri 18.2% 2.4% reported being able to "always answer natural product questions" and 1.7% were "very satisfied" with their level of natural product knowledge. Most felt they were "sometimes able to answer natural product questions" (61.6%) and that they were "somewhat satisfied" with their level of natural product knowledge (44.3%). The majority (79.8%) made efforts to learn about natural products 1 to 6 times per year.

5.8% of responding pharmacists stated that they "never" made an effort to learn more about CMs. Written continuing education (CE) was the most popular ways to improve knowledge about CM as rated by 70.2%.

Over half (56.9%) of all Missouri Pharmacist Survey (MPS) respondents indicated that they received questions about natural products on a weekly basis, with the vast majority (82.4%) reporting that they received questions at least monthly.

The topic areas that pharmacists ranked as "very important" were "interactions" (84.5%), "side effects/adverse events" (80.0%), "patient counseling" (71.2%), "therapeutic uses" (68.2%), and "dosing" (59.2%).
<table>
<thead>
<tr>
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<tr>
<td>2003</td>
<td>Welna et al (182)</td>
<td>U.S.</td>
<td>N=533</td>
<td>Half the pharmacists (51%) believed that herbs and natural products (H/NPs) were safe, but only 19% believed they were effective. The amount of government oversight of H/NPs was considered &quot;not adequate&quot; by 78% of pharmacists. Pharmacists working in community/outpatient settings and pharmacists living in non-urban areas were more likely to report use.</td>
<td>52.4%</td>
<td>53% reported personal use of herbs and natural products 45% reported having recommended them to a family member.</td>
<td>Slightly more than half of the respondents (56%) reported suggesting to a patient that he or she try an H/NP.</td>
<td></td>
<td>Trade journals/professional newsletters, continuing education coursework, reference texts, and reports of randomized clinical trials were considered very important sources of information about H/NPs. However, almost all respondents (95%) felt available information on H/NPs was &quot;not adequate&quot; or only &quot;somewhat adequate.&quot;</td>
<td>Patients' requests, consumer demand, manufacturer's reputation, and manufacturer's ability to provide product quality data were key factors influencing respondents' decisions to purchase and stock H/NPs in the pharmacy. On average, pharmacists reported that patients ask them questions regarding H/NPs 7 times per 40-hour workweek; other health care practitioners ask an average of 1.3 times/wk.</td>
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<td>Year of publication</td>
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<td>Description of respondents and setting</td>
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<tr>
<td>2003</td>
<td>Koh et al(183)</td>
<td>Singapore</td>
<td>N=420</td>
<td>convenience sample at conference, hospitals and community stores</td>
<td>Not reported</td>
<td>9.3% used CM because they thought 'it was natural and safer'</td>
<td>84.3% had used CM at some stage; 66.2% in the past 12 months</td>
<td>79% of CM users would also recommend it to family and friends</td>
<td>Knowledge score: 7.23± 1.96. (maximum score assumed to be 15 but not clearly stated).</td>
<td>81% stated their training did not equip them with necessary skills and knowledge to counsel patients about herbal medicines 90.5% thought the professional curriculum should have more components about herbal medicine 78% interested in future training on herbal medicine, 58% on TCM, 34.5% acupuncture, 27% homeopathy.</td>
</tr>
</tbody>
</table>

Chapter ONE Section B – Use of CTs by the general population, physicians and pharmacists
| CM: Back problems, sprains or strains, headache, allergies, insomnia. |
|---|---|
| 70.5% using both CM and conventional medicine did not inform or consult a doctor and 82% reported this was because they felt they did not need physician advice. |

<table>
<thead>
<tr>
<th>Self-rated knowledge of herbal medicine:</th>
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<tbody>
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<td>49% felt they did not know much about it, 40% felt they had moderate knowledge, 7% knew ‘nothing at all’; 4.5% knew ‘a great deal’.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Information sources:</th>
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</thead>
<tbody>
<tr>
<td>books/magazines(64%), friends/family(36%), internet(31%), pharmacists(17%), sales people(14%), TV(10%), doctors(4%), other means e.g. journals/seminars/university(20%).</td>
</tr>
<tr>
<td>Year of publication</td>
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<tr>
<td>2005</td>
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</table>
36% of hospital pharmacists had never used any form of CM compared to 16% of community pharmacists who had not used CMs.

Chief reasons for not recommending CM: lack of evidence (83%), satisfaction with conventional medicine (10%).

Conditions they would consider recommending CM for: insomnia (75%), arthritis (72%), anxiety (56%), PMT (57%), back problems (51%), sprains and strains (40%), depression (39%), headache (38%), allergies (29%), dysmenorrhea (27%), hypertension (14%), cancer (11%).

61% would consider continuing education about CM, 27% possibly consider and 13% not consider.

Most frequently used information sources were books and magazines (25%), journals (29%), combination (22%), university and other training (8%), manufacturer provided information (8%), Internet (4%).
<table>
<thead>
<tr>
<th>Year of publication</th>
<th>First author</th>
<th>Country where survey conducted</th>
<th>Sample size</th>
<th>Description of respondents and setting</th>
<th>Response rate</th>
<th>Beliefs and attitudes to CM</th>
<th>Use of CM – personal use and practise of</th>
<th>Referral patterns to CM</th>
<th>Training, knowledge and information</th>
<th>Other relevant information</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>Brown et al (185)</td>
<td>US N=107 Community pharmacists – state of Texas</td>
<td>27.0%</td>
<td>Among CM users, pharmacists most often encouraged CM use if medically appropriate. In pharmacies that stocked herbal or homeopathics, pharmacists significantly more likely to encourage use of CM when medically appropriate and recommend other CTs if appropriate. When no references available to research CM, pharmacists tended to neither encourage nor discourage CM use based on lack of scientific evidence of their effectiveness.</td>
<td>Pharmacists were not comfortable with responding to CM inquiries but believed they needed adequate knowledge about CM. In general, pharmacists rarely asked patients about their CM use. Pharmacists' rate of inquiry about CM use increased significantly when this information could be documented in patient profiles and when pharmacists had additional training in CM.</td>
<td>A majority (71.0%) of pharmacists had encountered patients who were using CM, which was defined broadly in the survey to include herbal products, vitamins and minerals, homeopathic products, massage, meditation, and other types of CM. Pharmacists documented CM use by patients in 11.0% of cases and reported monitoring for drug-related problems in 38.4% of users.</td>
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</table>
B.5.1.1 Results:

B.5.1.1.1 Description of studies

It is apparent that the majority of studies have been conducted in the United States (178;186-193), with one from Canada (194), one from Singapore (195) and one from Australia (196). All studies focus on community pharmacists and three included hospital pharmacists within their sample (197-199). For studies where response rates were reported, only one had a response rate above 60% (178) thereby limiting the generalisability of the results. Some studies focused on herbal medicines, while others asked about complementary therapies. For the case of this review, all studies incorporated some information about CMs in their survey.

B.5.1.1.2 Pharmacists beliefs and attitudes

There was little consistency in respect to pharmacist’s attitudes and beliefs about CMs. In the U.S. there is a perceived lack of regulation about the quality of herbal medicines and a perceived lack of efficacy of CMs as reported by Welna et al and Bouldin et al (200;201). In 1999, Bouldin et al reported that pharmacists’ attitudes toward herbals did not, on the whole, reflect much confidence in these products as currently supplied (202). It was suggested that some of this caution may be the result of an informational bias, in which pharmacists do not possess sufficient information on herbals, consequently resulting in limited understanding of these products and a low level of comfort with their use. Four years later, Welna et al produced similar results with only 19% of pharmacists believing herbal and natural supplements were effective and 51% believing herbs and natural products (H/NPs) were safe (203).

To date, only one Australian study has explored pharmacist’s beliefs and attitudes about CM and results remain to be confirmed in future studies. The survey of chiefly community pharmacists reported that pharmacists had a generally positive attitude to CM. Nearly three-quarters (74%) thought herbal medicine was useful, 77% thought
CM is a useful adjunct to conventional medicine; 73% thought CM included ideas from which conventional medicine could benefit (204).

A comparison of these results would suggest that Australian pharmacists have a more positive attitude to CM than overseas pharmacists however the attitudes of Australian pharmacists prior to 2004 were not known and may have been similar in the late 1990s when Bouldin et al and Rickert et al conducted their studies (192;205). It must also be noted that the regulatory environment of CMs in Australia and the United States is different and may account for some attitudinal differences.

**B.5.1.1.3 Personal use of CTs**

It is difficult to determine the percentage of pharmacists who use CMs or CTs as some studies do not tend to differentiate between the two in their surveys or results are not clearly reported. Despite these limitations, it appears that 37-53% of U.S. pharmacist use CMs, 39% of Australian pharmacists use CTs (74% are vitamins/herbs) and most (84%) pharmacists from Singapore and Malaysia use CTs. One survey suggested that pharmacists working in community/outpatient settings and pharmacists living in non-urban areas were more likely to report use of CMs than others (206). In Australia, vitamins/herbs were the most popular form of CM used with relatively little use of massage, acupuncture, homeopathy, naturopathy, chiropractic, relaxation, TCM, yoga, aromatherapy or Tai Chi. Those working in community pharmacy were significantly more likely to have used CM than hospital pharmacists.

**B.5.1.1.4 Referral patterns to CTs**

In 1990, osteopathy (38.6%) and chiropractic (33.5%) were the most commonly referred to CTs by U.S. pharmacists, whereas homeopathy (14.7%) and osteopathy (14.5%) were the most common CT referrals by British pharmacists (207;208). About 40% of the U.S community pharmacists recommended multivitamins more than five times a week compared to 28.6% of U.K. community pharmacists. Anaemia (48.6%), dieting (44.8%), alcoholism (42.3%), pregnancy (40.0%), and fatigue (36.8%) were
the five most common reasons for pharmacists to recommend vitamins and minerals. The non-specific symptoms of fatigue and stress were also common reasons for CT referral.

The number of U.S. pharmacists referring patients to use CMs increased over the next decade and by 2003, 56% of U.S. pharmacists reported suggesting to a patient they try a herb and natural supplement (209). It also appears that pharmacists working within pharmacies which stock herbal or homeopathic products were significantly more likely to encourage the use of CM when medically appropriate and to recommend other CM therapies appropriate for patients’ conditions (210). In 2005, an Australian study of chiefly community pharmacists found 23% recommended CMs daily whereas 16% had never recommended any form of CM. The most common reasons pharmacists recommended CM were if they perceived it had a proven mechanism of action and for the maintenance of good health. Overwhelmingly, the main reason pharmacists did not recommend CMs was if they perceived it lacked supportive evidence. Similarly, a U.S. study identified that pharmacists would not encourage or discourage use of CM when no references were available to research CM (211). A study of pharmacists mainly from Singapore and Malaysia found 79% of CM users would also recommend it to family and friends (212). Currently, there is limited information about hospital pharmacist’s referral patterns in the international literature and which specific CTs are actively encouraged or discouraged when patients express an interest in their use.

**B.5.1.1.5 Knowledge and information sources**

Considering their major role as medication advisors, it was thought that the issue of pharmacist’s knowledge and use of information sources was important to explore. Two studies have evaluated pharmacists’ actual knowledge about CMs with all studies conducted overseas and indicating that knowledge test scores were low (178;213). A 2000 study provides the most robust information and identified that average score on a herbal knowledge test was 6.3 (maximum score of 15) (178). Pharmacists with previous continuing education scored significantly higher than those without prior continuing education and pharmacists knew mostly about the uses of
herbal medications. No significant differences were seen between those who sold or did not sell herbal medicines, or community versus non-community settings. It should be noted that Chang et al incorporated the ‘I don’t know’ responses into the number of incorrect answers which may have decreased the knowledge scores. A similar test was undertaken with a convenience sample by Koh et al in Singapore who identified participants had an average score of 7.23 on a knowledge test (maximum score of 15 assumed but not clearly stated) (214).

Overseas pharmacists generally appear to be aware of their knowledge deficit and do not perceive they have sufficient knowledge about CM. They are also aware of not being able to answer CM-related queries on a regular basis and few are satisfied with their level of knowledge or are comfortable answering CM enquiries (181;213;215).

In contrast, Australian pharmacists perceived their level of knowledge about acupuncture, chiropractic, herbal medicine, massage, meditation, yoga to be sufficient to explain these therapies to patients if necessary however only 15% thought they had sufficient knowledge to be able to treat patients with herbal medicine (216). To date, no published studies are available which have focussed on Australian pharmacist’s actual knowledge about the safety and efficacy of commonly used CMs and limited information is available about hospital pharmacists in general.

Pharmacists use a variety of information sources for CM information, most commonly journals, professional publications, books and magazines (188;192;217-220). One survey also identified CM practitioners and service providers as an information source (221). The adequacy of information available is questionable according to Welna et al where 95% of respondents felt available information on herbs and natural products was "not adequate" or only "somewhat adequate."

**B.5.1.1.6 Pharmacists and CM training**

Although it is difficult to interpret the studies which have investigated pharmacists previous level of training about CM, it is apparent that many pharmacists are interested in future training with figures ranging from 61% (222) -84% (188).
Continuing education appears to be the most common method of receiving training in CM (178;181). Over 80% of Australian pharmacists supported CM training at undergraduate and post-graduate levels (223). Koh et al identified that 90.5% of pharmacists thought the professional curriculum should include more components about herbal medicine (224). The relevance of this finding to Australian pharmacists is unknown as the sample mainly consisted of pharmacists based in Asia.

**B.5.1.1.7 Patient communication about CM**

Communication between health care professionals and patients is an essential part of providing safe and effective health care. Whilst there has been substantial investigation into the communication behaviours and barriers of medical physicians and their patients regarding CM, relatively little is known about pharmacists. The information currently available is derived from two studies and suggests that pharmacists do not routinely ask patients about use of CMs however a pharmacists' rate of inquiry increases significantly if they have had received training about CMs or when the information could be documented in patient profiles (225;226). Pharmacists who personally used CMs were also more likely to ask patients about their use (227) however patient use is not routinely documented by pharmacists (228).

**B.5.1.1.8 Limitations of the available literature**

Despite the fact that 12 studies have explored pharmacists relationship with CTs from various perspectives, only one reported a response rate above 60% thereby limiting the generalisability of the results. In addition, all studies focussed on community pharmacists thereby providing limited information about hospital pharmacists and issues which are more distinctly relevant to their practice. Only one Australian study of pharmacists was identified which had a low response rate (32%) and involved chiefly community pharmacists, also reducing the generalisability of its findings. The definitions used to describe CMs varied between surveys with one survey specifically excluding multivitamins, calcium, iron or vitamin D from the definition, thereby leading to an under-estimation of use (188). Although three studies had reported
pharmacist’s knowledge of CM was poor, non-validated surveys were used and methodologies were not fully reported making it difficult to interpret the results.

**B.6.0 Summary**

Overall, there were several methodological concerns consistently identified by the systematic reviews presented in Section B.

Importantly, numerous studies failed to adequately report on the methodologies used to collect data making it difficult to interpret the quality of the study, the reported results, and their generalisability. For instance, numerous studies failed to report on response rates. Where response rates were reported, this was highly variable and in many cases well below 60%. In some studies, a convenience sample was used in the data collection, further detracting from the generalisability of results. In some studies, non-validated surveys were used whereas in others, insufficient information was presented to determine whether questionnaires had been validated. This makes it difficult to determine whether the questionnaires used in the study produced results which accurately reflected the behaviours, perceptions and knowledge of study participants. When these factors are considered together, it is clear that the strength of the conclusions drawn by the many studies with inadequately reported methodologies is diminished and there are considerable defects in the literature.

The methods used to collect data about the publics use of CMs and doctors and pharmacists attitudes, knowledge and use of complementary medicine included face to face interviews, self-administered surveys and computer assisted telephone surveys. When results from studies which gathered information about the same research question using different methodologies were available, these could be cross-referenced to see common themes that emerged. This was undertaken where possible and provided the basis for the findings presented in the systematic reviews.

Despite these limitations, it is apparent that the use of CTs is widespread in Australia, the United States, United Kingdom, Canada and Europe. The factors consistently associated with use are: gender, ethnicity, age, education and income. Complementary
medicine is used as an adjunct to conventional care due to a range of positive and negative motivations such as health promotion, pursuit of wellness, dissatisfaction with conventional care or failure of conventional treatments to provide adequate outcomes. Importantly, patients do not routinely disclose use of CMs to medical practitioners.

In Australia, vitamins are the most commonly used CMs whereas the use of herbal medicines is increasing, especially amongst women. There is limited information about the specific medicines being used or the prescribers of such medicines. The percentage of people visiting CM practitioners is also increasing. There is limited information about the information sources used by the public to learn about CM, their attitudes to CM or reasons for non-disclosure about use to medical physicians.

Overseas studies indicate that most physicians want more education about CM. There is limited information available about their perceived or actual knowledge of CM, information seeking behaviours or resources referred to for CM enquiries. It is difficult to assess the personal use and practice of CM by physicians due to variations in definitions used however it appears that approximately one-third of physicians have personally used CM, approximately 1 in 3 Israeli physicians practice CM, less than 1 in 3 physicians practice CM in the United States or U.K. and it is rare for Italian physicians to practice CM. Some physicians refer patients to CM however the patterns of referral are difficult to estimate based on current information. Physicians do not generally ask patients about their use of CMs and the attitudes and beliefs of physicians to CM is highly variable and once again, difficult to assess. Of note, few studies have been conducted with hospital doctors and no studies have been conducted with anaesthetists or surgeons regarding CM.

In Australia, most investigation has been conducted with GPs and very little is known about hospital doctors. At least 40% of GPs have personally used CM and at least two-thirds refer patients to CTs. Acupuncture, massage, meditation and yoga are considered the most efficacious CTs and most GPs think they know something of acupuncture, hypnosis, meditation and chiropractic. No studies were located which assessed physician’s perceived or actual knowledge of CM, information seeking
behaviours or resources used for CM enquiries. No studies have investigated whether physicians ask patients about CM use, reasons for non-communication or responses to patients if use is revealed. Importantly, information about hospital doctors is limited to one study of radiation oncologists and medical oncologists and there is no information about other hospital doctors, including anaesthetists and surgeons.

Studies of pharmacists in the international literature indicate that most research has focussed on community pharmacists and none have focussed on hospital pharmacists. For studies where response rates were reported, only one had a response rate above 60% and only one study has been conducted with Australian pharmacists. Overall, it appears there is little consistency in respect to pharmacist’s attitudes and beliefs about CTs and there more U.S. pharmacists use CMs than Australian pharmacists. Only two studies have evaluated pharmacists’ actual knowledge about CMs, both conducted overseas and demonstrating knowledge is limited. Overseas pharmacists are aware of their knowledge deficit however Australian pharmacists perceive they have sufficient knowledge to explain several CTs to customers. Currently, no published studies are available which have focussed on Australian pharmacist’s actual knowledge about the safety and efficacy of commonly used CMs and limited information is available about hospital pharmacists in general.
Chapter One

Section C
CMs and adult surgical patients

C.1.0 Introduction

This section presents a systematic literature review of adult surgical patients and CM that explores the prevalence of CM use, reasons for use, disclosure to hospital staff, beliefs and perceptions about CM, information sources used and interest in hospitals offering access CM services. It will start with a systematic review of relevant overseas studies and then focus on what is known about Australian surgical patients. This review will also encompass cardiac surgery patients as a special sub-group of interest.
C.2.0 International trends

The use of CMs by the general population living in Western countries is well established however less is known about their use by adult surgical patients. A systematic review of the peer-reviewed international literature was undertaken to determine what information is currently known about this population and CMs.
C.2.1 Systematic review of surgical patients and CM use

C.2.1.1 Aim:
The primary aim was to determine the incidence of pre-operative CMs and CTs use by adult surgical patients. Secondary aims were to investigate the frequency of surgical patient’s use of CMs that may induce adverse events during the intra-operative and perioperative periods, patients disclosure to hospital staff, reasons for use, beliefs and perceptions about CMs, sources of advice and recommendation regarding CM and interest in hospitals offering CM services.

C.2.1.2 Methodology:
A search was performed using the following databases for all years available through until October, 2006: Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE, ScienceDirect, Proquest. Search terms used included, but were not limited to:

- ‘Complementary medicine’ and hospital
- ‘Herbal medicine’ and ‘hospital’
- ‘Alternative medicine’ and ‘hospital’
- ‘Integrative medicine’ and ‘hospital’
- ‘Complementary and Alternative medicine’ and ‘hospital’
- ‘Naturopathy’ and ‘hospital’
- ‘Natural therapies’ and ‘hospital’

A search was also conducted whereby the word ‘medicine’ was replaced by the word ‘therapy’ and then ‘therapies’. The above terms were re-used again but ‘hospital’ was replaced with ‘surgery’, ‘surgeon’, ‘anaesthesia’ and ‘anesthesiology’.

Articles identified in this manner were searched to ascertain relevance to this systematic review. The reference lists of articles considered suitable for inclusion were also searched to identify additional relevant studies which have not been identified by the previous search strategy. Articles were considered eligible if they
were population based surveys, presented in English, published in the peer-reviewed literature and described research conducted with the surgical population.

**C.2.1.3 Results:**

**C.2.1.3.1 Description of studies**

Fourteen studies were considered eligible for this review. Eleven studies were conducted in the United States (229-239), one study in Denmark (240), one in the United Kingdom (241) and one in Australia (242). All studies were conducted prior to surgery except for Glintborg et al which was conducted after patients were discharged and involved a mixed sample of surgical and medical patients (243). Four studies focussed on CM therapies (236-239) and where response rates were reported, only one study had a response rate below 60% (231). One study was conducted in Australia and one study focussed on cardiac surgery patients (239;242). A summary of key findings from relevant articles is presented in **Table 1**. Relevant information from the Australian study and cardiac surgery study will be discussed in greater detail after this review.
<table>
<thead>
<tr>
<th>Date of publication</th>
<th>Author/s (Ref)</th>
<th>Setting</th>
<th>Sample size</th>
<th>Response rate</th>
<th>Usage findings</th>
<th>Specific CMs and CTs used</th>
<th>Description of CM users</th>
<th>Disclosure</th>
<th>Other relevant information</th>
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</table>
| 2000                | Tsen et al (235) | U.S. | Patients presenting for evaluation in the preoperative clinic | N=3106 | 81% | Herbal medicines: 22%  
Vitamin supplements: 51% | The five most commonly used herbal medicines were (from highest to lowest): Echinacea (7.3% of all patients), ginkgo biloba (4.0%), St John’s wort (3.3%), garlic (3.2%) and ginseng (3.2%) | Females more frequently used herbal medicines (23.6%) compared to males (19.2%).  
Significant variation amongst age groups with use of herbal medicines greatest in age group 50-70 years | Not reported | Reasons for use: health care provider recommendation (21%), recommendation of friend or family member (36%), TV or magazine advertisement (12%), decided 'on their own' (36%) |
| 2000                | Kaye et al (230) | U.S. | U.S. | N=755 | 68% | 32% were self-administering one or more herb-related product  
64% were actively taking one or more dietary supplement at the time of the survey | Of CM users: Multivitamins (90%), garlic (43%), ginkgo biloba (32%), St John’s wort (30%), ma huang (18%), Echinacea (12%), Aloe vera (10%), cascara (8%), licorice (3%) | Not reported | Nearly 70% of patients taking one or more herb-related product did not report use when asked during routine anaesthetic assessment |
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<th>Date of publication</th>
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<th>Disclosure</th>
<th>Other relevant information</th>
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<tbody>
<tr>
<td>2000</td>
<td>Norred et al (232)</td>
<td>U.S. Patients undergoing elective surgery</td>
<td>N=500</td>
<td>N/A</td>
<td>51% had used herbs, vitamins, dietary supplements, or homeopathic medicines within the 2 weeks prior to surgery</td>
<td>Use of CM products that could potentially inhibit coagulation: 27%</td>
<td>24% used substances from 2 or more categories of CMs (herbs, vitamins, dietary supplements, or homeopathic medicines)</td>
<td>Not reported</td>
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<td></td>
<td>Liu et al (244)</td>
<td>Cardiac surgery patients attending an urban, academic medical centre</td>
<td>N=263</td>
<td>70%</td>
<td>75% had used CM in the previous 12 months. When prayer and vitamins are excluded, usage is 44%</td>
<td>53.6% had used vitamins in the previous 12 months, 36.1% prayer, 17.1% nutritional therapy, 11.4% massage, 11.4% meditation,</td>
<td>For vitamins: college education or higher and older age.</td>
<td>17% discussed CM with physicians or surgeons: of those that didn't, 36%</td>
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<tr>
<td>Year</td>
<td>Study</td>
<td>Setting</td>
<td>Sample Size</td>
<td>CM Use</td>
<td>Types of CMs Used</td>
<td>Other Findings</td>
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<tr>
<td>2001</td>
<td>Leung et al (231)</td>
<td>Elective surgery patients at 5 U.S. teaching hospitals</td>
<td>N=2560</td>
<td>60%</td>
<td>39.2% used CMs; herbal medicine most popular type (67.6% of all CMs used), then vitamins supplements (15.1%) and minerals (7.3%)</td>
<td>53% ceased use prior to surgery. Specifically, of these 36.8% ceased used within 2 days before surgery, 28.4% within 8-14 days, 12.4% within 2-7 days, 12.4% between sites from 22% - 44%</td>
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<td>Herbs used: (from highest usage to lowest) echinacea (12.7% of total sample), ginkgo biloba (8.6%), garlic (7.9%), ginseng (7.4%), valerian (4.3%), St John’s wort (2.5%), Saw palmetto (2.3%), kava kava (1.3%), yohimbe (0.2%)</td>
<td>Users of CMs were more likely to be female, aged 35-49 years, have higher income levels, Caucasian, higher education, problems with sleep, joints, back, allergies, addiction, history of general surgery; decreased likelihood is diabetic, or using anti-thrombotic medicines</td>
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11.4% chiropractic, 9.9% herbal medicines, 4.2% acupuncture. No information about specific CMs used reported. 44.4% did not consult with primary physician, 56.4% did not inform anaesthetist prior to surgery. 73.7% of patients using CMs reported feeling benefits such as increased energy levels, decreased disease symptoms, disease prevention, mood elevation. Reasons for use: improve general health (54.9%), prevent disease (33.3%).
<table>
<thead>
<tr>
<th>Date of publication</th>
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<tbody>
<tr>
<td>2002</td>
<td>Wang et al (237)</td>
<td>U.S. Patients undergoing outpatient procedures only</td>
<td>N=857</td>
<td>85.7%</td>
<td>32% had used CM therapies</td>
<td>Massage (15.2%), herbal medicine (9.7%), relaxation therapy (8.3%), acupuncture (6.6%)</td>
<td>Not reported</td>
<td>A significant proportion of patients (42%) indicated their willingness to use acupuncture as a treatment modality for anxiety during the preoperative period; those with previous experience of CM had a significant greater interest compared to individuals who had no experience (66.3% vs. 29.9%)</td>
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<tr>
<td>2002</td>
<td>Norred (233)</td>
<td>U.S.</td>
<td>N=6852</td>
<td>91%</td>
<td>67% used CM within the previous 2 weeks</td>
<td>Herbs: garlic (9.5%), herbal teas (8.1%), cranberry (5.2%), ginkgo biloba (4.6%), ginseng (4.2%), echinacea (4.1%) and ephedra products (3.2%)</td>
<td>CMs users were significantly more likely to be female, older than 40 years of age, Caucasian, college-educated, admitted for neurosurgery than other procedures compared with CM non-users.</td>
<td>Not reported</td>
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<td>Vitamin supplements: calcium (21.5%), iron (7.0%), glucosamine (6.9%), zinc (5.5%), magnesium (4.7%), potassium (4.3%) and chondroitin (4.0%)</td>
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<td></td>
<td>Homeopathic medicines: 1%</td>
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<td>Date of publication</td>
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<td>Setting</td>
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<td>2002</td>
<td>Skinner and Rangasami (241)</td>
<td>Patients attending for anaesthesia in a British district general hospital</td>
<td>N=2723</td>
<td>81%</td>
<td>One or more herbal medicines was taken by 4.8% of the sample at the time of the survey or in the previous 2 weeks</td>
<td>Herbal medicines used (from highest to lowest): garlic (1.6% of all patients), ginseng (1.25%), ginkgo biloba (1.1%), St John’s wort (0.99%), echinacea (0.7%)</td>
<td>Females patients significantly more likely to be using herbal medicines than males</td>
<td>Not reported</td>
<td></td>
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<tr>
<td>2002</td>
<td>Norred (234)</td>
<td>U.S.</td>
<td>N=496</td>
<td>99%</td>
<td>73.4% used CMs in the 2 weeks prior to surgery Use of CM products that could potentially inhibit coagulation: 40% Affect blood pressure: 32% Cause sedation: 17% Have ‘cardiac’ effects: 20% Alter electrolytes: 9% Herbs recognized to interact with pharmaceuticals were consumed by 23% of patients</td>
<td>37% used herbal medicines in the 2 weeks prior to surgery; 59% used vitamin supplements; 45% used dietary supplements; 1% used homeopathic remedies</td>
<td>Not reported</td>
<td></td>
<td></td>
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</table>
2003

Wang et al (238) U.S.
Patients undergoing inpatient procedures

N = 1235 72%

57.4% had used in the past or were still using at least 1 type of CM therapy

* When prayer and chelation was removed, usage was 49.1%

Past and present use:
- Self-prayer (29%)
- Chiropractic (23%)
- Massage/reflexology (15%)
- Relaxation therapies (14%)
- Herbal medicines (13%)
- Megavitamins (9%)
- Acupuncture (7%)

Current use: 25.1% using at least one form of CM (excluding prayer)

Up to 20% of all respondents did not disclose use to perioperative physicians unless specifically asked. Inpatients were more likely to disclose use than outpatients.

Reasons for use:
- ‘few or no side effects’ (35.3%)
- ‘recommended by friend or medical doctor’ (18.9%)
- ‘keeps me healthy’ (13.4%)
- ‘works better or just as well as conventional medicine’ (11.4%)
- ‘problem not serious enough to be seen by a medical doctor’ (7%)
- ‘other’ (14%)

76% of all respondents were willing to use CM as part of their anaesthesia care. Most interest was expressed for acupuncture, hypnosis and herbal medicine.
<table>
<thead>
<tr>
<th>Date of publication</th>
<th>Author/s</th>
<th>Setting</th>
<th>Sample size</th>
<th>Response rate</th>
<th>Usage findings</th>
<th>Specific CMs and CTs used</th>
<th>Description of CM users</th>
<th>Disclosure</th>
<th>Other relevant information</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>Grauer et al (242)</td>
<td>Two public hospitals in Australia</td>
<td>N=1102</td>
<td>92%</td>
<td>14.3% used herbal medicine in previous 6 weeks &lt;br&gt; 20.4% used vitamin supplements</td>
<td>Herbs used (starting with highest use): Garlic, evening primrose, ginkgo biloba, St John’s wort and echinacea</td>
<td>Herbal and vitamin supplements users were younger than non-users</td>
<td>27.8% of herbal users informed hospital doctors about use</td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>Adusumilli et al (229)</td>
<td>U.S. Patients undergoing elective surgery</td>
<td>N=2186</td>
<td>65%</td>
<td>57% had used herbal medicine during their lives; 38% in past 2 years; 16% continued in the month of surgery &lt;br&gt; CMs usage by surgical subpopulations: &lt;br&gt; Cardiac surgery: 29% &lt;br&gt; Plastic surgery: 35% &lt;br&gt; General surgery: 37% &lt;br&gt; Urology: 45% &lt;br&gt; Neurosurgery: 41% &lt;br&gt; Gynecology: 52%</td>
<td>Herbs used in previous 2 years: echinacea (48%), aloe vera 30%, ginseng 28%, garlic 27%, ginkgo biloba 22%</td>
<td>Use of herbal medicines higher in patients undergoing gynecological and urological procedures than vascular procedures. &lt;br&gt; Significantly higher proportion of patients without a primary care physician (48%) reported using herbal medicines compared to those with one (38%). &lt;br&gt; Patients with heart, lung, gastrointestinal, neurologic or urinary disorders used herbs more than patients with other conditions.</td>
<td>Of the patients taking herbal medicines, 7% volunteered information about use to staff. &lt;br&gt; 20% were asked about use by the primary care physician; 17% by the operating surgeon, 4% by the nurse.</td>
<td>Information sources for people using herbal medicines: friends (36%), family (27%), magazines (11%), audiovisual media (8%), newspapers (6%), internet or healthfood shop (12%)</td>
</tr>
<tr>
<td>Year</td>
<td>Study</td>
<td>Setting</td>
<td>Participants</td>
<td>CM Use</td>
<td>Common CMs</td>
<td>Knowledge of Adverse Effects</td>
<td>Common Reasons for Non-Disclosure</td>
<td></td>
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<td>2005</td>
<td>Glintborg et al (245)</td>
<td>Copenhagen hospital — surgical and medical patients recently discharged</td>
<td>N=200 (n=83 surgical)</td>
<td>63% used CMs on a regular basis</td>
<td>Most common CMs used daily or on demand: multivitamins (41%), fish oils (14%), calcium (10%)</td>
<td>Not reported</td>
<td>Only 21% of hospital files had correctly recorded patients use of CMs</td>
<td>Patients generally unaware of the possibility of adverse effects with CMs</td>
<td></td>
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</tbody>
</table>

Symptoms were significantly less likely to use herbal medicine than patients without these symptoms.

Patients with a better perception of their health status were more likely to use herbs than those with a poor or average self-rating of health.

Herb use lowest in people with a history of diabetes mellitus, hypertension, high cholesterol.

Anaesthetist and 10% by another health-care worker.

The most common reasons for non-disclosure was thinking CMs are not ‘real medicine’

Health (26%), dissatisfaction with conventional care (17%), availability (14%), spiritual or religious beliefs (5%)
<table>
<thead>
<tr>
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<th>Disclosure</th>
<th>Other relevant information</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>Velanovich et al</td>
<td>U.S. Patients seen in a single surgeon's practice</td>
<td>N=151</td>
<td>100%</td>
<td>40% of patients used some type of CM. 17% used body/structure interventions (chiropractic, massage therapy, and acupuncture), 31% used herbal medications, and 3% used mind/spirit interventions (yoga, hypnosis). Eight (12%) patients used more than one type of CM.</td>
<td>Of patients using CMs, 21% used ginseng, 17% homeopathy, 15% glucosamine and chondroitin, 13% ginkgo biloba, 9% black cohosh, 4% saw palmetto, 4% flaxseed oil, 4% bee pollen, 4% echinacea, 2% carnitine, 2% ephedra, 2% grapeseed extract, 2% astragalus, 2% St John’s wort, 2% evening primrose oil, 2% megadose vitamins</td>
<td>47% of Caucasians used CM, compared to 29% of African-Americans. 44% of females used CM, compared to 34% of males (p = NS). 49% of patients ≤ 60 years old used CM, compared to 32% of patients &gt; 60 years old. 48% of patients with a cancer diagnosis used CM, compared to 31% of patients with a benign diagnosis.</td>
<td>Not reported</td>
<td>No actual postoperative adverse event occurred with use of CM. Suggestion that sample size too small to detect a true difference or not enough is known about the occurrence rates of these events</td>
</tr>
</tbody>
</table>
C.2.1.3.1 Methodological concerns

As is the case with many investigations in the field of CM, it is difficult to make accurate comparisons between studies because there is a lack of consistency between definitions used to describe CM. For example, Kaye et al used the term ‘nutraceutical’ without providing a clear definition, Norred excluded the use of CMs prescribed by medical practitioners and Wang (2003) provided a list of 19 CTs including some which are questionably called CM such as self-help strategies. Investigators asked about use of CMs or CTs over varying time frames and usage figures were reported in a variety of ways making a comparison difficult. As previously discussed, the surveys investigating patients potentially unsafe behaviours were based on an inaccurate and limited review and is unlikely to truly estimate patients use of potentially unsafe CMs. Non-English speakers were poorly represented in these studies and recall bias is likely to be a problem when patients are asked to remember their use of either CMs or CTs in the previous 12 months and may result in either an over-estimation or under-estimation of use (239).

C.2.1.3.2 Surgical patients using CMs and CTs

Three general factors have been associated with the use of CMs amongst surgical patients: being female (231;233;242), Caucasian (231;233;239;242) and highly educated (231;233;239;242). These same factors have been associated with use of CMs in general population surveys (1;14). The age group most likely to be using CMs appears to be between 35 years to 60 years (231;233;236).

CTs which are popular amongst surgical patients are: chiropractic, massage, herbal medicine, megavitamin therapy and relaxation techniques. Studies which have focussed on the use of all ingested medicinal agents such as herbal medicines, vitamins, dietary supplements, or homeopathic medicines, report prevalence of use ranging between 16% (229) and 73% (233) however it is difficult to interpret survey results because patients were asked about use over different time frames. For example, the prevalence of CMs use ranged from 51% (232) to 73% (234) when only studies that asked patients specifically about their use in the 2 weeks prior to surgery were considered. Adusumilli reported on patient use over three different time frames.
and stated that 57% of patients had used herbal medicine at some time during their lives, 38% in the previous 2 years and 16% in the month prior to surgery (229) whereas Kaye et al reported only on current use (230), Skinner et al on current use including use during the previous 2 weeks (241), Wang (2003) on current use or past use without defining a time frame and Grauer et al about use in the past 6 weeks (242).

As these studies highlight, asking patients about past use or use on the day of the survey will provide different results. It is suspected that studies asking about current use and immediate past use (such as the last 2 weeks) will provide the most accurate information as patients will have good recall of their habits in comparison to asking about behaviours conducted several months or years earlier. Considering the American Society of Anesthesiologists (ASA) advises that patients should discontinue use all herbal medicines two weeks prior to surgery, the time estimated for the compounds to be fully metabolized (246), determining current use and use during this period would be of most relevance when considering the potential implications for patient safety.

Some studies reported separate usage figures for herbal medicines and this ranged from 5% (241) in the United Kingdom to 37% (234) in the United States. In Australia, one study identified herbal use at 14.3% (242). The herbal medicines that surgical patients have consistently reported using are: *ginkgo biloba*, garlic, ginseng, St John’s wort, echinacea and ephedra products (in the United States only) (229-231;233;235;241;242). In regards to nutritional supplements, multivitamins were reported as the most commonly used (230;233;242).

**C.2.1.3.3 Use of CMs which have the potential to induce adverse events**

Whilst information can be extrapolated from general usage studies, three studies have been specifically conducted to determine the percentage of people taking CMs which could potentially increase the risk of haemorrhage, either due to interactions or direct pharmacological activity (232-234). The largest study of over 6000 participants conducted at 16 sites reported that 34% of patients were taking such products in the 2 weeks prior to surgery (233). All studies referred to information published in a review.
article co-written by the chief researcher as the basis for defining which CMs should be considered potentially unsafe (247).

The review by Norred and Brinker includes some CMs listed as potentially harmful based on theoretical concerns which are unlikely to be borne out in practice and some CMs are incorrectly included. For example, medicinal herbs with high concentrations of the prodrug coumarin were considered potentially dangerous (Apium graveolens, Matricaria recucita, Aesculus hippocastanum, Tanacetum parthenium) and the authors stated they could have additive effects with pharmacological anticoagulants if converted to 4-hydroxycoumarin. However, only certain moulds and fungus convert coumarin to a 4—hydroxycoumarin and the extent of conversion of coumarin to anticoagulant derivatives by humans is insignificant (248)(further discussion about CM safety in surgery is presented in Section D). As a result, the inclusion of these substances will lead to an over-estimation of patient’s potentially unsafe practices. Alternately, the Norred studies may under-estimate the true percentage of patients at risk as they solely focus on bleeding tendencies and fail to consider other mechanisms such as sympathomimetic effects and interactions with anaesthetic drugs and drugs used during the perioperative period.

C.2.1.3.4 Disclosure to hospital staff

Patient disclosure was poor in the five studies in which it was evaluated (229-231;238;239;242). Four studies investigated disclosure to various hospital doctors and one study referred to ‘health care staff” without defining this term further (229). No studies specifically reported on disclosure to hospital nurses or pharmacists. According to Kaye et al, nearly 70% of patients taking one or more CM product at the time of the survey did not report this information when asked during routine anaesthetic assessment (230). Adusumilli found that of the patients taking herbal medicines, only 7% volunteered this information to health-care staff in the preoperative period (229). In addition, they report that 20% of patients using CMs were asked about use by primary care physician, 17% by the operating surgeon, 4% by the anaesthetist and 10% by another health-care worker. Leung et al reported that 56% of patients did not disclose use of CM to an anaesthetist prior to surgery (231)
and Wang et al reported that 20% of patients did not tell physicians about CM use unless directly asked (238). Liu et al reported that 83% of cardiac surgery patients had not discussed use of CMs and CTs with their physician or surgeon and 48% of non-disclosers did not want to discuss use. In Australia, Grauer et al identified only 28% of surgical patients using herbal medicines as having informed hospital doctors about use (242).

Only one study investigated possible reasons for surgical patients non-disclosure in greater depth and reported that patients did not consider CMs as ‘real medicine’ and therefore did not think it relevant to inform health professionals about their use (229). Skinner et al, reported there was no documentation of use on the anaesthetic forms of patients using them (241) and suggested that either the anaesthetist or patient did not consider them to be of sufficient importance.

Studies with the general population report many other reasons for patient non-disclosure which are yet to be evaluated in this population. In addition, Skinner et al identified a lack of documentation regarding patient’s use of CMs, the reasons for this omission remain unclear and have not been investigated (241).

**C.2.1.3.5 Reasons for use**

Patients reported numerous and varied reasons for their use of CMs such as: because it had been recommended by a friend or family member, healthcare professional or they had self-selected, because patients had a sense of personal autonomy about their health, were dissatisfied with conventional health care, because CM was perceived as relatively safe, had few or no side effects, works just as well or better than conventional medicine, due to a TV advertisement, improvement of general health and disease prevention of disease, chronic medical problems, because the problem was considered not serious enough to consult a medical doctors (229;235;238). The most common reasons for use of herbs or vitamins supplements was in the treatment of chronic medical conditions according to the Australian study (242).
C.2.1.3.6 Sources of advice and recommendation

CMs were self-prescribed by 36% (235) - 70% (249) of surgical patients. Tsen further reported that 36% of people used CMs because of recommendations by family and friends (235) and Wang et al reported that 18.9% of patients using CMs did so because they were recommended by a ‘friend or medical doctor’ without differentiating between the two groups (238). Both Tsen et al and Grauer et al reported that a healthcare provider had recommended CMs without defining this term further (235;242). None of the studies clearly reported whether pharmacists, medical specialists, general practitioners or CM practitioners were also sources of recommendation.

Limited information is available about the sources of information used by the surgical population regarding CM. Only one study specifically investigated this issue and identified patients sources of information were: friends (36%), family (27%), magazines (11%), audiovisual media (8%), newspapers (6%), internet or healthfood shop (12%) (229). Of note, medical practitioners, pharmacists and other health care professionals were not included.

C.2.1.3.7 Beliefs and perceptions about CMs and CTs

Only Liu et al evaluated patients perceptions of the effectiveness of the CTs being used however this referred to CM as a whole and not individual therapies (239). Studies failed to directly evaluate patients beliefs and perceptions about use of CMs. Assuming their reasons for use is a reflection of their beliefs, it appears that some patients perceive CMs as safe and effective however little else is known and no information is available about Australian patients in this regard.

C.2.1.3.8 Interest in hospital CM service provision

Two studies asked patients about their willingness to use CM as part of perioperative medical care. One study reported that 76% of all respondents were willing to use CM as part of their anaesthesia care with most interest in acupuncture, hypnosis and herbal
medicine (238). In an earlier study of outpatients, 42% were willing to use acupuncture as a treatment modality for anxiety (237). Once again, no information is available about Australian patients in this regard.

C.2.1.4 Limitations of this review

As with the three other systematic reviews presented as part of this dissertation, the main limitation of this review relates to the heterogeneity of the included studies which reduced the ability to compare results and summarise key trends. Whilst every effort was made to locate relevant studies, it is possible that others exist which were not identified using the search strategy.

C.2.2 Australian hospitals

It is now well established that the general population uses CMs however published studies about the prevalence and patterns of CM use by hospital patients are limited. Three studies have been published in the peer-reviewed literature of people presenting at Emergency Departments (250-252), one study with inpatients (253), one study with patients being treated in a psychiatric unit (254) and one of surgical patients (242).

C.2.2.1 Emergency departments

A study conducted at Royal North Shore Hospital in Sydney revealed up to 52% of people presenting to the Emergency Department over a three-month period (n=325) used CM within the previous 12 months, 41.2% within the previous 3 months, 34.2% within the previous month and 30.5% in the previous week (252). The most commonly used CM products were tea tree oil preparations (13.3% of products), garlic capsules (10.6%), evening primrose oil (7.5%), aloe vera (4.3%), chamomile (10.2%) and ginseng (3.4%).

Most preparations were self-selected (41%) or recommended by a friend or family member (35.5%) although recommendations were also received from naturopaths (9%) and qualified medical practitioners (5%). Most respondents had at least once
consulted a CM practitioner (63.1%) with more women consulting naturopaths, iridologists, reflexologists and aromatherapists than men. Disclosure was poor as only 20.7% of CM users had told their primary medical practitioner about CM use. Reasons given for non-disclosure were a perceived lack of responsiveness by the doctor to CM, a belief that it was irrelevant to the doctor, or fear that disclosing use could jeopardise their continued use of CM.

A smaller follow-up study conducted at the same hospital and published 7 years later found 70.3% of patients (n= 94) had used at least one CM treatment in the last 12 months with nutritional supplements most frequently used (74.0%) followed by herbal medicines (26.3%), essential oils (14.2%) and traditional Chinese medicines (7.5%) (251). Most CM users (62%) were using conventional medicines at the same time. Within the month before admission, 56.4% reported using at least one CM treatment and of these 44% had taken CM within the 2-3 days prior to admission.

More recently, a cross-sectional survey of patients seen in the emergency department at the Royal Melbourne Hospital, Melbourne identified 68.1% as having used CM in the previous year (255), 50.2% within the previous week and 12.4% on the previous day (256). Patients who had used CMs in the previous year were significantly younger, better educated and more likely to female than patients who had not (257). Of the patients that had taken CMs during the previous year, 57% were also taking a prescription medicine at the same time. Documented drug-CM interactions were identified for 9 patients (3.3%) with warfarin and St Johns wort the most commonly involved medicines. Of these 9 patients, 3 had advised their physicians of CM use, two had advised their CM practitioner and 2 had told no one. Theoretical interactions were identified in 51 patients (18.6% of CM users). Disclosure to physicians about CM use in general was poor as 71.6% had failed to inform their physician about use.

**C.2.2.2 Other patients**

A study conducted at St Vincent’s Hospital Sydney found that 36% of the 511 inpatients surveyed took complementary medicines whilst in hospital, 74% of which were self prescribed and 51% not being recorded on the patients medication chart
Of those patients taking complementary medicines, 18% were considered substances that had the potential for adverse effects or interactions.

CM usage has been investigated amongst patients being treated in an Australian psychiatry unit (258). Structured interviews were conducted with 52 patients of which 48 were men with a mean age of 56.7 years. During the preceding 6 months, 51.9% of people had used CM. The most common products taken were vitamins and minerals (n = 18) and herbal medicines (n = 14). Use of CM products was not related to demographic or medical factors, but was significantly less frequent among patients seeing their local physician >1 time per month. Only 17 of the respondents using CMs (63.0%) informed their physician about these therapies. People using CM daily ranked their satisfaction level with these products significantly higher than with conventional therapies and their attitude toward CMs was positive overall, and was slightly more favorable among users than nonusers.

**C.2.2.3 Surgical patients**

The use of CMs by Australian surgical patients remains under researched. Currently, only one Australian study has been published in the peer-reviewed literature (242). This study evaluated preoperative use of CMs and rates of patient disclosure to hospital doctors and provided only limited information about these behaviours. As such, there remains no information about patient’s attitudes and beliefs about CM, reasons for non-disclosure or interest in hospitals offering CM services.

The study was conducted at two public hospitals in Victoria (Box Hill and St Vincent’s Hospitals) and collected data from 1102 patients attending pre-admission clinics over an 8 month period. The voluntary survey was anonymous and self-administered in English, thereby excluding non-English speakers. The sample population had an average age of 54 years and was predominantly female (61%). Participants were asked about use of CMs within the previous 6 weeks and 14.3% reported having used herbal medicines and 20.4% used vitamin supplements.
The most popular herbal medicines used by this sample were garlic (13.6% of all herbal medicines used), evening primrose (8.1%), ginkgo biloba (6.1%), St John’s wort (5.7%), echinacea (3.9%), valerian (3.5%), horseradish (3.5%), ginseng (3.5%), cranberry (2.6%), aloe (2.6%). It is worth noting that nearly 35% of all herbal medicines used were unspecified. The most popular vitamin supplements used were multivitamins (27.8% of all vitamins used), vitamin B (22.5%), vitamin C (21.5%), vitamin E (9.3%), vitamin D (3.9%), vitamin A (2.3%), vitamin K (0.3%) and 12.4% were unspecified.

Of those patients that had used CMs, 27.8% had disclosed this use to hospital doctors or staff and 41.8% had informed their general practitioner. Disclosure to other healthcare professionals was not investigated nor was reasons for non-disclosure. CMs were often self selected (63.2%) and 26.6% had taken them on the advice of a healthcare practitioner however this term was not further defined.

According to these results, prevalence of CMs use by Australian surgical patients was lower than typically reported by U.S. based studies. This is surprising when one considers over 50% of the Australian population use CMs compared to less than 20% in the U.S.(14;68). The researchers suggested this was partly explained by the more stringent regulation of herbal medicines in Australia and that most Australian health insurers do not reimburse the cost of CM products whereas numerous health insurance companies in the United States do this. This last point can be disputed as another source claims that most insurance companies in the United States do not cover herbal products or therapies (259). Another reason for the difference in results may relate to differences in sample characteristics however the Australian study did not report demographic data beyond age and gender so comparisons are not possible.
C.2.2.4 Cardiac surgery patients

Cardiac surgery patients were chosen as a sub-set of special interest because there is a paucity of information in the international literature about this population in regards to CMs despite CVD being highly prevalent in the Western World.

Cardiovascular disease affects over 3.2 million Australians with an expectation that this figure will substantially increase over the coming decades due to the growing number of older Australians (260). People with CVD use more health services than the average Australian including use of specialist care, pharmacotherapy, surgery and rehabilitation. When combined with advancing age, severity of disease and other co-morbidities, these patients are also exposed to increasing risk of adverse events and interactions.

Reviews on the role of CM in the management of CVD suggest that some treatments offer potential benefits such as in hyperlipidemia, hypertension and congestive heart failure (261;262) with evidence to support the use of supplements such as fish oils (263) and the herbal medicine Hawthorn (264).

Although potential benefits are possible with CMs, there are also potential risks. Of relevance to the patient with cardiovascular disease, some CMs such as St John’s wort, have the potential to interact with drugs such as warfarin, antiplatelet therapy, antihypertensives and digoxin (265). Adverse events can also be induced through direct effects on cardiac function or haemostasis. These safety concerns are of particular importance to patients with acute or severe disease, undergoing surgery, of advanced age or taking multiple medications. As an additional complicating factor, most Australians self-select CMs rather than receive professional advice and many fail to discuss use with medical practitioners (13).

A review of the peer-reviewed international literature indicates only three studies have evaluated use of CTs by cardiology inpatients and only one study has specifically focused on cardiac surgery patients and their use of CTs, leaving many questions unanswered (266-270).
Liu et al collected data from 263 patients undergoing preoperative or postoperative cardiothoracic surgical evaluations at an urban, academic medical centre in New York (271). Most respondents were male in this sample (70%) and overall, 75% were reported as having used CTs within the previous 12 months. It is important to note that the definition used to describe CTs included prayer and vitamin supplements and when these two approaches were excluded, usage was determined as 44%. More specifically, 53.6% used vitamin supplements, 17.1% nutritional therapy, 11.4% massage, 11.4% chiropractic, 11.4% meditation and 9.9% herbal medicines. The study found older people with college education or higher tended to use vitamins more than others. Similar to other studies of surgical patients in general, most patients had not discussed CM use with their physicians or surgeons. Of the 83% who had not discussed CM, 48% did not want to discuss the topic, 36% reported they would like to discuss it and 16% did not respond. Liu et al did not report which specific CMs were being used by cardiac surgery patients, who had prescribed them, reasons for use or whether patients had an interest in hospitals providing CM services (272).

Currently, the prevalence of CMs use by Australian cardiac surgery patients has not been investigated or published in the peer-reviewed literature.

**C.2.3. Summary**

Studies conducted overseas indicate that surgical patients use CMs prior to surgery and do not routinely disclose their use to hospital doctors. Their disclosure to other health care professionals is unknown and little investigation has been conducted to determine reasons for this behaviour. There is limited information available about surgical patient’s beliefs and perceptions about CMs and CTs, interest in hospitals offering CM services, information sources used and the prescribers to this population. Currently, information about Australian surgical patients is derived from only one study which provides limited information about usage and disclosure and no information about patients beliefs and perceptions about CM, reasons for non-disclosure, information sources used or interest in hospitals offering CM services.
Cardiac surgery patients are an under-researched group regarding CTs and only one study has been published in the literature suggesting they also use CMs and do not generally discuss use with physicians or surgeons.
Chapter One

Section D
CMs safety with a focus on issues relevant to surgical patients

D.1.0 Introduction

This chapter is a literature review of relevant information and research about the safety of CMs, with a focus on safety issues of relevance to the surgical patient. It will present a brief discussion about medication safety and explore the limitations of case reports and spontaneous reporting systems as methods of collecting data about the safety of CMs. This will include discussion about communication failures, practitioner and patient awareness of safety issues and limitations of several information sources. A systematic review is presented which explores the international literature for published reviews about the safety of CMs in the perioperative period and the limitations of the available evidence will further be discussed. The algorithm METOPIA is discussed at the end of this section.
D.1.1 What is safety?

Safety is a complex issue determined by considering the combination of ‘likelihood’ and ‘consequence’. These two variables will differ for each medicine and individual patient in their particular circumstance. The likelihood of an adverse reaction can be graded from rare to common and the consequence from clinically insignificant to fatal with many possibilities lying somewhere between these extremes (See Figure 1).

In regards to medication safety, avoidance of an adverse drug reaction (ADR) is paramount. Several factors have been associated with an increased likelihood of developing an ADR such as advanced age and polypharmacy however most ADRs occur in people who are prescribed treatment within the limits of accepted clinical practice (273).

![Interaction between the two variables of 'likelihood' and 'severity' of consequence in regards to medication safety.](image)

Figure 1. Interaction between the two variables of ‘likelihood’ and ‘severity’ of consequence in regards to medication safety.
D.2.0 Adverse reactions and CMs

The amount of literature published about the safety of pharmaceutical medicines is overwhelming. It has been estimated that 35% of the primary published literature about medicine-related adverse events appears as formal studies or randomised controlled trials and 30% in anecdotal reports (274). In regards to herbal medicines, there is a relative lack of clinical trials so reliable information from other sources is important such as well-documented case reports and spontaneous reporting schemes (275;276). For researchers, a cluster of case reports describing similar adverse drug reactions can provide grounds for hypothesis-testing experiments and they can be used to generate signals of possible safety concerns for clinicians. These methods of data collection rely on collecting sufficient information about individual events to allow causes to be identified and trends to be tracked. To enable the development of strategies which can reduce the risk of adverse drug reactions, data collection must also extend to other areas such as identification of system problems that contribute to medication related occurrences, evaluation of strategies to improve medication safety, comparison of incidence data locally and nationally and evaluation of health care professionals awareness of the potential problems (277).

Whilst well documented case reports and spontaneous reporting systems are well established methods for investigating safety concerns with pharmaceutical medicines, they have several important limitations. Notably, case reports tend to be incomplete, uncontrolled and retrospective (278;279) and there is much under-reporting of adverse drug reactions (280). In countries where CMs are not registered as medicines, spontaneous reporting schemes for adverse reactions are likely to be less effective as the degree of exposure (product sales, percent contamination) is difficult to know with certainty (278;281) and determining the prevalence of adverse reactions, almost impossible.

In a review of 1520 published case reports, Kelly identified many which ignore much of the Bradford Hill’s criteria and proposed that professional journals consider stricter requirements for publishing adverse drug event reports with the inclusion of an objective assessment of causality as a minimum standard (279). Karch agrees and suggests that an objective causality assessment, such as the Naranjo algorithm (282),
will allow the reader to impose some structure on the evaluation of individual case reports (278). Whilst the grading score provides no additional data, it does make clear the merits and faults of the report. The problem of case reports providing inadequate data also applies to CMs. For example, a systematic review of the literature and evaluation of reports of herb-drug interactions identified 108 cases of suspected interactions of which 68.5% were classified as 'unable to be evaluated,' and only 13% as 'well-documented' (283).

The question of whether the observed effect is a reaction to intrinsic or extrinsic factors must also be considered, particularly if the CM product in question was not manufactured under a code of GMP (284). Use of poor quality products with problems of adulteration, substitution or incorrect starting materials are not normally concerns with pharmaceutical medicines but are concerns with herbal medicines (276). To evaluate a case report involving a herbal medicine, confirmation of botanical identity is essential and detailed information about the herb used, part of plant use, type of extraction and formulation is important.

The widespread problem of under-reporting of adverse drug reactions is a major limitation of spontaneous reporting system. Research about under-reporting of serious ADRs in the United States and Canada indicates that formal reporting rates may be as low as 1.5% of total ADRs leaving many adverse reactions unidentified by this channel (280). It is likely that reporting rates of less severe ADRs are even lower leaving many mild to moderate side-effects undetected and a hidden source of patient morbidity. Under-reporting of adverse reactions is also accepted as a significant issue with CMs (276).

**D.2.1 Multiple communication failures?**

Australian surveys consistently report that patients self-select their CMs and do not routinely inform their medical practitioners about use (13;14). One study conducted with surgical patients in Victoria identified that most do not inform hospital doctors about their use of herbal medicines, suggesting the problem of non-disclosure may also be present within the hospital setting (242). Unless practitioners ask patients
about use, adverse reactions induced by CMs may be overlooked, mistakenly attributed to other causes or diagnosed as a new disease symptom and therefore remain undetected and unreported. Importantly, known or suspected adverse reactions cannot be anticipated and avoided if patient use is not identified.

Currently there are no published Australian studies which have identified whether medical practitioners ask patients about CMs, what barriers prevent them from initiating such a discussion, whether they are aware of safety issues associated with commonly used CMs or whether patient use is documented. These factors are important to investigate so that targeted strategies can be developed to encourage more open communication about CMs which will not only promote patient-centred care but also enable better detection and prevention of adverse events.

Pharmacists also play a role in lodging case reports of suspected adverse reactions to ADRAC and publishing case reports in the literature. Two studies conducted overseas with predominantly community pharmacists indicate that pharmacists do not routinely ask patients about use of CMs (285;286) thereby limiting their ability to identify and prevent adverse reactions induced by CMs unless patients volunteer the relevant information unsolicited. No studies have been identified in the peer-reviewed literature of Australian pharmacists which have explored whether they ask patients about CMs whilst taking a medication history, what barriers prevent them from initiating such a discussion, whether they are aware of safety issues associated with commonly used CMs or whether patient use is documented.

An Australian study of Western herbalists and naturopaths identified that they too observe adverse reactions to CMs. This study found that only one third indicated they report adverse events and 27% were aware of the Australian adverse drug reaction reporting procedures. Reports were generally made to manufacturers and/or professional associations with less reporting to the Australian Drug Advisory Committee or the Therapeutic Goods Administration. The study further states that 44% of practitioners felt their primary educational courses have not adequately prepared them for inter-professional communications (287).
Patients also play an important role in identifying adverse reactions and promoting patient safety. According to a study from the U.K., consumers are less likely to inform their healthcare professionals of adverse effects to herbal medicines (288) making their detection even more difficult. Studies have been conducted, mainly in the U.S., which evaluated patient’s patterns of non-disclosure (289) however these tend to focus on medical practitioners and often fail to consider whether patients inform pharmacists or other healthcare professionals about CMs. Currently there are no published Australian studies which have investigated patients reasons for non-disclosure to healthcare professionals.

Within hospitals, patients come into contact with many different healthcare professionals and the opportunities for communication failures are multiplied. Causes of communication failure may occur at the individual, team and organisational levels and could require more complex solutions than those necessary in community practises. Currently, there is a paucity of published literature about the communication failures present within hospitals in regards to CMs. Patient disclosure studies are generally conducted within community settings, and studies of medical practitioners and pharmacist’s communication behaviours regarding CMs also tend to involve community practises.

It is important to identify communication failures between patients and healthcare professionals and between healthcare professionals themselves as communication failures account for the overwhelming majority of unanticipated adverse events in patients (290). Communication failures also hinder the detection of adverse events and event reporting and thereby impede efforts to develop strategies which will improve patient safety in the future.

**D.2.2 Awareness of safety issues associated with CMs**

When open communication about CMs is successful, it seems prudent for healthcare practitioners to be aware of general safety issues that can arise and have some familiarization with what may be expected so that adverse events can be anticipated and avoided.
According to Cohen at al, Australian GPs perceive CMs as potentially harmful (166) and Pirrota et al report that approximately half of Australian GPs thought they knew something of herbal medicine, naturopathy and vitamin and mineral therapy (165), however there is no information about GPs actual knowledge of the safety issues associated with CMs. There is a paucity of information about hospital doctors and their perceptions of the potential safety of CMs and knowledge of actual safety issues in the international literature. The only Australian study of hospital doctors involved oncologists and demonstrated they considered diet therapies as harmful (291) however there is no published information about other groups or actual knowledge of safety issues for any group.

A study of pharmacists in the U.S. demonstrated that 49% thought herbs and natural products were not safe (292) and two other studies have identified that pharmacists’ actual knowledge about CMs is low (178;213). Information about Australian pharmacists is scant and the only study conducted and published to date reported they perceive their level of knowledge about herbal medicine to be sufficient to explain this therapy to patients (293). To date, no published studies are available which have focussed on Australian pharmacist’s actual knowledge about the safety of commonly used CMs and limited information is available about hospital pharmacists in general in the international literature.

**D.2.3 Information sources**

Biased and misleading media reporting can misinform both healthcare practitioners and their patients about medication safety. Moynihan et al identified that media coverage about new drugs often exaggerates their benefits and downplays the associated risks (294). Incomplete or inaccurate press releases generated by medical journals and provided to reporters further complicate the issue and are now considered more common than once thought (295). CMs are not immune to these same influences and misinformation about their safety and efficacy abounds.

One example is provided by the incomplete press release which describes results from an article entitled ‘Adverse reactions associated with Echinacea—the Australian
experience’ by Mullins and Heddle (296). The press release described five allergic reactions to different echinacea preparations and further stated that 51 adverse reaction reports involving echinacea had been reported to ADRAC (297). It failed to include the important fact that these reports were collected over a 21 year period, a detail included in the full-length article. This case also provides an example of peer-review failure as this important detail was not included in the article abstract.

There is evidence that CMs are widely assumed to be a safe, non-pharmaceutical option that can be used to prevent, treat and manage disease by the Australia public (13). MacLennan et al indicate that many people self-prescribe CMs without professional advice, no doubt on the assumption they are safe, however little has been published about the information sources they use (13) and currently, no Australian studies have been published which investigate hospital patients perceptions of the safety of CMs and what sources of information they use.

It has been reported in the literature that pharmacists refer to journals, professional publications, books and magazines for information about CM (188;192;298-301). Although there is limited information about the resources used by doctors, it can be assumed they also use peer-reviewed journals as an information source. As demonstrated by the Vioxx™ debacle at the New England Journal of Medicine, the peer-review procedure is vulnerable in a number of areas, including publication of information describing medication safety and adverse drug reactions (278). This is not limited to information about pharmaceutical medicine but also applies to information about the safety of CMs which is inconsistent, sometimes contradictory and incorrect.

**D.3 Surgical patients and CMs**

The systematic review presented in Chapter One section C found that numerous surveys have demonstrated that surgical patients use CMs however there is little published information about the reasons for communication failure in hospitals regarding CMs. Furthermore, there is little published information about the perceptions of practitioners and patients about the safety of CMs and the information sources they use to find information about CMs and CTs.
The use of CMs in the perioperative period has implications for the anaesthetist, surgeon, physician and patient. With the use of CMs by surgical patients and their lack of disclosure about use, adverse reactions and drug interactions can result and remain undetected and unmanaged leading to unanticipated perioperative anaesthetic or surgical complications (302-304).
D.4 Systematic review of the literature regarding CMs safety in the perioperative period.

D.4.1 Aim:
The primary aim was to review the international literature for what is considered to be the main safety issues associated with CMs use in the perioperative period and which CMs were commonly cited as posing a potential problem. The secondary aim was to identify limitations of the current literature.

D.4.2 Methods:
A search was performed between May and November 2006 using the following databases for all years available: MEDLINE, ScienceDirect, Clinicians Health Channel – Fulltext and Proquest. Search terms used included, but were not limited to:

The following search terms were used:
- ‘Complementary medicine’ and hospital
- ‘Herbal medicine’ and ‘hospital’
- ‘Alternative medicine’ and ‘hospital’
- ‘Integrative medicine’ and ‘hospital’
- ‘Complementary therapies’ and ‘hospital’
- ‘Herbal therapies’ and ‘hospital’
- ‘Alternative therapies’ and ‘hospital’
- ‘Integrative therapies’ and ‘hospital’
- ‘Naturopathy’ and ‘hospital’
- ‘Natural therapy’ and ‘hospital’
- ‘CAM’ and ‘hospital’
- All the above terms with ‘surgery’ instead of ‘hospital’
- All the above terms with ‘surgical’ instead of ‘surgery’
- All the above terms with ‘surgeon’ instead of ‘surgical’
- All of the above terms with ‘anaesthesia’ instead of ‘surgical’
- All of the above terms with ‘perioperative’ instead of ‘anaesthesia’

The bibliographies of articles relevant to CMs safety in surgery were scanned for additional review articles which may be appropriate for inclusion and the libraries of
the supervisor and researcher were searched for additional articles. Articles were considered eligible if they were published in English, available in the peer-reviewed literature, presented a review of the evidence and consisted of a fully referenced literature review.

**D.4.3 Results:**

**D.4.3.1 Description of articles**

The search identified 12 review articles (302-313) There is a dominance of herbal medicines in the articles and relatively little information included about other CMs. Three reviews were published in anaesthesia journals (304;306;307), three in complementary medicine or integrative medicine journals (308;313;314), three in surgery journals (309;311;312), one in a nursing journal (303), one in a medicine journal (310) and no review articles were found in any pharmacy journal. A summary of results from relevant review articles is presented in Table 1.
### Table 1. Review articles in the international literature which provide information about the safety of CMs for surgical patients

<table>
<thead>
<tr>
<th>Year of publication</th>
<th>Author/s</th>
<th>Main concerns relating to use of CMs</th>
<th>CMs noted as putting surgical patients at risk</th>
<th>Strengths of review</th>
<th>Limitations of review</th>
<th>Other observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>Leak (307)</td>
<td>Potential to elevate blood pressure or untoward cardiovascular effects, enhance potential for bleeding, potentiate or prolong anaesthetic agents, hepatotoxicity, hormonal effects, electrolyte disturbances</td>
<td>Ephedra, Panax ginseng, Licorice, Ginkgo, Garlic, Feverfew, Ginger, Valerian, Kava kava, Echinacea, Saw palmetto, Goldenseal</td>
<td>Numerous mechanisms considered in the review</td>
<td>No methodology provided to describe review process. The relevance of some information to surgical patients is unclear e.g. concerns over Saw palmetto because a secondary information source stated it may cause additive effects with hormonal therapies such as oestrogen</td>
<td></td>
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<tr>
<td>2000</td>
<td>Petry (315)</td>
<td>Potential to prolong bleeding time</td>
<td>Garlic, Vitamin E</td>
<td>Discusses benefits of selected CMs and CM therapies for the surgical patients together with some safety information</td>
<td>No methodology provided to describe review process.</td>
<td></td>
</tr>
<tr>
<td>Year</td>
<td>Author(s)</td>
<td>Title</td>
<td>Potential to prolong bleeding time</td>
<td>Botanical coumarins</td>
<td>Comprehensive review</td>
<td>No methodology provided to describe review process.</td>
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<tr>
<td>2001</td>
<td>Norred and Brinker (308)</td>
<td>Pharmacological effects mainly sympathomimetic, sedative and potential to prolong bleeding time</td>
<td>Ephedra</td>
<td>Panax ginseng</td>
<td>Editorial highlights possibility of safety issues</td>
<td>No methodology provided to describe review process. All information derived from German Commission E monographs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Licorice</td>
<td>Valerian</td>
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<td></td>
<td></td>
<td></td>
<td>Kava kava</td>
<td>St John’s wort</td>
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<td></td>
<td></td>
<td></td>
<td>Garlic</td>
<td>Ginkgo</td>
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<td></td>
<td></td>
<td></td>
<td>Ginger</td>
<td>Feverfew</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dorman (306)</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Table 1. Review articles in the international literature which provide information about the safety of CMs for surgical patients

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<th>CMs noted as putting surgical patients at risk</th>
<th>Strengths of review</th>
<th>Limitations of review</th>
<th>Other observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>Flanagan</td>
<td>Purity and contamination issues</td>
<td>Ephedra, Feverfew, Garlic, Ginger, Ginkgo, Ginseng, Goldenseal, Licorice, Senna, St John’s wort, Valerian</td>
<td>Advises readers to establish a local protocol</td>
<td>No methodology provided to describe review process.</td>
<td>Not one primary study or case report was cited out of 32 references</td>
</tr>
<tr>
<td>Year of publication</td>
<td>Author/s</td>
<td>Main concerns relating to use of CMs</td>
<td>CMs noted as putting surgical patients at risk</td>
<td>Strengths of review</td>
<td>Limitations of review</td>
<td>Other observations</td>
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<tr>
<td>2001</td>
<td>Sabar et al (310)</td>
<td>General adverse effects possible with the use of popular CMs</td>
<td>Echinacea, Garlic, Ginger, Ginkgo biloba, St John’s wort, Ginseng, Kava kava, Feverfew, Ephedra</td>
<td>Includes brief history of herbal medicine and its contribution to modern day medical practice</td>
<td>No methodology provided to describe review process. Origins of the evidence cited is often not mentioned in the text and no distinction is made between theoretical concerns and documented risks potentially overstating the risks</td>
<td>Of 110 references, 72 refer to primary studies, case reports or meta-analyses</td>
</tr>
<tr>
<td>Year of publication</td>
<td>Author/s</td>
<td>Main concerns relating to use of CMs</td>
<td>CMs noted as putting surgical patients at risk</td>
<td>Strengths of review</td>
<td>Limitations of review</td>
<td>Other observations</td>
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</tr>
<tr>
<td>2001</td>
<td>Pribitkin and Boger (309)</td>
<td>Increased risk of bleeding during surgical procedures:</td>
<td>Feverfew, Garlic, Ginger, Ginkgo, Asian ginseng</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2001</td>
<td>Cassileth and Barrazzual (305)</td>
<td>Purity and contamination of CMs, General safety, side effects and interactions with other drugs</td>
<td>Arnica, Bromelain, *Chaparral, Coenzyme Q10, *Comfrey, Danshen, Dong Quai, Echinacea, *Ephedra, Feverfew, Garlic</td>
<td>Comprehensive list of herbal medicines reviewed</td>
<td>No methodology provided to describe review process.</td>
<td>Several herbs listed are not available OTC in Australia</td>
</tr>
</tbody>
</table>

Some information is extrapolated from rare case reports or in vitro studies and much is based on theoretical reasoning without alerting reader to these limitations potentially overstating the risks. Many claims not referenced. Of 51 references, 31 are citations of secondary information sources about CMs safety and only 15 are primary information sources such as clinical trials or case reports.
Ginger
Ginkgo
Ginseng
Hawthorn
Horse chestnut
Jin bu huan
Juniper
Licorice
*Lobelia
*Mistletoe
Pau D’Arco
Pennyroyal
Poke root
Sassafras
Shark cartilage
St John’s wort
Tryptophan
*Yohimbe
<table>
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<tr>
<th>Year of publication</th>
<th>Author/s</th>
<th>Main concerns relating to use of CMs</th>
<th>CMs noted as putting surgical patients at risk</th>
<th>Strengths of review</th>
<th>Limitations of review</th>
<th>Other observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>Hodges and Kam (304)</td>
<td>General safety, side effects and interactions with other drugs</td>
<td>Echinacea, Garlic, Ginkgo, Ginseng, St John’s wort, Valerian, Ephedra, Kava kava, Grapefruit, Ginger</td>
<td>Included methodology used to conduct literature review. Both benefits and risks are discussed</td>
<td>Differentiates between theoretical risk, anecdotes and documented cases and formal studies</td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td>Tessier and Bash (311)</td>
<td>General safety, side effects and interactions with other drugs</td>
<td>Ephedra, Ginger, Garlic, Ginkgo, Ginseng (Korean and American)</td>
<td>Comprehensive</td>
<td>No methodology provided to describe review process.</td>
<td></td>
</tr>
</tbody>
</table>
Ginger
Dong quai
St John’s wort
Goldenseal
Licorice
Saw palmetto
Echinacea
Valerian
Chaparral
Guar gum
Kava kava
<table>
<thead>
<tr>
<th>Year of publication</th>
<th>Author/s</th>
<th>Main concerns relating to use of CMs</th>
<th>CMs noted as putting surgical patients at risk</th>
<th>Strengths of review</th>
<th>Limitations of review</th>
<th>Other observations</th>
</tr>
</thead>
</table>
| 2005                | deAzevedo Pribitkin (302) | Purity and contamination of herbal products  
The various pharmacological actions of herbs such as cardiovascular hypoglycemic, sedative, oestrogenic, photosensitization  
Interactions due to St John’s wort and interactions with digoxin | Coumarin containing herbs  
Salicylate containing herbs  
Numerous other herbs claimed to inhibit platelet function | Numerous mechanisms considered | No methodology provided to describe review process.  
Some information is incorrect and based on faulty assumptions e.g. coumarin and salicylate containing herbs automatically increasing risk of bleeding | Of 107 references, 29 refer to secondary sources |
| 2006                | Haller et al (312)   | Interactions with other drugs  
Increased risk of bleeding during surgical procedures  
Unwanted pharmacological effects | Chondroitin  
Glucosamine  
Ephedra  
Echinacea  
Ginkgo biloba  
Goldenseal  
Milk thistle  
Ginseng  
Kava kava  
Saw palmetto | Comprehensive | No methodology provided to describe review process. | |
St Johns wort

Ginger

Eicosapentaenoic acid

Vitamin E
D.4.3.1 Methodological concerns

Most review articles did not report on the methodology used to search the literature and some reviews cited numerous secondary sources of information without making it apparent that little information was based on evaluation of the original research. Many reported adverse effects and interactions reflected theoretical reasoning in the absence of clinical data and some were based on case reports and in vitro tests. Few articles discussed the limitations of such information sources and the problems inherent with making clinically relevant theoretical predictions from in vitro studies.

D.4.3.2 CMs commonly reported as posing a safety risk

The CMs which were commonly reported as posing a potential risk to surgical patients are: ephedra, echinacea, feverfew, garlic, ginger, *ginkgo biloba*, ginseng, goldenseal, kava kava, licorice, St John’s wort and valerian. CMs which were less commonly reported as presenting a potential risk were: saw palmetto, dong quai and chapparal, aristolochia, arnica, bromelain, coenzyme Q10, comfrey, dan shen, grapefruit, guar gum, hawthorn, horse chestnut, juniper, lobelia, mistletoe, pau d’arco, pennyroyal, poke root, sassafras, senna, shark cartilage, tryptophan, yohimbine. The CMs which were consistently reported as specifically increasing the risk of bleeding were: feverfew, garlic, ginger and *ginkgo biloba* and several articles included coumarin containing herbs.

D.4.3.3. Authors main concerns relating to CMs

The main concerns expressed by authors can be grouped into three broad categories. Firstly authors were concerned about the potential for CMs to exert unwanted pharmacological actions such as anti-platelet and anticoagulant activities, cardiovascular effects, hormonal and sedative effects. Drug interactions were another category although few authors identified the specific interactions of concern. Finally, the possible contamination of CMs was stated as a potential problem.
D.4.3.4 Lack of formal clinical studies

The frequent reliance on evidence other than clinical studies highlights the lack of research conducted in the area of CMs safety and is largely responsible for the inconsistent information presented in the published reviews. From a clinical perspective, evaluating the likelihood and consequence of a predicted adverse reaction and herb-drug interaction is of primary importance however this is difficult to determine from the available evidence.

To illustrate the problems clinicians face when wanting to find consistent and reliable information about the safety of CMs, Table 2 has been compiled which lists the main concerns that authors of five review articles raise about five CMs often reported as presenting a potential risk for surgical patients (302;304;306;307;310).
Table 2. Key themes emerging from the review articles about 5 CMs

<table>
<thead>
<tr>
<th>CMs reported as being known or suspected to pose a risk to surgical patients and main concerns of authors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Echinacea</strong></td>
</tr>
<tr>
<td>Concerns about hepatotoxicity effects most often reported and sometimes interactions with immunosuppressants (302;306;307)</td>
</tr>
<tr>
<td>May theoretically reduce effectiveness of corticosteroid drugs (307)</td>
</tr>
<tr>
<td>Mention of allergies to daisy family (304)</td>
</tr>
</tbody>
</table>

As Table 2 illustrates, there are inconsistencies in the information presented in peer-reviewed journals regarding the safety of herbal medicines in surgery. Furthermore, some information included is of questionable relevance to the perioperative period and a review of the literature suggests that inaccuracies are also present. It is likely that the scarcity of clinical data has resulted in misinterpretation and overstatement of the risks.

The reporting about garlic was most consistent and all 5 review articles stated that it may increase the risk of bleeding. Four out of 5 reviews stated ginger posed a bleeding risk and one added a concern about reducing blood pressure that was not reported in the other articles.
Three articles stated that feverfew inhibits platelet function and poses a bleeding risk although a review of the literature reveals that the evidence is not definitive. Several in vitro studies have demonstrated inhibition of platelet aggregation for feverfew (317;318) however, no significant effects were seen in a clinical study casting doubt on the relevance of the test tube findings (319).

The reporting about *ginkgo biloba* was interesting as three articles stated it could increase bleeding; referring to case reports and sometimes in vitro tests as supportive evidence and two other articles stated the risk was associated with the combined use of ginkgo and antithrombotic agents. All failed to mention three placebo-controlled studies which have not detected a significant effect for *ginkgo biloba* on platelet function or coagulation (320-322) One was an escalating dose study which found that 120 mg, 240 mg or 480 mg given daily for 14 days did not alter platelet function or coagulation (320). It is important to note that four of the five review articles were published prior to 2003 and the three clinical studies were reported in 2003, 2004 and 2005. This highlights the problems of extrapolating from case reports and test tube results and the importance of keeping up to date with the most recent clinical evidence.

Sabah et al (310) reported that echinacea was potentially hepatotoxic and the claim is referred back to a review by Miller published in 1998 (323) and not original research. In contrast, the review by Hodges and Kam published one year later states that although echinacea preparations contain pyrrolizidine alkaloids, hepatotoxicity is unlikely because they are structurally different to the pyrrolizidine alkaloids known to be hepatotoxic (304). This example highlights the inconsistencies present in the literature.

The problems of inconsistent and contradictory information about the safety of CMs are not limited to these reviews but also occur with electronic databases such as AltDexMed in the Micromedex database and others.

As demonstrated in the Chapter 1, section B, the systematic reviews of medical practitioners and pharmacists indicate that little is known about the resources used by hospital doctors and pharmacists for information about CMs and CTs. Although all
public hospitals in Victoria have access to AltDexMed in the Micromedex database, it is not known whether this resource is used.

D.5.0 Herb - drug interactions

D.5.1 Approaches used to evaluate herb interactions

Most studies conducted to investigate herb-drug interactions have used in vitro testing of herbal constituents in microsomal systems, supersomes, cytosols, expressed enzymes or cell culture systems such as transfected cell lines, primary cultures of human hepatocytes and tumour derived cells (324). There has also been some investigation in vivo in normal animals, transgenic and humanised animals and increasingly, there has been some investigation conducted in humans. Whilst these studies are useful, they are not without limitations. Table 3 presents a summary of the limitations relevant to different types of research. Most interactions studies conducted to date have focussed on herbal constituents and their effects on cytochrome (CYP) enzymes and increasingly P-glycoprotein (P-gp) with few studies investigating effects on drug transport or phase II metabolism.
Table 3. Advantages and limitations of herb-drug interaction studies

<table>
<thead>
<tr>
<th>Study type</th>
<th>Advantages</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>In vitro</td>
<td>• Provides information about mechanisms</td>
<td>• May use doses higher than can be achieved in clinical practice</td>
</tr>
<tr>
<td></td>
<td>• Relatively simple to conduct compared with clinical studies</td>
<td>• Does not account for poor bioavailability of the test compound</td>
</tr>
<tr>
<td></td>
<td>• Relatively cheap to conduct compared with clinical studies</td>
<td>• May use one isolated constituent whereas herbal extracts contain multiple constituents</td>
</tr>
<tr>
<td></td>
<td>• Relatively quick to conduct</td>
<td>• Does not account for human genetic polymorphism</td>
</tr>
<tr>
<td>In vivo using animal models</td>
<td>• Can address some of the issues relating to bioavailability</td>
<td>• Species variations make results different to interpret</td>
</tr>
<tr>
<td></td>
<td>• Can produce quicker results than clinical studies</td>
<td>• Selection of appropriate dosage can be difficult and often very large doses used</td>
</tr>
<tr>
<td></td>
<td>• Can provide information when clinical studies are not able to be conducted</td>
<td>• Does not account for human genetic polymorphism</td>
</tr>
<tr>
<td>Clinical studies</td>
<td>• Provide the most relevant information and are the most definitive</td>
<td>• Most studies conducted in healthy male subjects however most relevant results are obtained when conducted with the same population who will be using the product</td>
</tr>
<tr>
<td></td>
<td>• Inter-product variability in constituent ratios means tested product may not accurately represent effects of other products</td>
<td></td>
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<tr>
<td></td>
<td>• Cannot differentiate between gut and liver effects (e.g. cytochromes)</td>
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</tr>
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<td></td>
<td>• Does not provide information about mechanisms</td>
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<tr>
<td></td>
<td>• Costly to produce</td>
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<td></td>
<td>• Time consuming</td>
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<tr>
<td></td>
<td>• May never be done due to ethical reasons (e.g. safety studies in pregnancy)</td>
<td></td>
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</tbody>
</table>
D.5.2. An overview of the main interaction mechanisms

When one considers the great variation in physical properties and pharmacological effects of the numerous substances used as medicines, together with the variable nature of herbal medicines and food supplements, it is apparent that a virtually endless number of interactions are possible. Interaction mechanisms can be broadly categorised as pharmacodynamic or pharmacokinetic interactions (Figure 1). Regardless of the interaction mechanism at work, there remain three possible outcomes: increased therapeutic or adverse effects, decreased therapeutic or adverse effects or a unique response that does not occur when either agent is used alone (325).
Pharmacodynamic

Herb – drug interactions

Pharmacokinetic

Absorption e.g. P-gp, chelation
Distribution
Metabolism e.g. CYP enzymes
Excretion e.g. urinary pH

Neuro – endocrine e.g. sedatives
Cardiovascular e.g. hypertensives
Haemotological e.g. antiplatelet
Metabolic e.g. hypoglycemic

Others

Immune

Figure 1. Main classes of interactions
D.5.3 Problems in extrapolating data

A review of the peer-reviewed literature reveals that there is a lack of clinical data and research regarding interactions between herbs and drugs and it is apparent that much remains untested. Despite this, several OTC herbal medicines have demonstrated pharmacodynamic and pharmacokinetic interactions with drugs in clinical studies. One major concern is those herbal medicines which interact with transporters such as P-gp or cytochromes such as CYP3A4 which are responsible for the transport or metabolism respectively of many drugs commonly used in clinical practice.

In some instances results obtained in vitro or with animal models about interactions do not accurately predict clinically significant effects in humans. This makes predicting the clinical significance of a possible interaction problematic and a reliance on evidence other than clinical data is bound to lead to inaccuracies. The herbs *ginkgo biloba* and saw palmetto will be used here as examples to illustrate this point.

In vitro and/or tests with animal models have shown both cytochrome induction and inhibition for *ginkgo biloba* (326-341). In contrast, four clinical studies have failed to identify a clinical significant effect on a variety of cytochromes. In one clinical study, Gurley et al demonstrated that *ginkgo biloba* had no significant effect on CYP1A2, CYP2D6 or CYP3A4 activity (342). Markowitz et al also conducted a human study and found no significant effects on CYP2D6 or CYP3A4 activity (343). Two further clinical studies found no significant effect for *ginkgo biloba* on CYP2C9 activity (344;345).

Saw palmetto showed potent inhibition of CYP3A4, CYP2D6, and CYP2C9 in vitro (346) however no significant effect was observed on CYP2D6 or CYP3A4 activity according to a clinical study by Markowitz et al (347). Gurley et al also found no significant effect for saw palmetto on CYP1A2, CYP2D6, CYP2E1 or CYP3A4 activity in healthy subjects (348).
To add to the complexity of the problem, in some instances researchers have conducted testing with individual herbal components or different forms of a herb finding different effects on CYPs. For example Fukao et al demonstrated using animal models that diallyl sulphide (100 micromol/kg) slightly but significantly increased cytochrome CYP2E1 activity (1.6-fold vs. control), whereas diallyl disulfide and diallyl trisulfide did not affect CYP2E1 activity or the hepatic total CYP level or CYP1A1/2 activity (349). The significance of these results in clinical practice is difficult to determine as the overall effect on CYP activity will depend on the concentrations of these various constituents present in a garlic product. The example also highlights the general difficulty in extrapolating results for one herbal extract to another as there may be a significant chemical variation between batches of the same herbal product and between different products of the same herb produced by various manufacturers.

**D.5.4 M.E.T.O.P.I.A. algorithm**

Predicting whether a clinically significant drug interaction will occur is a complex process as many individual factors come into play. Firstly, understanding the basic mechanisms of action of each medicine is essential as is keeping in mind the level of evidence supporting the interaction. Additionally, the types of medicines involved, administration route, dosage and time frames of use must be considered. The severity of the interaction is also influenced by factors such as genetics, environmental influences, diet, underlying disease and age. Finally, the importance an interaction is given is related to some extent by the setting in which it occurs.

It has been suggested that the M.E.T.O.P.I.A. algorithm provides a framework for making rational decisions about the possibility of a herb-drug interaction (325;325;350).
The acronym M.E.T.O.P.I.A. refers to:

**Medication and mechanisms**
- Understanding the medicines involved is essential. For example, when drugs with a narrow therapeutic index are being used, extra care is required.
- An understanding of the pharmacokinetic parameters and pharmacodynamic effects of the medicines involved is fundamental to predicting the likelihood of a proposed interaction occurring. In the case of herbal medicines, this information be not be available and much will be speculative.

**Evidence available**
- A review of the literature is required to determine what evidence is available and its strengths and limitations. As illustrated, in vitro studies are poor indicators of the clinical significance of an anticipated interaction however it may be the only evidence available.

**Timing and dose — introducing which, when and for how long?**
- For physicochemical interactions in particular, the scheduled administration times of the medicines is important to consider.
- This step also includes considering the chronicity of use of the medicinal agents as interaction mechanisms may only develop over several days or weeks (such as CYP induction) or may occur rapidly.

**Outcomes possible**
- The time of onset and severity of the possible clinical consequence may be predicted from the available evidence however in the case of herbal medicines where much remains untested, this is likely to be speculative.

**Practitioner considerations**
- Evaluation of whether the practitioner is able and willing to monitor and manage a potential interaction, should it become clinically significant. This can be dependant on the practitioner and patients setting. For example, in a hospital setting, an interaction is may be considered important if it requires
something to be done to relieve patient symptoms or will have a significant impact on critical therapy. Practitioners and nursing staff are in an ideal position to detect and manage interactions should this be necessary. In a community setting, general practitioners, pharmacists, CM practitioners are better placed and adequate patient self-monitoring becomes more important.

**Individual considerations**

- Consideration of individual patient risk factors which may be present and increase the likelihood of an adverse reaction
- The patient’s individual treatment preferences
- The patient’s ability to self-monitor a potential interaction and seek professional advice if they are concerned

**Action required**

Having considered the previous steps to predict the ‘likelihood’ and ‘consequence’ of an interaction, five actions are possible.

- *Avoid the new medicinal agent* — the relatively high likelihood and/or severity of the consequence make it an unacceptable risk so an alternative treatment should be considered
- *Avoid unless adequate medical monitoring is possible* — the relatively high likelihood and/or severity of the consequence may be acceptable if professional help is available to manage the outcome and supervise treatment.
- *Caution* — the likelihood of an adverse effects is relatively lower and/or a more minor consequence is possible than the previous level making it an acceptable risk if patients are made aware of the possibility and seek professional advice if concerned.
- *Observe* — there is a relatively low likelihood and/or negligible clinical consequence of a predicted interaction making it an acceptable risk
- *Prescribe* — there is a relatively high likelihood of a beneficial consequence making the interaction clinically useful.
The evidence on herbal medicines safety is incomplete, complex, and confusing. Similar to pharmaceutical medicines, they are associated with both risks and benefits. As more people take herbal medicines, the pressure increases on healthcare professionals such as doctors and pharmacists to be well informed about the subject, and on researchers to fill the many and somewhat embarrassing gaps in our current knowledge (351). As Ernst points out, failing to do (and fund) this work would constitute the true risk associated with herbal medicines (351).
Chapter Two

Patient and practitioner surveys: aims, research design, methodology and ethical considerations

2.0 Introduction

This chapter describes the aims and objectives of the patient and practitioner surveys, the research design and methodology used to perform surveys of surgical patients and practitioners in regards to their attitudes, perceptions and behaviours regarding CMs and CTs. The various locations, samples, sampling procedures and recruitment details are outlined. It also encompasses inclusion and exclusion criteria. Finally, this chapter details the methods of data collection and analysis, and ethical considerations that may impact on the study.
2.1 Aims and objectives of practitioner and patient surveys

The main aim of the surveys is to determine how CMs used by surgical patients are managed in the hospital system by doctors and pharmacists and what patient and practitioner influences affect this management.

The main objectives of the hospital doctors and pharmacist surveys were:

- To establish whether a patient’s use of CMs is addressed in the work practices of hospital doctors and pharmacists
- To examine the personal beliefs and attitudes of hospital doctors and pharmacists regarding CMs
- To establish whether hospital doctors and pharmacists are familiar with the evidence supporting the use of CMs and the safety issues associated with the use of CMs
- To identify learning needs and concerns regarding the use of CMs and CTs.

The secondary objectives of these surveys were:

- To examine the perceptions of hospital doctors and pharmacists to other CTs
- To determine hospital doctors and pharmacists personal use of CMs and CTs and interest in future use
- To explore the extent of integration of CTs into professional practice by hospital doctors and pharmacists and interest in future practise
- To identify other CM-related issues that may be of relevance to medical and pharmacy practice and education

The main objectives of the surgical patients’ surveys were:

- To explore the prevalence and patterns of CMs use by surgical patients prior to surgery
- To investigate whether CMs which are potentially harmful in the perioperative period are being used by surgical patients
• To explore whether surgical patients using CMs prior to surgery receive professional advice about use
• To examine the personal beliefs and attitudes of surgical patients to CMs
• To establish whether surgical patients would consider using diet, lifestyle and CTs if offered by hospitals

The secondary objectives were:

• To determine which information sources are used by surgical patients for information about CMs and CTs
• To identify other CM-related issues that may be of relevance to surgical patients

Patient and practitioner surveys were compared with the aim to:

• identify communication barriers preventing patients and practitioners from discussing CMs - from both the patient and practitioner perspectives
• explore differences in attitudes to CMs, between patients and practitioners
2.2 Research design

The surveys performed attempted to describe the current situation in Victorian hospitals and provide baseline information from which future studies can be developed and compared.

Questionnaires were considered to be an appropriate tool to collect data in the hospital because they allowed participants time to consider their responses and facilitated the exchange of potentially sensitive information which may not have been offered as readily using focus groups. It was also felt that information provided anonymously would encourage open disclosure without participant’s fear of being judged negatively. This was an important factor as surveys undertaken in the community had indicated that patients taking complementary medicines can be fearful of telling their general practitioner about use and it was not known whether the same reluctance to admit use to a health care researcher would be encountered in the hospital setting.

There are several limitations of the survey method such as its lack of suitability for people who are illiterate, unable to comprehend the survey questions or who can not read or write English. These were not major factors in the health professional’s studies but were relevant in the patient’s studies. The impersonal nature of the study may have affected the response rates as people felt less compelled to participate than if asked directly by the researcher; however the surveys were disseminated by hand directly to potentially eligible participants, which was likely to help increase response rates. The range of responses from the questionnaires provided mainly categorical data and some descriptive, qualitative data.

The surveys were conducted in three phases (see Figure 1).

2.1.1. Phase 1

In Phase 1, a survey was conducted with cardiac surgery inpatients at one hospital site before the larger survey in phase 2 in order to identify whether the methods of data collection used were effective and the survey tool would require modification to yield
further constructive data not adequately collected by the original survey. Cardiac surgery patients were chosen as a sub-set of special interest to the researcher because there is a paucity of information in the international literature about this population in regards to CMs, some CMs have proven benefits in CVD (such as fish oils) (352), some are known or suspected to interact with drugs commonly used in CVD (353) and CVD is highly prevalent in the Western world.

The study site, Cabrini Hospital Malvern, was chosen because it has two dedicated cardiac surgery wards, the attending cardiovascular surgeons expressed interest and support for the study and the Directors of Nursing and Surgery offered to provide trained staff for data collection, thereby maximising data collection efficiency.

2.1.2. Phase 2

In Phase 2, a survey was conducted of all eligible surgical patients admitted to two tertiary hospitals. This second survey was undertaken to maximise generalisability in the sample being surveyed by providing greater diversity in socioeconomic background. Cabrini and Frankston Hospitals were selected as potential survey sites after interviews with the Directors of Surgery indicated their hospitals would provide patients of different socioeconomic backgrounds. Selection of the two hospital sites was ultimately decided when the Director of Clinical Practice Improvement at Frankston Hospital and the Director of Nursing at Cabrini Hospital offered to provide trained staff to undertake data collection on the wards thereby maximising data collection efficiency.

2.1.3. Phase 3

Three separate surveys were conducted in Phase 3.

The largest survey was conducted at Frankston Hospital and involved the complete medical and pharmacy staff. This provided information about the hospital staff responsible for taking medication histories, prescribing medication, and providing patients with drug information and counselling. Frankston Hospital was chosen as the
survey site for Phase 3 because of the interest shown by Directors of the Medical, Surgical and Clinical Improvement Departments. It was anticipated that this interest would provide a good response rate to the survey. The data collected enabled comparisons to be made between sub-groups of health care professionals working within the same setting and comparisons with the other two practitioner surveys. By grouping data collected from the medical practitioners at this site, meaningful comparisons could also be made with surveys of GPs in the community.

Two additional surveys were conducted to increase the reliability and generalisability of the results obtained. This involved increasing the number of study sites used for data collection thereby increasing the sample size and potentially, the diversity of participants. It was decided to focus on anaesthetists and pharmacists after a review of the published literature (see Chapter 1, section B) revealed that no surveys are available which have focussing on these sub-groups and their attitudes, perceptions, behaviours and knowledge of CM.
Figure 1. Outline of the research study
2.3 Methodology used in conducting the surveys

2.3.1 Settings

Four Victorian hospitals were selected as sites for data collection: Cabrini Hospital (Malvern), Frankston, Austin and Alfred Hospitals.

2.2.2.1. Frankston Hospital, Frankston

Frankston Hospital is part of Peninsula Health and is a 300-bed public, teaching hospital and the major provider of acute secondary and tertiary hospital services on the Mornington Peninsula in Victoria. It services both metropolitan and semi-rural areas and provides general and specialty medical and surgical services.

2.2.1.2. Cabrini Hospital, Malvern

Cabrini Hospital is a 460-bed private hospital in Melbourne with two cardiac wards. Although the hospital administrator and CEO does not collect demographic data about the hospital’s patients they are of the belief that patients attending this hospital will generally have higher education and higher income than those attending Frankston Hospital and the majority are English speakers.

2.2.1.3. Austin Hospital, Heidelberg

Austin Hospital is one of three sites that form Austin Health. Austin Health has more than 840 beds and treats approximately 65,000 inpatients and 130,000 outpatients a year. The Austin Hospital is a major teaching public hospital located in Melbourne’s north eastern suburb of Heidelberg.

2.2.1.4. Alfred Hospital, Prahran

The Alfred Hospital is one of three sites that form Bayside Health. It treats more than one quarter of a million patients annually. It provides the most comprehensive range of specialist medical and surgical services in Victoria and is located in Prahran which is in Melbourne’s inner south east.
2.2.2. Populations studied

Phase 1 and 2 of the surveys project involved surgical patients only.

- Phase 1: all eligible cardiac surgery patients admitted to Cabrini Hospital
- Phase 2: all eligible surgical patients admitted to Cabrini and Frankston Hospitals

Phase 3 involved three different population samples working within the hospital setting.

- A combined sample of surgeons, anaesthetists, medical physicians and pharmacists
- Anaesthetists
- Hospital pharmacists

2.2.2.1. Inclusion and exclusion criteria for surgical patients

Adult patients over 18 years of age and who were admitted to the surgical wards but had not yet undergone surgery, agreed to participate and were able to fill out the questionnaire unassisted, were included in the survey. Patients undergoing emergency surgical procedures were excluded from the survey.

In Phase 1, patients who met the general inclusion criteria and who were admitted by cardiothoracic surgeons to the two cardiac wards at Cabrini Hospital over the period for data collection were included. These wards were 1 North and 1 South.

In Phase 2, patients who met the general inclusion criteria and who were admitted to all surgical wards at Cabrini and Frankston Hospitals over the period for data collection were included. Wards where data collection had previously been undertaken were not included a second time. The inclusion/exclusion criteria aimed to maximise generalisability in the sample being surveyed by providing as much diversity as possible in age, gender and socioeconomic background.
2.2.2. Inclusion and exclusion criteria for hospital staff

Both part-time and full-time hospital pharmacists, surgeons, physicians and anaesthetists were included in the survey, including registrars and pre-registrants. There was no age restriction. The inclusion/exclusion criteria aimed to maximise generalisability in the sample being surveyed by providing as much diversity as possible in age, experience and sub-specialties.

Registrars were included because in the Australian medical system, after graduation, doctors generally practice within the hospital system before graduating to practice within the community. Therefore this period of training has an influence on community practise also. The number of years undertaken within the hospital system varies considerably depending on the doctor’s vocation. Following the initial one to two years, doctors may enter a training program in which they become known as a registrar. Upon successful completion of the program, the doctor is known as a consultant (e.g. medical physician, surgeon or anaesthetist) and becomes recognised as the Senior Medical Staff within the hospital system.

Clinical pharmacists interact with patients on daily ward rounds, conduct medication reviews and counselling sessions, liaise with medical teams to advise on appropriate use of medicine and provide drug information for nurses, doctors and other pharmacists. As such, they were considered important inclusions in the survey. Graduate pharmacists have recently completed a pharmacy degree and have to work for twelve months before registration exams. Known as pre-registrants, these pharmacists provide a perspective from a younger generation and were also included. Drug information pharmacists investigate and advise on the more difficult drug related problems and are likely to have greater knowledge of CMs so were also included in the survey.

2.2.3. Data collection

Data collection proceedings were slightly different for surgical patients at Cabrini and Frankston Hospitals and described in 2.2.3.1. Data collection for doctors and
pharmacists was supervised by the Director of each relevant department and described in subsequent sections 2.2.3.2; 2.2.3.3; 2.2.3.4.

### 2.2.3.1. Surgical patients surveys

Phase 1 survey of cardiac surgery patients was conducted at Cabrini Hospital Malvern between September and December 2004. Trained nursing staff undertook data collection on the designated wards during their daytime shifts after patient admission by cardiothoracic surgeons. Each ward was provided with a written sheet outlining the aims of the study and inclusion and exclusion criteria for patients and trained charge nurses helped to supervise staff in data collection. Nursing staff was involved in screening patients for eligibility and offered the survey in blank envelopes to patients in their rooms. It was later collected by nursing staff at the end of each shift and placed into a designated box in the charge nurses office for safe storage. The researcher visited the hospital wards regularly to answer queries from nurses and collect completed surveys from the wards.

Phase 2 survey of surgical patients was conducted at two sites: Cabrini Hospital, Malvern and Frankston Hospital, Frankston between July and November 2005. The same method of data collection was undertaken at Cabrini Hospital as had been previously used in the cardiac surgery patient survey. At Frankston Hospital, a trained research assistant undertook data collection on the surgical wards during the daytime shift. Returned surveys were stored in the research assistant’s office until the study period ended. Regular email and telephone communication was maintained between the researcher and research assistant during this time. The Director of Clinical Practice Improvement supervised the research assistant on site.

### 2.2.3.2. Anaesthetists survey

Data collection was undertaken between March and May 2005 at three tertiary public hospitals (the Austin, Alfred and Frankston Hospitals) in Melbourne after approval was obtained from the Directors of Anaesthesia and Human Research Ethics
Committees at RMIT University and all hospital sites. Cabrini Hospital was not included as a study site because it has no department of anaesthesia.

The anonymous, self-administered questionnaire was distributed by the department administration staff to all anaesthetists listed on department registers as working at the site at the time of the study. Anaesthetist’s not directly involved in patient care were asked to omit questions about patient communication. Over the following three months, non-responders were reminded at least twice to complete the survey. No inducements to participate were provided. Completed surveys were returned to the department and stored in their administration offices. The researcher maintained regular email and telephone contact with the data collection supervisor and sites were visited each month to collect completed surveys.

2.2.3.3. **Pharmacists survey**

The survey was conducted at four tertiary hospitals (the Austin, Alfred, Frankston and Cabrini Hospitals) in Melbourne between August 2004 and May 2005, after approval was obtained from the Directors of all Pharmacy departments and Human Research Ethics Committees at RMIT and all sites. The anonymous, self-administered questionnaire was distributed by Directors and/or a specified staff member to all pharmacists listed on department registers as working at the site at the time of the study. Pharmacists not directly involved in patient care were asked to omit questions about patient communication. Each site was given three months to complete the survey and over this period, non-responders were reminded at least twice. No inducements to participate were provided. Completed surveys were returned to the department and stored in their administration offices. The researcher maintained regular email and telephone contact with the data collection supervisor and sites were visited each month to collect completed surveys.

2.2.3.4. **Combined health professionals survey**

The survey was conducted between December 2004 and April 2005 at Frankston Hospital after approval was obtained from the Directors of Surgery, Medicine,
Anaesthesia and Clinical Practice Improvement and the Human Research Ethics Committees at RMIT University and Peninsula Health.

The anonymous, self-administered questionnaire was distributed to all hospital doctors and pharmacists listed on department registers as working at the site at the time of the study and who had not yet completed the survey from previous studies. The Director of Clinical Practice Improvement co-ordinated data collection with each department. Doctors and pharmacists not directly involved in patient care were asked to omit questions about patient communication. Non-responders were reminded at least twice to complete the survey during the study period. No inducements to participate were provided. Completed surveys were returned to the Department of Clinical Practice Improvement and stored in administration offices. The researcher maintained regular email and telephone contact with the data collection supervisor and the site was visited each month to collect completed surveys.

2.2.4. Survey tools

The main instruments for data gathering were the self-administered and structured questionnaires (see Appendix A,B,C).

Three different questionnaires were used. The survey used in Phase 1 for cardiac surgery patients was slightly modified for use in Phase 2. The survey used for the three health professional’s studies remained unchanged for the duration of the project.

All questionnaires were developed after systematic review of published studies (see Chapter 1 sections B, C, D) relating to the field of CMs. A consideration of this data helped enhance reliability and validity of the study. However, new items were required to capture additional information relevant to the projects aims. This became clear after conducting systemic reviews and face to face interviews about the proposed study design with the Directors of Pharmacy, Surgery, Anaesthesia and Clinical Practice Improvement. Many of the potential new items for the instrument were generated from these interviews.
Once drafts of the initial patient and practitioner questionnaires were developed, another series of in depth, face to face interviews with the Directors of Pharmacy, Surgery, Anaesthesia and Clinical Practice Improvement were conducted. Modifications to the questionnaire were made based on their feedback. Input was also sought from an experienced statistician, marketing consultant and the Director of Nursing at Cabrini Hospital who made recommendations and amendments to the initial questionnaire drafts. All Directors gave permission for the researcher to proceed with the survey and it was ascertained that ethics approval would be required from the hospitals before the surveys could be conducted.

Following this, both questionnaires were then pre-tested with a small group of hospital staff and lay persons who provided extensive feedback. A preliminary pilot test of the patient surveys was then conducted with three health care consumers (who were not included in the survey sample) who vetted any inappropriate, sensitive or ambiguous questions. A preliminary pilot test of the health professionals survey by an experienced anaesthetist, physician, surgeon, pharmacist and marketing consultant (who were not included in the survey sample) vetted any inappropriate, sensitive or ambiguous questions. They also evaluated the content of the questionnaire to help assess consistency and accuracy. The surveys were then re-drafted with a few minor changes made to the questionnaires before proceeding with the study.

Whilst these steps ensured the survey questions had face validity, a further formal validation process would have been valuable. Nevertheless, achieving high response rates provide confidence in the findings.

2.2.4.1. Cardiac surgery patient survey

Surveys identified in the literature search were used as a basis for the design and development of the patient surveys. The final questionnaire consisted of 25 questions with a range of multiple choice and multiple response questions and regular opportunities for respondents to provide additional comments in free text. Both closed and open ended questions were also used to collect more accurate data. Surveys did not collect participant names or addresses to encourage objective responses to potentially sensitive questions. Patient information about the study and consent details
were clearly stated on the first page. Also on the first page was a definition of the phrase ‘complementary medicines’. This was defined as herbal medicines, vitamin and mineral supplements and food supplements which can be bought in a supermarket, pharmacy, health-food store, on the internet, from a mail order company or from a practitioner. It was stated that this did not refer to therapies such as massage, acupuncture or chiropractic. The survey had five general sections and asked about the following: characteristics of respondents, behaviours, perceptions and attitudes regarding CMs and interest in CTs.

Seven questions provided data about respondent’s age, gender, education, country of birth, smoking status, income and confirmation that they were a surgical patient. Two further questions asked respondents about their use of prescription medicines and CMs in the 2 weeks prior to admission. Patients reporting no use of CMs were instructed to omit further questions pertaining to use and continue with the final questions regarding perceptions of CM safety, information sources and interest in CTs. If patients answered affirmatively to CMs use, they completed all questions in the remainder of the questionnaire. This included the name and number of CMs taken, reasons for use, intention to continue use in hospital and whether hospital doctors, staff or their general practitioner had been informed about use. Respondents were asked whether CMs were self-prescribed or prescribed by a health practitioner, their monthly spend on CMs, sources of information used regarding CMs and reasons for non-disclosure whilst in hospital (where relevant). The final question asked all respondents whether they would consider using a range of diet, lifestyle or CM therapies if offered by hospitals and to nominate which ones were of interest from a list of 16 therapies. An opportunity was provided for respondents to suggest other therapies not included in the list. The question did not state whether these would be offered as inpatient or outpatient services or how the services would be funded.

### 2.2.4.2 General surgery patient survey

Due to feedback from nurses and analysis of patient responses from the cardiac surgery survey, the initial survey was modified in order to provide more in depth information about patient attitudes and use of CMs and promote a higher response rate (See Appendix B). In summary, these changes were: the deletion of 2 questions
considered irrelevant, changed positioning of several questions to encourage better response rates, integrating 2 questions into one with a new question/answer format for easier patient use and the addition of 2 new questions to gather more information about patient attitudes.

A letter was sent to the HREC at Cabrini to notify them of the changes and seek approval for use of the new survey. Appendix G provides further details of the modifications made to the cardiac surgery patient survey.

2.2.4.3 Health professionals survey

Four studies were used as a basis for the design and development of the practitioner surveys (121;165;166;354). The final version consisted of 23 questions which included multiple choice and multiple response questions and regular opportunities for respondents to provide additional comments in free text (See Appendix C). Both closed and open ended questions were also used to collect more accurate data. Surveys did not collect participant names or addresses to encourage objective responses to potentially sensitive questions. Information about the study and consent details were clearly stated on the first page.

On the first page, the phrase ‘complementary medicines’ was defined as: "herbal medicines, vitamin and mineral supplements and food supplements which can be bought in a supermarket, pharmacy, health-food store, on the internet, from a mail order company or from a practitioner”. It was stated that this did not refer to therapies such as massage, acupuncture or chiropractic unless specified. Only respondents directly involved in patient care were asked to respond to all questions whereas those not directly involved in patients were asked to omit questions regarding patient communication. The survey had six general sections and asked about the following: characteristics of respondents, behaviours, perceptions, attitudes, confidence and knowledge of CMs.

Seven questions provided data about respondent’s age, gender, years in practice, position in the hospital, if directly involved in patient care, average number of patients seen each week and previous training received about CM. Seven questions asked
respondents about their behaviours. Four of the seven questions specifically asked about patient and staff communication and included: frequency of enquiry about patients’ use of CMs, reasons for not asking patients about use, advice given to CM-users and methods of communication about CMs use with other staff. These were included to identify current practice and some of the barriers which exist to prevent patient communication about CMs. Two of the seven questions collected data about respondents’ information seeking habits and information sources used for CM-related queries. One further question asked about their personal use of CMs and CTs and asked about use in the previous 12 months and interest in future use. Three questions asked about their perceptions of patients’ use of CMs prior to and after admission and the potential usefulness and harmfulness of 15 CTs available in Australia, as identified by Pirrotta et al (165). Attitudes to CMs were assessed using a 5-point Likert scale (strongly agree = 1, unsure = 3, strongly disagree = 5) which was applied to 5 attitudinal statements in a multi-part question. A maximum score of 25 was possible indicating a highly negative attitude and a minimum score of 5 indicating a positive attitude. One question asked respondents how they would generally respond if a patient asked whether they should use, or consult a practitioner of a specific CT. Four possible responses were provided and applied to 15 CTs: not confident to discuss the advantage or disadvantages with patients, actively encourage, actively discourage, or neither encourage or discourage. This question was included in order to get a deeper understanding of respondent’s attitudes to CTs and their confidence when dealing with CM-related issues. One further question was included regarding confidence, asking respondents about their confidence in detecting possible safety issues arising from patient use of CMs. Three studies were used as a basis for the knowledge section of the questionnaire (178;192;355). Multiple response questions were used to assess respondent’s knowledge of the efficacy and/or safety of 11 OTC CMs. These were: chamomile, coenzyme Q 10, echinacea, ginger, garlic, ginkgo, glucosamine, fish oils, St John’s wort, valerian, vitamin E. The eleven CMs were chosen after a review of the literature and discussion with staff at a major Australian CMs manufacturing company indicating they are widely used by the general community (356) and/or have the potential to induce adverse events of relevance to the surgical patient. Respondents were asked to match the listed properties to the listed CMs and were advised they could provide multiple responses if appropriate or tick a box indicating they were unsure of the answer. The ‘unsure’
box was included to minimize the chance of respondents guessing. These properties were: ‘has potential to increase bleeding, exert sedative activity, interact with warfarin, digoxin, selective serotonin re-uptake inhibitor (SSRI) drugs and/or cyclosporine, proven efficacy’. Definitions of the terms used in this section were not provided. On May 20, 2005 AltMedDex database from Micromedex was used to obtain answers to the knowledge section (357). It is a comprehensive electronic resource on drugs and CMs available at all public hospital sites participating in the study. According to this source, participants needed to mark 21 individual boxes to attain a score of 100%.

2.2.5 Statistics

The data was analysed using descriptive statistics via frequency distributions and cross-tabulations. In addition, sub-group analyses were performed to detect any interesting patterns in the responses among the various populations/patients.

Data was analysed using the software program SPSS 13.0 (Statistical Package for the Social Sciences) using descriptive statistics along with Chi-square tests to analyse categorical variables and ANOVA and paired t-test and Pearson r correlations to analyse continuous variables. P values of less than 0.05 were considered significant.

2.2.6 Ethics

The study required consultation with the Directors of Surgery, Medicine, Anaesthesia and Pharmacy in each participating hospital to ensure permission and support. At Cabrini Hospital, consultation with the Director of Nursing was also conducted. Applications were made to the HRECs of RMIT, Frankston, Austin, Alfred and Cabrini Hospitals and approval was granted from all sites (see Appendix F).

In order to ensure the questions were non-judgemental, pre-testing was undertaken. Recruitment for the survey was at the discretion of the Directors of each department and was voluntary. The names and addresses of individuals were not recorded in the survey, coding of the questionnaire did not link participants to their responses and participants were not and will not be identified in published data. Completed surveys
and all data was stored in a secure location in the researchers home office and only the researcher and supervisor have access to the data encrypted onto storage hardware.
Chapter Three

Results from patient and practitioner surveys

3.0 Introduction

This chapter presents results from the five studies conducted as part of this research project. It has been divided into five separate sections for ease of use and will present the results of each study individually.

Section 3.1 presents results from the anaesthetists study followed by Section 3.2 which presents results from the pharmacists study and finally Section 3.3 which presents results from the combined doctor/pharmacist study at Frankston Hospital. Results from the CS patient study and surgical patient study will be presented in Sections 3.4 and 3.5 respectively.

The complete raw data for all the survey results are presented in Appendix E.
3.1 Anaesthetists survey

Ninety seven completed questionnaires were received (61% response rate).

3.1.1 Sample characteristics

Respondent’s average age was 39.8 years (SD 8.6), 88% were male and 96% saw up to 50 patients each week. All were directly involved in patient care. The response group was made up of 67.5% senior anaesthetists, 26.2% registrars and 6.2% trainees whereas the non-response group was made up of 63.0% senior anaesthetists, 26.0% registrars and 10.8% trainees.

3.1.2 Communication with patients and other staff

Table 1 presents data about the frequency with which anaesthetists asked patients about use of CMs. There was no significant difference between respondents aged less than 40 years compared to those over 40 years with regards to this enquiry (F(1,93)=1.99, p=.162). Two people commented that use of CMs is generally written on the pre-admission form. Anaesthetists reported multiple reasons for not routinely asking patients about CMs including forgetting to ask (53.5%), assuming the patient would tell them (34%), ‘I don’t have sufficient knowledge about it’ (34%), not thinking the information was relevant (22%), it’s too time consuming (13%) and not having the opportunity to ask (2%).
Table 1. Frequency of patient enquiry, confidence in personal knowledge and use of resources.

<table>
<thead>
<tr>
<th>How often do you ask patients about use of CMs?</th>
<th>How often do you feel confident that you have sufficient knowledge to identify when CMs could adversely affect patient care?</th>
<th>How often do you check for side effects and drug interactions if CMs are being used?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always or often</td>
<td>8(10)</td>
<td>12(15)</td>
</tr>
<tr>
<td>Sometimes</td>
<td>13(16)</td>
<td>35(45)</td>
</tr>
<tr>
<td>Occasionally</td>
<td>17(21)</td>
<td>15(19)</td>
</tr>
<tr>
<td>Rarely or never</td>
<td>43(53)</td>
<td>16(21)</td>
</tr>
</tbody>
</table>

Data are presented as n(%)

The advice given to patients taking CMs is presented in Table 2. One respondent commented that they advised patients to stop taking “the ones beginning with ‘g’ because they cause bleeding”, another commented “any with anticoagulant action”, and a third “any they cannot name the ingredients of”. Two people commented that it was too late for them to advise patients about CM use because “I usually see them on the day of surgery”.

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Table 2. Advice given to patients identified as using CM products

<table>
<thead>
<tr>
<th>What advice do you generally give to patients taking CMs?</th>
<th>n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cease taking all CMs</td>
<td>18(20)</td>
</tr>
<tr>
<td>Cease taking specific CMs</td>
<td>41(45)</td>
</tr>
<tr>
<td>I don't feel confident to advise on CMs use</td>
<td>28(31)</td>
</tr>
<tr>
<td>Consult another health care practitioner about CMs</td>
<td>9(10)</td>
</tr>
<tr>
<td>Keep taking all CMs</td>
<td>3(30)</td>
</tr>
</tbody>
</table>

Data are presented as n(%)

Multiple answers were received to the question “If you do ask patients about use, what do you do with this information?” 78% recorded this information in the patient’s history, 6% on the patients medication chart, 28% verbally informed the relevant surgeon or physician, 1.5% told another health care professional (e.g. pharmacist) and 16% did not record the information anywhere.

When asked to estimate the percentage of patients taking CMs in the 2 weeks prior to admission, 76% thought usage was less than 40%. Post-admission, it was perceived by 93% that patient usage had reduced to less than 25%.

3.1.3 Confidence in dealing with CM-related issues

When patient’s use of CMs was identified, 15% of respondents always or often felt confident that they had sufficient knowledge to identify when use could adversely affect patient care. More data is presented in Table 1. Those who were more confident about CM related issues were significantly more likely to ask patients about possible use of CMs (r=-.429, p<.001).
3.1.4 Use of information resources

Most respondents (89%) did not routinely check for side effects and drug interactions if patient use was identified (Table 1). Resources used for information about CMs and CTs were peer-reviewed medical journals (used by 58%), databases such as Medline (49%), the internet (41%), colleagues (37%), seminars (35%), reference texts such as MIMs (31%) and 12% referred to pharmacists. Respondents who check for side effects are significantly more likely to attain greater knowledge scores than those that reported doing this rarely or never (r=-.275, p=.007).

3.1.5 Attitudes to CMs and CTs

The mean attitude score was 18.87 (SD2.22) indicating a moderately negative attitude to CMs (5 considered positive and 25 negative). Responses to attitudinal statements about CMs are presented in Table 3. Notably, there was widespread agreement with the statements “CMs need more hospital based research” and “Regulations for CM practitioners need to be tightened”. Figures 1 and 2 presents respondent’s perceptions of the potential usefulness and harmfulness of CTs. Most respondents perceived chiropractic as potentially harmful followed by Chinese herbal medicine and herbal medicine. Nearly all respondents thought acupuncture was potentially useful with many also reporting hypnosis, massage, meditation and yoga as potentially useful. Figure 3 presents perceptions of usefulness and harmfulness on the same graph, for ease of comparison with the other practitioner studies. Figure 4 presents respondents general advice given to patients enquiring about CTs.
Table 3. Responses to attitudinal statements

<table>
<thead>
<tr>
<th>Attitudinal statements</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SA</td>
</tr>
<tr>
<td>CMs are appropriate for use in the hospital setting</td>
<td>2(2)</td>
</tr>
<tr>
<td>CMs are generally a waste of time and money</td>
<td>13(13)</td>
</tr>
<tr>
<td>CMs are potentially dangerous and need to be monitored</td>
<td>12(12)</td>
</tr>
<tr>
<td>CMs offer a false sense of hope and exploit vulnerable individuals</td>
<td>11(11)</td>
</tr>
<tr>
<td>CMs offer patients cost effective treatment options</td>
<td>1(1)</td>
</tr>
<tr>
<td>CMs need more hospital based research</td>
<td>42(43)</td>
</tr>
<tr>
<td>CMs are something that most of my colleagues would consider</td>
<td>0(0)</td>
</tr>
<tr>
<td>Regulations for CM practitioners need to be tightened</td>
<td>36(37)</td>
</tr>
</tbody>
</table>

SA= strongly agree; A=agree; NAD=neither agree or disagree; D=disagree; SD=strongly disagree

Data presented as n(% of the total number of respondents for that statement)
Figure 1. Anaesthetists perceptions of the potential harmfulness of CTs
Figure 2. Anaesthetists perceptions of the potential usefulness of CTs
Figure 3. Anaesthetists perceptions of the potential usefulness and harmfulness of CTs, presented together
General responses to patients interest in using CTs

Figure 4. Anaesthetists response to patients enquiry about CTs.
3.1.6 Personal use and practice of CTs

Vitamin and mineral supplements had been taken by 10% of anaesthetists within the previous 12 months and 4% had taken herbal medicines. The most commonly used CMs were fish oils supplements, multivitamins, glucosamine, vitamin C and garlic. In regards to CTs, non-medicinal therapies were most popular chiefly massage (21%). When asked which CT they would like to receive in future, 66% were interested in massage, 61% acupuncture, 61% meditation, 60% yoga, 37% hypnosis and 33% vitamin/mineral therapy whereas 20% or fewer were interested in other CTs. Very few respondents were already practising a CT however there was interest in practising some CTs in the future, notably acupuncture (Figure 5).
Figure 5. CTs anaesthetists have practised and would consider practising
3.1.7 Training and knowledge

No formal training about CM had been received by 49% of the sample. Post-graduate lectures had been attended by 27%, under-graduate lectures by 9%, specific seminars by 8% whereas 27% had undertaken self-directed learning. A total of 69% were interested in further training about CMs and CTs.

Anaesthetists achieved a mean score of 20.08 (SD 15.95) out of a possible 100 in the knowledge section. When knowledge scores were compared between the three sites, no significant differences were found (F(2,96)=.578, p=.563) demonstrating the remarkable consistency of the results. No significant difference in knowledge scores was found between respondents aged less than 40 years compared to those older than 40 years (t(93)=1.64).

Participants who reported greater confidence in their ability to identify potential safety issues relating to CMs tended to achieve higher knowledge scores (r=-.429, p<.001) and those with higher knowledge scores tended to ask patients about their potential CMs use more frequently (r=-.303, p=.003) and were more likely to check for side effects and drug interactions when patient use was identified (r=-.275, p=.007). Seventy four respondents attempted the question about which CMs may increase bleeding (see Table 4). According to AltMedDex from Micromedex database, the correct answers were: garlic, ginkgo biloba, ginger and fish oils. Further details of results from the knowledge section are presented in Appendix E.
Table 4. Responses to question about which CMs may increase bleeding.

<table>
<thead>
<tr>
<th>CMs listed</th>
<th>Respondents who marked this response</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n(%)</td>
</tr>
<tr>
<td><strong>CMs which may increase the risk of bleeding?</strong></td>
<td></td>
</tr>
<tr>
<td>Garlic</td>
<td>59(79.7)</td>
</tr>
<tr>
<td>Ginkgo biloba</td>
<td>53(71.6)</td>
</tr>
<tr>
<td>Ginger</td>
<td>42(56.8)</td>
</tr>
<tr>
<td>Fish oils</td>
<td>6(8.1)</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>4(5.4)</td>
</tr>
<tr>
<td>Chamomile</td>
<td>4(5.4)</td>
</tr>
<tr>
<td>Echinacea</td>
<td>5(6.8)</td>
</tr>
<tr>
<td>Valerian</td>
<td>3(4.1)</td>
</tr>
<tr>
<td>Glucosamine</td>
<td>2(2.7)</td>
</tr>
<tr>
<td>Coenzyme Q10</td>
<td>2(2.7)</td>
</tr>
<tr>
<td>St Johns wort</td>
<td>14(18.9)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>74(100.0)</td>
</tr>
</tbody>
</table>

Data presented as n (% of the total number of respondents to that question)

In regards to their opinion about the importance of CM education to be included in the medical undergraduate curriculum, 29.2% thought it was very important, 61.5% thought it was somewhat important and 9.4% thought it was not important.
3.2 Hospital Pharmacists survey

Surveys were distributed to 140 pharmacists with 107 returning completed questionnaires (response rate 76%).

3.2.1 Sample characteristics

The majority of respondents were women (78%) and pharmacists directly involved in patient care (82%). Respondents mean age was 34.9 years (SD 12.3), mean number of years in practice was 12.4 years (SD 11.9) and mean number of patients seen each week was 72 (SD 97). The study sample shares age and gender characteristics with the National Pharmacy labour force (358).

3.2.2 Pharmacists communication with patients and staff

Table 1 presents data on the frequency with which pharmacists ask patients about use of CMs, their confidence in identifying potentially unsafe outcomes relating to CM use and the frequency of using resources to check for potential safety issues. There was a significant difference in the frequency of asking patients about CM use between age groups with younger pharmacists (under 25 years of age) significantly more likely to enquire than older pharmacists (35 years and older) (t(39.10)=4.08, p<0.001). There was no significant relationship between knowledge scores and frequency of enquiry(r=-.087, p=.417) or how often respondents checked for side effects and drug interactions and frequency of enquiry (r=-.144, p=.187).
Table 1. Frequency of patient enquiry, pharmacist’s confidence and use of resources

<table>
<thead>
<tr>
<th>How often do you ask patients about use of CMs?</th>
<th>How often do you feel confident that you have sufficient knowledge to identify when CMs could adversely affect patient care?</th>
<th>How often do you check for side effects and drug interactions if CMs are being used?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always</td>
<td>26(29)</td>
<td>3(3)</td>
</tr>
<tr>
<td>Often (more than 60% of the time)</td>
<td>23(26)</td>
<td>20(23)</td>
</tr>
<tr>
<td>Sometimes</td>
<td>14(16)</td>
<td>34(39)</td>
</tr>
<tr>
<td>Occasionally</td>
<td>11(12)</td>
<td>22(25)</td>
</tr>
<tr>
<td>Rarely (less than 5% of the time)</td>
<td>9(10)</td>
<td>7(8)</td>
</tr>
<tr>
<td>Never</td>
<td>6(7)</td>
<td>1(1)</td>
</tr>
</tbody>
</table>

Data presented as n(% of the total number of respondents for that question)

The main reasons pharmacists reported for not asking patients about CMs were forgetting to ask (58%), assuming patients will tell without being asked (27%), not having the opportunity (23%), not having sufficient knowledge (22%), not thinking it relevant (22%) or because it was ‘too time consuming’ (17%). If patient use of CMs was identified, 53% of pharmacists generally advised patients to cease taking specific CMs, 35% recommended they consult another healthcare practitioner for advice about them, 24% didn’t feel confident to advise patients about use, 9% advised to keep taking all CMs (9%), 7% advised to cease all CMs. Thirteen respondents added comments in free text expressing concerns about interactions and three others stated that hospital protocol advises them to tell patients to stop using all CMs.
Of those who asked patients about CMs, 59% stated they recorded usage information in the patient history, 28% recorded the information in the patients medication chart and 3% did not record the information. Some (29%) verbally informed the relevant surgeon, anaesthetist or physician and 28% verbally informed other healthcare professionals such as a dietician or other pharmacist. The advice given to patients using CMs is presented in Table 2.

Table 2. Advice given to patients identified as using CMs.

<table>
<thead>
<tr>
<th>What advice do you generally give to patients taking CMs?</th>
<th>n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cease taking all CMs</td>
<td>6(7)</td>
</tr>
<tr>
<td>Cease taking specific CMs</td>
<td>43(53)</td>
</tr>
<tr>
<td>I don't feel confident to advise on CMs use</td>
<td>19(24)</td>
</tr>
<tr>
<td>Consult another health care practitioner about CMs</td>
<td>28(35)</td>
</tr>
<tr>
<td>Keep taking all CMs</td>
<td>7(9)</td>
</tr>
</tbody>
</table>

Data are presented as n(%) where the % is the percentage of the total number of respondents

Most (77%) respondents thought that less than 40% of patients used CMs in the 2 weeks prior to admission and nearly all (92%) respondents thought patients usage reduced to less than 25% whilst in hospital.
3.2.3 Pharmacists attitudes towards CMs

Responses to attitudinal statements about CMs are presented in Table 3 and indicate pharmacists are concerned about safety, efficacy, regulatory and cost issues associated with CMs. The mean attitude score was 18.6 (SD2.18) which can be considered moderately negative (a score of 5 was considered positive and 25 considered negative). Notably, 87% of respondents agreed with the statement that CMs are potentially dangerous and need to be monitored, 88% agreed that CMs required more hospital based research and 92% agreed that CM practitioners required tighter regulation.
Table 3. Responses to attitudinal statements.

<table>
<thead>
<tr>
<th>Attitudinal statements</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMs are appropriate for use in the hospital setting</td>
<td>4 (4) 22(21) 38(37) 35(34) 5(5)</td>
</tr>
<tr>
<td>CMs are generally a waste of time and money</td>
<td>3(3) 32(31) 30(29) 38(36) 2(2)</td>
</tr>
<tr>
<td>CMs are potentially dangerous and need to be monitored</td>
<td>22(21) 71(66) 11(10) 3(3) 0(0)</td>
</tr>
<tr>
<td>CMs offer a false sense of hope and exploit vulnerable individuals</td>
<td>8(8) 35(33) 41(39) 21(20) 0(0)</td>
</tr>
<tr>
<td>CMs offer patients cost effective treatment options</td>
<td>1(1) 13(13) 28(27) 51(49) 11(11)</td>
</tr>
<tr>
<td>CMs need more hospital based research</td>
<td>45(43) 48(45) 10(9) 1(1) 2(2)</td>
</tr>
<tr>
<td>CMs are something that most of my colleagues would consider</td>
<td>2(2) 15(14) 45(43) 36(35) 6(6)</td>
</tr>
<tr>
<td>Regulations for CM practitioners need to be tightened</td>
<td>42(40) 55(52) 8(8) 1(1) 0(0)</td>
</tr>
</tbody>
</table>

SA= strongly agree; A=agree; NAD=neither agree or disagree; D=disagree; SD=strongly disagree

Data presented as n(% of the total number of respondents for that statement)

3.2.4 Training, information sources and knowledge

Some pharmacists (62%) had received training about CMs and CTs and 83% were interested in receiving further training. Undergraduate lectures were the main source of education (45%) followed by self-directed learning (24%), specific lectures/seminars (16%) and/or post-graduate lectures (10%) whereas 2% had undertaken formal study of a certificate, diploma or degree in CM. All respondents reported referring to resources for information about CMs and CTs. The most popular sources of information were databases such as Medline (67%), reference texts (65%),
the World Wide Web (59%), colleagues (39%), peer-reviewed journals (38%),
company literature (32%), seminars/conferences/lectures (30%), CM practitioners
(15%), family and friends (10%).

The knowledge section of the survey was attempted by 95% of respondents (n=102)
who had a mean score was 39.9 (SD 19.9) out of a possible 100. Those that reported
feeling confident more frequently in their knowledge of CMs safety were significantly
more likely to attain greater knowledge scores (r=-.429, p<.001). There was no
significant relationship between knowledge scores and age (r=-.09, p=.393), how
often respondents asked patients about CMs (r=-.087, p=.417) or how often
respondents checked for side effects and drug interactions (r=-.144, p=.187).

3.2.5 Patterns of personal use and perceptions about CTs

The CTs most commonly used by respondents in the previous 12 months were
vitamin and mineral therapy (27%) and massage (26%) and to a lesser extent, Chinese
medicine (10%), yoga (10%), herbal medicine (9%) and spiritual healing (9%). Over
50% of respondents would consider receiving treatment with a range of CTs in the
future. In order of popularity, these were: massage (64%), meditation (60%),
vitamin/mineral therapy (51%), acupuncture (51%), yoga (50%), aromatherapy
(40%), herbal medicine (39%), chiropractic (37%), Chinese herbal medicine (32%),
osteopathy (28%), naturopathy (20%) and reflexology (20%). Few pharmacists have
personal experience practicing any CT, however there is interest in practicing
vitamin/mineral therapy by nearly 35%, herbal medicine by over 25% and massage by
approximately 20% (Figure 1).

Figure 2 presents pharmacist’s perceptions of the potential usefulness and
harmfulness of 15 CTs. Notably, acupuncture, massage, vitamin/mineral therapy,
yoga, meditation, chiropractic, Chinese herbal medicine, herbal medicine were
considered useful by at least 70% of respondents and homeopathy was considered
least useful by the majority of respondents. Despite most respondents perceiving
herbal medicine, Chinese herbal medicine and chiropractic as potentially useful, they
were also considered potentially harmful whereas meditation, reflexology and
spiritual healing were not widely considered potentially harmful. If a patient were to
ask whether they should use CTs or consult a CM practitioner, more pharmacists encourage the use of massage and the least encourage the use of hypnosis, homeopathy, naturopathy and spiritual healing whereas homeopathy is the most discouraged CT (Figure 3).
Figure 1. CTs pharmacists have practised and would consider practising in the future
Perceptions of usefulness and harmfulness of CTs

Figure 2. Pharmacist’s perceptions of the potential usefulness and harmfulness of 15 CTs
Pharmacists response to patients enquiring about CTs

Figure 3. Pharmacists responses when patients enquire about CTs.
3.3 Combined Health Professionals survey – Frankston Hospital

A total of 158 Frankston hospital staff met the inclusion criteria with 127 participating (response 80.4%).

3.3.1 Sample characteristics

There were significantly more males than females ($t(126)=33.51$, $p<.001$) in the sample. The majority of medical staff was made up of males (89.7%) in contrast with the pharmacy group who were predominantly female (75.0%). The mean age of respondents was 44.59 years (SD10.20) however there was a significant difference in age ($t(123)=42.78$, $p<.001$). Pharmacists were the youngest group with a mean age of 39.00 yrs (SD16.76) and surgeons the oldest at 48.53 years (SD10.21). Within each group, the pharmacy group had the widest age variation, most likely due to the inclusion of a small group of pharmacy pre-registrants. There was also a significant difference in the number of years respondents had been in practice ($t(121)=16.69$, $p<.001$) and a significant difference in the average number of patients seen each week ($t(115)=15.97$, $p<.001$). For the complete sample, the mean number of years in practice was 18.98 years (SD12.56) with medical physicians having spent the most years in practice at 20.72 years (SD12.18) compared with pharmacists at 17.56 years (SD16.6). The mean number of patient seen each week was 53.33 (SD35.96) with surgeons seeing the most patients (mean 63.28 SD 31.89) and pharmacists the least (mean 45.60 SD23.97). Further sample characteristics are presented in Figure 1.
3.3.2 Communication and advice given to patients

As seen in Table 1, only 10% of respondents reported always asking patients about use of CMs. When individual groups were compared, no significant difference was found between them in regards to how often they asked patients about CMs (F(3,116)=2.34, p=.077). No significant difference was also found between medical staff and hospital pharmacists in the frequency of asking patients about use (F(1,118)=1.97, p=.163). There was a significant difference between age groups in how often patients were asked about their CM use (F(5,111)=2.68, p=.025). Respondents less than 40 years of age were more likely to ask patients about CMs than older respondents.
Table 1. Frequency of asking patients about CMs
Data presented as n(%) of the total number of respondents for that question

<table>
<thead>
<tr>
<th>Do you ask patients about use of CMs?</th>
<th>Position</th>
<th>Anaesthetist (incl. registrars)</th>
<th>Physician/ Specialist</th>
<th>Surgeon</th>
<th>All medical staff</th>
<th>Hospital pharmacist (incl. pre-registrants and students)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always</td>
<td></td>
<td>1(5.6)</td>
<td>6(10.9)</td>
<td>3(9.4)</td>
<td>10(9.5)</td>
<td>2(13.3)</td>
<td>12(10.0)</td>
</tr>
<tr>
<td>Often (more than 60% of the time)</td>
<td></td>
<td>2(11.1)</td>
<td>5(9.1)</td>
<td>1(3.1)</td>
<td>8(7.6)</td>
<td>1(6.7)</td>
<td>9(7.5)</td>
</tr>
<tr>
<td>Sometimes (30%-59%)</td>
<td></td>
<td>0(0.0)</td>
<td>16(29.1)</td>
<td>3(9.4)</td>
<td>19(18.1)</td>
<td>5(33.3)</td>
<td>24(20.0)</td>
</tr>
<tr>
<td>Occasionally (5%-29%)</td>
<td></td>
<td>5(27.8)</td>
<td>11(20.0)</td>
<td>11(34.4)</td>
<td>27(25.7)</td>
<td>4(26.7)</td>
<td>31(25.8)</td>
</tr>
<tr>
<td>Rarely (less than 5%)</td>
<td></td>
<td>7(38.9)</td>
<td>12(21.8)</td>
<td>10(31.3)</td>
<td>29(27.6)</td>
<td>3(20.0)</td>
<td>32(26.7)</td>
</tr>
<tr>
<td>Never</td>
<td></td>
<td>3(16.7)</td>
<td>5(9.1)</td>
<td>4(12.5)</td>
<td>12(11.4)</td>
<td>0(0.0)</td>
<td>12(10.00)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>18(100.0)</td>
<td>55(100.0)</td>
<td>32(100.0)</td>
<td>105(100.0)</td>
<td>15(100.0)</td>
<td>120(100.0)</td>
</tr>
</tbody>
</table>

The most common reasons reported for not asking patients about use of CMs were that they forget to ask 43.9%, don’t think it is relevant 37.8%, and/or don’t have sufficient knowledge about it to ask 33.7% (Table 2). Comparison between the groups reveals that for all groups except the surgeons, forgetting to ask was the most common reason given. For the surgeons, 54.2% stated they didn’t have sufficient knowledge and/or didn’t think it was relevant (45.8%). If respondents did ask patients about CM use, most (80.0%) recorded the information in the patient history or inpatient chart (Table 3).
### Table 2. Reasons reported by respondents for not asking patients about CMs

<table>
<thead>
<tr>
<th>Reasons for not asking patients about CMs</th>
<th>Anaesthetist (incl. registrars)</th>
<th>Physician/Specialist</th>
<th>Surgeon</th>
<th>All medical staff</th>
<th>Hospital pharmacist (incl. pre-registrants and students)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>I assume patients will tell me</td>
<td>4 (25.0)</td>
<td>12 (25.0)</td>
<td>5 (20.8)</td>
<td>21 (23.9)</td>
<td>4 (40.0)</td>
<td>25 (25.5)</td>
</tr>
<tr>
<td>I forget to ask</td>
<td>8 (50.0)</td>
<td>23 (47.9)</td>
<td>6 (25.0)</td>
<td>37 (42.0)</td>
<td>6 (60.0)</td>
<td>43 (43.9)</td>
</tr>
<tr>
<td>I don’t have sufficient knowledge about it</td>
<td>5 (31.3)</td>
<td>12 (25.0)</td>
<td>13 (54.2)</td>
<td>30 (34.1)</td>
<td>3 (30.0)</td>
<td>33 (33.7)</td>
</tr>
<tr>
<td>I don’t have the opportunity to ask</td>
<td>0 (0.0)</td>
<td>2 (4.2)</td>
<td>1 (4.2)</td>
<td>3 (3.4)</td>
<td>3 (30.0)</td>
<td>6 (6.1)</td>
</tr>
<tr>
<td>I don’t think it is relevant</td>
<td>4 (25.0)</td>
<td>19 (39.6)</td>
<td>11 (45.8)</td>
<td>34 (38.6)</td>
<td>3 (30.0)</td>
<td>37 (37.8)</td>
</tr>
<tr>
<td>It is too time consuming</td>
<td>3 (18.8)</td>
<td>5 (10.4)</td>
<td>3 (12.5)</td>
<td>11 (12.5)</td>
<td>1 (10.0)</td>
<td>12 (12.2)</td>
</tr>
<tr>
<td>Total</td>
<td>16 (100.0)</td>
<td>48 (100.0)</td>
<td>24 (100.0)</td>
<td>88 (100.0)</td>
<td>10 (100.0)</td>
<td>98 (100.0)</td>
</tr>
</tbody>
</table>

Data presented as n(%) of the total number of respondents for that question.
Table 3. Methods used to communicate information about patients use of CMs

<table>
<thead>
<tr>
<th>What respondents do with information about patients use of CMs</th>
<th>Anaesthetist (incl. registrars)</th>
<th>Hospital pharmacist (incl. trainees and students)</th>
<th>Physician/Specialist</th>
<th>Surgeon</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Record use in the patient history</td>
<td>12(80.0)</td>
<td>6(54.5)</td>
<td>41(83.7)</td>
<td>21(84.0)</td>
<td>80(80.0)</td>
</tr>
<tr>
<td>Record use on inpatient medication chart</td>
<td>2(13.3)</td>
<td>5(45.5)</td>
<td>2(4.1)</td>
<td>1(4.0)</td>
<td>10(10.0)</td>
</tr>
<tr>
<td>Verbally inform other health professionals about CMs use (e.g. pharmacist, dietician)</td>
<td>0(0.0)</td>
<td>3(27.3)</td>
<td>3(6.1)</td>
<td>0(0.0)</td>
<td>6(6.0)</td>
</tr>
<tr>
<td>Verbally inform relevant surgeon, anaesthetist, physician about CMs use</td>
<td>3(20.0)</td>
<td>0(0.0)</td>
<td>2(4.1)</td>
<td>1(4.0)</td>
<td>6(6.0)</td>
</tr>
<tr>
<td>I don't record this information</td>
<td>1(6.7)</td>
<td>0(0.0)</td>
<td>6(12.2)</td>
<td>5(20.0)</td>
<td>12(12.0)</td>
</tr>
<tr>
<td>Total</td>
<td>15(100.0)</td>
<td>11(100.0)</td>
<td>49(100.0)</td>
<td>25(100.0)</td>
<td>100(100.0)</td>
</tr>
</tbody>
</table>

Data presented as n(% of the total number of respondents for that question)

Respondents were asked about the advice they generally give to patients taking CMs. As seen in figure 2, few respondents tell patients to continue taking all their CMs and few advise patients to cease all CMs. When responses are compared between the groups, overall 35.3% of all medical staff don’t feel confident giving patients advice about CMs. This was most obvious amongst surgeons where 54.8% felt unconfident about giving advise. An explicit recommendation (to stop taking specific CMs) was given by most hospital pharmacists whereas only a third of medical staff gave similar advice. The difference in giving specific advice to patients and position held in the hospital was statistically significant ($\chi^2 (1) = 6.34, p=.012$). The medical staff that did
feel confident enough to give advice would suggest referral to another health care practitioner. This suggestion was most prevalent amongst anaesthetists (50.0%).

Figure 2. Advice generally given to patients using CMs.

### 3.3.3 Confidence in dealing with CMs-related issues

As seen in Figure 2, over a quarter of respondents did not feel confident giving patients advice about CMs. In addition, many hospital doctors and pharmacists lacked confidence that they had sufficient knowledge to identify when CMs could adversely affect patient care (see Figure 3). Analysis of individual groups found that surgeons were the only significantly different group when it came to confidence levels (t(114)=3.66, p<.001). A planned contrast revealed that anaesthetists were significantly more confident than surgeons (t(127)=2.47, p=.015) and physicians were also significantly more confident than surgeons (t(127)=2.79, p=.006). However as a
group, planned contrasts revealed that medical staff were significantly less confident than hospital pharmacists \(F(1,116) = 4.14, p=.044\).

<table>
<thead>
<tr>
<th>Frequency of feeling confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>always</td>
</tr>
<tr>
<td>often</td>
</tr>
<tr>
<td>never</td>
</tr>
<tr>
<td>rarely</td>
</tr>
<tr>
<td>occasionally</td>
</tr>
<tr>
<td>sometimes</td>
</tr>
</tbody>
</table>

Figure 3. Frequency respondents feel confident they have sufficient knowledge to identify when CMs could adversely affect patient care

### 3.3.4 Training, knowledge and information--seeking behaviour

When presented with a patient using CMs, only 17.5% responded they always or often checked for side effects or drug interactions and 36.7% rarely or never checked. Figure 4 presents responses by individual professional groups.

A significant difference was found between position in the hospital and how frequently they checked for safety information using a one-way analysis of variance (ANOVA) \(F(3,111)=8.10, p<.001\). On average, surgeons tended to check the least and this was significantly different to physicians \(t(111)=3.81, p<.001\) and hospital pharmacists \(t(111)=4.48, p<.001\). A One-way analysis of variance (ANOVA)
revealed that hospital pharmacists checked for side effects and drug interactions significantly more than combined medical staff (F(1,113)=8.78, p<.004).

![Bar chart showing the percentage of respondents who checked for safety information if patient using CMs within different positions: Hospital Pharmacists, Surgeons, Physician/Specialists, and Anaesthetists.]

**Figure 4. Frequency respondents checked for safety information if patient using CMs**

Most medical and pharmacy staff had not received formal, under-graduate or post-graduate training about CM (Table 4). Anaesthetist’s knowledge about CM was derived from postgraduate lectures (33.3%) and self-directed study (22.2%). Physician’s knowledge about CM chiefly came from self-directed study (20.0%). Only two surgeons reported receiving education about CM in post graduate lectures and only one surgeon reported attending seminars, receiving undergraduate training or undertaking self-directed learning. Self directed learning and undergraduate lectures were the main sources of training undertaken by pharmacists regarding CM. Interest in future training about CM was expressed by most pharmacists (77.8%) and anaesthetists (77.8%) with 51.8% of medical physicians and 45.5% of surgeons reporting interest in future training. **Figure 5** presents data about respondent’s perception of the importance of undergraduate medical training about CM.
Table 4. Training received by respondents regarding CM

<table>
<thead>
<tr>
<th>What CM training have you had in the past</th>
<th>Anaesthetist (incl. registrars)</th>
<th>Physician/ Specialist</th>
<th>Surgeon</th>
<th>All medical staff</th>
<th>Hospital pharmacist (incl. pre-registrants and students)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Formal study (certificate/diploma/degree)</td>
<td>0</td>
<td>.0%</td>
<td>0</td>
<td>.0%</td>
<td>0</td>
<td>.0%</td>
</tr>
<tr>
<td>Specific lectures/seminars</td>
<td>1</td>
<td>5.6%</td>
<td>3</td>
<td>5.5%</td>
<td>1</td>
<td>3.0%</td>
</tr>
<tr>
<td>No formal training</td>
<td>11</td>
<td>61.1%</td>
<td>40</td>
<td>72.7%</td>
<td>30</td>
<td>90.9%</td>
</tr>
<tr>
<td>Postgraduate lectures</td>
<td>6</td>
<td>33.3%</td>
<td>6</td>
<td>10.9%</td>
<td>2</td>
<td>6.1%</td>
</tr>
<tr>
<td>Self directed study</td>
<td>4</td>
<td>22.2%</td>
<td>11</td>
<td>20.0%</td>
<td>1</td>
<td>3.0%</td>
</tr>
<tr>
<td>Undergraduate lectures</td>
<td>3</td>
<td>16.7%</td>
<td>3</td>
<td>5.5%</td>
<td>1</td>
<td>3.0%</td>
</tr>
<tr>
<td>Total</td>
<td>18</td>
<td>100.0%</td>
<td>55</td>
<td>100.0%</td>
<td>33</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
Figure 5. Respondent’s perception of the importance of CM training in under-graduate medical education.

Hospital doctors and pharmacists requiring CM information referred to different resources. Hospital doctors referred to peer-reviewed medical journals (51.3%), databases such as MEDLINE (42.5%) and reference texts (40.0%) as their top three sources of information whereas hospital pharmacists preferred to use reference texts (70%), World Wide Web (60%), seminars and conferences (45.0%). Information about resources used by the complete sample is presented in Figure 6 and information about use by different groups is presented in Table 5.
Figure 6. Information sources used by respondents for CMs and CTs
<table>
<thead>
<tr>
<th>Where do you source CMs and CTs information?</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Anaesthetist (incl. registrars)</td>
</tr>
<tr>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Peer-reviewed medical journals</td>
<td>10</td>
</tr>
<tr>
<td>Reference texts such as MIMs</td>
<td>7</td>
</tr>
<tr>
<td>Databases such as Pubmed/Medline</td>
<td>8</td>
</tr>
<tr>
<td>The Internet (World Wide Web)</td>
<td>6</td>
</tr>
<tr>
<td>Community or hospital pharmacists</td>
<td>5</td>
</tr>
<tr>
<td>Colleagues</td>
<td>4</td>
</tr>
<tr>
<td>Seminars/conferences/lectures</td>
<td>7</td>
</tr>
<tr>
<td>Medical media/non peer reviewed journals</td>
<td>3</td>
</tr>
<tr>
<td>Company literature</td>
<td>1</td>
</tr>
<tr>
<td>Complementary medicine practitioners</td>
<td>2</td>
</tr>
<tr>
<td>Friends and/or family</td>
<td>0</td>
</tr>
<tr>
<td>Health food shop staff</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
</tr>
</tbody>
</table>
The mean score obtained in the knowledge section was 17.79% (SD 18.78). A one-way analysis of variance (ANOVA) found that hospital pharmacists attained a significantly higher knowledge score than medical staff (F(1,123)=35.06, p<.001). While hospital pharmacists achieved a mean score of 38.60%, medical staff achieved an average score of 14.06% (Table 6). When comparing knowledge scores of the individual medical groups, a significant difference was found (F(2,115)=13.42, p<.001) with anaesthetists achieving the highest score. The lowest scoring group was the surgeons with an average of 5.09% correct. Anaesthetists and surgeons (t(18.66)=4.10, p=.001); and physicians and surgeons (t(81.92)=4.31, p<.001) scored significantly different to each other.

Table 6. Knowledge scores for the individual groups and as totals

<table>
<thead>
<tr>
<th>Respondent group</th>
<th>Percent correct based on Micromedex</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetist (incl. registrars)</td>
<td>M %</td>
<td>SD</td>
</tr>
<tr>
<td>Physician/Specialist</td>
<td>24.37</td>
<td>18.66</td>
</tr>
<tr>
<td>Surgeon</td>
<td>16.24</td>
<td>16.86</td>
</tr>
<tr>
<td>Medical staff only as a total</td>
<td>5.05</td>
<td>7.43</td>
</tr>
<tr>
<td>Hospital pharmacist (incl. pre-registrants and students)</td>
<td>38.60</td>
<td>18.71</td>
</tr>
<tr>
<td>Total</td>
<td>17.79</td>
<td>18.78</td>
</tr>
</tbody>
</table>

Questions about the complementary medicines glucosamine, ginkgo biloba and St John’s wort attracted the most responses whereas questions about coenzyme Q10, echinacea and chamomile attracted the least. Detailed results from the knowledge section are presented in Appendix E.

3.3.5 Doctors and pharmacists attitudes to CMs

Responses to the attitudinal statement about CMs are presented in Table 7.
Table 7. Responses of the complete sample to attitudinal statement about CMs.

<table>
<thead>
<tr>
<th>Attitudinal statements</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SA</td>
</tr>
<tr>
<td>CMs are appropriate for use in the hospital setting</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>CMs are generally a waste of time and money</td>
<td>10 (8.2)</td>
</tr>
<tr>
<td>CMs are potentially dangerous and need to be monitored</td>
<td>17 (13.8)</td>
</tr>
<tr>
<td>CMs offer a false sense of hope and exploit vulnerable individuals</td>
<td>15 (12.2)</td>
</tr>
<tr>
<td>CMs offer patients cost effective treatment options</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>CMs need more hospital based research</td>
<td>47 (38.5)</td>
</tr>
<tr>
<td>CMs are something that most of my colleagues would consider</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Regulations for CM practitioners need to be tightened</td>
<td>54 (43.9)</td>
</tr>
</tbody>
</table>

SA= strongly agree; A=agree; NAD=neither agree or disagree; D=disagree; SD=strongly disagree

Data presented as n(% of the total number of respondents for that statement)

The mean attitude score was 18.86 (SD 2.24) indicating a moderately negative attitude to CMs (5 was considered positive and 25 negative) No significant differences were found in attitude scores between the four professional groups within the hospital (F(3,77)=.78, p=.509). There was also no significant difference in attitude scores between medical staff and hospital pharmacists (F(1,79)=.48, p=.49). There was also no significant correlation of attitude scores with age (r=.15, p=.188), the average number of patients seen each week (r=.08, p=.484), or the number of years in practice (r=.12, p=.287).
3.3.6 Perceptions about usefulness and harmfulness of specific CTs and patients use of CMs

Of the total sample, most (58%) thought 25% or fewer patients used CMs in the 2 weeks prior to admission, 30.4% thought usage was between 26-50% and 11.6% thought this was greater than 50% during this period. Once patients were admitted to hospital, 89.8% of respondents thought CMs usage had reduced to 25% or less with 8.3% thinking 26-50% of inpatients used CMs and 1.8% thought this was above 50%.

Hospital doctors and pharmacists were also asked about their opinion of the potential usefulness and harmfulness of 15 CTs. Over 70% of respondent’s perceived acupuncture, massage, yoga and chiropractic as potentially useful whereas few people thought reflexology and homeopathy were potentially useful (figures 6 and 8). The medicinal therapies (herbal medicine, Chinese herbal medicine and vitamin/mineral therapy) and manipulative therapies were considered potentially harmful by the most respondents whereas relatively few people thought meditation was potentially harmful (figures 7 and 8). Perceptions of potential usefulness and harmfulness of CTs are presented together in Figure 8 where it is apparent that acupuncture, meditation, massage and yoga are considered potentially useful and low risk whereas chiropractic, although considered useful, is also considered potentially harmful by the majority of respondents.
Figure 6. Opinions of all participants responding to the question regarding the potential usefulness of CTs.
Figure 7. Opinions of all participants responding to the question regarding the potential harmfulness of CTs.
Perceptions of usefulness and harmfulness of CTs

Figure 8. Perceptions of usefulness and harmfulness plotted together
3.3.7 Doctors and pharmacists past behaviours with CTs and interest in practising or receiving CT treatment in the future

Respondents were asked about whether they had received or would be interested to receive treatment with a CT and also whether they had practised or would be interested in practising a CT. Results are presented in Figure 9. Overall, hospital doctors and pharmacists in this sample have little personal experience using CTs or practising CTs. Of note, only 12.7% of respondents had taken vitamins and/or minerals in the previous 12 months and 4.1% had taken herbal medicines. Massage was the most commonly received CT in the previous 12 months and the practice of vitamin/mineral therapy was of interest to the highest number of people. There was most interest in receiving acupuncture, massage, meditation and yoga amongst respondents and little interest in receiving or practising homeopathy, reflexology or spiritual healing.

Respondents are interested in receiving treatment with the CTs they also consider useful – acupuncture, meditation, hypnosis, massage and yoga. Additionally, there is interest in receiving vitamin/mineral therapy even though this is not considered useful by as many respondents. Despite many respondents ranking chiropractic amongst the most potentially harmful CTs, 25.2% would consider receiving treatment with this modality in the future.
Figure 9. Respondents past behaviours regarding CTs and interest in receiving or practising CTs in the future.
3.3.8 **Doctors and pharmacists actively encouraging or discouraging patients about CTs**

Respondents would actively encourage the use of massage and meditation followed by yoga and acupuncture (**Figure 10**). These are the same CTs they considered potentially useful. Homeopathy and reflexology are the CTs most respondents would discourage patients use. This response does not appear to be due to their potential harmfulness but because of their perceived lack of usefulness. For most CTs, approximately one third of respondents did not feel confident to advise patients about use.
Figure 10. General responses to patients enquiry about whether they should use a CT
3.4 Cardiac surgery patients survey

A total of 205 cardiac surgery patients met the inclusion criteria and 161 completed and returned the survey (78% response rate).

3.4.1 Sample characteristics

Participants had an average age of 69.6 years (+/- 13.1 years). Further demographic and baseline data is presented in Table 1. Of note, 93% of respondents were taking at least 1 prescription medicine in the 2 weeks prior to admission.
Table 1. Characteristics of respondents

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N(%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>98(61%)</td>
</tr>
<tr>
<td>Female</td>
<td>62(38.5%)</td>
</tr>
<tr>
<td>Missing</td>
<td>1(0.5%)</td>
</tr>
<tr>
<td>Total number of respondents</td>
<td>161(100%)</td>
</tr>
<tr>
<td>Highest Level of Education attained</td>
<td></td>
</tr>
<tr>
<td>Did not complete high school</td>
<td>29(18%)</td>
</tr>
<tr>
<td>Completed high school</td>
<td>45(28.5%)</td>
</tr>
<tr>
<td>Completed technical studies/apprenticeship</td>
<td>34(21.5%)</td>
</tr>
<tr>
<td>Completed university studies</td>
<td>50(32%)</td>
</tr>
<tr>
<td>Place of birth</td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>109(68%)</td>
</tr>
<tr>
<td>Elsewhere</td>
<td>51(32%)</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>1(0.5%)</td>
</tr>
<tr>
<td>Past smoker</td>
<td>77(48%)</td>
</tr>
<tr>
<td>Non-smoker</td>
<td>82(51%)</td>
</tr>
<tr>
<td>Number of prescription medicines taken in the 2 weeks prior to admission</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>12(8%)</td>
</tr>
<tr>
<td>Unsure</td>
<td>1(0.5%)</td>
</tr>
<tr>
<td>One (1)</td>
<td>12(8%)</td>
</tr>
<tr>
<td>Two (2)</td>
<td>15(10%)</td>
</tr>
<tr>
<td>Three (3)</td>
<td>23(15%)</td>
</tr>
<tr>
<td>Four (4)</td>
<td>25(16%)</td>
</tr>
<tr>
<td>Five or more</td>
<td>23(15%)</td>
</tr>
<tr>
<td>Annual household income</td>
<td></td>
</tr>
<tr>
<td>Less than $20,000</td>
<td>26(19%)</td>
</tr>
<tr>
<td>$20,001-$60,000</td>
<td>73(52%)</td>
</tr>
<tr>
<td>$60,001-$100,000</td>
<td>31(22%)</td>
</tr>
<tr>
<td>Over $100,000</td>
<td>10(7%)</td>
</tr>
</tbody>
</table>

% of total respondents

3.4.2 Patterns of CMs use by cardiac surgery patients

Overall, 50.6% of patients had used at least one CM product in the 2 weeks prior to admission. Of these patients, 35% had taken 1-2 products, 8% three products and 8% four or more products. The following factors were not significantly associated with CMs use: gender ($\chi^2$ (1) =1.24, p=.265), income (over $60K/yr compared with <$60K; $\chi^2$ (1) =.36, p=.551), education (F(3,151)=.139, p =.139) or age (r=.059, p =.466). Table 2 lists the distribution of CMs used.
Table 2. Complementary medicines used by cardiac surgery patients in the 2 weeks prior to admission

<table>
<thead>
<tr>
<th>List of CMs</th>
<th>n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish oil supplements</td>
<td>18 (25%)</td>
</tr>
<tr>
<td>Multivitamins</td>
<td>18 (25%)</td>
</tr>
<tr>
<td>Glucosamine</td>
<td>16 (22%)</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>15 (21%)</td>
</tr>
<tr>
<td>Vitamin B complex</td>
<td>12 (17%)</td>
</tr>
<tr>
<td>Calcium supplements</td>
<td>11 (15%)</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>9 (12.5%)</td>
</tr>
<tr>
<td>Magnesium</td>
<td>8 (11%)</td>
</tr>
<tr>
<td>Coenzyme Q10</td>
<td>6 (8%)</td>
</tr>
<tr>
<td>Evening Primrose Oil</td>
<td>4 (6%)</td>
</tr>
<tr>
<td>Macuvision ® (by Blackmore's Products Australia)</td>
<td>3 (4%)</td>
</tr>
<tr>
<td>Echinacea</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Ginkgo Biloba</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Chinese herbal medicines</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Ginger tablets</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Guarana</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Liquid herbs</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Garlic tablets or more than 1 clove daily</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Celery (the herb)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Licorice (the herb)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Ginseng (Korean or Panax)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Grapeseed extract</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Horseradish tablets</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Policosanol</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>St John's Wort (Hypericum perforatum)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Feverfew</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Valerian</td>
<td>0 (0%)</td>
</tr>
<tr>
<td><strong>Total patients responding</strong></td>
<td>72 (100%)</td>
</tr>
</tbody>
</table>

% of total respondents
Of those patients taking CMs prior to admission, 42% intended to continue use whilst in hospital. In hospital, CMs were self-supplied by 71% of patients and 21% asked family and friends to deliver their supplements. Prior to admission, 75% of respondents spent less than $50 each month buying supplements with 5% spending more than $100.

3.4.3 Reasons for use

Patients reported using CMs to maximise health and wellbeing (71%), treat (30%) or prevent (20%) disease.

3.4.4 Sources of recommendation to cardiac surgery patients

Medical practitioners were the main source of recommendation as shown in Table 3. Females were significantly more likely to be taking medically prescribed CMs than males (58% compared to 52%;F(1,154)=3.93, p=.049). No significant differences were found for age (<=55yrs, 56-70yrs, 71-85yrs, 86+yrs;F(3, 154)=.904, p=.441). The CMs most often medically prescribed were fish oils and glucosamine supplements however most respondents reported using fish oil supplements without a medical recommendation.
### Table 3. List of people who had prescribed the CM products being taken by respondents

<table>
<thead>
<tr>
<th>Prescriber of CM product</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical practitioners (general practitioners, physicians and surgeons)</td>
<td>52 (56.5%)</td>
</tr>
<tr>
<td>Self-prescribed</td>
<td>19 (21%)</td>
</tr>
<tr>
<td>CM practitioner</td>
<td>15 (16%)</td>
</tr>
<tr>
<td>Friend or family</td>
<td>14 (15%)</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>6 (6.5%)</td>
</tr>
<tr>
<td>Health food store staff</td>
<td>3 (3%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>92 (100%)</strong></td>
</tr>
</tbody>
</table>

#### 3.4.5 Communication with healthcare professionals pre- and post-admission

In the two weeks prior to admission, 47.1% of cardiac surgery patients using CMs had discussed use with their GP, 29.4% a medical specialist, 17.6% a natural therapist, 11.8% a surgeon, 2.9% a nurse, and no one had discussed use with a pharmacist.

Whilst in hospital, 52% of CM users reported being asked about CMs by a nurse, 12% a surgeon, 12% a pharmacist and 8% an anaesthetist. Overall, 56% of CM users did not disclose use to any hospital staff member of which 67% reported that the main reason was not being asked, 54% thought it unimportant, 5% thought doctors ‘wouldn’t understand’ and 5% didn’t want to be judged negatively. Only 12% of patients reported writing the information on a hospital form. Of those who did
disclose use to hospital staff, 54.8% told a nurse, 22.6% medical specialist, 16.1% pharmacist, 16.1% surgeon, 12.9% a GP and 6.5% an anaesthetist.

3.4.6 Sources of information about CMs and CTs

The five most popular sources of general information reportedly used by cardiac surgery patients are pharmacists (43.8%), medical doctors (41.1%), health food stores (23.3%), natural therapists (21.9%) and books or magazines (21.9%). There was a non-significant trend for females to be more likely than males to have consulted natural therapists (29.4% compared to 15.8%) or health food store staff (29.4% compared to 15.8%) for information. For safety information about CMs, pharmacists (50.0%) and medical doctors (44.7%) were most often consulted, followed by a natural therapist (17.1%), health food store staff (15.8%) and books or magazines (13.2%). Females were more likely than males to consult a natural therapist on safety issues (20.0% compared to 14.6%), ask staff at the health food store (25.7% compared to 7.3%) or pharmacy store staff (14.3% compared to 4.9%).

3.4.7 Cardiac surgery patients perceptions about the safety of CMs

Most respondents (48.5%) thought some CMs were safe whereas some (37.7%) were unsure about the safety of CMS and only 6.9% thought all CMs were safe with 6.2% stating they were safer than pharmaceutical medicines. Few (2.3%) thought no CMs were safe and 9.2% thought they were less safe than pharmaceutical medicines.

3.4.8 Use of diet, lifestyle and CTs in hospitals

85% of the total sample stated they would consider using at least one of the listed therapies if offered by hospitals with most interest shown in dietary advice and massage (Figure 1). Younger age and previous CM usage were predictive of a greater interest in the listed therapies ($\chi^2$(1)=7.82, p=.005; r=-.184, p=.041) whereas gender ($\chi^2$(1)=.48, p=.488), income ($\chi^2$(3)=4.555, p=.207) or education ($\chi^2$(3)=1.203, p=.752) were not significantly predictive.
Figure 1. Diet, lifestyle and CTs which respondents would consider using if offered by hospitals.
3.5 Surgical patient survey

The survey was offered to 602 patients, of whom 508 participated, giving a response rate of 84%.

3.5.1 Sample characteristics

The average age was 52.7 years (SD 17.6). Demographic and descriptive data is presented in Table 1. Of note, 68.6% were taking prescription medicines in the two weeks prior to admission.
Table 1. Participant demographic and descriptive data.

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>% of total respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>240</td>
<td>47.2%</td>
</tr>
<tr>
<td>Female</td>
<td>266</td>
<td>52.4%</td>
</tr>
<tr>
<td>Missing</td>
<td>2</td>
<td>.4%</td>
</tr>
<tr>
<td>Total number of respondents</td>
<td>508</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>Highest Level of Education attained</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not complete high school</td>
<td>110</td>
<td>21.9%</td>
</tr>
<tr>
<td>Completed high school</td>
<td>145</td>
<td>28.9%</td>
</tr>
<tr>
<td>Completed technical studies/apprenticeship</td>
<td>86</td>
<td>17.1%</td>
</tr>
<tr>
<td>Completed university studies</td>
<td>160</td>
<td>31.9%</td>
</tr>
<tr>
<td><strong>Place of birth</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>375</td>
<td>74.1%</td>
</tr>
<tr>
<td>Elsewhere</td>
<td>131</td>
<td>25.9%</td>
</tr>
<tr>
<td><strong>Smoking status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>77</td>
<td>15.2%</td>
</tr>
<tr>
<td>Past smoker</td>
<td>164</td>
<td>32.5%</td>
</tr>
<tr>
<td>Non-smoker</td>
<td>264</td>
<td>52.3%</td>
</tr>
<tr>
<td><strong>Number of prescription medicines taken in the 2 weeks prior to admission</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>157</td>
<td>31.4%</td>
</tr>
<tr>
<td>Unsure</td>
<td>4</td>
<td>.8%</td>
</tr>
<tr>
<td>One (1)</td>
<td>110</td>
<td>22.0%</td>
</tr>
<tr>
<td>Two (2)</td>
<td>80</td>
<td>16.0%</td>
</tr>
<tr>
<td>Three (3)</td>
<td>50</td>
<td>10.0%</td>
</tr>
<tr>
<td>Four (4)</td>
<td>42</td>
<td>8.4%</td>
</tr>
<tr>
<td>Five or more</td>
<td>22</td>
<td>4.4%</td>
</tr>
<tr>
<td><strong>Annual household income</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than $20,000</td>
<td>87</td>
<td>19.6%</td>
</tr>
<tr>
<td>$20,001-$60,000</td>
<td>170</td>
<td>38.4%</td>
</tr>
<tr>
<td>$60,001-$100,000</td>
<td>103</td>
<td>23.3%</td>
</tr>
<tr>
<td>Over $100,000</td>
<td>83</td>
<td>18.7%</td>
</tr>
<tr>
<td><strong>Average monthly spend on complementary medicines</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than $15</td>
<td>101</td>
<td>43.2%</td>
</tr>
<tr>
<td>$16 to $30</td>
<td>84</td>
<td>35.9%</td>
</tr>
<tr>
<td>$31 to $50</td>
<td>21</td>
<td>9.0%</td>
</tr>
<tr>
<td>$51 to $75</td>
<td>10</td>
<td>4.3%</td>
</tr>
<tr>
<td>$76 to $100</td>
<td>10</td>
<td>4.3%</td>
</tr>
<tr>
<td>More than $100</td>
<td>8</td>
<td>3.4%</td>
</tr>
</tbody>
</table>
3.5.2 Patterns of CMs use

Overall, 46.4% of respondents had used CMs in the two weeks prior to admission of which 54% intended to continue use whilst in hospital with 39% bringing their own supplies to hospital and 9% would have friends and family bringing them in. Of those patients taking prescription medicines during this pre-admission period, 46% also used at least one complementary medicine product.

Education was significantly associated with CMs use ($F(3,483)=5.705$, $p=.001$). People with a university education were significantly more likely to use CMs than people who did not complete high school (60% compared to 38%; $t(480)=3.62$, $p<.001$). Other significant predictors of use were female gender ($\chi^2(1)=12.057$, $p=.001$), current smoking status ($\chi^2(1)=12.057$, $p=.004$) and annual income ($F(3,429)=4.5$, $p=.004$). High income earners (> $Au 100,000/year) were significantly more likely to use CMs than low income earners (< $Au 20,000/year) ($t(163)=3.622$, $p<.001$). Age was not a significant predictor of use ($\chi^2(4)=3.96$, $p=.412$) nor was being Australian born ($\chi^2(1)=.151$, $p=.697$).

Of those surgical patients taking CM products in the two weeks prior to admission, many used multiple products. More specifically, 41% of CM users had taken one CM product, 26% took two products, 13% took three, 5% took four, 2.5% took five and 8% took more than five. Vitamins and/or minerals were most popular and used by 53% whereas 21% used herbal medicines and 30% used other CMs. Table 2 lists the distribution of CMs used.
Table 2. CMs used by surgical patients in the 2 weeks prior to admission

<table>
<thead>
<tr>
<th>CMs used in 2 weeks prior to admission</th>
<th>n</th>
<th>% of total respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multivitamins</td>
<td>91</td>
<td>42.1%</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>58</td>
<td>27.0%</td>
</tr>
<tr>
<td>Fish oil capsules (omega 3 essential fatty acids)</td>
<td>55</td>
<td>25.5%</td>
</tr>
<tr>
<td>Glucosamine</td>
<td>50</td>
<td>23.1%</td>
</tr>
<tr>
<td>Vitamin B complex</td>
<td>40</td>
<td>18.5%</td>
</tr>
<tr>
<td>Calcium</td>
<td>35</td>
<td>16.2%</td>
</tr>
<tr>
<td>Iron supplements</td>
<td>22</td>
<td>10.2%</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>17</td>
<td>7.9%</td>
</tr>
<tr>
<td>Magnesium</td>
<td>16</td>
<td>7.4%</td>
</tr>
<tr>
<td>Echinacea</td>
<td>14</td>
<td>6.5%</td>
</tr>
<tr>
<td>Garlic product or eating 1 clove daily</td>
<td>13</td>
<td>6.0%</td>
</tr>
<tr>
<td>Evening primrose oil</td>
<td>12</td>
<td>5.6%</td>
</tr>
<tr>
<td>Antioxidant formula</td>
<td>12</td>
<td>5.6%</td>
</tr>
<tr>
<td>Zinc</td>
<td>8</td>
<td>3.7%</td>
</tr>
<tr>
<td>Valerian</td>
<td>6</td>
<td>2.8%</td>
</tr>
<tr>
<td>Coenzyme Q10</td>
<td>6</td>
<td>2.8%</td>
</tr>
<tr>
<td>Liquid herbs</td>
<td>6</td>
<td>2.8%</td>
</tr>
<tr>
<td>St John’s wort (Hypericum perforatum)</td>
<td>4</td>
<td>1.9%</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>4</td>
<td>1.9%</td>
</tr>
<tr>
<td><em>Ginkgo Biloba</em></td>
<td>4</td>
<td>1.9%</td>
</tr>
<tr>
<td>Chinese herbal medicine (s)</td>
<td>3</td>
<td>1.4%</td>
</tr>
<tr>
<td>Selenium</td>
<td>3</td>
<td>1.4%</td>
</tr>
<tr>
<td>Cranberry supplements</td>
<td>3</td>
<td>1.4%</td>
</tr>
<tr>
<td>Folic acid</td>
<td>3</td>
<td>1.4%</td>
</tr>
<tr>
<td>Ginseng (Korean or Panax)</td>
<td>2</td>
<td>.9%</td>
</tr>
<tr>
<td>Soy supplements</td>
<td>2</td>
<td>.9%</td>
</tr>
<tr>
<td>Probiotics (e.g. acidophilus)</td>
<td>2</td>
<td>.9%</td>
</tr>
<tr>
<td>Green barley</td>
<td>2</td>
<td>.9%</td>
</tr>
<tr>
<td>Celery (the herb)</td>
<td>1</td>
<td>.5%</td>
</tr>
<tr>
<td>Fibre supplements</td>
<td>1</td>
<td>.5%</td>
</tr>
<tr>
<td>Ginger tablets/capsules/liquid</td>
<td>1</td>
<td>.5%</td>
</tr>
<tr>
<td>Licorice (the herb)</td>
<td>1</td>
<td>.5%</td>
</tr>
<tr>
<td>Policosanol</td>
<td>1</td>
<td>.5%</td>
</tr>
<tr>
<td>Spirulina</td>
<td>1</td>
<td>.5%</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>1</td>
<td>.5%</td>
</tr>
<tr>
<td><strong>Total number of respondents</strong></td>
<td>216</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
3.5.3 Reasons for use

Surgical patients reported using CMs because ‘it keeps me healthy/prevents disease’ (58%), ‘they were recommended by my doctor, pharmacist or friend’ (29%), ‘it gives me a sense of well-being’ (28%), ‘to treat a specific disease (27%), ‘it fits into my way of life/philosophy (13%) ‘they have few side effects’ (12%) and ‘they work better or just as well as conventional medicines’ (9%).

3.5.4 Sources of recommendation

Of those patients using CM products, 38.2% of people had self-prescribed, 28.5% were taking CMs on the recommendation of friends or relatives, 26.8% due to recommendations by a GP, 14.0% by a medical specialist, 11.8% by a naturopath or herbalist, 11.8% a pharmacist and 11.0% by health food shop staff and 0.9% by a dietician..

3.5.5 Discussion with health care professionals pre- and post-admission

63% of patients using CMs in the 2 weeks prior to admission did not discuss their use with any community-based or hospital-based health professionals during this period. Of those that had, 31.6% discussed their CMs use with a general practitioner, 27.6% a surgeon, 19.7% a medical physician, 15.8% a naturopath or herbalist, 10.5% an anaesthetist, 7.9% a community pharmacist, 6.6% health food store staff whereas 10.5% were unsure or couldn’t remember.

After admission, 58% of CM-users did not discuss use of supplements with hospital staff and 56% reported not being asked. Of those patients who did discuss use, it was predominantly with nursing staff (83.5%) and fewer patients disclosed use to anaesthetists (24.7%) or surgeons (20.0%). When asked which hospital staff
member/s had asked them about use of CMs, it was reported that nursing staff were also most likely to ask (Table 3)

**Table 3. Hospital staff who asked patients about use of CMs**

<table>
<thead>
<tr>
<th>Staff who asked about CMs use</th>
<th>N(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse</td>
<td>150(73.2)</td>
</tr>
<tr>
<td>Anaesthetist</td>
<td>49(23.9)</td>
</tr>
<tr>
<td>Surgeon</td>
<td>39(19.0)</td>
</tr>
<tr>
<td>Physician (medical specialist)</td>
<td>19(9.3)</td>
</tr>
<tr>
<td>Unsure or can't remember</td>
<td>29(14.1)</td>
</tr>
<tr>
<td><strong>Total number of respondents</strong></td>
<td>205(100.0)</td>
</tr>
</tbody>
</table>

% of total respondents

When patients were asked why they had not told hospital staff about CMs, few reported being concerned about being judged negatively (0.7%) whereas 80.1% stated it was simply because they were not asked. More information is presented in Table 4.

**Table 4. The reasons patients using CMs reported for not disclosing use to hospital staff**

<table>
<thead>
<tr>
<th>Reasons for non-disclosure whilst in hospital</th>
<th>N(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not want to appear 'disloyal'</td>
<td>0(0.0)</td>
</tr>
<tr>
<td>Didn't think it was important</td>
<td>55(40.4)</td>
</tr>
<tr>
<td>Did not want to be negatively judged</td>
<td>1(0.7)</td>
</tr>
<tr>
<td>It's none of their business</td>
<td>1(0.7)</td>
</tr>
<tr>
<td>Not asked</td>
<td>109(80.1)</td>
</tr>
<tr>
<td>Thought the hospital doctors wouldn't understand</td>
<td>4(2.9)</td>
</tr>
<tr>
<td><strong>Total number of respondents</strong></td>
<td>136(100.0)</td>
</tr>
</tbody>
</table>

% of total respondents
3.5.6 Sources of information

Many (69.3%) of the surgical patients look for information about CMs and CTs however females are significantly more likely to look for information than males (81.5% vs 55.4%; \( \chi^2(1)=37.84, p<.001 \)). Respondents most often gathered information from their health food store (36.8%), GP (34.8%), naturopath/herbalist (26.8%), parents, family or friends (24.8%), books or magazines (20.6%), 17.1% used the internet, 15.8% used pamphlets in store, 13.9% went to the community pharmacist, and 11.6% referred to the media. Only 6.8% referred to their medical specialist and a total of 3.2% referred to the nurse, anaesthetist or surgeon for information.

3.5.7 Perceptions and attitudes

Of those patients using CMs, 25.5% thought their products were very effective, 30% thought they were effective enough and 9% thought they were slightly effective whereas 30% were unsure of their effectiveness. Nearly half (47%) thought some CMs were safe, 1.7% thought none were safe, 32.1% thought CMs were just as safe as conventional medicines while 42.1% of the respondents were not sure about the safety of CMs and 50.8% of respondents were not sure how safe they were compared to conventional medicines.

Responses to the attitudinal statement are presented in Table 5. Of note, the statement about whether CMs are appropriate for use and should be made available in hospitals attracted the most responses and 55% agreeing with the statement whilst 39% were undecided and 6% disagreed.
Table 5. Surgical patient responses to attitudinal statements

<table>
<thead>
<tr>
<th>Responses</th>
<th>SA</th>
<th>A</th>
<th>NAD</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Complementary medicines ....</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are appropriate for use or should be made available in a hospital setting</td>
<td>59 (13)</td>
<td>192 (42)</td>
<td>180 (39)</td>
<td>24 (5)</td>
<td>13 (5)</td>
</tr>
<tr>
<td>Are generally a waste of time and money</td>
<td>16 (4)</td>
<td>35 (8)</td>
<td>126 (29)</td>
<td>202 (46)</td>
<td>58 (13)</td>
</tr>
<tr>
<td>Can be dangerous and need to be supervised</td>
<td>43 (10)</td>
<td>159 (37)</td>
<td>141 (32)</td>
<td>80 (18)</td>
<td>12 (3)</td>
</tr>
<tr>
<td>Are a cost effective way of looking after health</td>
<td>13 (5)</td>
<td>75 (27)</td>
<td>130 (46)</td>
<td>51 (18)</td>
<td>13 (5)</td>
</tr>
<tr>
<td>Can cause dangerous interactions with conventional drugs</td>
<td>26 (9)</td>
<td>84 (30)</td>
<td>138 (49)</td>
<td>27 (10)</td>
<td>8 (3)</td>
</tr>
<tr>
<td>Need more scientific research</td>
<td>60 (14)</td>
<td>199 (45)</td>
<td>144 (33)</td>
<td>26 (6)</td>
<td>10 (2)</td>
</tr>
<tr>
<td>Are something most of my friends would consider using</td>
<td>26 (6)</td>
<td>192 (44)</td>
<td>171 (39)</td>
<td>43 (10)</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Regulations need to be tightened for complementary practitioners</td>
<td>36 (13)</td>
<td>107 (38)</td>
<td>112 (39)</td>
<td>23 (8)</td>
<td>6 (2)</td>
</tr>
</tbody>
</table>

SA = strongly agree; A = agree; NAD = neither agree or disagree; D = disagree; SD = strongly disagree

*% of the total number of respondents for that statement
3.5.8 Use of CM, dietary and lifestyle therapies in hospitals

Of the total sample, 85.0% were interested in hospitals offering at least one of the listed therapies, as depicted in Figure 1. These patients were significantly more likely to be female (females 90.1% compared to males 79.7%; $\chi^2(1)=9.80, p=.002$), have higher annual earnings ($>$Au 100,000/yr 88.9% compared to 73.7% for $<$Au 20,000/yr; $t(134.89)=-2.46, p=.015$) and have previously used CMs ($\chi^2(1)=4.52, p=.034$).
Patients interest in hospital based therapies

<table>
<thead>
<tr>
<th>Patients interested in</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Massage</td>
<td>48%</td>
</tr>
<tr>
<td>Dietary Advice</td>
<td>57%</td>
</tr>
<tr>
<td>Exercise Consultation</td>
<td>45%</td>
</tr>
<tr>
<td>Stress management</td>
<td>38%</td>
</tr>
<tr>
<td>Meditation</td>
<td>27%</td>
</tr>
<tr>
<td>Yoga</td>
<td>24%</td>
</tr>
<tr>
<td>Naturopathy</td>
<td>23%</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>21%</td>
</tr>
<tr>
<td>Herbal Medicine</td>
<td>19%</td>
</tr>
<tr>
<td>Aromatherapy</td>
<td>17%</td>
</tr>
<tr>
<td>Chinese Herbal Medicine</td>
<td>16%</td>
</tr>
<tr>
<td>Osteopathy</td>
<td>16%</td>
</tr>
<tr>
<td>Ayurvedic (Indian) Medicine</td>
<td>11%</td>
</tr>
<tr>
<td>Hypnosis</td>
<td>9%</td>
</tr>
<tr>
<td>Homoeopathy</td>
<td>9%</td>
</tr>
<tr>
<td>Unsure</td>
<td>5%</td>
</tr>
<tr>
<td>Unsure</td>
<td>8%</td>
</tr>
</tbody>
</table>

Figure 1. Diet, lifestyle and CTs patients would consider using
Chapter Four

Interpretation of survey findings

4.0 Introduction

Five surveys were conducted, three of which were conducted with healthcare professionals working within Victorian hospitals and two with surgical patients attending two of the same hospital sites.

This chapter is divided into six sections with the first five sections presenting a separate discussion of the results obtained for each survey and the final section providing a general discussion of the overall results and emerging themes. The final discussion also outlines the limitations of the surveys and how the information gained from this research project can be of value to hospital practice and the wider community.
4.1 Anaesthetists survey

According to the Workforce Survey 2002 reported by the Australian and New Zealand College of Anaesthetists (ANZCA), our sample represents approximately 15% of all active ANZCA Fellows in Victoria. The ratio of males to females in the sample is representative of the Australian anaesthesia workforce however our respondents are slightly younger (39.8 years vs 46.2 years). This is most likely because the survey was undertaken at teaching hospitals and some respondents were in the training program. Although non-response bias has influenced our results, the data available suggests that the characteristics of respondents and non-respondents were comparable.

4.1.1 Communication breakdown

The documented reluctance of patients to disclose their use of CMs means anaesthetists must take an active role in initiating the discussion. This requires them to be familiar with CMs and have the confidence and knowledge to be able to conduct such a discussion in a meaningful manner.

Although just over half the anaesthetists surveyed reported they forget to ask patients about CMs, this study has identified that lack knowledge about the evidence of CMs efficacy and safety, lack of confidence in dealing with issues relating to CMs and a perception of low patient usage are important underlying factors standing in the way of anaesthetists initiating the discussion. These same factors have been previously reported as communication barriers in studies involving physicians (16;121). As a result, anaesthetists are largely relying on indirect communication through admission forms or patients unprompted disclosure to learn about their use.

An important finding from the present study is the challenge encountered by anaesthetists when presented with patients using CMs. Most anaesthetists feel inadequately prepared to counsel patients about CMs and have limited knowledge about the safety and efficacy of these medicines. As a result, they are less likely to ask
patients about use of CMs. Documentation of patient use is also inconsistent and the advice provided is inadequate and incomplete.

Robinson and McGrail reported that the three main reasons patients did not disclose use of CM to physicians were because they were not asked, did not think it relevant because the physician could not provide useful information and fear of receiving a negative response (359). The results from this study indicate that anaesthetists don’t routinely ask about CMs and if a patient was to tell their anaesthetist about use, they are unlikely to receive informed advice and may receive a negative opinion about their appropriateness for use within the hospital. As such, the reasons for patients non-disclosure described in the review by Robinson and McGrail are also observed with this group of doctors.

Important strategies towards closing the communication gap between patients and anaesthetists about CMs would be to increase their familiarisation with CMs through further education and providing ready access to appropriate resources. Furthermore, clear guidelines are required to encourage anaesthetists to ask patients about CMs and direct them towards the next steps required once use has been identified.

### 4.1.2 Anaesthetists attitudes to CMs

The attitudes of anaesthetists to CMs can be described as moderately negative, based on their responses to the attitudinal statements. It is apparent that anaesthetists are reluctant for CMs to be used alongside conventional medicine within the hospital setting and many think CMs are not cost effective and offer a false sense of hope. Considering nearly all agreed that more hospital based research is required, it is possible they think there is insufficient research at present to support their use. There is also a prevailing view that CMs are potentially dangerous and their use needs to be monitored. Of note, over 90% thought herbal medicines were potentially dangerous.

It is not clear what influences have shaped these attitudes. Our sample had received little training about CM, had little knowledge of the evidence base of commonly used
CMs and little personal experience using CMs, so other influences must be at work. It is possible that perceived pressure from peers to confirm to a negative view is an influence, as suggested by their responses to the attitudinal questions, however knowledge and publication bias may also be influences.

### 4.1.3 Anaesthetists perceptions and attitudes to CTs

If acceptance of a CT can be considered when over 80% of respondents think it is useful then acupuncture, hypnosis, massage, meditation and yoga have become accepted by anaesthetists and are unlikely to be considered fringe therapies by this group. In particular, acupuncture stood out as being well accepted in terms of effectiveness and also attracted relatively higher interest in future personal use and practise than other CTs. Despite the high interest in this modality, less than 5% have practised acupuncture in comparison with 18% of Australian GPs, suggesting little integration (166). The ingested treatments (CMs) and chiropractic were perceived as potentially harmful by the most respondents which is a similar perception to Australian GPs and spiritual healing and reflexology were considered least useful (166).

### 4.1.4 Little personal use and practice of CTs

Anaesthetists have similar patterns of personal use of CTs to UK GPs but relatively less usage than Australian and German GPs (129;166). A comparison with the survey by Cohen et al of Australian GP practises indicates that there is little practise of any CT by anaesthetists and the integration of CTs into general practice is far more advanced than in the practise of anaesthesia in the hospital setting (166). This is not surprising as GPs have a broader scope of practise than the specialist practise of anaesthesia and therefore more opportunities where the use of CTs may be relevant.

It was surprising to find very little practise of acupuncture despite it being regarded as useful by nearly all respondents and there being convincing evidence from
randomised controlled trials and systematic reviews for perioperative applications such as preoperative anxiety and for postoperative pain relief (360). Manual acupuncture requires specialist training and is labour-intensive and time-consuming, which may be limiting its applicability in many units.

4.1.5 Training, knowledge and information seeking behaviour

In the book *Australasian Anaesthesia 2003* published by the ANZCA (Australian New Zealand College of Anaesthetists), Grauer states: “for the benefit of the patient and the physician, it is important for anaesthetists to inform themselves about the potential benefits, drug interactions and adverse effects of herbal medications and familiarity with the common 15-20 herbs .. is all that is really required” (361). This survey has identified that anaesthetists are not aware of the safety and efficacy evidence for 11 commonly used CMs identifying a significant unmet need for further education about CMs. This also confirmed the findings of a smaller survey which demonstrated that anaesthetists have limited knowledge about herbal medicines (362). Particularly disturbing was the lack of awareness of common CMs which potentially increase bleeding.

Unexpectedly, anaesthetist’s lack of confidence dealing with CMs, lack of knowledge, and belief that CMs are potentially dangerous, did not generally motivate them to seek information when patient use was identified. Time constraints, lack of opportunity and lack of ready access to appropriate information resources are some explanations however the real reasons remain unknown. Approximately two thirds of anaesthetists in this survey reported they were interested in future training about CMs and CTs indicating a willingness to devote some time and effort to changing the current situation.

How anaesthetists should respond to patient’s use of CMs if identified remains uncertain. Currently the American Society of Anesthesiologists advises anaesthetists to ask patients to discontinue use of all herbal medicines two weeks prior to surgery, the time estimated for the compounds to be fully metabolized (246) however the
ANZCA has no formal policy or guidelines about CMs although Grauer advises that a more targeted approach be taken. Furthermore, he proposes that the question ‘Do you take any herbal medications or any other substances?’ should be a routine part of every anaesthetists pre-operative assessment.

As the popularity of CMs continues, anaesthetists will no doubt come into increasingly frequent contact with patients who are using these medicines thereby making the issues of confidence, knowledge and strategies to improve patient safety more urgent.
4.2 Hospital pharmacists survey

The three major functions of the pharmacist are: identifying potential and actual drug related problems, resolving actual drug-related problems and preventing potential drug-related problems (171). This requires knowledge of the available evidence regarding the drug, knowledge of the patient and their disease and communication with the patient and other health care professionals.

As a reflection of the increased use of CMs by patients, the APAC (Australian Pharmaceutical Advisory Council) guidelines specify that CMs are to be included as part of a standard medication history and according to the National Strategy for the Quality Use of Medicine (QUM), the safe and appropriate use of CMs is also to be promoted. Professional associations in North America have also responded to the widespread use of CMs and between 2000 and 2004, the American Society of Health-System Pharmacists (ASHP), the American College of Clinical Pharmacy (ACCP) and the Canadian Society of Hospital Pharmacists (CSHP) recommended that the pharmacy profession actively embrace CMs as part of a pharmacist’s scope of practice (363).

Within the hospital setting, pharmacists play an essential role as medication counsellors within the healthcare team and promote medication safety and quality use of medicines. Many hospital pharmacists have direct input into patients’ clinical care, help determine whether self-medication is appropriate and conduct medication reviews to verify patients’ use and dosage.

4.2.1 Pharmacists and communication failure

Good communication between health professionals and patients is an essential part of providing safe and effective health. Whilst studies have been conducted to determine what communication barriers exist to prevent patients and physicians discussing CM use (359), relatively little is known about pharmacists in this regard. Studies with community pharmacists in the United States have produced inconsistent results with one study identifying that pharmacists rarely ask patients about CM use (364)
compared to another reporting 52% regularly ask patients about CMs (365). The present survey has identified that 29% of pharmacists describe themselves as ‘always’ asking patients about CMs and 26% as ‘often’ asking patients with younger pharmacists more likely to ask patients about use. Surprisingly, having greater knowledge of CMs safety and efficacy was not associated with more frequent patient enquiry. The most common reason given for not asking all patients was forgetting to ask, whilst some pharmacists assumed patients would volunteer information unsolicited or that asking patients is too time consuming. This establishes that considering CMs is not part of the pharmacist’s usual routine and efforts are required to educate them to include CMs as part of a standard medication history and the practise of QUM.

Lack of practitioner enquiry combined with lack of patient disclosure has previously been described as a ‘don’t ask, don’t tell’ culture in which communication barriers are continually reinforced (121). Not only is this situation potentially dangerous, it also means a missed opportunity to learn from patients about their reasons for using CMs which can reveal important details about their health and the effectiveness and limitations of their current treatments.

4.2.2 Pharmacists training, knowledge and information sources

As the use of CMs and CTs continues, hospital pharmacists are likely to come into contact with an increasing number of patients taking or enquiring about both. Although the majority of pharmacists have no formal training in CM, many believe it is their responsibility to have knowledge of CMs to be able to inform patients about their treatment options (178;366). Overseas studies have reported that pharmacists are generally not satisfied with their level of knowledge about CMs (181) and are not comfortable with responding to CM inquiries (367). Respondents to this survey felt similarly which may account for the substantial number interested in further training. Overall, pharmacists actual knowledge of CMs is limited, a finding that has been reported elsewhere (178;368) and which confirms the urgent need for improved undergraduate training and further continuing professional education.
Identifying reliable information sources about CMs is difficult and the accuracy and currency of the information available varies considerably. Previously, books and magazines have been cited as major sources of CM information for pharmacists (369; 370) however hospital pharmacists favour electronic information sources and the World Wide Web for information, with Medline reported as their most popular choice. Whilst many would consider Medline a credible and up-to-date information resource, its usefulness is limited by the information seeking skills of the user and the lack of availability of full-length research articles. In regards to CMs and CTs, these issues are further complicated by the diverse nature of the area, the lack of consensus as to what CMs and CTs constitute and how they are best evaluated.

4.2.3 Perceptions and attitudes to CMs and CTs

Hospital pharmacists are concerned about safety, efficacy and cost issues associated with CMs and overall can be described as having a moderately negative attitude to CMs. It is difficult to make a detailed comparison with the only other Australian study of pharmacists however the overall impression is that there a discrepancy in attitudes between the two and hospital pharmacists are more cautious than community pharmacists regarding CMs (371).

If acceptance of a CT can be considered when over 80% of respondents think it is useful, then acupuncture, massage, vitamin/mineral therapy and yoga have become accepted by hospital pharmacists and are unlikely to be considered fringe therapies by this group. Of these, relatively few pharmacists actively encourage the use of acupuncture and vitamin/mineral therapy, possibly because they are also perceived as potentially harmful by many respondents. In comparison with the anaesthetist’s survey, relatively few pharmacists think hypnosis is useful whereas fewer anaesthetists think vitamin/mineral therapy and herbal medicine is useful. It is likely that pharmacist’s greater focus on medicines and familiarity with commonly used CMs is responsible for this difference.

Other CTs accepted as useful by over 70% of hospital pharmacists are Chinese herbal medicine, herbal medicine, chiropractic and meditation however less than 10% would
actively encourage their use, except for meditation which would be encouraged by 30%. Once again, the variations in which CT would be encouraged appear to be a reflection of their perceived potential to cause harm.

These results are similar to those reported in a study of predominantly Australian community pharmacists with the majority perceiving massage, acupuncture, meditation, herbal medicine and chiropractic as potentially useful (371). In comparison, a study of U.S. pharmacists by Welna et al reported that only 19% thought herbs and natural supplements were effective indicating a major difference in attitude between US and Australian pharmacists (372).

In contrast, there is little acceptance of homeopathy by hospital pharmacists as few consider it potentially useful, there is little interest in personally receiving treatment and virtually no encouragement of its use. These results are similar to those obtained for anaesthetists and hospital doctors indicating overall little acceptance of this modality. According to Cohen et al, few Australian GPs consider homeopathy useful whereas Naidu et al reported nearly 40% of pharmacists ranked it amongst the top 10 most useful CTs (166;373). It is likely that community pharmacists have greater exposure to homeopathy than hospital pharmacists and medical practitioners as many retail pharmacies stock these medicines and as a result, may have received information from manufacturers or patient feedback about their effects whereas hospital pharmacists and medical practitioners are unlikely to have received either.

Hospital pharmacists also perceive some CTs as potentially harmful, particularly the ingested medicines which is a similar finding to that reported for Australian GPs (166).

4.2.4 Pharmacists personal use and practice of CTs

A cross-cultural comparison reveals 37-53% of U.S. pharmacists use CMs, 29% of Australian pharmacists according to Naidu et al and most (84%) pharmacists from Singapore and Malaysia use CTs (188;201;213;371). Australian hospital pharmacists also use CMs with 27% reporting use of vitamins/minerals in the previous 12 months,
10% Chinese medicine and 9% herbal medicine. Similarly to the finding by Naidu et al., medicinal treatments were the most commonly used CTs by pharmacists (371). This survey further identified that massage was popular amongst hospital pharmacists and had been used by 26% in the previous 12 months whereas relatively few pharmacists in the other pharmacy survey reported use.

Although medicinal CTs and massage were most frequently used by hospital pharmacists, many expressed an interest in receiving treatment with a range of other CTs such as meditation, acupuncture and yoga. Not surprisingly, these CTs were also considered useful by a majority of pharmacists. When the results of this survey are compared with the anaesthetists and Frankston Hospital surveys, it is apparent that more pharmacists are interested in practicing the medicinal therapies than hospital doctors. Once again, this is somewhat expected as their training and professional practice has a focus on medicines.
4.3 Frankston Hospital – combined hospital doctors and pharmacists survey

This survey of the medical and pharmacy population working at one hospital site provides information about the hospital staff responsible for taking medication histories, prescribing medication, and providing patients with drug information and counselling. The data collected enables comparisons to be made between sub-groups of health care professionals working within the same setting and when results from solely medical staff at Frankston Hospital are considered, it can be compared to surveys of Australian GPs to identify similarities and differences between hospital doctors and GPs.

4.3.1 Don’t ask and don’t tell

Clear and open communication is necessary for the practice of concordance and EBPC and is essential for the delivery of high quality, safe patient care (290). Previously, two studies in the international literature demonstrated that medical practitioners in Canada and Israel do not routinely ask patients about use of CM whereas there is no published information about Australian doctors in this regard (121;135). This survey has demonstrated that the problem of poor communication is widespread and hospital doctors and pharmacists do not routinely ask patients about CMs despite this being considered a standard part of taking a medication history and important for QUM. If patient use of CMs was recognised, this survey further identified that documentation of use is inconsistent making communication within the healthcare team ineffective and the identification and reporting of adverse reactions to CMs extremely difficult.

Numerous studies demonstrate that Australians use CMs and use has increased in the last decade (14;15). This means hospital doctors and pharmacist are now coming into contact with patients who have been using or are still using CMs. This has been documented in studies conducted overseas and in Australia and now confirmed by the two surgical patients surveys conducted as part of this research project. In response to the widespread use of CMs and their potential to induce adverse effects and interact with conventional drugs, numerous articles have been published in the peer-reviewed
press of various professional disciplines describing the safety evidence. Nationally, CMs are incorporated within the practice of QUM and locally in Victoria, the Victorian Therapeutic and Advisory Group (VicTAG) and the Victorian Drug Usage Advisory Committee (VDUAC) has produced CM guidelines for all Victorian Hospitals which aim to promote open discussion about CMs and patient safety (374). Clearly, these avenues have had little impact on hospital practice and a change in medication history taking has not occurred.

Grol and Grimshaw note that barriers to change can act at different levels – the individual, team and organisational levels (37). Within the context of this study, barriers have been identified within these levels and provide some explanation for the current behaviours.

At an individual professional level, doctors and pharmacists have set routines that do not currently include considering patients use of CMs. This is seen in their responses to the questions regarding patient enquiry where forgetting to ask patients about CMs was commonly reported. Pharmacists fared better than hospital doctors and were more frequently asking patients about CMs however this was still not part of their standard routine. Attitudinal barriers were also detected as some respondents thought it irrelevant to ask patients about CMs. Cognitively, the individuals surveyed have limited knowledge of the safety and efficacy of commonly used CMs although many think they are potentially harmful and require monitoring. Emotionally, many do not feel sufficiently knowledgeable and confident when dealing with CM-related issues and are likely to be uncomfortable discussing CMs with patients.

From a larger perspective, the prevailing opinions and behaviours of peers are other influences. The attitudinal section of the survey identified that 42% did not think CMs are appropriate for use within the hospital setting and nearly 50% thought CMs were a waste of time and money and presented false hope to patients. As such, the prevailing opinion does not encourage the use of CMs and can be described as somewhat dismissive of these treatments.

From an organisational perspective, Frankston hospital does not have a designated CM policy or CM guidelines however it is expected that patient’s use of CMs is
considered during standard medication history taking procedures. Additionally, there have been no formal initiatives to increase awareness amongst patients or hospital doctors and staff about use of CMs and their potential benefits and hazards. As such, lack of communication with patients and inconsistent responses to patients use may also be attributed to a system failure.

4.3.2 Lack of confidence is widespread

In regards to communicating with patients about CMs, 27% were not confident to advice patients about CMs and only 2% were always confident they had sufficient knowledge to identify when CMs could adversely affect patient care. Within the four groups surveyed, both medical physicians and anaesthetists were more confident than surgeons and as a group, pharmacists were more confident than the complete medical group. This reflects the differences in their knowledge scores, information seeking behaviours and previous training about CMs compared with medical doctors.

For example, surgeons achieved the lowest knowledge scores and were least likely to use resources to check for CM safety information or undertake post-graduate training or self-directed learning compared with the other groups. In contrast pharmacists achieved the highest knowledge scores, more frequently used resources for CM safety information and were most likely to have attended undergraduate lectures, specific seminars about CMs or undertaken self-directed learning. These results imply that surgeons may benefit from liaising with their pharmacist colleagues about CMs and undertaking formal training themselves.

A study of UK GPs reported that although a minority were confident discussing CM with patients the CTs they were most confident discussing were: acupuncture and homeopathy (375). In contrast, this study found the CTs most hospital doctors and pharmacists were confident providing general advice about were chiropractic, massage, meditation and yoga with relatively less confident with acupuncture and homeopathy.
Of these four CTs, massage was the only one in which hospital doctors and pharmacists were most likely to encourage use whereas the general response to the other three would be neither encouragement nor discouragement. It is possible that more respondents felt confident providing general advice and encouragement for massage because it is widely perceived as useful, with low risk and 20% had personally received a treatment within the last 12 months. Whilst meditation and yoga were also perceived as useful and low risk by most respondents, only 6% reported personal use of meditation and 4% yoga which may explain why fewer respondents were confident in encouraging their use. Chiropractic was perceived as useful by most respondents’ but also potentially harmful and few (5%) had personally experienced a treatment which may explain respondent’s confidence in providing general advice but not displaying a distinct trend towards encouragement or discouragement.

There was obvious interest in acupuncture and widespread agreement that it is a potentially useful therapy however only 4% had personally experienced a treatment within the last 12 months. It is possible that fewer people were confident encouraging its use because very few people were personally familiar with this treatment and the prevailing attitude is that it is also potentially harmful.

### 4.3.3 Similar attitudes to CMs

The results obtained in the attitudinal sections of all three practitioner surveys were remarkably similar and indicated a moderately negative attitude to CMs amongst all groups. At Frankston Hospital, few doctors and pharmacists agreed that CMs are appropriate for use in the hospital setting, there was more agreement that CMs are a waste of time and money than there was disagreement and over 80% thought CMs are potentially dangerous and need to be monitored. Similar to the other surveys, there was widespread agreement that CMs require more hospital based research, regulations for CM practitioners need to be tightened and CMs do not offer patients cost effective treatment options. When combined with their responses to other parts of the survey, it is clear that doctors and pharmacists are cautious about CMs and many perceive them to be potentially useful but also associated with various risks such as patient harm, financial loss and false hope.
Surveys in the literature tend to report on physician or pharmacists attitudes to CTs as a complete entity rather than isolating CMs as a specific group making comparisons with other studies difficult.

### 4.3.4 Perceptions about CTs

The systematic review of physicians and CM in Chapter 1 Section B identified varying levels of interest and acceptance of CTs by physicians with results generally indicating a growing curiosity about specific CTs. According to Schmidt et al, the overall attitude of U.K. and German GPs toward CM was positive with a slightly more positive attitude expressed by the German GPs (376). The results of this survey indicate that numerous CTs are considered potentially useful by doctors and pharmacists and there are several which staff would be interested to personally receive treatment with and/or practise in the future, also demonstrating a level of acceptance and growing curiosity.

Similar to the results obtained in the previous practitioner surveys, acupuncture, massage, meditation and yoga have become accepted by this group of hospital doctors and pharmacists as useful and are unlikely to be considered fringe therapies. When results for the medical participants at the site are grouped together and compared with pharmacists then it is apparent that hypnosis is also accepted by medical doctors but far less so by pharmacists. Pharmacists also differed in their perceptions and interest in medicinal CTs as they widely accept vitamin/mineral therapy as potentially useful, most would consider receiving treatment and half were interested in practising it in the future whereas less interest and acceptance was demonstrated by doctors. Although the sample of pharmacists in this survey was small, similar results were obtained in the larger pharmacist’s survey confirming this finding.

When the results of all individual groups at this site are compared, it is apparent that anaesthetists in particular have a high level of acceptance of acupuncture with all anaesthetists in this sample considering it useful, and a relatively higher number
interested in receiving treatment and considering practise with this modality. These findings are consistent with the results obtained in the larger anaesthetist survey.

There appears to be a cultural difference between the UK, US and Australia regarding practitioners perceptions of whether homeopathy, herbal medicine and chiropractic are useful and effective (120;166;377). Similar to a survey of US academic physicians, very few Frankston Hospital doctors and pharmacists perceived homeopathy as effective, whereas UK GPs were less sceptical. Herbal medicine was considered useful by over 60% of Australian hospital doctors and pharmacists and Australian GPs according to Cohen et al, whereas it received little support for being effective by UK GPs or academic physicians in the US. Results for chiropractic were also varied with many Australian hospital doctors and pharmacists and UK GPs perceiving it as useful however U.S academic physicians considered chiropractic amongst the least useful CT (120;166;378).

In regards to perceptions of harmfulness, a study of primary care practitioners in Israel identified that 51% thought herbal medicines had no or only mild side effects, and 63% claimed that they had no or only mild interactions with conventional drugs (121). In contrast, over 80% of hospital doctors and pharmacists perceived herbal medicine as potentially harmful and in need of supervision.

Overall, the perceptions of Australian hospital doctors and pharmacists are closely aligned with Australian GPs and indicate acupuncture, massage, yoga and meditation are widely regarded as useful whereas reflexology, homeopathy and spiritual healing attract little support (166). Similarly, there is the perception amongst community and hospital-based groups that chiropractic, Chinese medicine and herbal medicine are potentially harmful.

**4.3.5 Little personal use and practice of CTs**

Hospital doctors have similar patterns of personal use of CTs to UK GPs but relatively less usage than Australian and German GPs (129;166). A comparison with the survey by Cohen et al of Australian GP practises indicates that there is relatively
little practise of any CT by Australian hospital doctors and the integration of CTs into general practice is far more advanced than in the hospital setting (see Table 1) (166).
Table 1. A comparison between hospital doctors at Frankston Hospital and Australian GPs as reported by Cohen et al (166).

<table>
<thead>
<tr>
<th>Complementary therapy</th>
<th>Personal usage in the past 12 months</th>
<th>Would consider receiving in future</th>
<th>Have practised in the past 12 months</th>
<th>Would consider practising in future</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% hospital doctors</td>
<td>% GPs</td>
<td>% hospital doctors</td>
<td>% GPs</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>4</td>
<td>12</td>
<td>52.5</td>
<td>56</td>
</tr>
<tr>
<td>Aromatherapy</td>
<td>2</td>
<td>3</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Chinese herbal medicine</td>
<td>1</td>
<td>4</td>
<td>17</td>
<td>23</td>
</tr>
<tr>
<td>Chiropractic</td>
<td>8</td>
<td>7</td>
<td>22</td>
<td>27</td>
</tr>
<tr>
<td>Herbal medicine</td>
<td>3</td>
<td>5</td>
<td>15</td>
<td>26</td>
</tr>
<tr>
<td>Homeopathy</td>
<td>0</td>
<td>3</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>Hypnosis</td>
<td>3</td>
<td>3</td>
<td>34</td>
<td>45</td>
</tr>
<tr>
<td>Massage</td>
<td>20</td>
<td>26</td>
<td>51.5</td>
<td>55</td>
</tr>
<tr>
<td>Meditation</td>
<td>6</td>
<td>11</td>
<td>51.5</td>
<td>56</td>
</tr>
<tr>
<td>Naturopathy</td>
<td>1</td>
<td>3</td>
<td>13</td>
<td>16</td>
</tr>
<tr>
<td>Osteopathy</td>
<td>1</td>
<td>3</td>
<td>16</td>
<td>20</td>
</tr>
<tr>
<td>Reflexology</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>11</td>
</tr>
<tr>
<td>Spiritual healing</td>
<td>3</td>
<td>3</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>Vitamin/mineral therapy</td>
<td>12</td>
<td>13</td>
<td>32</td>
<td>27</td>
</tr>
<tr>
<td>Yoga</td>
<td>4</td>
<td>10</td>
<td>44</td>
<td>52</td>
</tr>
</tbody>
</table>
The therapies of most interest for personal use by both Australian hospital doctors and GPs are acupuncture, massage and meditation and not surprisingly, these are the same therapies they consider effective (166). Both groups have similar interests in regards to the CTs they would consider practising in future – notably meditation, acupuncture and massage with the exception of vitamin/mineral therapy where 13% of hospital doctors expressed an interest compared with 10% of GPs. Many more GPs were interested in practising yoga compared with hospital doctors, 18% and 8% respectively and no hospital doctors would consider practising homeopathy or reflexology compared with 4% and 2% respectively of GPs.

A cross-cultural comparison of GPs in the UK and Germany has identified acupuncture had been personally used by 2% of UK GPs and 11% of German GPs whereas 4% of Australian hospital doctors reported use (379). A similar finding was obtained for use of chiropractic with 8% of Australian hospital doctors having received treatment compared with 6% and 7% respectively for UK and German GPs respectively. In regards to homeopathy, 2% of UK GPs and 5% of German GPs reported use compared with no respondents in the present survey. Schmidt et al used the term phytotherapy to describe herbal medicine use and identified 1% of UK GPs and 4% of German GPs had previously used it. This survey divided phytotherapy into herbal medicine and Chinese herbal medicine for which 3% and 1% usage was identified respectively. Aromatherapy usage was also similar for all three groups and reported at 2%, 1% and 1% in the UK, Germany and Australia respectively. No other overseas studies reported specific information about the personal use of individual CTs such as massage, meditation, yoga, hypnotherapy or spiritual healing so no further comparisons can be made.

Surveys of GPs in the UK, US, Germany and Australia and physicians in the UK demonstrate that acupuncture is practised in all countries by these groups however no hospital doctors in this study reported having practise acupuncture (117;131;166;380;381). Homeopathy is also practised by some GPs in the UK and Germany whereas only 1% of Australian GPs reported practise in the study by Cohen et al and no hospital doctors according to the present survey (129;166). Lewith et al identified that manipulative therapies were being practised by physicians in the UK, Schmidt et al reported that 11% of German GPs practised chiropractic and 3%
osteopathy whereas no hospital doctors reported having practised chiropractic or osteopathy (117;129). Similarly, Cohen et identified only 1% of Australian GPs as having practised chiropractic and osteopathy (166).

4.3.6 Training, knowledge and information sources

Despite the increasing number of research and review articles published about CMs and continuing education programs available, there is still substantial room for improvement in hospital doctors and pharmacists knowledge. The need to increase their familiarisation about the safety and efficacy of CMs and confidence in dealing with CM-related issues is urgent in order to safeguard patients from potentially harmful behaviours and avoid unnecessarily advising patients to cease use of safe and effective treatments. Additionally, lack of training and confidence breeds concerns about legal liabilities (382).

Studies conducted with GPs in the U.S. have found that over 80% want more CM education (16;118). Similar results were obtained for anaesthetists and hospital pharmacists whereas approximately half the medical physicians and slightly less surgeons wanted further education. This indicates a general willingness to change the current situation and suggests an opportunity for further education would be welcomed by many practitioners.

In Chapter 1 Section B, the systematic reviews of medical practitioners and CM identified a study of U.S. gastroenterologists which reported that 76% obtained information about CM from medical journals, 57% the media, 48.1% continuing medical education, 22.4% the internet, or other sources (15.9%) (141). Similarly, hospital doctors in Australia use peer-reviewed journals, MEDLINE and the internet however they also reported using reference texts (40%) and pharmacists (31%) for information. It is imperative that hospital doctors and pharmacists have ready access to reliable information sources about CMs, particularly as they have received little formal education about these treatments and have limited knowledge about them. It is also essential that their information seeking skills are adequate so that relevant information can be retrieved when required.
4.3.7 Implications for patient safety and wellbeing

The practise of EBM requires healthcare professionals to use current best evidence in making decisions (22). The shared decision making models such as concordance require a partnership to be formed between practitioner and patient, two-way communication, information giving and agreement. Based on the results of this survey, it is improbable that EBM or concordance is being achieved regarding CMs and patient safety and wellbeing is being compromised. Practitioners generally fail to ask patients about CMs and in turn, patients fail to disclose use. This prevents a therapeutic partnership from developing and is a clear breakdown in communication. If patients do provide information about their use of CMs, healthcare practitioners are unfamiliar with the evidence of CMs safety and efficacy and generally do not seek further information. As a result, the information they can provide is limited to their personal perceptions and biases and is of questionable value. A culmination of the previous factors means that an agreement about patient care cannot be achieved within this domain.

This survey has further identified several barriers preventing the integration of evidence based CMs into hospital practice. These are lack of knowledge about the available evidence, due to limited training and irregular information seeking behaviours, little personal experience of using and practising CTs from which to gain familiarisation and understanding of their effects, the belief that CMs are not cost-effective and that colleagues would not consider the use of CMs, thereby reaffirming their discomfort with it. Despite these observations, there is interest amongst hospital doctors and pharmacists in CTs and many are interested to learn more about them.
4.4 Cardiac surgery patients survey

Cardiovascular disease (CVD) affects 3.2 million Australians with an expectation that this figure will substantially increase over the coming decades due to the growing number of older Australians (383). Of those people with CVD, 69% took pharmaceutical medication for heart or circulatory conditions in 2001 and in 2001-2, 40 201 coronary angioplasties and coronary artery bypass grafts (CAGS) were performed nationally in hospitals (260). Because of progressive ageing of the population and other factors, such as the increased use of pharmaceutical agents, the direct costs have been predicted to increase to approximately $11.5 billion by 2011 (384).

This is the first Australian survey to demonstrate that CMs are widely used by cardiac surgery patients and most are medically prescribed. Importantly, it identified that approximately 40% of patients using CMs preoperatively intended to continue use whilst in hospital and at least half of these patients did not tell hospital staff. Unlike general community usage patterns, CMs use was not associated with female gender, education, age or income (13;14;63).

The survey demonstrated 51% of cardiac surgery patients take CMs in the 2 weeks prior to admission. This is consistent with international prevalence surveys which show that CMs use by surgical patients ranges from 51% (232) to 73% (234) in the 2 weeks prior to surgery. Results from this survey contrast to a Melbourne survey of general surgical patients which found 20% used vitamin supplements in the 6 weeks prior to surgery and 14% used herbal medicines (242).

It is also relevant to compare the results of this survey with Brownie and Rolfe as they investigated the patterns of CMs use amongst older Australians (> 65 years) and the average age of the cardiac surgery patient sample was 69.9 years (108). Both surveys found fish oils, multivitamins and vitamin C were amongst the most popular supplements being used although glucosamine supplements were also highly favoured by cardiac surgery patients. The relatively higher use of fish oil supplements amongst cardiac surgery patients compared with participants in the Brownie and Rolfe survey
may be due to a higher prevalence of cardiovascular disease and the substantial evidence supporting the use of fish oils for this condition (385).

In the international literature, only one study has been published which evaluated cardiac surgery patients use of CMs and CTs however it is difficult to compare prevalence findings as Liu et al enquired about use in the previous 12 months whereas this survey was limited to a shorter time frame, only 2 weeks (239). The U.S. survey did not report which specific CMs were being used by cardiac surgery patients or who had prescribed them so further comparisons cannot be made (386).

In 2006, MacLennan et al reported that 70% of people use CMs to maintain general health, a result which was almost identical to the one obtained for cardiac surgery patients in this study and both studies found there was less emphasis on using CMs to treat disease (14). In comparison to the 2002 MacLennan et al study, nearly half the cardiac surgery patients thought some CMs were safe and by inference, some weren’t, compared with 65% who thought CMs could be potentially unsafe (13).

4.4.1 Patient safety and CMs

Some of the CMs used by the patients in this study are relatively innocuous, such as multivitamins and vitamin C, while others such as fish oils and coenzyme Q10 may be beneficial for the cardiovascular patient (387;388). The most concerning group are those patients taking CMs with the potential to induce adverse surgical events and drug interactions. A report by the Australasian Society of Cardiac and Thoracic Surgeons (ASCTS) together with the Department of Human Services states the most common adverse outcome after cardiac surgery is post-operative bleeding (389). Some of the CMs used by patients in this study, such as fish oils, vitamin E, evening primrose oil, garlic, ginger and ginkgo biloba, could potentially increase the risk of haemorrhage, either due to interactions or direct pharmacological activity (325).

Previously, three surveys in the United States have been specifically conducted to determine whether surgical patients are taking CMs which could potentially increase the risk of haemorrhage (232-234). Using the same methodology employed by these
surveys, it was found that seven different CMs were being used which have potential antiplatelet or anticoagulation activity, notably 25% of cardiac surgery patients using CMs were taking fish oils and 12.5% were taking vitamin E supplements.

In this survey, no cardiac surgery patient reported using St John’s wort, kava kava or garlic oil which are CMs which can induce pharmacokinetic interactions with numerous drugs used in cardiovascular disease management such as nifedipine, propranolol, simvastatin, verapamil and warfarin (390-392).

It is important to note that the average age of participants was 69.9 years as older age is associated with an increased likelihood of adverse events (393). Furthermore, over 90% of cardiac surgery patients were taking at least one prescription medicine in the 2 weeks prior to admission, with 74% taking three or more. As such, there is the possibility of interactions with other drugs being used.

Despite the potential for many OTC CMs to induce adverse events in hospital patients, there is still little information about actual occurrence rates for two main reasons. Firstly, there is little accurate information about the number of patients which use CMs and secondly, the number of perioperative complications and other adverse events definitively induced by CMs remains unknown.

4.4.2 Cardiac surgery patients communication with others

Communication between health care professionals and patients is an essential part of providing safe and effective health care. Consistent with findings from studies of general surgical patients (230;231;242) and patients visiting GPs in the community (13;14), there is little discussion about CMs between hospital staff and cardiac surgery patients. This survey further adds that patients don’t tell hospital doctors or pharmacists about their use of CMs because they are not asked and don’t think it is important and not because they fear a negative response. This is contrast to other studies which report fear of disapproval as a major reason for non-disclosure to medical doctors (359) and may be due to the considerable rate of medical prescribing.
In the hospital where the study was conducted, it is expected that admission nurses routinely enquire about CMs use however this method appears inadequate as 56% of CM users remained unidentified. Of concern, this method is not backed up by routine enquiry from surgeons, anaesthetists or pharmacists suggesting that better co-ordination between staff is required to ensure that information about CMs is effectively collected, appropriately recorded and managed. Patient education is also necessary to increase their awareness that vitamin and mineral supplements and herbal medicines are medicines which should be discussed with hospital doctors and pharmacists to ensure they will not compromise patient safety.

4.4.3 Medical acceptance?

Medical practitioners were the chief source of recommendation of CMs to cardiac surgery patients which raises several questions. Firstly, on what basis do doctors make (or fail to make) recommendations about CMs? In Australia, the teaching of CM in medical schools remains highly variable between sites and there are few dedicated CM familiarisation courses in medical schools (394). Results from the anaesthetist’s survey and Frankston hospital survey suggest that few medical practitioners receive undergraduate training about CMs. Secondly, should hospital pharmacies supply medically prescribed supplements? According to these results, patients currently bring in their own supplies and rely on family and friends whilst in hospital. These means hospital staffs have limited control over the quality of supplements being used and monitoring patients use is more difficult. Thirdly, if a CM product is medically prescribed, does this signify it has been adopted as a conventional medicine? According to this study, fish oil and glucosamine supplements, which have been traditionally considered as complementary or alternative medicines, may have gained a level of acceptance.

4.4.4 Health promotion and patient preferences

In the context of CVD, health prevention relates to the promotion of healthy eating, regular physical exercise, quitting smoking, maintaining healthy weight and reducing blood pressure and cholesterol (260). Additionally, risk factors for CVD are strongly
influenced by wider circumstances such as access to social services. In the landmark INTERHEART study conducted in 52 countries, the risk of MI was associated with depression and psychosocial factors such as social isolation in the same order of magnitude as conventional risk factors such as hypertension, smoking and dyslipidemia (395;396). There are numerous pharmaceutical treatments available for hypertension, dyslipidemia and more recently, smoking cessation however many other health prevention strategies such as stress management, regular exercise and the consumption of fruits and vegetables can require patient education and motivation. As a result, it was of relevance to gauge patients interest in hospitals offering diet, lifestyle and complementary therapies, some of which would fit into the context of health promotion for CVD and prevention of MI.

A large proportion of cardiac surgery patients would consider using at least one of the diet, lifestyle or complementary therapies if provided by hospitals regardless of gender, income or education. This interest was highest amongst younger cardiac surgery patients and those who reported using CMs prior to admission. Unexpectedly, only 45% were interested in receiving diet advice and 32% exercise consultations, despite good nutrition and physical activity being widely promoted as beneficial in CVD. It is possible cardiac surgery patients feel they have sufficient information already about diet and exercise, would prefer to use off site institutions and healthcare professionals for these services or lack interest in these areas however the reasons for this finding are unknown. It is notable that 41% of cardiac surgery patients were interested in massage and may reflect an unmet need for greater intimacy in the hospital setting. Of those therapies which could be described as providing psychosocial support, meditation and stress management were most popular. The introduction on these CTs into the hospital setting would provide patients with the opportunity to learn new skills that could be used after discharge and possibly have a beneficial impact on future disease.

Currently, cardiac rehabilitation programs aim to maximize physical, psychological and social functioning of people with pre-existing cardiac disease and typically include health education, physical activity, counselling, behaviour modification and strategies for self management. According to these results, there is patient interest in a
variety of CTs such as massage, chiropractic, stress management and meditation which could also be considered.
4.5 Surgical patients survey

This survey demonstrated that CMs are used by 46% of surgery patients at Cabrini and Frankston Hospitals in the 2 weeks prior to admission and unlike cardiac surgery patients in the previous survey; most are self-prescribed or recommended by family and friends. Importantly, it identified that the combined use of CMs and prescription medicines was not uncommon, many did not tell hospital doctors and pharmacists about use and approximately half of these patients intended to continue use whilst in hospital. Perioperative CMs usage raises practical issues such as communication and record keeping, safe storage and administration as well as safety, legal and ethical issues.

The prevalence of CMs use identified for this sample was slightly less than reported in international prevalence surveys which ranges from 51% (232) to 73% (234) in the 2 weeks prior to surgery but more consistent with findings from the cardiac surgery patients survey. This is the second survey to find the prevalence of CMs use amongst surgical patients was higher than previously reported for surgical patients at two Melbourne hospitals indicating the Grauer study has under-estimated use (242).

Use of CMs by surgical patients was associated with female gender, higher income, higher education and being a non-smoker which is consistent with international studies of surgical patients and the Australian general public (14;231;233). This study provided the additional observation that age is not a significant predictor of use amongst surgical patients. This finding is important as older age is associated with an increased likelihood of adverse events (397).

Similarly to the results obtained in the cardiac surgery patient survey and the survey of older Australians by Brownie and Rolfe, multivitamins, vitamin C and fish oils supplements were the most commonly used CMs (108) and the main reason for using CMs in general was for disease prevention and health maintenance. In accordance with the cardiac surgery survey, glucosamine was also found to be a popular supplement and used by nearly a quarter of patients and approximately half the patients using CMs thought they were effective or effective enough and thought some CMs were safe, and by inference, some were not.
4.5.1 You didn’t ask

Consistent with findings from overseas studies (229-231), patient disclosure about their use of CMs is inconsistent. It is noteworthy that if surgical patients using CMs prior to admission did talk to a health care professional about use, it was most likely with a GP. Although the survey did not examine the reasons for this behaviour, it is possible patients feel more comfortable having this discussion with their GP than a hospital doctor or that GPs are more likely to ask patients about use however this remains to be further investigated.

It appears that once patients are admitted to hospital, a ‘don’t ask, don’t tell’ scenario prevails. The practitioner surveys have established that hospital doctors and pharmacists don’t routinely ask patients about possible use of CMs and the patient surveys have established they don’t volunteer the information unsolicited and some think it is unimportant. Adusumilli et al identified a similar scenario in a New York study where few surgeons or anaesthetists enquired about CMs and patient disclosure was extremely low (229).

4.5.2 Patient safety

Although most over-the-counter CMs are considered safe, they can induce adverse effects, particularly when used by high risk patients or in high risk situations such as the perioperative period which is often characterised by polypharmacy and surgery or anaesthetic-induced physiological changes (398).

Numerous interactions between CMs and prescription medicines have been documented, some of which have special significance for the surgical patient. Response to agents such as midazolam and fentanyl may be reduced with *Hypericum perforatum* (St John’s wort) due to pharmacokinetic interactions whereas a pharmacodynamic interaction may occur with tramadol (399). Data from human studies and case reports indicate that St John’s wort interacts with warfarin and cyclosporine by significantly reducing serum levels of both drugs due to cytochrome 3A4 induction which has implications for the organ transplant patient or those requiring anticoagulation pre- and post-operatively (400). Coagulation disturbances
are also possible with numerous CMs due to direct anti-platelet activity or pharmacodynamic interactions with antiplatelet or anticoagulant drugs (248).

Of the CMs being used preoperatively, fish oil supplements were most prevalent. Whilst there is strong evidence to support the use of fish oils, there is also evidence that it can increase the risk of haemorrhage when used in high doses and should therefore be used with caution (325). In addition, herbal licorice was being used which can induce hypokalaemia and elevated blood pressure (401). The herb St John’s wort was being used by four patients which is important because of its potential to interact with numerous drugs (402) and therefore influence other aspects of patient care beyond the perioperative period.

It is interesting to observe that different information sources will report different CMs as potentially increasing the risk of haemorrhage. For example, using the same methodology employed by Norred in three published studies of surgical patients, (232-234), it could be concluded that besides fish oils, eight different CMs were being used by surgical patients which have the potential to increase bleeding risk, including licorice and celery (248). In contrast, using Braun and Cohen as an information source, there are seven CMs which may put patients at risk of bleeding besides fish oils, however these do not include licorice or celery but does include policosanol (325). This discrepancy highlights the problems practitioners face when trying to locate reliable information about CMs as inconsistencies in the literature are common. Until further investigation of the safety of CMs can be established using clinical studies and well documented case reports, variations in the literature will continue to prevail and patient safety and wellbeing may be jeopardised.

4.5.3 Sources of information and recommendation

Unlike the cardiac surgery survey, most patients in this sample self-prescribed their CMs which is similar to the finding by MacLennan et al for the general community (13). It is possible patients do not seek professional advice before using CMs in the belief that their potential benefits outweigh any potential harm and recommendation from a healthcare professional is not necessary. Self care is important and provides
patients with a sense of control, promotes an active interest in personal healthcare and can have economic and social benefits. However, in order for patients to make informed choices, they require access to easily understood, evidence based information. Surgical patients reported referring to a wide variety of information sources. The most popular are health food stores and GPs followed by naturopaths and herbalists, family and friends, books and magazines. Considering some of these sources may not provide up-to-date evidence based information, such as books and magazines, and some are unlikely to be familiar with the evidence, such as family and friends, it is imperative that medical practitioners, pharmacists and CM practitioners have adequate education to enable them to provide an informed, evidence based opinion.

4.5.4 Health promotion with diet, lifestyle and CM therapies

A major finding of this study is that a majority of surgical patients would consider using diet, lifestyle and CM therapies if offered by hospitals, suggesting there is an interest in seamless care and a desire to bridge the current divide between services offered in the community and hospitals. If future studies confirm this interest then practitioner and institution issues should be examined together with funding models to determine the feasibility of providing selected CTs to patients, as has already been done in numerous U.S. hospitals (8;403).
4.6 General Discussion

Despite many strategically orientated initiatives developed in Australia to promote EBM, it appears that CMs have been largely ignored and overlooked in the practice of medicine and pharmacy within the hospital system. The anaesthetists, pharmacists and Frankston Hospital surveys have indicated that several barriers are preventing the integration of evidence based CMs into hospital practice as well as the detection of potentially harmful or non-evidence based CMs and these are present at the individual and group levels.

A review of the literature reveals that barriers to the adoption of evidence into clinical practice are continuously being investigated in healthcare however CMs have not been investigated elsewhere. Some of the barriers identified in the literature are: lack of time and opportunity to become familiar with the evidence, lack of access to the evidence, organisational barriers, ineffectual continuing education programs, not being convinced of the evidence, not knowing how to apply it and also characteristics of the new evidence (37;38). This study has identified that many of the same barriers apply to the integration of evidence based CMs into hospital practice and several additional barriers specific to CMs.

Importantly, there is a general lack of explicit knowledge about the available evidence of the efficacy and safety of commonly used CMs. This appears to be due to limited training and/or ineffective training and irregular information seeking behaviours. Whilst pharmacists performed better than medical practitioners in the knowledge section and were more likely to search for information about CMs, they still have limited knowledge about CMs and are ill-equipped to provide patients with evidence-based opinions about their safe and appropriate use. Ultimately, individual professionals need to be informed, motivated and trained to incorporate the latest evidence into their daily work.

Several surveys have identified that medical practitioners rely heavily on the opinion of colleagues when making clinical decisions (43;404-406). Furthermore, Mayer and Piterman identified that if medical practitioners found evidence conflicted with their own prior beliefs, they discuss the evidence with colleagues for psychological support.
and affirmation (407). The prevailing opinions of peers have been identified previously as an obstacle to adopting EBM in practice and appear to be a factor in the present study (37). The present study identified that 37% of anaesthetists, 37% of pharmacists and 29% of staff surveyed at Frankston Hospital refer to colleagues for information about CMs and CTs. Based on results obtained in attitudinal section of the survey, it is highly possible that if a systematic review supporting the use of a CM product was identified and the individual was uncertain, they may want to discuss the evidence with a colleague. Within Frankston Hospital, it is likely that their medical or pharmacy colleague would have little knowledge of CMs thereby propagating uncertainty about the evidence at hand. Similarly, if an anaesthetist or pharmacist from one of the study sites were to ask an opinion of another anaesthetist or pharmacist, it is unlikely they will receive an informed opinion.

Surveys have also demonstrated that practitioners place a great deal of importance on personal and professional experiences in the process of applying evidence with some considering previous experience of greater importance in clinical practice than external research evidence (39;406).

All professional groups surveyed in this study reported little experience of personally using and practising CTs thereby failing to gain familiarisation and understanding of their potential benefits and harms via these avenues. In addition, not regularly asking patients about their use of CMs means a failed opportunity to learn about CMs from patients experiences. As a result, they have little tacit knowledge and few personal or patients experiences from which to draw when reading the literature or discussing CMs with colleagues and patients.

In current health care practice, practitioner judgments often reflect clinician or societal values concerning whether intervention benefits are worth the cost (408). Over 60% of anaesthetists, pharmacists and Frankston staff did not think CMs offer patients a cost effective treatment option suggesting that this perception may be another barrier preventing their consideration.

Ideally, education about CMs should be incorporated into under-graduate and post-graduate training programs for doctors and pharmacists. In the United States, the
Integration of complementary medicine education into the medical school curriculum has increased substantially over the past decade with two-thirds of US and Canadian medical schools including either required CM instruction in their curriculum or CM electives (409). In Australia, the teaching of CM in medical schools remains highly variable between sites and there are few dedicated CM familiarisation courses in Australian medical schools (410).

This study has identified that only 9% of anaesthetists have received undergraduate training about CM and 6.6% of hospital doctors at Frankston however the extent of training about CMs specifically is not known. Considering that most respondents are in their mid 40’s and have been in practise for 20 years, this reflects the lack of CM education in under-graduate training during that period. As this study shows, educational efforts regarding CMs to date have left doctors with little knowledge of the CMs that are potentially harmful or useful for their patients and little confidence dealing with CMs-related issues.

Post-graduate lectures about CM have been attended by 27% of anaesthetists and 13.2% of Frankston hospital doctors which suggests anaesthetists have been more active in learning about CM than surgeons and medical physicians. Not surprisingly, anaesthetists performed better on the knowledge section of the surveys than medical physicians and surgeons making them the most informed medical group in regards to CMs. The observation that knowledge scores were not significantly different for anaesthetists aged under 40 ears of age and over 40 years suggests any recent changes to undergraduate or specialty training in regards to CMs has had little impact on their knowledge base. In addition, relatively more anaesthetists are interested in future training about CMs and CTs compared with surgeons and medical physicians, further setting them apart from their other medical colleagues.

Milden and Stokols suggest that medical practitioners receive little or no training about CTs due to the fundamental philosophical divide which has long separated Western medicine and CM (118). Many advances in Western medicine are largely due to the cultivation of objectivism, reductionism and the scientific method however these thinking styles have traditionally neglected the influence of the mind and spirit on health and disease, which are important features of many CTs. Wynia et al propose
that there is disinterest in including CM education because of practical issues which are considered more urgent and taken precedence (411). The results of the practitioner surveys provide some support for this view as most hospital doctors think it is somewhat important, approximately 10% think it is not important and approximately 30% think it is very important for education about CM to be incorporated into the medical undergraduate curriculum. It is interesting to note that a higher percentage of pharmacists (48.6%) thought it was very important for CM education to be included within the medical undergraduate curriculum compared with hospital doctors. This may relate to their greater familiarity with the evidence about commonly used CMs (as observed in the knowledge section) or their greater interest in CMs.

Education about CMs has been introduced into the pharmacy undergraduate curricula in the U.S. and Australia (412). In 1999, a survey of the Colleges of Pharmacy in the U.S. found that of the 58 colleges who responded, 19 had dedicated curricula in place with another 27 indicated that CM was being incorporated into existing courses. In Australia, most CMs training is incorporated into existing pharmacy undergraduate courses as part of pharmaceutics, pharmacognosy, therapeutic treatment of diseases and medication safety. The pharmacist survey identified that 45% had attended undergraduate lectures about CM, far more than reported for any medical group, and one factor likely to be responsible for their higher knowledge scores. Specific seminars had been attended by 16% and post-graduate lectures by 10% suggesting relatively little continuing education. Despite these efforts, current training about CMs is insufficient and many pharmacists are unconfident and ill-prepared to counsel patients about the safe and appropriate use of CMs.

Of all the professional groups studied, pharmacists showed the most interest in future training about CM, particularly about vitamins, minerals and herbal medicines. If given the opportunity for further training, pharmacists are likely to maintain their position as the more knowledgeable group regarding CMs and could feasibly develop specialist expertise in herbal and nutritional supplement counselling within the hospital.

In their review, Grol and Grimshaw suggest that the more successful educational strategies used to facilitate change in the workplace involve CME activities which are
conducted with small groups in an interactive style, computerised decision support systems and reminders such as posters and labels with messages (37). These approaches are relevant to this discussion and can be applied to improve awareness of safety and efficacy issues associated with CMs within hospitals.

In today’s age, medical practitioners and pharmacists are no longer the main providers of healthcare information and advice. Previously, MacLennan et al reported that the main sources of advice people receive about CMs are from themselves, family/friends, medical doctors, the media, health food store, CM practitioners and for less than 10% of people it was the chemist (13). In both patient surveys, the sources of information about CMs and CTs were explored and slightly different results were obtained.

For cardiac surgery patients, pharmacists and medical doctors were the chief sources of general and safety information regarding CMs and CTs and used by over 40% of respondents with approximately 1 in 5 patients referring to CM practitioners and health food stores. It is important to note that over 90% of cardiac surgery respondents were taking prescription medicines suggesting they have regular contact with medical practitioners and pharmacists and may more readily rely on them for healthcare information in general than people taking fewer prescription medicines. Patients in the other study reported that health food stores and GPs were their main source of information and approximately one quarter obtained information from naturopaths and herbalists, family and friends, 17% the internet and 14% from a pharmacy.

As these results demonstrate, medical practitioners are relied upon as a source of information about CMs and CTs and pharmacists are also utilised, although less frequently. Considering people also use resources which may not provide evidence based information such as health food stores and the internet and those unlikely to be familiar with the evidence such as family and friends, it is imperative that medical practitioners, pharmacists and CM practitioners have adequate education to enable them to provide an informed, evidence based opinion.
4.6.1 EBPC, concordance and CMs within the hospital

Originally, the skills necessary for evidence-based practice were described as: the ability to precisely define a patient problem, and what information is required to resolve the problem, conduct an efficient search of the literature, select the best of the relevant studies, apply rules of evidence to determine their validity, and to extract the clinical message and apply it to the patient problem (408). In 2000, a more patient-centred approach was incorporated, specifically, an understanding of the patient’s values and how they affect the balance between advantages and disadvantages of the available management options and the ability to appropriately involve the patient in the clinical decision making process. The pragmatic and humanistic basis of patient-centred care is summed up by Hart who stated ‘health is the product of healthcare, and patients are one of the producers, not simply customers’ (413). Today, methods of eliciting information about patient values, understanding their beliefs and incorporating them in the clinical decision making process remains an important challenge in EBM (408).

Systematic reviews show that patient-centred care results in increased adherence to management protocols, reduced morbidity and improved quality of life for patients (414). As a result, patient-centeredness has been promoted extensively in the literature and is now considered by many to be the standard for quality interpersonal care and both good clinical and moral practice (51).

In parallel with these changes, the practice of pharmacy also began to evolve from a paternalistic approach to a more patient centred approach commonly known as concordance. Concordance aims to achieve the best possible use of medicines and requires a frank exchange of information, negotiation and a spirit of co-operation between the health care prescriber and the patient (56). It requires health care prescribers to take into account patients beliefs, concerns and experiences of their illness and treatments and necessitates good communication and consultation skills. Australian pharmacists are supportive of the principles of concordance and believe that establishing a “therapeutic alliance” is a high priority in the consultation between pharmacists and their patients (57).
Both shared decision making models require a partnership to be formed between practitioner and patient, two-way communication, information giving and agreement. Based on the results of this study, it is unlikely that EBPC or concordance is being achieved regarding CMs.

This study found that medical practitioners and pharmacists do not routinely ask patients about CMs and most patients fail to disclose use, chiefly because they are not asked and/or don’t think it is relevant and not because they fear a negative response. For a patient using CMs, this omission may hinder the development of an open therapeutic partnership and is a clear failure in effective communication. It is also an opportunity lost for practitioners to learn more about their patient’s values, beliefs and priorities, their experiences with CMs and reasons for use which may relate to their current treatments lack of efficacy or side effects. This study suggests that when patients do provide information about their use of CMs, healthcare practitioners are unfamiliar with the evidence of CMs safety and efficacy and do not necessarily seek further information so the information they can provide is likely to be limited to their personal experiences, perceptions, attitudes and feelings. Previously Rosenbaum et al had demonstrated that practitioners personal use of CM affects their attitudes and perceptions of CM and correspondingly, the advice given to patients (415). Considering that medical practitioners and pharmacists have limited personal experience with CMs, their attitudes and perceptions must be shaped by other influences such as peer-group values and possibly the opinions and experiences of family and friends. The cumulative effect of these factors means that the fourth and final step of achieving an agreement with the patient about their health care will not be satisfactorily achieved within this domain.

The three practitioner surveys identified several barriers which prevent the first step towards achieving patient-centred care from being conducted i.e. open communication. It was consistently found that hospital doctors and pharmacists forget to ask patients about CMs suggesting this is not part of their standard routine. Furthermore, their attitudes suggest many are not aware of the relevance of asking, they lack confidence dealing with CM-related issues and have a perceived and actual lack of knowledge about CMs. The obvious remedies are to provide further education about the available evidence, ensure reliable resources are accessible and used when
in doubt and practical guidelines are developed and promoted which take into account patient’s possible use of CMs. The practitioner surveys also identified that databases such as MEDLINE were used by approximately half the hospital doctors and two-thirds of pharmacists when looking for information about CMs and CTs. Evaluation of practitioner information seeking skills may also be required and training to improve them so evidence relevant to CMs can be more readily located.

From the patient’s perspective, the main reason consistently reported for not telling hospital staff about use was not being asked and/or not thinking it is relevant. Patient education is required to encourage them to talk about their use of CMs, even without being directly asked, and to provide reasons why disclosure is important. It is possible that some patients may not consider their use of vitamins or food supplements as CMs so this should also be addressed.

Besides communication serving the purpose of two-way information exchange, it is often a major component of the medical management in chronic and palliative care. Buckman states that compared with most medications, communication skills have undoubted symptom relieving effects, a wide therapeutic index and the most common problem in practise is sub-optimal dosing (416). At a more mercenary level, poor communication skills have been shown to be a predictor of medicolegal vulnerability. Whilst not every discussion about CMs will necessitate a change in medication or advice to actively alter current practice, it may improve patient wellbeing whilst fostering a more open relationship and also reduce the risk of medicolegal proceedings should an adverse outcome arise.

Once a discussion about CMs commences, it will quickly become apparent that patients and the medical practitioners and pharmacists providing them with healthcare advice and treatment have different attitudes.

A comparison between anaesthetists, pharmacists and Frankston hospital staff responses to attitudinal statements and the surgical patient’s responses reveals a major mismatch in beliefs about CMs and is an important finding of this study. In practice, this will present a major challenge for hospital doctors and pharmacists as they strive to practice EBPC whilst holding very different views. For example, 55% of patients
believe that CMs are appropriate for use and should be made available in a hospital setting whereas only 25% of pharmacists agree that CMs are appropriate for use in the hospital setting, 15% of anaesthetists and 16% of the Frankston staff. This raises issues of creating consensus in clinical practice as many hospital doctors and pharmacists are clearly not supportive of CMs within the hospital setting yet their patients are interested and do use them. It also raises the concern that doctors and pharmacists may risk legal liability by ignoring patients use and preference for CM (417).

Another disparity regards the perceived cost-effectiveness of CMs. Nearly half the anaesthetists and Frankston staff surveyed thought CMs are generally a waste of time and money compared with only 12% of patients. This is important to bear in mind when practitioners are considering whether CMs are worth the cost as their patients may believe that they are.

Approximately 80% of anaesthetists and Frankston staff thought that CMs are potentially dangerous and require monitoring whereas only 47% of patients agreed and thought they need to be supervised. This presents a discrepant perception about the safety of CMs and provides a further explanation as to why patients don’t feel compelled to tell staff about CMs. It is interesting to find most doctors and pharmacists agree that CMs require monitoring yet they do not themselves routinely monitor use. It is possible that protocols have not been adequately developed and implemented so clinicians are unsure how to deal with issues surrounding the use of CMs or they think the responsibility of monitoring CMs lies with someone else.

The statements about CMs requiring more research also attracted different responses with over 85% of hospital doctors and pharmacists agreeing they need more hospital based research and 59% of patients thinking they need more scientific research in general. This is somewhat expected as the practice of EBM emphasises the need to locate and use evidence when considering treatment options whereas the public appear to be less interested in the need to have scientific evidence supporting CMs products.
Whilst there is an obvious gap in beliefs between those in the hospital bed and the doctors and pharmacists standing next to it, this does not mean a meaningful conversation about CMs cannot ensue. Practitioners have an ethical obligation to respect patient values and an obligation to discuss treatment options whilst being frank about the level of understanding and experience with CMs (418). Sugarman and Burke suggest that a broad range of responses can arise when patient use and interest in CTs is identified (418). It can range from feeling a sense of obligation to stifle harmful practices, mere acceptance of non-harmful modalities to encouragement of beneficial CTs. In situations when conventional medicine is clearly ineffective, it may be somewhat easier to accept patient’s interest and use of CMs however it is more complex when conventional treatments have some evidence of efficacy yet are not entirely satisfactory. Additionally, it is more complex when a literature review reveals the available evidence does not correspond with ones personal views or is inconclusive or non-existent.

In the latter two situations, practitioners could be described as operating within a grey zone in which clinical expertise and reasoning are the main tools available and these will always be influenced by personal bias (413). This is of particular relevance for CMs as some have not yet been subjected to investigation in RCTs. It is also relevant for other CTs where controlled clinical testing may not occur for many years, leaving clinicians to work within the grey zone.

As discussed previously, when a clinician is faced with evidence which is discrepant with their personal bias, they may discuss the information with a colleague and seek reassurance however a range of other responses are also possible such as denial, disbelief, curiosity or acceptance depending on the practitioners level of awareness. It is possible that hospital doctors and pharmacists views that CMs are not cost effective, offer false hope and are potentially harmful have been major barriers preventing the integration of ‘proven’ CMs into their everyday practice. In the words of Anaïs Nin, "We don't see things as they are, we see things as we are." (419).

It can be argued that following the steps in EBM can protect against bias, however there always remains the possibility that personal bias (whether consciously or unconsciously) influences interpretation of even the most rigorously conducted
research study and painstakingly developed guidelines. In the article ‘Mindful practice’, Epstein proposes that mindful critical self reflection can help to uncover and manage personal bias (419). Furthermore, mindfulness can link evidence-based and relationship-centered care and help to overcome the limitations of both approaches. It is likely that the integration of evidence based CMs into hospital practice will require practitioners to become more self-reflective and aware of their personal biases in addition to the attainment of greater knowledge and familiarisation with CMs and development of guidelines to provide a practical direction.

4.6.2 Integration of CTs into hospital practice

For decades the concept of integration has transformed innovation and change in healthcare and consisted of forging links between providers, caregivers and patients (420). Integration reduces fragmentation and aims to improve efficiency and effectiveness in healthcare.

A national survey of 5,810 hospitals in the United States identified that 15% offered CM services with nearly half of these centres reporting that patient demand was the primary motivating factor (420). The CTs offered include: acupuncture, massage, mind-body techniques (e.g. meditation), nutritional counselling and herbal medicine counselling. Most started as outpatient clinics either employing CM practitioners or providing consultative and referral services and nearly 80% have research ties. Interviews with centre directors indicated that deciding which CTs to provide was reliant on identifying what the patients want, what doctors thought was credible and practitioner availability. In some instances, suitably qualified doctors and nurses provide CM services however this is mainly undertaken by licensed CM practitioners. Another national survey found that most hospitals offering CM services also offer external CM education programs to the community and internal education for staff (421).

Based on the practitioner survey findings, there is little practise of any CT by Victorian hospital doctors and the integration of CTs into general practice is far more advanced than in the hospital setting (166). Similarly, community pharmacists see
CM as an integral part of their practise however the same cannot be said of hospital pharmacy practice in Victoria (373). Whilst this is the current situation, these surveys identified several CTs which are widely accepted as potentially useful by hospital doctors and pharmacists and some specific CTs which are of special interest. In particular, approximately one quarter of anaesthetists would consider practising acupuncture, 35% of pharmacists would consider practising vitamin/mineral therapy and 27% herbal medicine. There is also broad acceptance of massage, meditation, hypnosis and yoga as useful modalities of little harm, and chiropractic as potentially useful but also potentially harmful.

Results from the larger surgical patient survey indicate that nearly 60% would consider hospital based massage, approximately half would consider clinical nutrition/diet advisory services and exercise consultations, over a third would consider stress management and approximately 1 in 4 would consider meditation, yoga and naturopathy. There was also patient interest in chiropractic with approximately 20% reporting they would consider use of this modality.

If a comparison is made between what patients want (arbitrarily considered as being at least 20% of patients) and what hospital doctors and pharmacists think is potentially effective (arbitrarily considered as being over 70% agreeing they are useful) then the list of CTs remaining is: massage, meditation, yoga, chiropractic and possibly acupuncture (19% surgical patients interested and 22% cardiac surgery patient) (see Figure 1). Whilst acupuncture was considered useful by nearly all hospital doctors and pharmacists, the larger patient study reported 19% would consider using it however the cardiac surgery patient survey identified 22% as showing interest, thereby placing this on the borderline. Whilst over 20% of patients also expressed an interest in clinical nutrition/dietary advice, exercise consultations and stress management, these have not been included in this analysis because the perceptions of doctors and pharmacists were not evaluated for these lifestyle approaches. If further investigation revealed they were also considered useful by a majority of practitioners, then the overlap list would be longer.
Figure 1. The overlap between what CTs patients would consider using and which CTs most hospital doctors and pharmacists think are effective.

Whilst CM services have been integrated into some hospitals in the United States, several barriers have been identified which are relevant to this discussion. Santa Ana suggests three main barriers exist: a perceived lack of research and data about CM, reimbursement complexity and conflict between medical practitioners and CM practitioners (422). Ruggie and Cohen confirm that maintaining financial self-sufficiency is difficult for many centres and ‘belief’ barriers exist whereby medical practitioners do not believe CTs are worthwhile offering (8).

The practitioner surveys identified that many hospital doctors and pharmacists have limited education about CM and knowledge of the evidence of CMs. This study did
not evaluate practitioner’s awareness of the evidence for other CTs although it did detect that many CTs are considered potentially useful. As such, the first barrier of perceived lack of research data appears to be relevant to the integration of CMs but may not be as relevant to acupuncture, massage, meditation, chiropractic and yoga. The second barrier regarding reimbursement complexity and financial sustainability was not investigated in this research project and in depth investigation of potential funding models, health insurance coverage and patients willingness to pay for services is required to establish whether this too may be a barrier.

Conflict between medical practitioners and CM practitioners is likely to be based on their philosophical differences in their understanding of health, disease, treatment and management. By focussing on the common goal of improving patient’s quality of life, these viewpoints may align more closely and conflicts avoided. U.S. surveys further indicate that CM practitioners must also be committed to teamwork and the idea of integrated care if the provision of integrated CM services is to be successful (420).

Based on experiences from Integrative Medicine (IM) centres in the United States, six factors must be taken into account when considering the integration of CTs into hospitals (8;403;423;424). These are: mission consistency, patients interests, organisational interest, scope of service, staffing and financial viability. The practitioner and patient surveys have provided baseline information for four of these factors. They have identified which CTs are of interest to surgical patients and which CTs are accepted as useful by doctors and pharmacists, although their attitudes towards hospitals offering these services was not evaluated. By cross-referencing CTs accepted by doctors and pharmacists and those of interest to patients, suggestions have been made as to which CTs could be considered within the scope of service. Identifying that most doctors and pharmacists do not consider regulation of CM practitioners as sufficiently stringent has emphasized the need to ensure staff is well trained and appropriately credentialed.

Currently Victoria is the only Australian jurisdiction to formally regulate CM therapists, requiring practitioners using the title ‘acupuncturist’, ‘Chinese herbal medicine practitioner’ or ‘Chinese medicine practitioner’ to register with the Chinese Medicine Registration board (425). All state jurisdictions have legislation for
registration of chiropractors and osteopaths however the regulation of naturopaths, Western herbalists and massage therapists remains subject to various forms of self-regulation.

As such, if CM practitioners are to be considered for the provision of CTs, training and credentialing will need to be rigorous and is extremely important. In regards to patient safety, this will be of particular importance in the provision of chiropractic and acupuncture as many respondents perceived them as potentially harmful. Meanwhile, it is feasible that hospital doctors and pharmacists could more readily accept other health care professionals providing CTs, such as anaesthetists providing acupuncture and pharmacists providing advice about herbal medicine and vitamin/mineral therapy, as they already have registration and are integrated into the hospital system. If excellence of care is to be achieved, then it is important that clinicians don’t underestimate the depth and breadth of knowledge involved in practising CTs. Appropriate training and adequate experience is essential before providing these services.

Further investigation is required to confirm these results and evaluate the level of acceptance and interest of other patient and practitioner groups at the same and other hospital sites, hospital administrators and hospital board’s level of interest and importantly, an evaluation of potential funding models.

The containment of rising healthcare costs and patient morbidity are major goals of clinicians, hospital administrators and government. CTs may offer the potential for substantial public health gains and cost savings from a number of perspectives such as in the areas of preventative medicine, optimisation of health and management of chronic diseases which are not adequately treated by conventional medical approaches. There is also the possibility of long-term cost savings such as reduced length of hospital stays and re-admission rates, reduced drug requirements and incidence of adverse events, such as admission for gastrointestinal haemorrhage due to the use of non-steroidal anti-inflammatory drugs(426). Currently there are too few studies to make firm conclusions about cost-savings for all CTs however, there is already evidence that several may be beneficial, notably spinal manipulation therapy (such as chiropractic)(426), acupuncture (426) (427) and herbal medicine (427).
Investigation of some lifestyle approaches such as meditation and yoga has also started and provided some encouraging results. For example, a 5 year study undertaken by a U.S. insurance company found that people who practise meditation had a 63% reduction in healthcare expenditure, 11.4 times fewer hospital admissions for CVD, 3.3 times fewer admissions for cancer and 6.7 times fewer admissions for mental disorders and substance abuse compared with those who did not practise meditation (428). Another example is provided by the randomised controlled study conducted by Dean Ornish which demonstrated that a comprehensive lifestyle program which included meditation, yoga and a vegetarian diet in conjunction with standard care was associated with improved quality of life, a reversal of coronary heart disease angiographically and a cost savings of $58,000 (US) per person when compared with a control group who solely received standard care (429). Since then, one of the largest health insurers in the U.S. has started offering the plan to its subscribers on site in Pittsburgh and of more than 350 participants who have participated since the programs inception, none have suffered a heart attack or stroke, none have required bypass surgery and only one has required a surgical procedure (430). Based on these impressive results, Highmark Blue Cross Blue Shield has created a new company to expand the program around the country.

4.6.3 Patient safety and CMs

CMs manufactured in Australia according to the code of Good Manufacturing Practice (GMP) and available over-the-counter (OTC) are regulated as low risk products by the Therapeutic Goods Administration however data from in vitro, in vivo and human studies and case reports indicate that adverse events and interactions with pharmaceutical medicines are possible (284). Safety is of particular concern when used without professional supervision by patients at higher risk of adverse events such as the elderly, those using multiple medicines or high alert medicines (e.g. narrow therapeutic index medicines), with reduced renal or hepatic function, with acute or serious disease or who are confused. Safety is also of concern when used by patients in situations which can put them at higher risk of adverse events such as hospitalisation (431) and the perioperative period which is often characterised by polypharmacy and surgery-induced physiological changes (398;432).
There is a culture of continual improvement in patient safety within the hospital setting. One important aspect of this relates to medication safety. Part of the strategic plan for medication safety in hospitals includes communication, error detection and reporting and the use of information to improve medication safety. Hospital doctors and pharmacists play an important role in promoting medication safety when taking medication histories and recording patient use, prescribing medicines and providing information about medicines to patients and other health care professionals.

The medical practitioner and pharmacist surveys indicate there are important omissions in the current systems which have allowed surgical patients to take potentially harmful CMs during the preoperative period without being identified or supervised by an informed practitioner. The likelihood that hospital doctors and pharmacists will be able to detect and prevent drug-CM interactions or adverse events induced by CMs is slim. The current situation makes it extremely difficult to safeguard patients from harmful outcomes associated with the use of CMs and strategies are required on multiple levels to remedy the situation.

The use of CMs in the perioperative period has important implications for anaesthetists, surgeons and their patients. Morbidity and mortality associated with CMs may be more likely in the perioperative period due to the physiological alterations that occur during this period and the frequent use of multiple pharmaceutical agents. Complications may include excessive bleeding, cardiovascular instability, prolonged or inadequate anaesthesia, adverse immunological effects and drug interactions with serious outcomes such as organ transplant rejection (398;433).

It has been reported that the most common adverse outcome after cardiac surgery is post-operative bleeding (389). As demonstrated in the cardiac patient survey, CMs with the potential to induce bleeding are being taken preoperatively by these patients however it is not known how many or to what extent complications can be attributed to their use. Well-documented usage information and case reports are valuable when considering whether bleeding may be a significant risk with CMs and provide grounds for hypothesis-testing experiments in the future. Importantly, further research is
required to determine the clinical significance of existing evidence which is often obtained from in vitro and animal studies.

Research is also required to establish whether the use of CMs together with other agents affecting coagulation (e.g. heparin and anti-platelet drugs) will further increase the risk of bleeding, as is already seen with some pharmaceutical antiplatelet medicines (434). Norred and Brinker report that potentiation of anticoagulant effects is suspected when vitamin E is used together with warfarin and documented interactions resulting in excessive bleeding have occurred when *ginkgo biloba*, garlic, devil’s claw, dan shen or dong quai were used with warfarin (248). Currently, much of this information is based on case reports and remains speculative as most lack laboratory analysis of the alleged substances.

Besides having the potential to increase bleeding risk or other unwanted effects in surgery, CMs have the potential to interact with drugs used in standard care. Both patient surveys identified that the combined use of prescription medicines with CMs is not uncommon, presenting the possibility of interactions. Of note, many patients in the larger surgical patient study had self-prescribed their CMs, over 40% were also taking prescription medicines and several were taking the herbal medicine St Johns wort which has demonstrated numerous drug interactions in clinical studies. Results from the practitioner surveys indicate that few hospital doctors are aware of interactions with commonly used CMs and checking for safety information about CMs does not regularly occur. Pharmacists were better in these regards and appear to be more likely to detect and prevent interactions if given the opportunity to screen patients.

Current knowledge of the pharmacodynamic and pharmacokinetic properties of many CMs is incomplete making it difficult to predict when patients should be advised to cease use of CMs known or suspected to affect coagulation or cause other unwanted effects. The American Society of Anesthesiologists advises anaesthetists to ask patients to discontinue use of all herbal medicines two weeks prior to surgery, the time estimated for the compounds to be fully metabolized however this time frame is largely speculative (246). Grauer proposes a more targeted approach (361) as does
Ang-Lee et al who suggest the use of various herbal medicines should be discontinued 24 hours to 7 days prior to surgery based on the available pharmacokinetic data (398). In clinical practice, following these recommendations is problematic. The patient surveys found that many do not discuss use of CMs with a health care professional within the 2 week period before admission and not all discuss use with hospital doctors and pharmacists prior to surgery. It has also yet to be established whether GPs and other healthcare professionals in the community are sufficiently informed of the potential risks associated with preoperative use of CMs and are able to provide an informed opinion to surgical patients.

This discussion of CMs safety has primarily focussed on surgical patients however CMs also have the potential to induce adverse effects in other hospital patients and patients after discharge. According to Reidle and Casillas, factors which increase the likelihood of a general adverse drug reaction include serious illness, renal insufficiency, liver disease, polypharmacy and alcoholism (435). Immune reactions also occur and are more likely in female patients, adults, those with HIV infection, concomitant viral infection, and previous hypersensitivity to a chemically related drug, asthma, specific gender polymorphisms, SLE and dependant on the route of administration (436). Although CMs have not been specifically investigated in this regard, it is likely that similar factors apply and healthcare practitioners should be particularly vigilant with these higher-risk groups.

The prevention, recognition and treatment of complications due to CMs begin with explicitly eliciting and documenting a history of CMs use and familiarisation with the scientific literature. There is an urgent need to provide hospital doctors and pharmacists with education about CMs so they are more aware of the possible risks associated with use, more confident discussing CMs with patients and more likely to document use when taking a medication history. Whilst many patients already perceive CMs as potentially unsafe, some are uncertain and many will not tell hospital staff about their use because they are not asked or don’t think it’s important. This indicates a need for patient education so they will understand the importance of discussing their use of CMs with doctors and pharmacists, regardless of whether they have been asked or not.
Whilst this research has identified the potential for ADRs induced by CMs to go undetected and unsupervised, the actual rate and extent of ADRs remains unknown. Further research is urgently required for specific CMs and their potential to induce ADRs to determine the clinical relevance of these safety issues.

4.6.4 Limitations of the surveys

The practitioner surveys have several limitations which must be acknowledged. Firstly, results and care must be taken when results are generalized to hospital anaesthetists, pharmacists and doctors nationally since the surveys were conducted in metropolitan Melbourne, Victoria. Secondly, whilst the survey instrument was pre-tested before distribution, it was newly developed and could benefit from a more rigorous validation process. Thirdly, it is possible that respondents misunderstood survey questions although it was assumed that individuals interpreted questions in the intended manner. Fourthly, AltMedDex database was used to provide answers to the knowledge section because it is widely available in Victorian hospitals through the Clinicians Health Channel however because of variations in the published literature, the use of another database or resource may have produced a different set of correct answers thereby influencing the results. Finally, this was a voluntary, self-administered survey, so incomplete data collection may have resulted in response bias.

The patient surveys also have several limitations which must be acknowledged. The results obtained provide baseline data about a select group of surgical patients attending either Cabrini or Frankston Hospitals in Victoria and care must be taken when results are generalized to surgical patients nationally. It was a voluntary survey, distributed by nurses and self-administered by patients therefore response bias due to incomplete survey distribution and data collection is possible. Additionally, whilst the survey instrument was pre-tested before distribution, it was newly developed and could benefit from a more rigorous validation process. Several other caveats are also acknowledged such as exclusion of non-English speakers and participants misunderstanding some questions and the term ‘complementary medicines’, even
though an explanation was provided. Some patients may not have been aware of the ingredients within their CMs or forgotten what was being used and have incorrectly indicated which ones they use or omitted the information entirely. Whilst the inclusion of medically prescribed CMs may be questioned as they may be considered part of standard care and not ‘complementary’, the primary aim of the study was to be exploratory in nature, and therefore it was decided to be over-inclusive.

Overall, for both the practitioner and patient surveys, survey items had been carefully constructed after extensive consultation and interviews with relevant heads of hospital departments, peers, mentors and a statistician which ensured the survey questions had face validity however a further formal validation process would have been valuable.

Whilst collecting information by a second method such as additional face-to-face interviews and then cross-referencing the results to identify emerging themes would have been beneficial, the very good response rates achieved in all surveys, amongst all groups at all sites provides confidence in the findings.
5.0 Final Conclusion

Despite many strategically orientated initiatives developed in Australia to promote EBM, it appears that CMs have been largely ignored and overlooked in the practice of Medicine and Pharmacy within the hospital system. Furthermore, it appears that in regards to CMs a ‘don’t ask, don’t tell, don’t know’ culture exists within hospitals and that evidence based patient-centred care and concordance is not being achieved and thus patient safety and wellbeing is being compromised. Further research is required however to ascertain the extent of any possible adverse outcomes.

Surgical patients have a high usage of CMs such as fish oil supplements, multivitamins, vitamin C and glucosamine supplements as well as other CMs considered as potentially increasing the risk of bleeding or inducing drug interactions. Although many CMs taken by surgical patients are medically prescribed, their usage is not routinely documented or monitored within the hospital system and it is uncommon for patients using CMs to tell hospital staff about this use, mainly because they are not asked. Thus many surgical patients are currently taking potentially harmful CMs during the preoperative period without being identified or supervised by an informed medical practitioner or pharmacist. Further research is required to ascertain whether the use of CMs is common amongst other inpatients and so enable educational and policy development to be targeted to the relevant healthcare professionals.
The unidentified and unsupervised use of CMs by surgical patients highlights some important omissions in current hospital practice. Currently, hospital doctors and pharmacists do not routinely ask patients about CMs and do not consistently document patient use despite this being considered a standard part of taking a medication history and important for QUM. Hospital staff also appear unfamiliar with the evidence around CMs and there is likely to be under-reporting of adverse events and interactions both internally (within the hospital) and externally (to spontaneous reporting schemes). There also needs to be better identification of which CMs should be ceased before surgery, when this should happen and when they can be safely reintroduced. Further clinical research is also required to evaluate the extent of adverse reactions to CMs and their clinical significance along with identifying the CMs that may help produce positive health outcomes for surgical patients.

In line with the principles of QUM, drug committees should consider the addition of safe and clinically proven CMs to hospital drug formularies, especially when they may be more cost effective than pharmaceutical treatments. The inclusion of CMs into hospital drug formularies will further promote the integration of evidence based CMs into hospital practice and allow patients improved access. It will also allow closer supervision of patient use and provide some quality assurance that products manufactured under GMP are being used.

While there is the need to further document the use of CMs by hospital patients and to establish the clinical significance of both the adverse and positive effects of these medicines, it seems that at present the data is not being collected. It is of paramount importance that all patients are asked about their use of CMs and this information is recorded in the history and medication chart. It should also be communicated to GPs via the discharge summary. The two steps of enquiry and documentation are essential first steps towards preventing, detecting and managing adverse reactions and interactions. Formal CM policy which is based on the best available evidence will ensure greater awareness amongst hospital doctors and pharmacists to elicit information from patients and document CMs use and thereby optimise patient care.

Several barriers currently prevent the inclusion of evidence based CMs into Medical and Pharmacy practice within hospitals. These barriers include a lack of confidence
amongst hospital staff in dealing with CMs-related issues which appears to stem from the perception of having insufficient knowledge, actual limited knowledge and little personal experience with CM along with irregular information seeking behaviours and little discussion with patients. Furthermore while hospital medical staff and pharmacists support further hospital-based research on CMs, they appear to maintain a sense of wariness about CMs expressing concerns about their safety, efficacy and cost effectiveness. Barriers also exist at the organisation level as many hospitals do not have a designated CM policy or CM guidelines.

While hospital staff currently have little training in or knowledge of, CMs many practitioners are interested in further education in this area. Education is urgently required at a post-graduate and under-graduate level to ensure current and future medical practitioners and pharmacists can provide patients with informed, evidence based advice about CMs. In this way patients will not only be safeguarded against the use of potentially harmful treatments but also be prescribed safe and effective CMs.

More reliable internet-based and electronic CM databases and reference texts are required within various hospital settings including libraries, pharmacy departments and wards. Staff continuing education sessions are necessary to ensure that practitioners are aware of these resources and able to retrieve the information. Communication with CM practitioners may also be useful when patients are unable to provide adequate details of the CMs they are taking. The appointment of dedicated staff in the hospital, ideally with both mainstream and CM qualifications, would provide a further resource as well as providing leadership in regards to maintaining and disseminating information about CMs in the hospital.

There is substantial interest in hospital-based diet, lifestyle and CTs by surgical patients with 85% of surgical patients stating that they would consider using CTs if offered by hospitals. Furthermore, a majority of hospital based practitioners perceive CTs as potentially useful and express personal interest in receiving and practising some CTs. This was most notable amongst anaesthetists and pharmacists. Several CTs are accepted by doctors and pharmacists as potentially useful, especially acupuncture, massage and meditation, whereas chiropractic and the medicinal CTs were considered potentially harmful. Medical practitioners further consider hypnosis as a useful
modality whereas fewer pharmacists are of the same opinion and are more likely to consider Chinese medicine, herbal medicine and vitamin/mineral therapy as potentially useful. Despite this interest and the growing evidence base to suggest that some CTs have proven health benefits, there is currently little practise of CTs by Victorian hospital doctors and the integration of CTs into general practice is far more advanced than in the hospital setting (166). Similarly, community pharmacists see CM as an integral part of their practise however hospital pharmacy do not appear to have actively embraced CMs as part of their scope of practice (373).


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About this Survey

The following survey has been designed to assess hospital patient’s understanding of herbal products and supplements and their influence on health. The study hopes to identify areas where practices can be improved. The results from this survey are to be used as part of a PhD project conducted by Lesley Braun under the supervision of Prof Marc Cohen in the School of Health Sciences at RMIT University. No identifying personal information will be recorded and all information will be treated as confidential and anonymous. No information from the survey will be given to any health care professional involved in your care and answering this survey is voluntary and will not influence the care that you receive in hospital. The pooled results will be written up for publication in a medical journal and information may be released through the media. Data will be kept for a period of 5 years. For further information about this project please contact Lesley Braun or Prof Marc Cohen on 9925 7440.

It is estimated this survey will take you approximately 10-15 minutes to complete. Participation is voluntary and your consent is implied by you completing the survey. If you do not wish to fill in the survey, just put back into the envelope and return it - your decision will not affect the care you receive.

This survey has been approved by the Human Research Ethics Committee at RMIT University and the Cabrini Hospital Ethics Committee. Any complaints about your participation in this project may be directed to the Secretary, RMIT Human Research Ethics Committee, University Secretariat, RMIT, GPO Box 2476V, Melbourne, 3001. Telephone (03) 9925 1745. Details of the complaints procedure are available from the above address.

Survey on complementary medicine use in hospital patients

In this survey, the phrase ‘complementary medicines’ refers to herbal medicines, vitamin and mineral supplements and food supplements which are products that can be bought in a supermarket, pharmacy, health-food store, on the internet, from a mail order company or from a practitioner. It does not refer to therapies such as massage, acupuncture or chiropractic unless specified.

1) What is your age? (please specify) ________ years

2) What is your gender? □ Male □ Female

3) What is your highest level of education?
   □ Did not complete high school □ Completed high school
   □ Completed technical studies/apprenticeship □ Completed university studies

4) What is your country of birth?
   □ Australia □ Other – (please specify) ____________________________________________

5) What is your smoking status?
   □ Current Smoker □ Past Smoker □ Non-Smoker

6) What is your level of household income per year?
   □ Less than $20,000 □ $20,001 - $60,000 □ $60,001 - $100,000 □ over $100,000

7) Why are you in hospital?
   □ Unsure
   □ Surgery (please specify what type) _____________________________________________
   □ Health problem (please specify) _____________________________________________
   □ Injury (please specify) _____________________________________________________
8) How long do you expect to be in hospital?
   - [] Less than a day
   - [] Overnight stay
   - [] More than one night stay

9) How many different prescription medicines have you taken in the 2 weeks before being coming to hospital?
   - [] None
   - [] Unsure
   - [] One (1)
   - [] Two (2)
   - [] Three (3)
   - [] Four (4)
   - [] Five (5)
   - [] More than five

10) How many different complementary medicine products have you taken in the 2 weeks before coming to hospital?
    - [] None (go directly to question 20 on the last page)
    - [] Unsure
    - [] One (1)
    - [] Two (2)
    - [] Three (3)
    - [] Four (4)
    - [] Five (5)
    - [] More than five

11) Please indicate which complementary medicines products you took in the 2 weeks before coming to hospital.
    (Please tick as many as appropriate)
    - [] Multivitamins
    - [] Vitamin C
    - [] Vitamin E
    - [] Vitamin B complex
    - [] Fish Oil
    - [] Evening primrose oil
    - [] Calcium supplements
    - [] Coenzyme Q10
    - [] Valerian
    - [] Policosanol
    - [] Ginkgo Biloba
    - [] Garlic tablets or more than 1 clove/day
    - [] Ginger tablets
    - [] Licorice (the herb)
    - [] Glucosamine
    - [] Echinacea
    - [] Ginseng (Korean or Panax)
    - [] Horseradish tablets
    - [] St John’s Wort (hypericum)
    - [] Feverfew
    - [] Grapeseed extract
    - [] Guarana
    - [] Liquid herbs
    - [] Chinese herbal medicine
    - [] Other (please specify below)

12) Who recommended or prescribed the complementary medicine products you are taking?
    - [] GP
    - [] Specialist
    - [] Pharmacist
    - [] Health food shop staff
    - [] Friend/Relative
    - [] Myself
    - [] Complementary medicine practitioner (eg naturopath/herbalist)

13) Are you taking a complementary medicine product for the problem that brought you to hospital?
    - [] No
    - [] Yes (please specify which complementary medicines)
14) With whom did you discuss your use of complementary medicine products during the 2 weeks prior to coming to hospital?

(Please tick as many as appropriate)

☐ I did not discuss this with anyone (Go to Question 18)
☐ Can’t remember or unsure
☐ General Practitioner
☐ Anaesthetist
☐ Physician (medical specialist)
☐ Surgeon
☐ Hospital Pharmacist
☐ Community Pharmacist
☐ Nurse
☐ Hospital information form
☐ Natural Therapist
☐ Other (please specify) ________________________________

15) If you did not tell anyone in the hospital about your use of complementary medicine products was it because:

(Please tick as many as appropriate)

☐ I was not asked
☐ I didn’t think it was important
☐ The hospital doctors would not understand
☐ It’s none of their business
☐ I did not want to be judged negatively
☐ I did not want to appear ‘disloyal’
☐ Other reasons (please specify) ________________________________

16) Do you intend to continue taking your complementary medicine products while in hospital?

☐ Yes ☐ No ☐ Don’t know

17) How will you obtain your complementary medicine products while in hospital?

☐ I brought them to hospital myself
☐ Family or friends will bring them in
☐ They will be delivered by a pharmacist
☐ They will be delivered by a naturopath or herbalist
☐ Other way of receiving them (please specify) ________________________________

18) Why do you take complementary medicine products?

(Please tick as many as appropriate)

☐ To maximise my health and well-being
☐ To prevent disease(s)
☐ To treat disease(s) (please state which disease(s)) ________________________________
☐ Other (please specify) ________________________________

19) On average how much do you spend on complementary medicine products per month?

☐ Less than $25 ☐ $26 to $50 ☐ $51 to $75
☐ $75 to $100 ☐ $100 - $150 ☐ More than $150
20) Which of the following people **directly asked you** about your use of complementary medicine products? *(Please tick as many as appropriate)*

- [ ] General Practitioner
- [ ] Anaesthetist
- [ ] Surgeon
- [ ] Physician ( medical specialist)
- [ ] Hospital pharmacist
- [ ] Community pharmacist
- [ ] Nurse
- [ ] None of the above people asked
- [ ] Can’t remember or unsure

20) Which of the following statements about complementary medicine products do you think is correct?

- [ ] All are safe
- [ ] Some are safe
- [ ] None are safe
- [ ] Don’t know

21) Where do you go to for **general information** about complementary medicine products?

*(Please tick as many as appropriate)*

- [ ] I don’t ask or look for general information about natural and complementary medicines
- [ ] Parents, family or friends
- [ ] Media
- [ ] Internet
- [ ] Books or magazines
- [ ] Pharmacist
- [ ] Other *(please specify)*

22) Where do you go to for **safety information** about complementary medicine products?

*(Please tick as many as appropriate)*

- [ ] I don’t ask or look for safety information about natural and complementary medicines
- [ ] Parents, family or friends
- [ ] Media
- [ ] Internet
- [ ] Books or magazines
- [ ] Pharmacist
- [ ] Other *(please specify)*

23) Which of the following complementary therapies, would you consider using if they were made available in hospitals?

*(Please tick as many as appropriate)*

- [ ] Stress Management
- [ ] Dietary Advice
- [ ] Exercise Consultation
- [ ] Massage
- [ ] Chiropractic
- [ ] Osteopathy
- [ ] Chinese Herbal Medicine
- [ ] Homeopathy
- [ ] Hypnosis
- [ ] Naturopathy
- [ ] Meditation
- [ ] Acupuncture
- [ ] Herbal medicine
- [ ] Aromatherapy
- [ ] Ayurvedic Medicine
- [ ] Yoga
- [ ] None of the above
- [ ] Other *(please specify)*

**THANKYOU FOR TAKING THE TIME TO COMPLETE THIS SURVEY**
About this Survey

The following survey has been designed to assess hospital patients use and understanding of herbal products and supplements and their influence on health. The study hopes to identify areas where hospital practices can be improved. The results from this survey are to be used as part of a PhD project conducted by Lesley Braun under the supervision of Prof Marc Cohen in the School of Health Sciences at RMIT University. No identifying personal information will be recorded and all information will be treated as confidential and anonymous. No information from the survey will be given to any health care professional involved in your care and answering this survey is voluntary and will not influence the care that you receive in hospital. The pooled results will be written up for publication in a medical journal and information may be released through the media. Data will be kept for a period of 5 years. For further information about this project please contact Lesley Braun or Prof Marc Cohen on 9925 7440.

It is estimated this survey will take you approximately 10-15 minutes to complete and consists of 6 pages. Participation is voluntary and your consent is implied by your completing the survey. If you do not wish to fill in the survey, just put back it into the envelope and return it - your decision will not affect the care you receive.

This survey has been approved by the Human Research Ethics Committee at RMIT University and Peninsula Health. Any ethical complaints about your participation in this project may be directed to the Convenor, Peninsula Health Research and Ethics Committee on 9784 7695.

Survey on complementary medicine use in hospital patients

In this survey, the phrase ‘complementary medicines’ refers to herbal medicines, vitamin and mineral supplements and food supplements which are products that can be bought in a supermarket, pharmacy, health-food store, on the internet, from a mail order company or from a practitioner. It does not refer to therapies such as massage, acupuncture or chiropractic unless specified.

1) What is your age? (please specify) ________ years

2) What is your gender? □ Male □ Female

3) What is your highest level of education?
   □ Did not complete high school □ Completed high school
   □ Completed technical studies/apprenticeship □ Completed university studies

4) What is your country of birth?
   □ Australia
   □ Other (please specify)______________________________________

5) What is your smoking status?
   □ Current Smoker □ Past Smoker □ Non-Smoker
6) Why are you in hospital?
☐ Surgery - please specify what type
_________________________________________________________________
_________________________________________________________________
☐ Medical condition/s – please list them
_________________________________________________________________
_________________________________________________________________
☐ Injury – please specify
_________________________________________________________________
☐ Unsure

7) How long do you expect to be in hospital?
☐ Less than a day ○ Overnight stay ○ More than one night stay

8) Please indicate which of the following people in the hospital directly asked if you were taking any nutritional supplements, herbal products or complementary medicines?  
   Tick as many as appropriate
☐ Surgeon ○ Nurse ○ Anaesthetist ○ Hospital pharmacist
☐ Physician (medical specialist) ○ None of the above people asked
☐ Can’t remember or unsure

9) How many different prescription medicines have you taken in the 2 weeks before coming to hospital?
☐ None ○ Unsure ○ One (1) ○ Two (2)
☐ Three (3) ○ Four (4) ○ Five (5) ○ More than 5

10) How many different vitamin, mineral or herbal products or complementary medicines have you taken in the 2 weeks before coming to hospital?
☐ Unsure ○ One (1) ○ Two (2) ○ Three (3)
☐ Four (4) ○ Five (5) ○ More than five
☐ None (please go directly to question *21 on page 5 to continue the survey)

11) On average, how much do you spend on nutritional supplements, herbal products or complementary medicines each month?
☐ Less than $15 ○ $16 to $30 ○ $31 to $50
☐ $51 to $75 ○ $76 to $100 ○ More than $100
12) Here is a list of popular supplements and complementary medicines. Please tick the boxes to indicate which ones you have taken or are taking now.

<table>
<thead>
<tr>
<th>Supplement/Substance</th>
<th>I was taking in the 2 weeks before coming to hospital</th>
<th>I am taking while in hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multivitamins</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Calcium supplements</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Magnesium supplements</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Iron supplements</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Coenzyme Q10</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Antioxidants (e.g. Macuvision®)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Vitamin B complex (e.g. Berocca®)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Fish oil capsules (omega 3 essential fatty acids)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Glucosamine</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Echinacea</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Ginkgo biloba</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Ginger tablets / capsules / liquid</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Garlic product or eating 1 clove daily</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Evening primrose oil</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>St John’s wort (Hypericum)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Liquorice (the herb)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Policosanol</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Ginseng (Korean or panax)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Valerian</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Celery (the herb)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Liquid herbs</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Chinese herbal medicine(s)</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

- If the product or complementary medicine(s) you have been taking or are still taking is not in the list, or you are not sure, please write down the name(s) on the following line.

------------------------------------------------------------------------------------------------------------------
13) Why do you take nutritional supplements, herbal products or complementary medicine/s? *Tick all the answers that apply to you*

- [ ] keeps me healthy / prevents disease
- [ ] gives me a sense of control
- [ ] gives me a sense of wellbeing
- [ ] because they have few side effects
- [ ] fits into my way of life / philosophy
- [ ] they are less expensive
- [ ] problem not serious enough to see a doctor
- [ ] they work better or just as well as conventional medicines
- [ ] they were recommended by my doctor, pharmacist or friend
- [ ] to treat a specific disease(s) or condition
- [ ] Other reason for taking them – *please specify*

14) Who recommended or prescribed your nutritional supplement, herbal product or complementary medicine/s? *Tick all the answers that apply to you*

- [ ] GP
- [ ] Medical specialist
- [ ] Pharmacist
- [ ] Health food shop staff
- [ ] Friend / Relative
- [ ] Myself
- [ ] Naturopath / herbalist
- [ ] Other – *please specify*

15) How effective is the nutritional supplement, herbal product or complementary medicine/s you have been taking or are taking now?

- [ ] ineffective / useless
- [ ] very effective
- [ ] slightly effective
- [ ] extremely effective
- [ ] effective enough
- [ ] don’t know, unsure

16) How will you obtain your nutritional supplements, herbal products or complementary medicines while in hospital?

- [ ] I brought them to hospital myself
- [ ] Family or friends will bring them in
- [ ] They will be delivered by a pharmacist
- [ ] They will be delivered by a naturopath or herbalist
- [ ] Other way of receiving them *(please specify)*

18) With whom did you discuss your use of nutritional supplements, herbal products or complementary medicines during the 2 weeks before coming to hospital? *Tick all answers that apply to you*

- [ ] I did not discuss this with anyone
- [ ] General practitioner (GP)
- [ ] Surgeon
- [ ] Community pharmacist
- [ ] Physician (medical specialist)
- [ ] Health food store staff
- [ ] Anaesthetist
- [ ] Naturopath / herbalist
- [ ] Can’t remember or unsure
- [ ] Other person – *please specify below*
19) Who have you told in the hospital about your use of nutritional supplements, herbal products or complementary medicines? *Tick all answers that apply to you*

- [ ] I did not discuss this with anyone
- [ ] Surgeon
- [ ] Physician (medical specialist)
- [ ] Anaesthetist
- [ ] Can’t remember /’ unsure
- [ ] General practitioner (GP)
- [ ] Nurse
- [ ] Naturopath / herbalist
- [ ] Wrote it on hospital form
- [ ] Other person – please specify

20) If you did not tell anyone in the hospital about your use of these products, was it because: *Tick all answers that apply to you*

- [ ] I was not asked
- [ ] I didn’t think it was important
- [ ] hospital doctors would not understand
- [ ] I did not want to be judged negatively
- [ ] Other reasons - please specify
- [ ] It’s none of their business
- [ ] I did not want to appear ‘disloyal’
- [ ] not applicable

*21) Which of the following statements about complementary medicines do you think is correct?  *Tick one box from each list*

- [ ] All are safe
- [ ] None are safe
- [ ] Some are safe
- [ ] Don’t know
- [ ] They are safer than conventional medicines
- [ ] They are just as safe as conventional medicines
- [ ] They are not as safe as conventional medicines

22) Where do you go for information about vitamin, mineral and herbal products, complementary medicines or therapies? *Tick all the answers that apply to you*

- [ ] I don’t ask or look for information about these medicines
- [ ] Parents, family or friends
- [ ] Media (e.g. TV, newspaper)
- [ ] Internet
- [ ] Books or magazines
- [ ] Pamphlets in stores
- [ ] Product labels
- [ ] G.P.
- [ ] Medical specialist
- [ ] Surgeon
- [ ] Anaesthetist
- [ ] Community pharmacist
- [ ] Pharmacy shop staff
- [ ] Nurse
- [ ] Naturopath / herbalist
- [ ] Health food store
- [ ] Other – please specify on line below
23) Do you agree or disagree with the following statements? 
(Please tick one box in each column)

- Complementary, alternative medicines and therapies
  - should be made available in hospitals [ ] [ ] [ ] [ ] [ ]
  - are generally a waste of time and money [ ] [ ] [ ] [ ] [ ]
  - can be dangerous and need to be supervised [ ] [ ] [ ] [ ] [ ]
  - offer people a false sense of hope [ ] [ ] [ ] [ ] [ ]
  - need more scientific research [ ] [ ] [ ] [ ] [ ]
  - are something most of my friends would consider [ ] [ ] [ ] [ ] [ ]

24) Which of the following complementary and alternative therapies have you used in the last month or are still using now? 
(Tick all the answers that apply to you)

- Stress Management [ ]
- Exercise Consultation [ ]
- Chiropractic [ ]
- Acupuncture [ ]
- Hypnosis [ ]
- Meditation [ ]
- Naturopathy [ ]
- Aromatherapy [ ]
- Unsure [ ]
- Other – please explain __________________________________________

25) Which of the following complementary and alternative therapies would you consider using if they were made available by hospitals? 
(Tick all the answers that apply to you)

- Stress Management [ ]
- Exercise Consultation [ ]
- Chiropractic [ ]
- Acupuncture [ ]
- Hypnosis [ ]
- Meditation [ ]
- Naturopathy [ ]
- Aromatherapy [ ]
- Unsure [ ]
- Other - please suggest a therapy ________________________________

26) What is your level of household income per year?

- Less than $20,000 [ ]
- $20,001 - $45,000 [ ]
- $45,001 - $60,000 [ ]
- $60,001 – $100,000 [ ]
- over $100,000 [ ]

THANK YOU FOR TAKING THE TIME TO FILL IN THIS SURVEY
About this Survey

The following survey has been designed to assess hospital staff’s attitudes and understanding of complementary medicines and therapies and their influence on patient health and safety. The study hopes to identify areas where current practice can be improved. The results from this survey are to be used as part of a PhD project conducted by Lesley Braun under the supervision of Prof Marc Cohen in the School of Health Sciences at RMIT University. No identifying personal information will be recorded and all information will be treated as confidential and anonymous. The pooled results will be written up for publication in a medical journal and information may be released through the media. Data will be kept for a period of 5 years. For further information about this project please contact Dr Michael Ben Meir on 0413089529 or at the Emergency Department on 95081500 or Lesley Braun on 0417362900 or Prof Marc Cohen on 99257440

It is estimated this survey will take you approximately 15 - 20 minutes to complete.

Participation is voluntary and your consent is implied by you completing this survey.

This survey has been approved by the Human Research Ethics Committee at RMIT University. Any complaints about your participation in this project may be directed to the Secretary, RMIT Human Research Ethics Committee, University Secretariat, RMIT, GPO Box 2476V, Melbourne, 3001. Telephone (03) 9925 1745. Details of the complaints procedure are available from the above address.

Survey on complementary medicine use in hospitals

In this survey, the phrase ‘complementary medicines’ refers to herbal medicines, vitamin and mineral supplements and food supplements which are products that can be bought in a supermarket, pharmacy, health-food store, on the internet, from a mail order company or from a practitioner. It does not refer to therapies such as massage, acupuncture or chiropractic unless specified.

1) What is your position in the hospital?
   □ Obstetrician / gynecologist  □ Emergency Medicine Doctor  □ Paediatrician
   □ Hospital pharmacist           □ Anaesthetist
   □ Physician/Specialist – (please specify specialty) __________________________
   □ Surgeon (please specify specialty) _________________________________________
   □ Other (please specify) ___________________________________________________

2) What is your age? (please specify) ________ years

3) What is your gender?  □ Male    □ Female

4) How many years have you been in practice? (please specify) ________ years

5) Are you directly involved in patient care?  □ Yes  □ No (go to question 14)

6) What is the average number of patients you see each week? ______________

7) Do you ask patients about use of complementary medicines?
   □ Always  □ Often – more than 60% of the time
   □ Sometimes – (30% – 59%)  □ Occasionally -(5% –29%)
   □ Rarely – less than 5%  □ Never (go to question 9)

Comment ________________________________________________________________
8) If you do ask patients about use, what do you do with this information?
(Please tick as many as appropriate)
- Verbally inform relevant surgeon, anaesthetist or physician about CM use
- Verbally inform other health professionals about CM use (eg. pharmacist, dietician)
- Don’t record patient use
- Record use in the patient history
- Record use on inpatient medication chart
- Other (please specify below)

9) Reasons for not asking patients about complementary medicines use include:
(Please tick as many as appropriate)
- It’s too time consuming
- I forget to ask
- I don’t have the opportunity to ask
- I don’t have sufficient knowledge about it
- I don’t think it is relevant
- I assume patients will tell me
- Other (please specify below)

10). Do you feel confident that you have sufficient knowledge to identify when complementary medicines could adversely affect patient care?
- Always
- Often – more than 60% of the time
- Sometimes – (30% – 59%)
- Occasionally -(5% – 29%)
- Rarely – less than 5%
- Never

Comments -

11) How often do you check for side effects and drug interactions if complementary medicines are being used?
- Always
- Often – more than 60% of the time
- Sometimes – (30% – 59%)
- Occasionally -(5% – 29%)
- Rarely – less than 5%
- Never

12) What advice do you generally give to patients who are taking complementary medicines? (Please tick as many as appropriate)
- I don’t feel confident to advise on complementary medicines use
- Advise them to consult another health care practitioner about complementary medicines
- Advise them to keep taking all their complementary medicines
- Advise them to cease taking all their complementary medicines
- Advise them to cease taking specific complementary medicines (Please specify which ones below)

Comments

THANKYOU FOR TAKING THE TIME TO COMPLETE THIS SURVEY
13) What percentage of your patients do you think take complementary medicines products in the 2 weeks prior to coming to hospital?

☐ None  ☐ Less than 10%
☐ 10%-25%  ☐ 26%-40%
☐ 41%-50%  ☐ 51%-60%
☐ 61%-70%  ☐ above 70%

14) What percentage of your patients do you think take complementary medicines products during their hospital stay?

☐ None  ☐ Less than 10%
☐ 10%-25%  ☐ 26%-40%
☐ 41%-50%  ☐ 51%-60%
☐ 61%-70%  ☐ above 70%

15) To what extent do you agree with the following statements:
(Please tick one box in each column)

<table>
<thead>
<tr>
<th>Complementary medicines</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither agree or disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>are appropriate for use in a hospital setting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>are generally a waste of time and money</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>are potentially dangerous and need to be monitored</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>offer a false sense of hope and exploit vulnerable individuals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>offer patients cost effective treatment options</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>need more hospital based research</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>are something that most of my colleagues would consider</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>regulations for complementary medicine practitioners need to be tightened</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

16) Where do you source information about complementary medicines and therapies?
(Please tick as many as appropriate)

☐ I don’t refer to any sources  ☐ Reference texts such as MIMs
☐ Databases such as Pubmed/medline  ☐ Internet – world wide web eg. google
☐ Peer-reviewed medical journals  ☐ Medical media/non peer reviewed journals
☐ Seminars / conferences/ lectures  ☐ Community or hospital pharmacist
☐ Friends and/or family  ☐ Colleagues
☐ Complementary medicine practitioners  ☐ Health food shop staff
☐ Company literature  ☐ Other *(please specify)* __________________________
17) What level of training have you had about complementary medicine and therapies

☐ No formal training
☐ Lectures during my postgraduate training
☐ Lectures in my undergraduate course
☐ Self directed study
☐ Attended specific lectures / seminars
☐ Formal study (cert/diploma/degree)
☐ Other (please specify) ____________________________

18) Are you interested in receiving further training about complementary medicines/therapies?

☐ Not interested
☐ Interested

19) How important do you think it is for education on complementary medicine to be included in the medical undergraduate curriculum?

☐ Not Important
☐ Somewhat Important
☐ Very important

20) Below is a list of commonly used complementary medicines. Which ones (if any) do you consider to have the following properties. (Please tick as many as appropriate)

<table>
<thead>
<tr>
<th>May increase the risk of bleeding</th>
<th>Has CNS sedative activity</th>
<th>Has proven clinical use</th>
<th>Interacts with warfarin</th>
<th>Interacts with digoxin</th>
<th>Interacts with SSRIs</th>
<th>Interacts with cyclosporin</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Unsure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2) Chamomile</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3) Co Q10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4) Echinacea</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5) Ginger</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6) Garlic</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>7) Ginkgo Biloba</td>
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<td>8) Glucosamine</td>
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<td>9) Fish oils</td>
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<td>10) St John's Wort</td>
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<td>11) Valerian</td>
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<td>12) Vitamin E</td>
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THANKYOU FOR TAKING THE TIME TO COMPLETE THIS SURVEY
21) **Indicate your opinion of the potential usefulness AND potential harmfulness in general, of the following complementary therapies by ticking the appropriate boxes**

(Please tick “No opinion” or one box in each category)

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<thead>
<tr>
<th>NO OPINION</th>
<th>USEFULNESS</th>
<th>HARMFULNESS</th>
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<td>NOT USEFUL</td>
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<td>o) Yoga</td>
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<td>p) Other ___________ (please specify)</td>
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Comments:

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THANKYOU FOR TAKING THE TIME TO COMPLETE THIS SURVEY
22a) Have you *received, or considered receiving*, treatment yourself with any of the following therapies?

22b) Have you *practiced or considered practicing* any of the following therapies?

*(Please tick as many as appropriate)*

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a) Acupuncture
b) Aromatherapy
c) Chinese Herbal Medicine
d) Chiropractic
e) Herbal Medicine
f) Homeopathy
g) Hypnosis
h) Massage
i) Meditation
j) Naturopathy
k) Osteopathy
l) Reflexology
m) Spiritual Healing eg Reiki
n) Vitamin / Mineral Therapy
o) Yoga
p) Other ____________________________ (please specify)

Have you personally used any vitamin, mineral, herbal or other supplement in the past 4 weeks?
If so please list them below.

_________________________________________________________________________________
_________________________________________________________________________________
23) **If a patient asked you whether they should use, or consult a practitioner of one of the following therapies how would you generally respond?**

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<tr>
<th>Therapy</th>
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<td>o) Yoga</td>
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<td>p) Other (please specify)</td>
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</tbody>
</table>
24) In the past 4 weeks can you estimate how many patients have you seen who you consider to have experienced the following:

<table>
<thead>
<tr>
<th>DON’T KNOW or UNABLE TO ESTIMATE</th>
<th>ADVERSE EVENT from a complementary therapy</th>
<th>INTERACTION between complementary therapy and medical therapy</th>
<th>INAPPROPRIATE WITHDRAWAL from medical therapy by a complementary therapist</th>
<th>DELAY IN DIAGNOSIS or effective treatment due to inappropriate use of complementary therapies</th>
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<tbody>
<tr>
<td>No of patients</td>
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<tr>
<td>p) Other (please specify)</td>
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Please write the number of corresponding patients in each box or place a zero or line through boxes that do not apply to your patients.
Complementary and Alternative Medicines

Use of Complementary and Alternative Medicines (CAMs) by Inpatients

VicTAG Working party: Carmela Corallo (Eastern Health), Michael Dooley (Peter MacCallum Cancer Centre), Kay Dunkley (VDUAC), Helen Leach (Melbourne Health), Brian Lilley (Royal Children’s Hospital), Chris O’Callaghan (Austin Health), Mary O’Reilly (Eastern Health), Bill Thomson (VDUAC), Phung To (Austin Health), Sue Wright (Eastern Health).

Other contributors: Deborah Foy, Corporate Counsell, Eastern Health, Lesley Braun, Pharmacist, Naturopath, Herbalist and Industry Consultant, PhD Candidate RMIT.

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Complementary and Alternative Medicines

Preamble
This resource document has been developed by VicTAG as a model that can be adapted to the needs of individual health care facilities in accordance with hospital policy and the approval of the hospital’s Drug and Therapeutics Committee. The model aims to encourage open disclosure and discussion about the use of CAMs by patients and their health care providers in order to promote patient safety and minimise adverse events.

- Currently 50 to 60% of the adult population use CAMs on at least an annual basis. Australian data suggest that 39% of people taking CAMs will also consume conventional medicines. CAMs are also commonly administered by parents or guardians to paediatric or dependant patients.
- Information about CAMs is variable. Some CAMs have good quality evidence about their benefits and risks, whereas others have very limited information about their effects. For this reason, interactions with other medicines, conditions and procedures can be unpredictable. Use of CAMs can lead to adverse drug interactions and increase the risk of bleeding during or after surgery.
- It is important to be open-minded and non-judgmental about CAMs and encourage patients/carers to inform healthcare professionals if they have been using them, and if they wish to continue their use while in hospital.
- Taking a positive, pro-active approach to CAM usage is important in order to maintain a positive professional relationship with the patient/carer and apply an evidence-based approach to minimizing patient harm.

Definitions
The primary body that regulates drug registration in Australia is the Therapeutics Goods Administration (TGA). It is a requirement under the Therapeutic Goods Act 1989 (the Act) that medical products to be imported into, supplied in, or exported from Australia be included in the Australian Register of Therapeutic Goods (ARTG) as either a registered medicine or a listed medicine. In order for a product to be included in the ARTG, a sponsoring company is required to make an application, which usually consists of a form accompanied by data to support the quality, safety and efficacy of the product. Individually compounded medicines prepared for an individual do not have to be registered or listed.

Registered medicines
Prescription medicines
Medicines assessed as having a higher level of risk must be registered (not listed). The degree of assessment and regulation they undergo is rigorous and detailed, with sponsors being required to provide comprehensive safety, quality and efficacy data. Prescription medicines fit into the sub-category of registered medicines as high-risk registered products. This group includes all prescription medicines (ie. medicines with ingredients which are included in Schedule 4 or Schedule 8 of the Standard for the Uniform Scheduling of Drugs and Poisons) and some specified products such as sterile injectables. These medicines are identified by an ‘Aust R’ number on their packaging e.g. for Lipitor®, the Aust R number is 59603.

Non-prescription (OTC) medicines
Low-risk Registered products are non-prescription medicines. They usually contain ingredients which are described in Schedule 2, Schedule 3, and sometimes Schedule 5 or 6 of the Standard for the Uniform Scheduling of Drugs and Poisons. Products in this category are considered to be lower risk than prescription medicines. However, they still require a high level of scrutiny, for example to ensure adequate labelling for appropriate use.
Complementary and Alternative Medicines

Listed medicines
Listed medicines are usually considered to be relatively benign, so the regulations allow for sponsors to 'self assess' their products in some situations. The majority of listed medicines are self-selected by consumers and used for self-treatment. They are all unscheduled medicines (ie. not described in the Standard for the Uniform Scheduling of Drugs and Poisons) with well-known established ingredients, usually with a long history of use, such as vitamin and mineral products or sunscreens. These are assessed by the TGA for quality and safety but not efficacy. This does not mean that they do not work. It simply means that the TGA has not evaluated them individually to see if they work. It is a requirement under the Act that sponsors hold information to substantiate all of their product's claims. For example, sunscreens can be a listed product yet, they must have complied with testing under the Australian standard for sunscreens. These medicines are identified by an ‘Aust L’ number on their packaging e.g. for CoEnzyme Q®, the Aust L number is 69050.

Complementary and alternative medicines (CAMs)
CAMs describe a group of products that are not presently considered to be part of ‘conventional medicine’. People use CAMs in a variety of ways. CAMs used alone are often referred to as ‘alternative therapies’. CAMs used in addition to ‘conventional medicine’ are referred to as ‘complementary’ or ‘integrative’. CAMs include vitamin, and mineral supplements, herbal medicines, other nutritional supplements, traditional medicines such as ayurvedic medicines and traditional Chinese medicine (TCM), homeopathic medicines and aromatherapy oils. CAMs may be either registered or listed, depending on their ingredients and the claims made. Most CAMs included in the ARTG are listed and some are registered. Individually compounded CAMs prepared for an individual and some other CAMs (particularly those imported from overseas) are usually not registered or listed. The quality of such products may vary or not be known.

Special Access Scheme (SAS)
The SAS refers to arrangements that provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis. It requires approval from the TGA or from a delegate appointed to act on TGA's behalf.

Hospital Formulary
Within the hospital, medications can be:
(a) **Available on the formulary.** This means that doctors in the hospital are authorised to prescribe them and the hospital is able to supply them. There can be some restrictions on who can prescribe formulary medications and these restrictions usually relate to cost and safety. Some formulary items may also be prescribed by nursing staff e.g., paracetamol. To be available on the formulary, medications must be assessed by the Drug and Therapeutics Committee or equivalent body that is responsible for drug therapy within the hospital. This committee has the authority to add any medicinal compound to the formulary. Some CAMs may be available on the hospital formulary for example calcium supplements, folic acid, vitamin and mineral supplements etc.

(b) **Non formulary items.** Many medications that are registered or listed for use by the TGA are not on the formulary. This may be because they are new products and an application for inclusion on the formulary has not been made, there may be no perceived need for that medication to be available on the formulary e.g., a similar medication of the same class may already be available, or a decision may have been made not to include the medication on the formulary because of concerns about cost, safety or efficacy. If a patient is already using a non formulary medication when admitted to hospital they may be asked to provide their own supply in circumstances when the medication is not readily available within the hospital.
Complementary and Alternative Medicines

When non formulary items, including CAMs, are being prescribed frequently a submission should be made to the hospital’s Drug and Therapeutics Committee or equivalent body for formulary inclusion. The hospital Drug and Therapeutics Committee or equivalent body will then evaluate the safety and efficacy of the medications.

Other Definitions
Guardian – the term guardian, as used in these guidelines, refers to those who have the legal right to make decisions on behalf of a patient, this may include parents.
Carer – the term carer as used in these guidelines refers to any person who may assist in the care of a patient and includes parents, guardians, other family members and friends. A carer is not able to make decisions on behalf of a patient unless they have been legally appointed as a guardian.

Guideline statement
This guideline is not an endorsement for or against general use of CAMs, rather, it is an acknowledgement by the hospital that CAMs are widely used by the public. This guideline aims to provide procedures within the hospital for the handling of CAMs and can be modified in accordance with local hospital policy as approved by the hospital’s Drug and Therapeutics Committee.

The hospital has a duty of care to all patients to ensure that any materials, drugs, substances or equipment supplied to or used by inpatients including any CAMs used within the hospital, whether patient/carer administered or not, are used as safely as possible taking into account quality, safe dosage and storage, and usage.

This guideline applies to CAMs where use is initiated by in-patients or by their guardians, and the CAM(s) is/are brought into the hospital to be administered during their stay in hospital. It does NOT apply where use of the CAMs is initiated and prescribed by hospital clinicians. These fall within general hospital policies about the supply, administration, and safe storage of medicines.

The fundamental requirements within the guidelines are:
• It is the patient’s or their guardian’s prerogative if they wish to continue using CAMs, however, they must discuss this with their treating doctor(s), particularly if the CAMs will be taken during their inpatient stay.
• The treating doctor(s) must decide whether to approve usage or advise the patient or their guardian against use. The doctor should also advise the patient and their carers of any changes to their primary treatment which are necessary because of the patient’s use of CAMs and document this in the medical record.
• When the use of CAMs is approved by the doctor they must be prescribed on the Medication Chart and be administered by the nursing staff.
• When the doctor advises the patient or their guardian that use of CAMs is not recommended but the patient or their guardian wishes to continue using these CAMs, the patient or their guardian is required to sign a usage statement listing products used without their doctor’s approval and self medicate with documentation on the CAM Self Medication Chart. The doctor should also sign the usage statement to indicate that they have advised against the use of the listed CAMs during the hospital stay and note why they have recommended against the use of the listed CAMs.
• The CAM Self Medication Chart must be kept with the Medication Chart. A note should be made on the Medication Chart to indicate that the CAM Self Medication Chart is being used.
• When CAMs are prescribed on the Medication Chart or recorded on the CAM Self Medication Chart a full description of the product including active ingredient(s), brand name, strength and the dosage must be recorded.
Complementary and Alternative Medicines

- Patients and their carers are responsible for the procurement of their own supply of CAMs (unless they are available on the hospital formulary and prescribed by a medical officer).
- The hospital and the treating doctor(s) do have a duty to advise a patient or their guardian of any risks which may arise given the patient’s or their guardian’s wish to continue with any CAMs. The hospital and the treating doctor(s) may determine, in the patient's best interest, that they should not provide any treatment or service which will increase any risk to the patient’s health, given the patient’s or their guardian’s wish to continue use of any CAMs. In all circumstances the doctor(s) should ensure that the advice given and the decision of the patient is clearly documented in the medical record.
- Suspected adverse drug reactions or interactions involving CAMs should be reported to the Adverse Drug Reaction Advisory Committee (ADRAC) in the same manner as for ‘conventional medications’. The same hospital procedures for handling suspected adverse drug reactions or interactions should be applied to both CAMs and ‘conventional’ medicines.

Responsibilities

Responsibilities of patient or guardian
- To notify clinical staff of any CAMs they are using and/or wish to use during their inpatient stay.
- To obtain approval from their treating doctor if they wish to use CAMs during the inpatient stay.
- If the patient or their guardian is advised by their treating doctor that use of any CAMs is not recommended and the patient or their guardian wishes to use the CAMs against medical advice, the patient or their guardian is required to:
  1. Sign a usage statement listing the products.
  2. Self medicate with documentation on the CAM Self Medication Chart.
  3. Notify nursing staff when doses are required.
  4. Inform nursing staff when doses are administered.
- To supply any CAMs not available on the hospital formulary.
- To give the CAMs, in their original packaging clearly labelled with the patient's name, to nursing staff to safely store in the locked ward cupboard, locked bedside locker, drug trolley or other medication storage facility.

Responsibilities of hospital clinical staff
- Hospital clinical staff should not administer CAMs or permit the administration of CAMs by patients or carers except according to the hospital policy.
- On admission, medical, nursing and pharmacy staff should specifically ask patients and carers about use of CAMs when taking the medication history.
- On admission patients and their carers should be provided with the CAM patient information brochure.
- Discuss with the patient and their carers the use of CAMs with the aim of ensuring that:
  - the patient and their carers can distinguish between CAMs that may be helpful and those that are potentially harmful.
  - the patient and their carers are advised:
    - of the importance of disclosing information about use of CAMs to health care professionals because interactions with other prescribed and over the counter medications can be unpredictable. In certain cases there is strong evidence to say that these interactions are harmful.
    - that quality control is not guaranteed with all CAMs in the same way as conventional medicines.
    - the possibility of any risk of interaction with their primary treatment.
    - the possibility of any risks associated with a procedure.
    - of any potential adverse effects.
Complementary and Alternative Medicines

- how to report any adverse effects or withdrawal effects associated with using CAMs.
- Communicate with other health professionals involved in the care of the patient regarding the use of CAMs as required with the patient’s or guardian’s permission.

Responsibility of the treating doctor(s)
- To seek information about the potential effects and quality of the patient’s CAMs
- Provide information about the potential effects and quality of the patient’s CAMs to the patient and their carers.
- To ensure that the patient and their carers have been provided with the CAM patient information brochure.
- Decide whether to approve the use of CAMs or advise against use of CAMs during the hospital stay.
- If the decision is to approve use of CAMs during the inpatient stay then to prescribe the CAMs on the Medication Chart as with other pre-admission medication. A full description of the product including active ingredient(s), brand, strength and dosage must be recorded.
- If the decision is to advise against use then to advise the patient and their carers that the use of the specified CAMs is not recommended and explain why they are not recommended and document this in the patient’s medical record.
- Advise the patient and their carers of any changes to their primary treatment which are necessary because of the patient’s use of CAMs and document this in the patient’s medical record.
- If the patient or their guardian wish to continue the use of CAMs against medical advice then to:
  1. Document this decision and the CAMs being used in the patient’s medical record.
  2. Ask the patient or their guardian to sign the usage statement listing the products being used against medical advice.
  3. Sign the usage statement and document the reasons why the products are not recommended.
  4. Ask the patient or their guardian to complete the CAM Self Medication Chart.
- Ensure that any use of CAMs is recorded in the patient’s medical record and on the discharge summary (including if they are not used during inpatient stay). The information recorded should include:
  - discussions regarding the approval process;
  - the name of the CAMs being used;
  - when and how administered;
  - in what dosage; and
  - who is responsible for administration.
- Record and report any adverse reactions as per hospital guidelines.

Responsibility of nursing staff
- Monitor use and safe storage of CAMs.
- Safely store CAMs in the locked ward cupboard, locked bedside locker, drug trolley or other medication storage facility.
- Provide CAMs to patients and their carers when they are to ‘self administer’ a dose.
- Only administer CAMs when prescribed on the medication chart.

Resources

Useful resources for information about CAMs
- Hospital Drug Information Centre
- Altmedex (from Clinician’s Health Channel)
- Review of Natural Products (Facts & Comparisons)
- AusDI – herbal monographs
Complementary and Alternative Medicines

- Herbal Medicines (Pharmaceutical Press, UK)
- Natural Medicines Comprehensive Database (http://www.naturaldatabase.com/)
Appendix 1

**CAM self medication chart**

Name:

UR number:  
*or affix patient label*

This chart is to be filled out by the patient or guardian and must be kept with the Medication Chart at all times.

\[ √ = \text{medication taken} \quad x = \text{not taken} \]

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<tr>
<th>CAMs</th>
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Appendix 2.

Complementary & Alternative Medicines (CAM) Usage Statement for Inpatients

Background
CAMs describe a group of products that are not presently considered to be part of ‘conventional medicine’. People use CAMs in a variety of ways. CAMs used alone are often referred to as ‘alternative therapies’. CAMs used in addition to ‘conventional medicine’ are referred to as ‘complementary’ or ‘integrative’. CAMs include vitamin, and mineral supplements, herbal medicines, other nutritional supplements, traditional medicines such as ayurvedic medicines and traditional Chinese medicine (TCM), homeopathic medicines and aromatherapy oils.

This hospital has a duty of care to all patients to ensure that CAMs used within the hospital, whether self-administered by the patient or guardian or not, are used as safely as possible, taking into account quality, safe dosage and storage and appropriate use. If inpatients wish to use CAMs within this hospital, they may use them only within the guidelines.

For the full guideline refer to the pharmacy department.

If a patient or their guardian wishes to use CAMs while he/she is an inpatient, he/she must first discuss it with his/her treating doctor. If the doctor recommends against use but the patient or guardian still wishes to use the CAMs they must sign the CAM usage against medical advice statement.

Patient/guardian section
I…………………………………….(patient/guardian) of………………………………………………
………………………………………………………………………………………………….…(address)
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AGAINST THE ADVICE OF THE TREATING DOCTOR Dr ………………………………………
I have been advised that continuing use of these CAMs is not, in the opinion of the above named doctor, in my/the above named patient’s best medical interests. Despite receiving this advice, I wish to continue use of the CAM(s) listed above.
I have been given the opportunity to obtain information on the effects and interactions between these CAMs and other medicines and procedures. I understand that there may be limited information available and therefore I have been advised that some adverse effects and interactions that may present a risk to me/the patient named above may occur and cannot be predicted.

I have been given a copy of the CAM brochure and I agree to:
1. Supply the CAM(s) for myself/the patient named above.
2. Take/give the dose recommended by the supplier of the CAM(s).
3. Notify nursing staff when I take/give each dose of CAM(s).
4. Label the CAM(s) with my/the patient’s name and give the CAM(s) to nursing staff to store.
5. Record on the CAM Self Medication Chart when each dose has been taken.

I agree to take/give the CAMs according to the above conditions and the guideline as outlined.

Patient or guardian name  Signature  Date

Medical practitioner section
I…………………………………………………..medical practitioner of ……………………………..
……………………………………………………………………………………………………………….(address)

have advised ………………………………………………………(name of patient or their guardian)

that in my opinion continuing treatment with the CAM(s) listed above is not in the best medical interest of this patient because of the following reasons………………………………………………

……………………………………………………………………………………………………………….

……………………………………………………………………………………………………………….

……………………………………………………………………………………………………………….

Medical practitioner name  Signature  Date
Using Complementary and Alternative Medicines (CAMs)

What are complementary and alternative medicines (CAMs)?
CAMs describe a group of products that are not presently considered to be part of conventional medicine. People use CAMs in a variety of ways. CAMs used alone are often referred to as ‘alternative’ therapies. CAMs used in addition to ‘conventional’ medicine are referred to as ‘complementary’ or ‘integrative’. CAMs in Australia include herbal medicine, vitamin and mineral supplements, other nutritional supplements, traditional medicines such as ayurvedic medicines and traditional Chinese medicine (TCM), homeopathic medicines and aromatherapy oils. An herbal practitioner or naturopath or your general practitioner may have prescribed these. You may have purchased them from a pharmacy, supermarket, health food store, on-line or you may have prepared them at home using ingredients passed on by generations of family members.

How can I be sure that CAMs are safe and effective?
A common misconception with CAMs is that many people think that because they are “natural” they are safe. However harmful effects have occurred and can be quite serious, such as liver poisoning. It is therefore important to discuss all medicines including CAMs with your doctor. In Australia, registered medicines are required to meet strict standards. Most medicines prescribed by your doctor are TGA registered. This means that there are scientific studies to prove that they are safe and effective. An ‘Aust R’ number on their packaging identifies these medicines. Medicines can also be TGA listed. Listed medicines are considered to be safe, but there may be limited information to say that they are effective. These medicines have an ‘Aust L’ number on the label.
If a medicine or CAM does not have an Aust R or L number there is limited information to say that it is safe and effective and the quality of the product may vary or not be known.

Use of CAMs in hospital
Information about CAMs is variable. Some CAMs have good quality evidence about their benefits and risks, whereas others have very limited information about their effects. For this reason their interactions with other medicines, conditions and procedures can be unpredictable. We want to provide you with the best care we can. By telling medical staff, nursing staff or the pharmacist about ALL your medicines including CAMs, we can discuss with you the risks or benefits about continuing them while you are in hospital.

You need to tell your doctor, nurse and pharmacist about:
♦ All medicines prescribed by your GP and any specialists.
♦ Patches, HRT (hormone replacement therapy), eye drops, inhalers.
♦ Creams, ointments or lotions used for medical conditions.
♦ CAMs, eg Naturopathy, homeopathy, health shop products.
♦ Pharmacy medicines available without a prescription.
♦ Vitamins, mineral, supplements and herbs.
♦ Preparations prescribed by your naturopath or herbalist.
♦ Traditional herbal preparations used by your family.
If in doubt, ask your doctor, nurse or pharmacist.

CAMS and interactions with other medicines
Over half of the Australian population use CAMs each year. Many will take conventional medicines at the same time. Information about interactions is increasing, but some effects are still unpredictable. For your safety, your doctor may recommend that you cease your CAMs when new medication is started.
For example the following CAMs may increase the risk of bleeding in patients who are taking warfarin, though the effect can depend on the amount you are taking: Carnitine, Celery, Dong Quai, Evening Primrose Oil, Fish Oils, Garlic, Ginger, Ginkgo, Korean Ginseng, Policosanol, Vitamin E.
Complementary and Alternative Medicines

These are only examples and it is important that you speak to your doctor or pharmacist to see if there is any risk of interactions between your CAMs and conventional medicines.

CAMs and surgery
If you are booked or admitted for surgery you should always tell your doctor or pharmacist about all your medicines, including CAMs. Some CAMs can lead to complications during or after surgery.
For example the following CAMs may increase your risk of bleeding during or after surgery, though the effect can depend on the amount you are taking:
Celery, Devil's Claw, Dong Quai, Feverfew, Vitamin E, Garlic, Ginkgo, Korean Ginseng, Green Tea, Policosanol.
Other CAMs can affect blood pressure and blood sugar which may cause problems when you have an anaesthetic.
Your doctor may advise stopping your CAMs for about a week before surgery to minimise the risk of complications. However, if you have any concerns about stopping your CAMs you should discuss this with your doctor. The products listed are only examples and it is important to provide your doctor with a full list of all the medicines you are taking, including CAMs.

What if I wish to keep taking CAMS in hospital?
If you wish to continue taking CAMs during your hospital stay discuss this with your treating doctor. Occasionally we may advise you to stop taking CAMs, because of concerns about possible interactions with conventional medicines, risks associated with a procedure or with your medical condition. If your doctor recommends that you stop your CAMs during your hospital stay but you wish to continue using them we will ask you to sign a usage statement.
Your doctor will explain the reasons why you should stop taking any CAMs

If I get side effects from starting or stopping CAMs should I report this?
It is important that you tell medical staff, nursing staff or the pharmacist about any side effects that you think may be caused by starting or stopping CAMS so that they can be reported. This information may help healthcare professionals to assess the benefits and risks both for you and for other patients in the future.

Will the hospital supply CAMs?
If you are continuing the use of CAMs during your admission, you may use your own supply of CAMs during your hospital stay. These will be locked safely in the hospital’s medicine cupboard, in accordance with our medicines policy. You can ask the nursing staff for them when you need them. The hospital will not be responsible for supplying or administering CAMs unless prescribed by your doctor.

Our responsibilities
• To ask you about all of your medicines.
• To advise you about the safety of all medicines.

Your responsibilities
• To tell us about all of your medicines.
• To tell us if you wish to continue taking a complementary medicine while you are in hospital.
• To supply your own complementary medicines while you are in hospital.
• To give all your medicines to the nurses for safe storage.

Where can I obtain more information about CAMs?
You should always discuss your CAMs with your doctor or pharmacist.
The NPS Medicines Line is a consumer medication information service that is available on weekdays during normal business hours on 1300 888 763
Interpreter Services
Patients and carers who experience English language difficulties may ask to have a professional interpreter to assist with any queries about the information provided. Please ask the staff to make arrangements for an interpreter to visit whilst in hospital. Telephone interpreter service 131450

This brochure is available in translation.
Appendix 4

Flowchart for use of CAMs

**Patient wishes to use CAM(s) whilst in hospital.**

- **No**
  - Treating doctor approves of CAM(s) use.

- **Yes**
  - Prescribe CAM(s) on the medication chart:
    - Include full description of product and dosage.
    - If the product is a non-formulary item, ask patient to provide own supply.
    - All CAM(s) to be labelled with the patient’s name and kept in locked medication storage facility.

  - Treating doctor to counsel patient or guardian regarding risks associated with continued use of CAM(s).

  - **Yes**
    - Patient signs usage statement. Treating doctor documents reasons for recommendation and signs usage statement.
    - Patient or carer records non-approved CAM(s) on the CAM Self Medication Chart including a full description of the product and dosage.
    - Record the use of the CAM Self Medication Chart on the Medication Chart and keep the two charts together.
    - Patient or carers to supply all CAMs in original containers and labelled with the patient’s name.
    - All CAMs kept in locked medication storage facility.

  - **No**
    - Patient wishes to continue use of CAMs.

    - **Yes**
      - Discontinue use and document in the patient’s medical record.

    - **No**
      - Patient signs usage statement. Treating doctor documents reasons for recommendation and signs usage statement.
      - Patient or carer records non-approved CAM(s) on the CAM Self Medication Chart including a full description of the product and dosage.
      - Record the use of the CAM Self Medication Chart on the Medication Chart and keep the two charts together.
      - Patient or carers to supply all CAMs in original containers and labelled with the patient’s name.
      - All CAMs kept in locked medication storage facility.
28 January 2005

Lesley Braun
3 Meek Street
BRIGHTON VIC 3188

Dear Lesley

Re: Reducing clinical risk in surgical patients taking complementary medicine products

Thank you for your recent request for approval to conduct an anonymous survey, for the project referred to above.

On behalf of the Alfred Human Research Ethics Committee, I would like to inform you that your survey activity, as outlined in your proposal has been approved to be conducted at The Alfred.

Please contact me if you require any further information.

Yours sincerely,

Rowan Frew
Ethics Manager
Research & Ethics Unit
22\textsuperscript{nd} June 2004

Dear Lesley

Cabrini Pharmacy are pleased to be involved in your complementary medicine research project. A pharmacist will distribute the surveys to patients prior to surgery whilst on the wards and collect them once completed. If you have anything else that needs to be attended to please do not hesitate to let us know.

Thank you,

\[signature\]

Amanda Footit
Director of Pharmacy
21st June, 2004

DRAFT

Dear

Lesley Braun is a PhD. Student at the RMIT who is conducting research into the safety of complementary medicines in surgical patients. In particular, their interactions with our standard therapies and the influence on the risk of complications, such as haemorrhage.

Ultimately, she will produce a resource tool which can be applied to reduce the risk of adverse effects of such medication.

As part of the project, she would need to survey our patients. Each survey should take no more than 10 minutes and then should be completed by the patient on the evening before surgery. It would be most convenient if the survey forms could be distributed to those patients by the nursing staff on admission to the ward with instruction that after completion, they should be placed in the accompanying envelope which would then be sent by internal mail to the pharmacy.

Ms. Braun has presented this plan to the cardiac surgical group at Cabrini Hospital and has received unanimous support for it.

Yours sincerely

GIL SHARDEY
CONVENOR CARDIAC SURGICAL GROUP
GS:RKP
RESEARCH & ETHICS COMMITTEE
APPROVAL TO COMMENCE PROJECT

Peninsula Health REF NO: 2004-31 Health Professional Survey at Frankston Hospital.
Lesley Braun

Date: 19 July 2004

Complimentary Medicine Study – Survey of health professionals, including Physicians. Approval for Survey was given by Dr P Bradford. This approval was ratified by the Research & Ethics Committee at the June meeting.

Dr Peter Bradford
Research & Ethics Committee
Peninsula Health
PO Box 52
Frankston Victoria 3199 Australia
Telephone 03 9784 7777

Peninsula Health
RESEARCH & ETHICS COMMITTEE
RESEARCH PROPOSAL
APPROVAL TO COMMENCE TRIAL

21 June 2005

Mrs L Braun
C/- J Sharp
Thoracic Research
Peninsula Health

Dear Researcher,

The Research & Ethics Committee advises that your Trial, listed below, has Full Approval to commence.

TRIAL DETAILS:
Ref 2005-27 Reducing clinical risk in surgical patients taking complementary medicine products. Principal Researcher: Mrs Lesley Braun (non sponsored) Duration of Trial: June 2005-December 2005

DATE OF CONSENT FORM & PATIENT INFORMATION FORM (Implied consent) May 2005
All documentation presented to the Research & Ethics Committee is covered by this approval.

PLEASE NOTE THAT IT IS A CONDITION OF APPROVAL THAT ANY ETHICAL ISSUES MUST BE REPORTED TO THE CONVENOR OF THE COMMITTEE IMMEDIATELY YOU BECOME AWARE OF THEM.
All Amendments, Modification etc must be presented to the Research & Ethics Committee.
Adverse events must be forwarded to the Research & Ethics office. VMIA will be then be notified.
An Annual Progress Report is required.

Recommendations from Committee:
This trial is fully approved with the following recommendations.
• Exclusion to the Trial: The documentation should clearly show that "If a patient is suffering from 'obvious confusion' the patient will automatically be excluded."
• The following is drawn to the researcher's attention:
• Refer Application Form: Point 8, Q: "Are hospital services required for the research?" No is indicated, this should be changed to "Yes". Refer Point 14 of the Application: Referee declaration: Dr Brian Wood's name is to be included. Reference to Dr Fiddes
Researcher has acknowledged recommendations from Committee (21.6.05)

Carolian Dodd - Convenor
Research & Ethics Committee

At Peninsula Health we value:
Service Integrity Compassion Respect Excellence Professionalism
25th June 2004

Ms Lesley Braun  
C/- RMIT  
Faculty of Life Sciences  
Department of Complementary Medicine  
Bundoora Campus

Dear Lesley

Re: A Survey of Surgical patients in the Use of Complementary Medicines. Ph.D Study

I write to confirm my approval for you to survey surgical patients in Cabrini Hospital, Malvern.

It is my understanding that you will run a trial survey on wards 1 North and 1 South and following this trial, the other hospital surgical wards will be surveyed.

With best wishes for your research.

Yours sincerely

[Signature]
Professor Sandra Legg  
Director of Nursing
3rd May 2005

Lesley Braun
Meek Street
Brighton VIC 3186

Dear Lesley,

FLSAPP 14 – 04 Reducing clinical risk in surgical patients taking complementary medicine products

Thank you for your email dated 4th April 2005 applying for an extension to your study to include the anaesthetics department at the Austin Hospital.

Your request was tabled at meeting 03 – 05 held on Wednesday 6th April 2005. I am pleased to inform you that the committee has approved this request. It was also noted by the committee that the Austin Hospital HREC had approved this request in January 2005

An extract of the minutes is given below. You may also note in this extract of minutes that the committee have given their approval for me to review any further minor inclusion / modifications to your project and give approval when appropriate.

4.2 Modifications to Applications for Consideration

14 – 04 BRAUN Reducing clinical risk in patients taking complementary medicine products

An application for expansion of this project to include the anaesthetics department at the Austin Hospital was tabled. The committee approved this application. It is noted that the Austin Hospital HREC at a meeting held on the 21/01/05 also gave approval.

The RMIT HREC-SC committee gave approval for the Chair (Barbara Polus) to review any further inclusions / modifications to this project and the Chair may approve minor amendments as appropriate to this application

Let me take this opportunity to wish you all the best with your research.

Yours faithfully,

Dr Barbara Polus,
Chair, Science, Engineering & Technology Portfolio
HREC Sub-committee (Biomedical)

cc: March Cohen
3rd September 2004

Lesley Braun
3 Meek Street
Brighton
Vic 3186

Dear Lesley

FLSAPP 14 – 04 BRAUN Reducing clinical risk in surgical patients taking complementary medicine products

Thank you for submitting your amended application for review.

I am pleased to inform you that the committee has approved your application for a period of **12 months to September 2005** Subject to receipt of a complete clean copy of you updated proposal, once this has been received your research may proceed.

The committee would like to remind you that annual reports are due during December for all research projects that have been approved by the Human Research Ethics Sub Committee.

The necessary form can be found at:
http://www.rmit.edu.au/browseID=6sqpx7so8wkg;STATUS=A%3FQRY=human%20ethics&STYPE=ENTIRE

Yours faithfully,

Barbara Polus,
Chair, Science Engineering & Technology
Portfolio HREC Sub-committee (Life Sciences)

cc: Marc Cohen
Peter Obendorf
9th December 2004

Dear Lesley,

FLSAPP 14 – 04 BRAUN “Reducing clinical risk in patients taking complementary medicine products”

Thank you for your letter regarding an amendment / extension to your research project. The committee reviewed your request at meeting 11 – 04 on Wednesday December 1st 2004

It was noted under G2 on your original application that the following Hospitals would be used for data collection purposes. Monash Medical Centre, (Clayton Campus), Frankston Hospital, Cabrini Hospital and Alfred Hospital. The committee further noted that it has only sighted an Ethics approval / Hospital approval letter from the Cabrini Hospital. The committee must sight these documents prior to the commencement of data collection. The committee requests that these documents be forwarded to Julie Barnett at your earliest convenience.

I am pleased to inform you that the committee has recommended that your request to extend your study sample to include Pharmacy staff at the Austin Hospital and Royal Melbourne Hospital be approved subject to receiving the relevant approval from both these organisations

If you require any further clarification please contact me on 9925 7714 or via email Barbara.palus@rmit.edu.au

Once you have met these requirements you will receive confirmation that you can commence your research.

Yours faithfully,

Barbara Polus,

Chair, Science Engineering & Technology
Portfolio HREC Sub-committee (Life)

cc: Marc Cohen
12 August 2004

Ms Lesley Braun  
C/- Prof Marc Cohen  
RMIT University  
Swanston Street  
MELBOURNE  VIC  3000

Dear Lesley

01-09-08-04

Complementary medicines use in surgical patients.

The Cabrini Human Research Committee discussed your project at its meeting on 9 August 2004. The questionnaire was approved for use after the following amendments are incorporated:

- increasing the font size to at least 12 pitch; and
- including the Cabrini complaints person.

The questionnaire would be enhanced by the incorporation of a definition of complementary medicine.

Please advise whether input from nurses has been considered. It is noted that nurses are expected to administer the study. It is acknowledged that prescribers are surveyed.

The focus groups are not yet approved, due to lack of information. Please clarify who will be recruited to the focus groups, what their role will be, how focus groups will be conducted and their expected outcomes.

Prof Legg and A/Prof Lording have been delegated by the CHREC to review your amendments and give final approval.

We look forward to hearing from you.

Yours sincerely

Val Johnson  
Manager  
Cabrini Human Research Ethics Committee
Friday 19 November 2004

To HRE-SC

RE Amendment/ extension of our research project

Dear Dr Polus and members of the HRE-SC,

I am very pleased to report that the Complementary Medicines in Hospitals study is progressing well and generating a lot of interest. Last week I was invited to speak at the Victorian Therapeutic Advisory Group meeting about this research project and have since been asked to formally advise on their Complementary Medicine in hospital guidelines. This meeting was attended by Directors of pharmacy departments at numerous Victorian hospitals and has generated further support for the project.

As a result, I would like to extend the sample to include hospital staff at two other Victorian hospitals in addition to the ones listed in the original ethics application. Specifically, I would like to include pharmacy staff at the Austin hospital and Royal Melbourne Hospital as these hospitals have large departments and their involvement will greatly aid the study.

The purpose of this letter is to ask permission for the sample to be extended to include these two additional groups. The same survey tool will be used and provided with envelopes to preserve anonymity and data collection will be undertaken in the same way. Directors of each department have been notified and are aware of the project.

I look forward to hearing from you soon.

Kind regards,

Lesley Braun

Marc Cohen
9th December 2004

Dear Lesley,

**FLSAPP 14 – 04 BRAUN “Reducing clinical risk in patients taking complementary medicine products”**

Thank you for your letter regarding an amendment / extension to your research project. The committee reviewed your request at meeting 11 – 04 on Wednesday December 1st 2004

It was noted under G2 on your original application that the following Hospitals would be used for data collection purposes. Monash Medical Centre, (Clayton Campus), Frankston Hospital, Cabrini Hospital and Alfred Hospital. The committee further noted that it has only sighted an Ethics approval / Hospital approval letter from the Cabrini Hospital. The committee must sight these documents prior to the commencement of data collection. The committee requests that these documents be forwarded to Julie Barnett at your earliest convenience.

I am pleased to inform you that the committee has recommended that your request to extend your study sample to include Pharmacy staff at the Austin Hospital and Royal Melbourne Hospital be approved subject to receiving the relevant approval from both these organisations

If you require any further clarification please contact me on 9925 7714 or via email Barbara.polus@rmit.edu.au

Once you have met these requirements you will receive confirmation that you can commence your research.

Yours faithfully,

Barbara Polus,

**Chair, Science Engineering & Technology**

Portfolio HREC Sub-committee (Life)

cc: Marc Cohen
Hi Lesley

Project Title       Reducing clinical risk in patients taking complementary medicine products
Project No         H2003/02130

I am pleased to be able to advise you that your study has been approved under the Expedited Ethical Review Process pending advice from Kent Garrett that he is happy for his staff to participate. The study may commence once we receive this advise.

This approval will be tabled at the next HREC meeting on 20.01.2005 for ratification.

regards
Pauline

Pauline Jacklin
Administrative Secretary
Research Support Unit

Tel 9496 4090

-----Original Message-----
From: Lesley Braun [mailto:lgbraun@bigpond.net.au]
Sent: Monday, 20 December 2004 11:57
To: JACKLIN, Pauline
Subject: expedited HREC forms attached

Hello Pauline, here is the information regarding the complementary medicine survey.
If you need more, please don't hesitate to ask, kind regards, Lesley Braun

*******************************************************************************
This email contains confidential information intended only for the person named above and may be subject to legal privilege and confidentiality obligations imposed by legislation or be subject to intellectual property protection or copyright. If you are not the intended recipient, any use, disclosure, copying or distribution of this transmission is prohibited. If you have received this message in error, please notify us immediately by return email and delete the original email and any attachments. Austin Health provides no guarantee that this transmission is free of virus or that it has not been intercepted or altered.
*******************************************************************************
Hello Lesley

Just a quick note to let you know that your extension was approved at Monday night's meeting.

You will receive written notification as soon as we get the chance to type the letter!

Best wishes

Val Johnson
Manager, Cabrini Clinical Education and Research Institute
183 Wattletree Rd
Malvern 3144

ph 9508 1376
fax 9508 1993

email vjohnson@cabrini.com.au

This email and any attachments may be confidential, and are intended solely for the use of the individual(s) or entity to whom they are addressed. If you are not the intended recipient of this communication, please notify the sender immediately and delete the email and any attachments. Cabrini does not guarantee that this email is virus or error free.
Dear Lesley,

I have been given authority by the HRE-SC to recommend approval for this extension of your study (Frankston cohort) subject to the condition that, as you outlined below, the methods for distributing and collecting surveys is the same as has been previously approved at Cabrini, that the survey is essentially the same as those previously approved by the HRE-SC except that minor changes that need to be made so that relevant questions are asked for each survey group and that copies of the final survey are delivered to Julie Barnett so they can be filed along with your application. Frankston HREC approval also needs to by sighted and filed by us.

A copy of the extract of the minutes which determined this method of handling extensions to your project will be forwarded to you as quickly as possible.

I wish you well in your research endeavours.

 Regards,

Dr. Barbara Polus  
Chair, HRE-SC (Biomedical)  
SET Portfolio  
RMIT University

Hi Barb,  
The study is progressing very well and data is pouring in at the moment from austin and alfred hospitals.

The Frankston staff survey has achieved over a 70% response rate with all medical and pharmacy staff. Needless to say, they are now interested to have their patients included in the study to determine actual patient use and attitudes at their site.  
A research assistant from the Dept of Thoracic medicine is available and has agreed to undertake data collection of 2 key groups at the hospital -  
a/ surgical inpatients  
b/ oncology outpatients  

Together, with Dr Gary Braun (Thoracic physician at frankston hospital - also my husband), we will fill in the ethics papers for that site so i would like to apply to extend the study to include these patients. The surgical inpatient population will be given their survey in a blank envelope on the ward by the research nurse who will also collect them which is essentially the same methodology as before. The same patient survey as has been used at Cabrini will be used for this group.  

The oncology outpatient group will be given their survey whilst waiting to be seen by their Dr in the outpatient waiting area. Once again, the survey is an anonymous one and will be delivered in a blank envelope. This patient survey will have minor modifications from the cabrini patient survey and a sample of the finalised survey will be forwarded to you when complete.
Thanking you in advance,
Lesley Braun

---

Dear Lesley

Thanks for your enquiry. You have ethics approval to conduct this survey in Anaesthesia.

Best wishes.

Rowan Frew
Ethics Manager, Research & Ethics Unit
Alfred Hospital
Commercial Road
Melbourne VIC 3004
Ph +613 9276 3848
Fax +613 9276 2222
Email r.frew@alfred.org.au

-----Original Message-----
From: Lesley Braun [mailto:lgbraun@bigpond.net.au]
Sent: Wednesday, 9 March 2005 10:47
To: r.frew@alfred.org.au
Subject: CM study at the Alfred

Good morning Rowan,
The complementary medicine study has started with the Alfred's Pharmacy department and I am now contacting you in regards to extending the study to include staff anaesthetists. I have contacted Paul Myles who has agreed for his department to be involved and now would like to apply for ethics approval so we can move ahead.
The same survey will be used as the one already approved for the pharmacists which is an anonymous, self administered survey.

Thanks, Lesley Braun
Cabrini hospital surgical patients – phase 2
Modification to cardiac patient surveys for general surgical patient survey.

Having completed the pilot study amongst inpatients on wards 1 north and 1 south, it is now clear that some modifications would be desirable to the original survey.

These modifications are in blue on the attached sample survey and in summary, are the following –

a. deletion of 2 questions  
b. changed positioning of several questions  
c. condensing 2 questions into one question with new question/answer format for easier patient use  
d. addition of 2 new questions (1 from the approved staff survey) for more information about patient attitudes  
e. addition of extra answer options for some questions to provide more specific information  
f. clarification of the term ‘complementary medicines’ throughout the survey

In detail, these changes are the following -

1. Although the phrase complementary medicine was defined on the first page, it appears that further clarification is required within the actual survey. As such, the phrase has been expanded and is now ‘vitamin, mineral, herbal products or complementary medicines’ or ‘nutritional supplements, herbal products or complementary medicines’ where appropriate.

2. Nursing staff suggested that some respondents were not interested in filling out the survey because it asked them to divulge their income. In order to encourage more participants, this question has now been placed at the end of the survey.

3. The list of complementary medicines has been expanded to include additional answers that have been received from respondents in the pilot study. E.g. magnesium and zinc supplements

4. The position of previous question 20 has been shifted to appear earlier in the survey and is now after question 12. This means people are asked why they take complementary medicines after recording which ones they take. This should provide more accurate information. Answers to this question have also been expanded to allow more details to be recorded.

5. The position of previous question 22 has been shifted to appear earlier in the survey and is now after question 7.

6. The position of previous question 19 has been shifted to appear earlier in the survey and is now after question 10.

7. Question 15 is a new question and asks people about their perception of how effective their complementary medicines are. This will help to determine why they are taking them and may be an influence on disclosure rates.

8. In questions 18 and 19, the term ‘natural therapist’ has been replaced with ‘naturopath / herbalist’ which is more specific.

9. Previous questions 13 and 25 have been removed.

10. Previous questions 11 and 14 have been condensed into new question 12. Now people are asked which complementary medicines they were taking 2 weeks prior to admission and which ones they are still taking in hospital within the same question. The format is also different to make this question easier to answer.

11. Question 21 – a new answer option has been added

12. Question 23 is a new question. This is adapted from question 14 in the approved staff survey. It provides all respondents with an opportunity to express negative or positive attitudes to complementary medicine.