



## Complementary medicines use amongst elective surgery patients at a public tertiary hospital: A prospective observational cohort study in Australia



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### ABSTRACT

**Background:** and purpose. Complementary medicines (CM) use may result in untoward effects perioperatively. The study purpose is to identify CM pattern of use amongst elective surgery patients, and improve effectiveness of information collection relating to CM use.

**Materials and methods:** This is a prospective observational cohort study. CM questionnaire was administered alongside standard hospital forms at pre-admission clinic over eight weeks.

**Results:** 992 patients attended pre-admission clinic; 317 patients were included in analysis. Introduction of CM questionnaire increased disclosure rate by 11.7% giving a total prevalence of 44.2%. CM use was significantly higher in females and in older patients. Top CM reported were vitamin D (12%) and omega-3 (12%). Majority of patients did not plan to withhold CM before surgery, and were not concerned about perioperative risks.

**Conclusion:** Pre-admission clinics need to encourage CM disclosure. Patient education of potential risks and greater engagement of clinicians in patient assessment is required.

### 1. Introduction

Complementary and alternative medicine (CAM) is a broad term that encompasses products and practices that do not fit into conventional treatment practice, and are used by patients for the purpose of prevention or treatment of illness, ranging from medicinal preparations to therapies such as acupuncture [1,2]. Definitions used in the field often vary from one country to another owing to the varying cultures and diversities in different countries or regions. In Australia, the Therapeutic Goods Administration (TGA) provides specific definition for “complementary medicines (CM)” instead of “CAM”. CM are regulated by the Australian TGA, which defines them as herbs, vitamins, minerals, nutritional supplements, homeopathies and certain kinds of aromatherapies [3]. Alternative therapies or practices such as chiropractic, massage, music and yoga are not defined within the TGA CM definition and are not currently regulated by the TGA [4].

The use of CM has significantly increased during the last couple of decades, and with that the potential risks for perioperative complications such as excessive bleeding, potentiation of anaesthetics, hypoglycaemia and interactions with medicines [5–10]. Previous studies have shown that most patients do not speak with their general

practitioners regarding the use of CM, which may have clinical implications [11–14].

In Australia, patients are required to attend a pre-admission clinic before undergoing an elective surgery - an operation which is medically necessary, but can be delayed for at least 24 h [15]. In some hospitals, patients may be given a form to complete prior to the day of pre-admission clinic in order to capture information relating to their health, however this procedure can differ between facilities. The purpose of a pre-admission clinic is to gather information about the patient's medical and medication history and conduct a number of health assessments. If the patient meets certain referral criteria such as taking five or more regular medications, they will see a pharmacist who will reconcile the patient's medicines and be provided counselling about any medications that should be stopped prior to surgery. After the initial assessments, the patient will be seen by an anaesthesiologist who will explain the upcoming procedure [15,16].

To our knowledge, there is currently no published data exists on the prevalence and use of CM amongst elective surgery patients when they present at hospital pre-admission clinics prior to their surgeries, in the Australian context. The aim of this study was to determine the pattern of use of CM amongst elective surgery patients and to evaluate the

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effectiveness of the current hospital forms (Patient Health Assessment and Medication Management Plan) in capturing relevant information relating to CM.

## 2. Materials and Methods

This study received the Royal Perth Hospital Governance, Evidence, Knowledge and Outcomes (GEKO) system approval (14544) and the Curtin University Human Research Ethics Committee reciprocal ethics approval (HRE2017-0188).

### 2.1. Study design and setting

This was a prospective observational cohort study which was carried out at a pre-admission clinic at a public tertiary hospital in Western Australia, over an eight-week period between 15 May and 7 July 2017.

### 2.2. Inclusion and exclusion criteria

This study included all patients who completed the CM questionnaire over the eight-week study period. Patients who were unable to provide answers in English, younger than 18 years of age, and those who did not have medical records with either hospital forms, were excluded from the study.

### 2.3. Measurement instruments and data collection

A total of 992 patients attended the pre-admission clinic during the eight-week period between 15 May and 7 July 2017. A total of 638 returned completed CM questionnaire (64.3% response rate). All patients who attended the pre-admission clinic on the day of admission during the study period were presented with a one-page CM questionnaire consisting of eight questions. The CM questionnaire was initially developed based on information from literature search and discussion amongst the research team with local hospital staff from the pharmacy department and the pre-admission clinic. The developed questionnaire was then circulated amongst five academic colleagues for face and content validation. Feedback were sought from validators specifically in relation to the clarity and flow of the questions asked, and whether the questions were structured and presented in an efficient manner that met the aims of the study, as well as whether there were any omission or any questions that were considered unnecessary. Only minor amendments were made to the CM questionnaire as a result of the validation process, to improve clarity of the questions. The first question asked the patient if they were currently taking a CM, and if

they answered affirmatively they would move on to the remainder of the questionnaire. If the patient answered negatively, they would skip to the last question asking about use of alternative therapies. A participant information sheet was provided alongside the CM questionnaire which informed the patient of the purpose of the study, and that participation was voluntary.

Medical records containing patients' hospital forms (Patient Health Assessment and Medication Management Plan) were obtained for the purpose of comparing prevalence (i.e. disclosure rates) of CM against the CM questionnaire. The Patient Health Assessment form used in the hospital had only one question related to CM use (yes/no) with no further prompting of which CM they were using, and whilst a section of the form asked the patient to list all medications, it did not explicitly specify CM. Medical records of patients from two weeks before the study period were gathered in order to compare the similarities between CM prevalence/disclosure rate. A similar disclosure rate would confirm that the optional CM questionnaire did not influence the disclosure of CM in hospital forms. For the purposes of this study, the definition of CM was based on the definition and description of CM provided by the TGA in Australia.

### 2.4. Data analysis

Data from the CM questionnaire and hospital forms were entered into Microsoft Excel, cleaned and analysed using the Statistical Package for Social Sciences (SPSS) v23.0. Pearson's Chi-square test and Fisher's exact test were used to explore use of CM across all forms by demographics. The relationship between use of CM on hospital forms and CM questionnaire was analysed with Pearson's Chi-square test. A Logistic Regression model was used to explore any influence of age or gender on CM disclosure on any of the forms. Results were reported as odd ratios for CM disclosure and their 95% confidence intervals (95% CI). A  $p$ -value  $< 0.05$  was taken to indicate a statistically significant association in all tests.

## 3. Results

### 3.1. Demographic characteristics of respondents

A total of 992 patients attended the pre-admission clinic during the eight-week study period and a total of 638 returned completed CM questionnaire (64.3% response rate). Of those who returned completed questionnaires, medical records of 397 patients were made available to the research team by the hospital. Of these 397 patients, 80 did not meet the inclusion criteria (see Materials and Methods section),

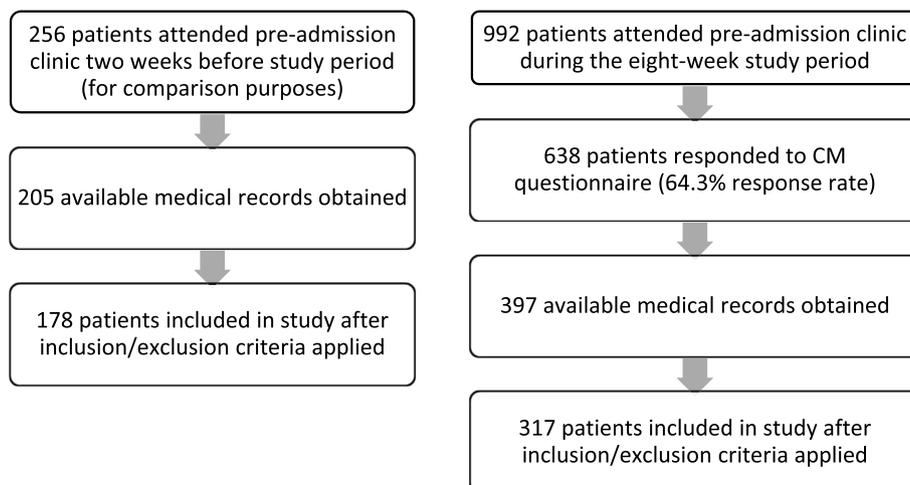


Fig. 1. Schematic representation of data collection.

**Table 1**  
Participant demographic characteristics and prevalence of complementary medicines (CM) use across all forms.

Variable	Total number of patients (%) N = 317	Disclosure of CM <sup>a</sup> (%) N = 140	p-value <sup>c</sup>
Age group			
18–30	32 (10.1)	8 (25)	< 0.001
31–50	76 (24)	23 (30.3)	
51–70	141 (44.5)	68 (48.2)	
71–90	68 (21.5)	41 (60.3)	
Gender			
Male	159 (50.2)	52 (32.7)	< 0.001
Female	158 (49.8)	88 (55.7)	
Surgery type			
Orthopaedic	62 (19.6)	34 (54.8)	0.093 <sup>b</sup>
Gastroenterology	48 (15.1)	19 (39.6)	
Plastic	45 (14.2)	20 (44.4)	
Urology	45 (14.2)	15 (33.3)	
ENT <sup>d</sup>	28 (8.8)	8 (28.6)	
Vascular	20 (6.3)	9 (45.0)	
Eye	19 (6.0)	9 (47.4)	
Breast	15 (4.7)	11 (73.3)	
Spinal	11 (3.5)	7 (63.6)	
General	9 (2.8)	3 (33.3)	
Cardiology	7 (2.2)	3 (42.9)	
Maxillofacial	4 (1.3)	1 (25.0)	
Dental	1 (0.3)	1 (100.0)	
Unknown	3 (0.9)	0 (0.0)	

<sup>a</sup> ENT: Ear, nose and throat (otolaryngology); CM: Complementary medicines.

<sup>b</sup> p-value obtained from Fisher's Exact test.

<sup>c</sup> P-values assess the statistical significance of differences between users and non-users of CM. The p-values were obtained from the Chi-square test, unless otherwise marked.

resulting in a final sample of 317. Therefore, a total of 317 patients during the study period and 178 patients from two weeks prior to the study period formed the final sample groups after all the exclusion criteria were applied (Fig. 1). The demographics of the sample group during study period consisted of 159 males and 158 females admitted to a total of 14 types of surgeries (Table 1). Age of respondents ranged from 18 to 90 years with a mean age of  $56 \pm 17$  years. The most common surgeries patients were admitted to were from specialities of orthopaedic (19.6%), gastroenterology (15.1%), urology (14%) and plastic surgery (14%).

### 3.2. Prevalence of CM use

The prevalence of CM use in our sample group of 317 patients across both hospital forms and CM questionnaire combined was 44.2% (n = 140). Separately, the prevalence of CM use disclosed only on the hospital forms was 32.5% (n = 103), and 38.8% (n = 123) only on the CM questionnaire (Table 2). Females were significantly more likely to use/disclose the use of CM than males (55.7% vs 32.7%,  $p < 0.001$ ). The CM disclosure rate was higher in the 71–90 age group (60.3%),

**Table 2**

Comparison of complementary medicines (CM) disclosure between hospital forms and CM questionnaire.

CM <sup>a</sup> form (%)	Hospital forms (%)		Total	p-value <sup>b</sup>	
	Yes	No			
CM <sup>a</sup> form (%)	Yes	86 (69.9)	37 (30.1)	123	< 0.001
	No	17 (8.8)	177 (91.2)		
Total	103	214	317		

<sup>a</sup> CM: Complementary medicines.

<sup>b</sup> The p-value was obtained from the Chi-square test, and assesses the association between the two forms in relation to reporting CM use.

compared to the 18–40 age group (20.6%). This trend was statistically significant, even after adjustment for gender. The multivariable logistic regression model showed that, relative to the 18–40 age-group, the odds ratios for age increased from 2.5 (95%CI: 1.0–5.9;  $p = 0.042$ ) for 41–50 year olds to 6.2 (95% CI: 2.8–13.7;  $p < 0.001$ ) for the 71–90 year olds. The odds ratio for females was 2.7 (95% CI: 1.7–4.3;  $p < 0.001$ ) compared to males. The prevalence of CM use in the group of 178 patients from two weeks prior to study period was 33.7% (n = 60), which was similar to the sample group.

### 3.3. Types of CM, frequencies, duration and length of use

A total of 350 CM were disclosed across all three forms. Of which, 31.7% (n = 111) were disclosed only in the CM questionnaire by 40.7% (n = 57) of all patients that took a CM (Fig. 2).

The amount of CM each patient used ranged from one (41.2%, n = 58) to more than seven (5.7%, n = 8). When asked about their duration and length of use, 69.9% (n = 86) reported taking at least one CM over the course of one year or longer, and 91.9% (n = 113) reported taking at least one CM on a daily basis.

### 3.4. Indications for CM use, perceived effectiveness and sources of recommendation

Most of the patients (77.2%, n = 95) gave at least one indication for their CM use. The most commonly cited indications were to boost general health (23.2%), arthritis (17.9%), cramps prevention (11.4%), enhance bone health (10.6%), pain management (6.3%) and cold prevention (6.3%). Nearly two thirds were satisfied with the effectiveness of one or more of their CM. The major sources of recommendation and information were patients' usual GPs (59.3%), family or friends (24.6%) and pharmacists (21.1%) (Table 3).

### 3.5. Disclosure of CM to health professionals and perceptions of safety and risks

Most of the patients (86.2%, n = 102) stated that the GP or hospital staff were aware they took CM. Approximately one third (30.1%, n = 37) of patients considered CM to be safer than conventional medicines and 13.2% (n = 16) stated they were unsure. The vast majority of patients (93.5%, n = 115) were not concerned about any potential risks of using CM before surgery. The primary concern expressed by the minority was the uncertainty of interaction between CM and surgery. 65.9% (n = 81) of patients did not plan to withhold their CM prior to surgery.

### 3.6. Use of alternative therapies

Of those who responded, 10.7% (n = 34) reported at least one alternative therapy not otherwise considered as CM based on the TGA definition on the CM questionnaire, of which 61.8% (n = 21) used them concurrently with a CM treatment. The most common alternative therapies were chiropractic therapies (45%), acupuncture (23%) and yoga (17.6%).

## 4. Discussion

In the absence of CM questionnaire, the prevalence of CM use disclosed on the standard hospital forms was 32.5%. This was increased by 11.7% when a separate CM questionnaire was introduced to give a total of 44.2% disclosure rate. Considering the potential negative consequences of the use of some CM peri-operatively, an improvement in the disclosure rate is essential to mitigate any potential risks or untoward effects of using a CM prior to, or during, a surgery.

The prevalence of CM use based on what was disclosed on the standard hospital forms between patients during the study period and

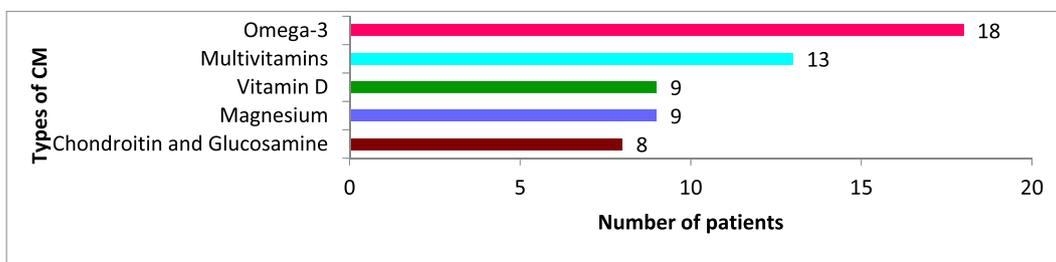


Fig. 2. Most commonly used CM which are only disclosed on the CM questionnaire (n = 111). Overall, the most popular CM were vitamin D (12%, n = 42), omega-3 (12%, n = 42), magnesium (10.8%, n = 38), calcium (8.9%, n = 31) and multivitamins (7.7%, n = 27) (Fig. 3).

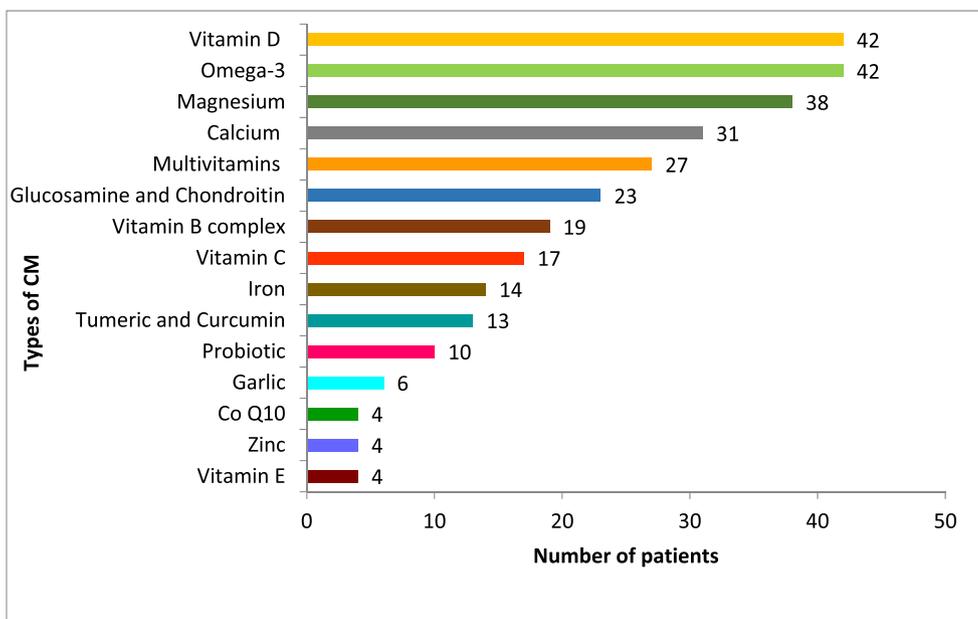


Fig. 3. Most commonly disclosed CM overall across all forms (n = 350).

Table 3  
Sources of recommendation and information.

Sources of recommendation/information	Number of patients (%)
Doctor (usual general practitioner)	73 (59.3%)
Family or friends	29 (24.6%)
Pharmacist	26 (21.1%)
Media (Television, magazine, radio, internet, newspaper)	12 (9.8%)
Naturopath	11 (8.9%)
Self-medicated	7 (5.7%)
Others	4 (3.3%)

those from two weeks before the study period were comparable (33.7% and 32.5%, respectively). This confirms that the responses given in the hospital forms during the study period were not subjective to outside influence of the CM questionnaire.

The prevalence of CM use in this study was higher than previous published studies, in particular in countries other than Australia. It was higher than a Canadian study involving 357 patients from general, hepatobiliary and oncology surgeries (27%), as well as a retrospective review involving 434 patients in a study conducted in the United States (23% reported use of a natural product), a Turkish study (9.5% reported use of a herbal product) and one study in Australia (14.3% and 22.5% reported use of herbal and vitamin use, respectively) [2,17–19]. The differences in prevalence of CM use are likely attributable to the availability of CM in different countries or regions, as well as local cultural, experience or media influences. In addition, as the CM

questionnaire provided description and examples of CM, this may have further prompted patients to disclose their use, leading to a higher prevalence than the aforementioned studies. It was similar to a UK study including 100 elective plastic surgery patients (44%), an Italian cross-sectional survey of preoperative patients (49.8%), and a prospective observational study of elective surgery patients in Jamaica (45.1% used botanicals within two weeks of surgery) [13,20,21]. In contrast, there was one Australian survey of patients undergoing cardiac surgery, which found that 51% took at least one CM during the two weeks before admission [22]. There was significantly greater CM use amongst females compared to males, and for older versus younger respondents. This is consistent with findings in some of the studies, however other studies showed no significant associations [2,17,18,21,22].

Among the top fifteen CM taken by patients in this study were omega-3 (combination of fish and krill oil), glucosamine and chondroitin, garlic, coenzyme Q-10 and vitamin E. The most common CM disclosed only in the CM questionnaire was omega-3. In other words, if a CM questionnaire had not been used in those cases, the clinicians would not be aware of these patients' use of omega-3. This in itself is of clinical importance as omega-3 has been shown to prolong bleeding time by inhibiting platelet aggregation, as well as causing hypotension, which are of particular relevance to a patient undergoing an elective surgery [2,23,24]. Other CM that have been reported to similarly induce perioperative bleeding include chondroitin, garlic, coenzyme Q-10 and vitamin E [2,23,24]. Glucosamine has also been reported to cause hypoglycaemia [2]. Guidelines recommend that these CM should be discontinued at least two weeks prior to surgery [2,20,25]. This finding

highlights the importance of appropriate mechanism to facilitate patient disclosure of a CM use to allow interventions by clinicians.

CM were perceived as a safer alternative to conventional medicine. In this study, it was found that 30.1% of elective surgery patients that disclosed the use of CM thought that it was safer than conventional medicines. 13.2% wrote ‘unsure’ despite the fact that there were only two available answers (yes/no), suggesting a gap in knowledge about CM safety amongst the public. Additionally, a large percentage of patients were not concerned about any potential risks that CM can cause before surgery, and two in three patients had no plans of stopping them. This is concerning and it highlights that there is a need for education amongst patients prior to surgery to raise their awareness of the potential risks of CM use peri-operatively.

This study has limitations. The CM questionnaire was self-administered, voluntary and non-verbal in nature. Patients that did not understand a question or were not able to recall which CM they were taking could have provided a different or a negative answer, which could have underestimated the prevalence. As this study was conducted in one major tertiary hospital in Australia, the findings may not be representative of CM use in other countries. There were also time constraints given the fact that the CM questionnaire had to be completed on the day of admission, which could have impacted on the accuracy and completeness of responses. This study did not collect information in relation to the reasons for disclosure for those patients who did disclose their CM use.

The findings of study highlights a number of policy and practice implications. The use of a CM questionnaire in this study over the eight week study period improved CM disclosure rate. This in itself is of significance as it highlights the need to ensure procedures are in place in hospital pre-admission clinics to encourage disclosure of CM use amongst patients prior to elective surgery. Issues raised in this paper also highlight the need for patient education to raise their awareness of the potential risks of using certain CM peri-operatively, as well as greater engagement of hospital staff in patient assessment and advice provision. Recommendations can be made to local hospitals to make amendments on the Patient Health Assessment form to encourage CM disclosure rate. This could be done by explicitly having additional space for a question asking the patient to disclose all CM and providing a definition or description of CM to provide clarity. Considerations should also be given to update guidelines for referral criteria at the pre-admission clinic to include these high risk CM to allow interventions by clinicians, which include counselling on risks and provide recommendations for discontinuation of CM, if relevant, prior to surgery. On-going monitoring and audits should also take place to continuously improve practice to ensure patient safety prior to, and during, and after, surgery.

## 5. Conclusions

The use of CM is common amongst patients prior to surgery. However, there appears to be a lack of understanding about CM safety amongst patients prior to elective surgery, which can place them at risk of perioperative complications such as excessive bleeding and interactions with anaesthetics. In addition to policy and practice implications, this study also highlights a need for future research to improve disclosure rates and patient safety prior to, and during, surgeries, including patients’ understanding of the potential risks involved and any barriers to disclosure and efforts to overcome the identified barriers from the clinicians’ perspective.

## Declarations of interest

None. The authors have no competing interests to declare.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ctcp.2019.03.012>.

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