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Original Article

What is integrative medicine? Establishing the decision criteria for an operational definition of integrative medicine for general practice health services research in Australia

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ABSTRACT

Background: Operational definitions outline how a conceptual definition will be measured for consistent, reproducible data collection and analysis. This article reports the decision criteria that will be used for an operational definition of integrative medicine (IM) in a secondary analysis of an Australian national survey of general practitioner activity.

Methods: A multidisciplinary team applied an iterative approach, informed by expert knowledge and literature reviews to establish decision criteria for categorizing the terms in the Australian clinical interface terminology of the International Classification of Primary Care, second edition (ICPC-2 PLUS) and the Coding Atlas for Pharmaceutical Substances, according to whether they reflected IM, conventional/mainstream medicine (MM), or both IM and MM (IM/MM).

Results: The final decision criteria categorized all terms for examinations, investigations, advice/counselling, and drugs with synthetic ingredients, and terms for referrals to secondary care services and healthcare practitioners that are not a traditional or complementary medicine practitioner as MM. Terms that could apply to both styles of clinical practice (e.g., preventive health, lifestyle medicine, psychosocial and some drugs with natural ingredients) were categorised as IM/MM. The remaining terms, that mostly reflected the World Health Organization's theoretical definitions of traditional and complementary medicine, were categorized as IM.

Conclusion: Differentiating between integrative and conventional/mainstream medicine in general practice is context specific and not always possible. The category IM/MM proposes integrative medicine as an extension, rather than an alternative. The rationale for the integrative medicine operational definition has relevance for researchers and health services in Australia, and internationally.

1. Introduction

The last few decades have seen a growing interest in the practice of integrative medicine (IM). Although the term continues to evolve, the combining of traditional and complementary medicine (T&CM) with conventional or mainstream medicine (that collectively, will be abbreviated to MM) and an emphasis on patient-centred, holistic care, and health promotion are consistent features of IM descriptions and definitions.^{1–9}

Deciding whether a healthcare approach is MM or T&CM is not always straightforward, as definitions can differ according to the region or country, and over time.^{4,10} The World Health Organization uses the term 'traditional medicine' when referring to the healing practices that are indigenous to a region (Table 1).¹¹ These may or may not be a com-

ponent of the region's dominant healthcare. When a traditional medicine is exported, it is often referred to as 'complementary medicine' and/or 'alternative medicine'.¹¹ The exception is the term 'Western medicine', that has its traditional medicine roots in Western Europe,¹² yet, is the dominant medical system in many other countries and regions across the globe. In Western European, North American and Australasian regions the term 'conventional medicine' or 'mainstream medicine' is often used when referring to Western medicine healthcare practices, as this is the dominant system that is taught in medical schools and to allied healthcare practitioners.^{1,13} Notably, like Western medicine, other traditional medicine practices continue to evolve. Examples of modern T&CM interventions include manufactured nutritional supplements and herbal medicine extracts (including for intravenous or intramuscular administration), and electro- and laser acupuncture.

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Table 1
Conceptual definitions relevant to general practice in Australia.

Excerpts from the Royal Australian College of General Practice (RACGP), Integrative Medicine Contextual Unit,³ the Australasian Integrative Medicine Association (AIMA),^{1, 2} and the WHO Traditional Medicine Strategy 2014–2023.¹¹

Integrative Medicine (IM) refers to the blending of conventional and evidence-based natural and complementary medicines and/or therapies with lifestyle interventions to deliver holistic, patient-centred care. The overarching aim of integrative medicine is to use the most appropriate, safe, ethical and evidence-based modality(ies) available, with a particular focus on prevention and lifestyle interventions. This practice is informed by evidence and patient preference and enables a broader range of therapeutic options and disciplines to be made available for patients to achieve optimal clinical outcomes... It does not reject or compete with conventional healthcare and overlaps significantly with what is currently widely accepted as quality general practice.³

*Integrative Medicine reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, health care professionals and disciplines to achieve optimal health and healing. It takes into account the physical, psychological and social wellbeing of the person with the aim of using the most appropriate, safe and evidence-based treatments available.*²

Traditional Medicine (TM) has a long history. It is the sum total of the knowledge, skill and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.¹¹

Complementary Medicine (CM) refers to therapies and medicines that are not conventionally used by doctors, but which may complement medical management and thus be successfully integrated into medical practice.³

*The terms “complementary medicine” or “alternative medicine” refer to a broad set of health care practices that are not part of that country’s own tradition or conventional medicine and are not fully integrated into the dominant health-care system. They are used interchangeably with traditional medicine in some countries.*¹¹

Traditional and Complementary Medicine (T&CM) merges the terms TM and CM, encompassing products, practices.¹¹

Conventional or Mainstream Medicine (MM) refers to medical interventions that are taught extensively at Australian medical schools, generally provided at Australian hospitals, or meet the requirements of the generally accepted standard of care as determined by professional [medical] colleges such as the RACGP.¹

Delineating between different healthcare approaches is important, as these definitions and descriptions ultimately inform practitioners’ scope of practice, the delivery of health services and policy, and patient/consumer choices. It is also important for research. Operational definitions specify how a concept will be measured.¹⁴ They aim to ensure consistent and reproducible data collection and analysis.

Inconsistencies in the operational definitions used in primary studies of IM and T&CM have hampered systematic comparisons between geographical regions and across time.^{15,16} Surveys of general practitioners (GPs) in Australia for example, have reported various rates for IM practice ranging from 34 to 90%.^{17–26} Discrepancies between these findings partly reflect sampling bias, reporting bias, along with the different IM operational definitions that are used, as there is no nationally agreed definition. Consequently, it is unclear the extent to which GPs in Australia have integrated T&CM into their clinical practice and whether this has changed over time.

The largest, nationally representative survey of GP activity in Australia, the Bettering the Evaluation and Care of Health (BEACH) study,^{27,28} is yet to be analysed from the perspective of IM practice. The BEACH study was a national cross-sectional survey, with single-stage, cluster sampling of approximately 1000 GPs from across Australia that began in April 1998 and closed after 18 years of continuous data collection in June 2016. Each participating GP documented data from 100 consecutive patient encounters. The study aimed to provide reliable, valid data reporting the character of GP-patient encounters in Australia.²⁸ A secondary analysis of this dataset would therefore provide reliable data on IM activity in general practice across Australia and over time. However, prior to conducting the analysis an operational definition is required.

The BEACH study used two coding systems: the Australian clinical interface terminology of the international classification of primary care, second edition (ICPC-2 PLUS)²⁹ and the Coding Atlas for Pharmaceutical Substances (CAPS) that was an in-house classification mapped at the generic level to the Anatomical Therapeutic Chemical (ATC) classification.³⁰ As neither of the coding systems were designed for an IM analysis, the first step is to establish decision criteria for the operational definition that will then be used to identify and categorize the terms and their corresponding codes when conducting the secondary analysis of the BEACH study.

Definitions and descriptions of IM that are relevant to general practice in Australia range from relatively simple constructs where components of T&CM are assimilated into MM and are used in an adjunctive, supportive context, through to the concept of a new, transformative practice.^{4–7,31,32} As summarised in Table 1, conceptual definitions of IM and MM articulated by peak bodies in Australia,^{1–3} closely align with

international definitions^{9,33} and also with descriptions of IM reported in surveys and in-depth interviews with Australian GPs.^{17,20,32,34–36} While the integration of T&CM is an obvious component, the practice of IM in Australia is described as being much broader and overlaps with MM.³ Examples of IM interventions used by GPs that would also be considered a component of MM practice include cognitive behavioural therapy, musculoskeletal trigger point therapy, nutritional supplements for deficiencies, and many aspects of environmental medicine such as advice about exposure to allergens, pollution and sun.³ Lifestyle medicine, health promotion, health education, counselling and longer consultations are also emphasised as core components of IM by GPs practicing in Australia,^{1,3,17–26,32,34–37} yet many aspects of these clinical activities would also be reflected in MM practice.³

In consideration of these definitions and descriptions of T&CM, IM and MM, this article reports the formulation of the decision criteria that will be used for the operational definition of IM activity in the secondary analysis of the BEACH study.^{27,28}

2. Methods

An iterative process was applied that involved (1) familiarisation with the two coding systems and their structures, (2) applying the expert knowledge of the research team, supplemented by the literature to formulate a provisional criteria for selecting the relevant ICPC-2 PLUS processes of care terms and CAPS terms, (3) conducting preliminary screens of the two coding systems, (4) critically appraising and refining the criteria, and (5) finalising the decision criteria.

The content and face validity of the decision criteria were continually assessed throughout the iterative development process. For the purpose of this study, content validity is defined as the extent to which the criteria represent the theoretical concepts that will be measured (*page 115–116*),³⁸ and face is defined as the extent to which the criteria are likely to be subjectively judged as appropriate by those who will be using the criteria (*page 115*).³⁸ Assessments of both content and face validity are mostly subjective (*page 115–116*).³⁸ Content validity was assessed according to the alignment of the decision criteria with the related operational definitions and theoretical definitions summarized in 2.2 Information Sources, and the expert judgments of the research team who took into account the historical context of general practice and IM practice in Australia during years of the BEACH study (1998–2016). Assessing face validity involved multiple discussions with the BEACH researchers and the members of the research team who will be applying the decision criteria to the BEACH datasets. Any disagreements were resolved through consensus.

2.1. Research team

The composition of the research team aimed to represent both IM and MM perspectives and expertise. Authors JHu, MP, JC, and JHa all have IM/T&CM research experience. JHu is a GP with MM and IM clinical experience. Author MP is a GP with MM clinical experience and was involved in the development of the RACGP IM curriculum.³ Both GPs were in clinical practise at the time the BEACH study, however, neither participated in the study. Author JC is a community Pharmacist with T&CM dispensing experience. JHa is an academic pharmacy educator with a clinical background in nutrition, naturopathy and IM. The authors liaised with the BEACH researchers throughout the process of establishing the criteria.

2.2. Information sources

The development of the decision criteria for the operational definition was informed by theoretical definitions, descriptions and examples of IM and T&CM,^{2,4-8,21,39} the Cochrane Complementary Medicine Field's operational definitions,^{10,40,41} a core list developed for population surveys of practitioner-based and self-administered T&CM that are commonly used in Western countries,³⁹ consensus statements from peak medical bodies in Australia,^{1,3,42} USA,^{9,33,43} and the World Health Organization,⁴⁴ and from Australian surveys and interviews with GPs,^{17-26,32,34-37} medical students,⁴⁵ consumers,^{46,47} and health services.⁴⁸ Classifications, lists and categories were also reviewed, including the Therapeutic Goods (Permissible Ingredients) Determination list⁴⁹ that is used for regulating complementary medicines (CMs) in Australia,⁵⁰ the national Pharmaceutical Benefits Scheme of medicines, including medicines regulated as CMs that are or were subsidised by the Australian Government,⁵¹ the Australian Government's review of natural therapy practitioners,⁵² the Australian AUSNUT 2011-13 Food and Dietary Supplement Classification System,⁵³ national Australian surveys of T&CM use,^{46,47} IM training for physicians in the USA,^{33,43} and the Medical Subject Headings (MeSH).^{54,55}

2.3. Rationale for three categories: IM, MM & IM/MM

Familiarisation with the structures and terms used in ICPC-2 PLUS and CAPS coding systems confirmed there were a large number of terms that would clearly be categorized as either MM or IM. For example, medicines with pure synthetic compounds as the active ingredient, immunisations, and surgical procedures would be categorized as MM. Similarly, other terms such as acupuncture, naturopath, osteopath, chiropractor, yoga, ginseng, echinacea, fish oil, and co-enzyme Q10 would be categorized as IM.

However, it was immediately apparent that some terms applied to both IM and MM. In some instances, the clinical context in which the term was used would dictate the category. For example, vitamin K used for neonates would be considered MM, whilst its use for osteoporosis management would be IM. There would be other instances however when irrespective of the context the term applied to both IM and MM. Examples include liniments with menthol oils that are used for musculoskeletal aches and pains, fibre supplements with ingredients such *Psyllium hydrophil mucil* that are used for constipation, folate for prevention of neural tube defects, and calcium for osteoporosis. Cognitive behaviour therapy, lifestyle medicine, and environmental medicine were other examples that are listed by the RACGP in their IM Contextual Unit,³ yet are also well-established components of MM. Rather than dichotomise general practice, we eventually decided to create a third category (IM/MM) that acknowledged the overlap.

These deliberations drew heavily on the only detailed operational definition that was identified: the Cochrane Complementary Medicine Field's definition of complementary, alternative and integrative medicine (CAIM).^{10,40,41} Like the Cochrane Field for Complementary Medicine, we rejected categorizing terms as MM based on there

being scientific evidence demonstrating efficacy.¹⁰ This was because evidence-based medicine is consistently emphasized as an overarching principle of IM practice,¹⁻³ and there would be numerous instances when a MM intervention had insufficient evidence.⁵⁶

The Cochrane Complementary Medicine Field also provided some helpful high-level statements about clinical contexts where a natural therapy would not be considered CAIM, and listed examples when nutritional supplements, exercise therapies, psychotherapies and light therapy would be considered MM.^{10,40} However, there were some instances that did not apply to the context of general practice in Australia and the BEACH study. For instance, the Field excluded nutritional supplements administered parenterally in hospital settings. In Australian general practice however, the setting would not help differentiate IM from MM, as most parental administration would be in primary care locations irrespective of whether it was for an IM or MM indication. The Field categorized over-the-counter supplements that had been integrated into the dominant healthcare system as "CAM-related", as they are "generally self-administered and not dependant on medical professionals".¹⁰ Again this did not apply, as the BEACH study only collected data about occasions when GPs were administering, prescribing or recommending the intervention.

The Cochrane Complementary Medicine Field also excluded psychotherapy and lifestyle medicine interventions unless it was clearly a component of CAIM practice or was "unconventional". In Australia however, lifestyle medicine was described as being a core component of IM,^{36,43} and the RACGP IM curriculum lists psychological interventions, such as cognitive behavioural therapy and mindfulness techniques as examples of IM.³ The pragmatic compromise was to categorize these interventions as IM/MM when they were provided by the GP, and IM when provided by a T&CM practitioner.

3. Results

The following summarizes the decision criteria and rationale that will be used for categorizing terms as mainstream medicine (MM), integrative medicine (IM) or both mainstream and integrative medicine (IM/MM) in the BEACH study operational definition.

3.1. Processes of care terms

Table 2 summarizes the decision criteria that will be used to categorize the processes of care terms in the ICPC-2 PLUS coding system. For terms that could apply to either IM or MM, pragmatic decisions were made that were informed by discussions with the BEACH researchers. For instance, all terms for examinations, tests and investigations would be categorized as MM, as would terms for GP advice, consultations with, or referrals to secondary care, allied health, and other healthcare practitioners that were not a T&CM practitioner. We appreciated that on some occasions this could have included IM as there were no terms for quite few T&CM practitioners and therapies,³⁹ so a code for non-specific processes of care may have been used. Additionally, some secondary care services in Australia provide IM, albeit a very limited amount.^{48,57} Similarly, despite there being no terms for traditional healers or practices indigenous to Australia, referrals and services from Aboriginal health workers, would also be categorized as MM as Aboriginal health workers and Aboriginal health practitioners deliver culturally appropriate MM primary care.⁵⁸ Given the terms for these processes of care would mostly reflect MM activities they would be categorized as such.

Cognitive behavioural therapy and mindfulness techniques were consistently listed in the RACGP documents as a component of IM,^{3,42} they would therefore be categorized as IM/MM, but only when the GP provided the therapy. Like other allied health, referrals to psychologist or other practitioners would be categorized as MM. Terms for multidisciplinary care plans would also be categorized as IM/MM, as these plans can include referrals to chiropractors and osteopaths that are rebated by the national health insurance scheme (Medicare).⁵⁹

Table 2
Conceptual definitions relevant to general practice in Australia*.

<p>INTEGRATIVE MEDICINE ONLY (IM) Traditional, Complementary and Integrative Medicine: advice/education, counselling, procedures, interventions, or referrals. Potential examples include:</p> <ol style="list-style-type: none"> 1. Traditional medicine and healing practices indigenous to Australia 2. Complementary medicine practices and systems traditional to other regions e.g., Naturopathy, Western Herbal Medicine, homeopathy, Rongoā Māori, Chinese medicine, Ayurveda, Unani, Siddha, Persian medicine, etc. 3. Manual therapies e.g. Chiropractic, Osteopathy, Roling Structural Integration, Massage, Craniosacral therapy 4. Acupuncture, including acupressure, electro- or laser acupuncture, moxibustion 5. Mind-body movement therapies e.g. Yoga, Pilates, Feldenkrais method, Alexander technique, Tai Chi, Qigong 6. Mind-body psychological therapies e.g. Relaxation, Hypnotherapy, Mindfulness, Meditation, Biofeedback, Guided imagery 7. Mind-body breathing therapies/techniques e.g. Buteyko, Pranayama 8. Mind-body expressive therapies e.g. Music, Art, Dance, Drama or Play 9. Mind-body touch therapies e.g. Reiki, Hands-on-healing, Kinesiology 10. Prayer, Spiritual healing, Distance healing 11. Vitamin or mineral injection/infusion used for an IM indication (see Table 3) <p>INTEGRATIVE MEDICINE & MAINSTREAM MEDICINE (IM/MM) Lifestyle medicine: advice/education, counselling, or referrals for one or more of the following domains:</p> <ol style="list-style-type: none"> 1. Nutrition, diet including special diets such as Carbohydrate-restricted, Vegetarian, Vegan, Casein-free, Wholefood, Organic, Low salicylate, Food sensitivities, Ketone, Atkins and Mediterranean 2. Exercise, including exercise physiology and personal trainer 3. Stress management 4. Weight loss 5. Smoking 6. Alcohol (NOTE: addiction services are excluded) 7. Sleep 8. Environment <p>Multidisciplinary Care Plans: Care plans, Chronic Disease Management Plans and Team Care Arrangement referrals † Other interventions, advice, education, counselling that are provided by the GP for a commonly listed core component of IM, for example:</p> <ol style="list-style-type: none"> 1. Vitamin or mineral injection/infusion when used for an IM/MM indication (see Table 3) 2. Musculoskeletal or pain management interventions and procedures <ol style="list-style-type: none"> a. Postural advice, therapeutic exercises b. Joint manipulation or mobilisation c. Prolotherapy or trigger point injection d. Microwave therapy, laser therapy, electrical stimulation, transcutaneous electrical nerve stimulation (TENS), short wave therapy, ultrasound therapy 3. Psychological interventions <ol style="list-style-type: none"> a. Cognitive behavioural therapy, mindfulness (NOTE: referrals for these services are excluded) <p>MAINSTREAM MEDICINE ONLY (MM)</p> <ol style="list-style-type: none"> 1. Examinations, tests, investigations 2. Infectious disease prevention (e.g. immunisations, preventive medications, travel medicine, hygiene). 3. Contraception, family planning, perinatal care, pelvic floor exercises 4. Advice, education, counselling about MM preventive activities e.g. self-breast examination, sun protection, injuries, cancer screening 5. Secondary care (including referrals to secondary care) <ol style="list-style-type: none"> a. hospital, day hospital, accident & emergency care b. specialist medical practitioners (e.g. physicians, surgeons, radiologists, anaesthesiologists, psychiatrists) c. associated secondary care services (e.g. psychiatric, addiction, sleep disorders, rehabilitation, occupational health, palliative, hyperbaric) 6. Consultations, case conference or referrals to allied health practitioners and services (e.g. Aboriginal health worker or practitioner,‡ community health, diabetes education, nursing, occupational or diversional therapy, pharmacy, physiotherapy, podiatry/chiroprody, and psychology) and any unspecified healthcare practitioner or allied health service 7. All procedures (e.g. surgery, preventive procedures, injections and infusions) not listed in the IM or IM/MM categories 8. Advocacy, liaison, financial, legal processes of care 9. Any other general or specific advice, education, counselling or patient group activities not listed in the IM or IM/MM categories

*Processes of care terms apply to the ICPC-2 PLUS coding systems. † The Australian Government, Department of Health, introduced Chronic Disease Management (CDM) Medicare items (721, 723 and 731) for GPs in 2005. These plans include the option to refer patients for Medicare rebated services (i.e., from the national health insurance) for a limited number of consultations with a chiropractor or osteopath.⁵⁹ ‡ In Australia, Aboriginal health worker and Aboriginal health practitioner provide culturally appropriate MM primary care.⁵⁸

However, terms for case conferences would be categorized as MM, as these typically involved GPs coordinating care with MM secondary care services.

Terms pertaining to the domains of lifestyle medicine would be categorized as IM/MM. The exception was alcohol and sleep. Advice, education or counselling about alcohol and sleep provided by the GP would be categorized as IM/MM, whilst investigations and referrals for management of alcohol addiction or sleep disorders would be categorized as MM. Any terms pertaining to genetics would also be categorized as MM, as genome sequencing for personalised medicine only became available in Australia during the last few years of the BEACH study. Similarly, terms for care provided to groups of patients would be categorized as MM, as shared medical appointments for lifestyle medicine were yet to be commonly provided by GPs in Australia,⁶⁰ and integrative group medical visits that aim to improve access to IM in the United

States of America,⁶¹ were yet to become a feature of IM practice in Australia.

Terms for other preventive activities (e.g. self-breast examination, sun protection, injuries and cancer screening) would be categorized as MM. As would terms for non-specific processes of care, such as advice, education, counselling, or preventive procedures for physical, psychological or social problems. Discussion with the BEACH researchers suggested that categorizing these terms and their corresponding codes as IM/MM would most likely lead to overcounting with spurious results.

3.2. Drug terms

The decision criteria for categorizing the drug terms in the CAPS coding system are presented in Table 3. All terms for drugs with at least one active ingredient that is a pure synthetic compound would be

Table 3

Criteria for categorizing drug terms*.

INTEGRATIVE MEDICINE ONLY (IM)Drugs with only natural or naturally derived active ingredients⁵⁰ that do not meet the criteria for a IM/MM or MM category:

1. an amino acid
2. charcoal
3. a choline salt
4. an essential oil
5. plant or herbal material (or a synthetically produced substitute for material of that kind), including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll
6. a homoeopathic preparation
7. a microorganism, whole or extracted, except a vaccine
8. a mineral including a mineral salt and a naturally occurring mineral
9. a mucopolysaccharide
10. non-human animal material (or a synthetically produced substitute for material of that kind) including dried material, bone and cartilage, fats and oils and other extracts or concentrates
11. a lipid, including an essential fatty acid or phospholipid
12. a substance produced by or obtained from bees, including royal jelly, bee pollen and propolis
13. a sugar, polysaccharide, or carbohydrate
14. a vitamin or provitamin

Drugs with only bioidentical hormones ± other natural/naturally derived active ingredients:

15. melatonin not used for assistance with sleep
16. Triest or Biest compounded formulations of bioidentical oestrogen, prescribed in isolation or co-prescribed with topical, vaginal or oral bioidentical progesterone
17. topical (not vaginal) bioidentical progesterone prescribed in isolation or co-prescribed with oral, topical, vaginal or nasal inhalation bioidentical oestrogen (oestradiol E2 including 17β-oestradiol, oestradiol acetate and oestradiol hemihydrate), estriol E3 and/or estrone E1)
18. topical low dose bioidentical testosterone formulations for females
19. dehydroepiandrosterone (DHEA)
20. desiccated thyroid extract
21. bioidentical testosterone in males that do not meet the criteria for IM/MM or MM
22. oral hydrocortisone (cortisol) for non-specific fatigue conditions such as chronic fatigue syndrome, myalgic encephalomyelitis, post-viral fatigue etc.

INTEGRATIVE MEDICINE & MAINSTREAM MEDICINE (IM/MM)

Drugs with only natural or naturally derived active ingredients that do not meet the criteria for the MM category:

1. were on the national Pharmaceutical Benefits Scheme (PBS)⁵¹ at some time during the BEACH study (1998–2016), including
 - a. Iron, vitamins B1, B9 (folate) and B12 (oral tablets/capsules, or for injection)
 - b. iron + folic acid (oral)
 - c. magnesium aspartate (oral)
 - d. calcium carbonate (oral)
 - e. vitamin K (oral or injection)
 - f. pancrelipase (oral)
2. were also historically used by MM and IM for the same indication. The exception is when the marketing emphasised there were natural ingredients, or a traditional medicine claim was made in which case it is categorized as IM.
 - a. mineral formulations (any route, except ophthalmic) marketed as antacids, laxatives, urine alkalinisers, or nasal washes
 - b. oral cough formulations with Polygala senega and ammonia
 - c. potassium iodine expectorants
 - d. boracic/boric acid (vaginal)
 - e. topical formulations with urea, vitamin A1 (retinol), vitamin E, zinc oxide, or selenium sulphate
3. were prescribed, recommended or administered by the GP for a well-established MM indication at the time of the BEACH study (1998–2016) that is also an IM indication
 - a. a vitamin or mineral used to treat a diagnosed deficiency
 - b. iron and/or folate and/or vitamin B12 used for anaemia or other related terms
 - c. vitamin B1 for alcohol abuse
 - d. oral calcium and/or vitamin D for osteoporosis/osteopenia management
 - e. oral folate with or without iodine for perinatal use (including pregnancy and breastfeeding multivitamin/mineral supplements with the recommended doses)
 - f. oral fibre supplements (e.g. Psyllium hydrophil mucil) and Senna glycoside for constipation
 - g. formulations with oils (e.g. menthol) that are used topically for musculoskeletal aches and pains, or as an inhalant or topically for upper respiratory symptoms

Drugs with only bioidentical hormones ± other natural/naturally derived active ingredients:

4. melatonin for assistance with sleep
5. oral, topical, vaginal or nasal inhalation bioidentical oestrogen (oestradiol E2 including 17β-oestradiol, oestradiol acetate and oestradiol hemihydrate), estriol E3 and/or estrone E1) prescribed in isolation or co-prescribed with bioidentical progesterone or that do not meet the criteria for IM
6. oral progesterone for peri-menopausal hormone replacement therapy bioidentical testosterone for testosterone deficiency in males that do not meet the MM criteria

MAINSTREAM MEDICINE ONLY (MM)

Drugs with one or more active ingredients that are:

1. pure synthetic compounds
2. immunisations
3. petroleum based (e.g. paraffin, mineral oil)
4. foods such as infant formulas, meal replacement, shakes, drinks or enteral nutrition
5. nutritional supplements developed for specific diseases (e.g. multivitamin/mineral for phenylketonuria, Lorenzo's oil for adrenoleukodystrophy or adrenomyeloneuropathy)
6. sodium, potassium, bicarbonate, phosphate and/or glucose and rehydration formulas formulations that are used as replacement therapies for medical conditions
7. saline (any route) and all topical ophthalmic formulations, unless the marketing for the drug emphasised it was 'natural' or a traditional medicine claim was made.
8. minerals in formulations only used for pre-operative bowel preparation (e.g. high dose sodium phosphate)
9. minerals in antacid formulations with ingredients such as aluminium hydroxide or magnesium trisilicate in high doses that are not in the Therapeutic Goods (Permissible Ingredients) Determination⁴⁹
10. naturally derived ingredients not listed as an active ingredient (except as a homoeopathic ingredient) in the Therapeutic Goods (Permissible Ingredients) Determination⁴⁹ that had well established mainstream medicine indications during the time of the BEACH study (1998–2016)
 - a. opioids
 - b. retinoids except for retinol (vitamin A1)
 - c. calcitriol
 - d. mannitol
 - e. quinine

(continued on next page)

Table 3 (continued)

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- f. enzymes used for rare genetic diseases (e.g. Alglucosidase alfa, Taliglucerase alfa)
 - g. digestive enzymes with formulations containing ursodeoxycholic acid, velaglucerase, or cysteamine
 - h. all other sex hormones not categorized as IM or IM/MM, including oestrogen NOS, conjugated oestrogen, Oestradiol hemihydrate, ethyl oestradiol, oestradiol valterate, hydroxyprogesterone caproate, methyltestosterone and testosterone esters (e.g. cypionate, enanthate, acetate, propionate, phenylpropionate, isocaproate, caproate, decanoate, and undecanoate)
 - i. cortisol/hydrocortisone any route other than oral
 - j. all other hormones not categorized as IM or IM/MM, including insulin, levothyroxine, liothyronine, parathyroid hormone and growth hormone
 - k. cannabis, as the only legally available medicine in Australia during the BEACH study was Sativex® for multiple sclerosis (registered November 2012)
 - 11. naturally derived ingredients used for surgery related procedures
 - a. armellose, gelatine and pectin topical powders used around a stoma
 - b. silver nitrate used as a chemical cauteriser
 - c. hyaluronic acid or collagen for injection
 - 12. naturally derived ingredients used to make textile dressings
 - a. calcium alginate dressings
 - b. cotton dressings
 - 13. naturally derived ingredients and formulations when prescribed, recommended or administered by the GP for a well-established MM indication that would not also be considered an IM indication, examples include:
 - a. vitamin K1 (phytonadione) for hypoprothrombinemia or for neonates
 - b. magnesium sulphate injections for pre-eclampsia or hypomagnesaemia
 - c. calcium gluconate injections for hypocalcaemia or cardiac arrest
 - d. oral activated charcoal for acute poisoning
 - e. acetylcysteine injections for paracetamol poisoning
 - f. acetylcysteine inhalations for cystic fibrosis
 - g. oral cortisol/hydrocortisone that is not an IM indication
 - h. bioidentical testosterone for males younger than 30 years of age or for confirmed testicular disease or pituitary failure in males of any age
 - i. bioidentical oestrogen/progesterone or testosterone used for feminization or masculinization, respectively
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*Drug terms apply to the ICPC-2 PLUS coding systems.

categorized as MM. Terms for drugs with only natural or naturally derived active ingredients such as those listed by the TGA complementary medicines in Australia⁵⁰ would be categorized as IM, IM/MM or MM depending on the context. As would terms for bioidentical hormones, that in Australia were all prescription only, including melatonin. The specifics of the criteria and rationale for these decisions are detailed below.

3.2.1. Drugs with natural or naturally derived active ingredients

In Australia, complementary medicines are regulated as a medicine by the Therapeutic Goods Administration (TGA) and the TGA lists examples of natural or naturally derived ingredients that are allowed in complementary medicines.⁵⁰ However, there were also numerous terms for drugs with only natural active ingredients that would also be considered a MM. Additionally, there were terms for various botanical/herbal ingredients and some intravenous vitamins that were not on the Therapeutic Goods (Permissible Ingredients) Determination for complementary medicines.⁴⁹

The criteria for categorizing the terms for drugs with only natural or naturally derived ingredients therefore focused on the clinical context (i.e., diagnosis and reason for use) and historical context (e.g., ingredients or formulations developed for, or used by MM, IM, and/or T&CM practitioners). For instance, if a drug with only natural active ingredients was developed and predominantly used for MM (e.g., intravenous rehydration/resuscitation formulas, mineral formulations used for pre-operative bowel preparation, topical ophthalmic formulations, otic and oropharyngeal mineral solutions, saline administered by any route, and surgical substances and dressings) the term would be categorized as MM. If an active natural ingredient was not listed on the Therapeutic Goods (Permissible Ingredients) Determination for complementary medicines⁴⁹ and historically that ingredient was not a core component of T&CM practice in Australia (e.g. opioids, quinine, mannitol, calcitriol, and some antacid and digestive enzyme formulations) the term would be categorized as MM. We recognised there might be some occasions when a GP who identified as practicing IM might specifically select these drugs because they were 'natural'. However, categorizing these terms and their corresponding codes as IM/MM would most likely lead to overcounting with spurious results.

Similarly, terms for foods such as infant formulas, meal replacements, enteral nutrition and nutritional supplements developed for spe-

cific diseases (e.g., phenylketonuria) would also be categorized as MM. Although historically, these might also be recommended by a T&CM practitioner and therefore be a component of IM, they are a major, core component of MM dietetic practice in Australia. Additionally, any prescriptions or recommendations for food terms from GPs for these formulations would still be captured by the various ICPC-2 PLUS terms for nutrition (Table 3).

The aforementioned criteria would suffice for categorizing a substantial proportion of the CAPS terms. For other terms, an analysis that identified the clinical context would be required. For example, oral activated charcoal would be categorized as MM when used for acute poisoning and IM when used for irritable bowel syndrome.

We deliberated over how to categorize vitamins and minerals when used to prevent or treat deficiencies and their sequelae. Some were straightforward and would be categorized as MM (e.g., vitamin K1 given to neonates, or intravenous calcium or magnesium for hypocalcaemia and hypomagnesaemia respectively). Many other instances were not clear cut. Even for relatively straightforward conditions such as iron, folate or vitamin B12 deficiency, there are wide variations in the diagnostic investigations and thresholds that GPs use.⁶²⁻⁶⁴ Based on our own professional knowledge, some IM GPs use non-conventional diagnostic techniques or apply a lower laboratory threshold for diagnosing deficiency or may even describe it as "insufficiency". The BEACH study only records the GP's diagnosis and was not designed to detect these nuances. Therefore, terms for many of the vitamins and minerals would be categorized as IM/MM if the indication was recorded as a deficiency or any other related term (e.g. anaemia, macrocytosis, malnutrition, scurvy, Beriberi etc.). Terms such as folate when used to prevent neural tube defects or calcium for osteoporosis management that are recommended in MM guidelines, would also be categorized as IM/MM as these are also core components of IM practice. For the remaining drug terms for vitamins and minerals, if it was not used in a MM or IM/MM context, it would be categorized as IM.

For terms that correlated with a formulation listed on the national Pharmaceutical Benefits Scheme (PBS)⁵¹ at some time during the BEACH study (1998–2016), unless it met the MM only criteria then irrespective of the clinical context it would be categorized as IM/MM. By definition, being listed on the PBS indicated that it was also a component of MM.

3.2.2. Bioidentical hormones

Terms for hormones such as insulin, levothyroxine, liothyronine and parathyroid hormone, that are almost only used in Australia in an MM context would all be categorized as such. Decision criteria for many of the other bioidentical hormones was less straightforward. We found little guidance on which bio-identical hormones should be classified as IM, IM/MM or MM. The decisions were therefore informed by our own professional knowledge about IM practice in Australia.

Terms for dehydroepiandrosterone (DHEA) and desiccated thyroid extract, that were only available as unregistered medicines (i.e., compounded by a pharmacist) would be categorized as IM. Terms for hydrocortisone would be categorized as MM when administered to infants, or via any route other than oral (including not otherwise specified) to patients of any age. Oral hydrocortisone would only be categorized as IM when used for 'non-specific' causes of fatigue (e.g., chronic fatigue syndrome, myalgic encephalomyelitis), otherwise MM. Terms for growth hormone (somatotropin) would be categorized as MM. We appreciated there may have been a few occasions when it was used off label for anti-ageing in adults, however, these would not be identifiable due to there being no terms in ICPC-2 PLUS for anti-ageing or wellness, nor for MM indications such as late onset growth hormone deficiency. In Australia, melatonin was a prescription only medicine during the BEACH study, therefore, terms for melatonin when used to assist sleep or not otherwise specified would be categorized as IM/MM rather than IM. When used for any other off-label clinical indication (e.g. adjunctive cancer management, mental health etc.) it would be categorized as IM.

Terms for bioidentical sex hormones prescribed or administered to female patients would be categorized as IM if it was an unregistered, compounded medicine such as Biest (oestradiol and oestriol) or Triest (oestradiol, oestrone and oestriol) or topical progesterone cream (not per vaginal). As would any terms for registered medicines that were low dose testosterone formulations for females (i.e., not for masculinization). For the other bioidentical oestrogen and progesterone terms, they would be categorized as IM when co-prescribed with an unregistered bioidentical sex hormone, IM/MM with a registered bioidentical sex hormone, and MM when co-prescribed with a non-bioidentical sex hormone. When oral, topical or vaginal bioidentical progesterone was prescribed in isolation, the term would only be categorized as IM/MM if it was for hormone replacement therapy, otherwise it would be categorized as MM, as would all other remaining terms for oestrogen and progesterone.

The rationale used to categorize bioidentical testosterone hormones prescribed or administered to male patients reflected known off-label prescribing of testosterone by GPs during the years of the BEACH study that eventually led to the Australian Government tightening the Pharmaceutical Benefits Scheme (PBS) criteria for testosterone deficiency in 2015.⁶⁵ These PBS changes were during the last 12 months of the BEACH study, it was therefore likely that some GPs would have documented non-specific information such as 'testosterone deficiency' irrespective of whether the PBS criteria was met. It was also highly likely that male patients younger than 30 years of age would have met the PBS criteria irrespective of what the GP documented. Therefore, bioidentical testosterone hormones prescribed or administered to male patients would be categorized as MM if the patient was younger than 30 years of age, or the indication was for confirmed testosterone deficiency from an established pituitary or testicular disorder in males of any age. If the indication term was 'testosterone deficiency', it would be categorized as IM/MM. Off label indications (e.g., andropause, low libido, impotence, infertility, fatigue, non-communicable chronic diseases etc.) would be categorized as IM.

Lastly, all terms for bioidentical oestrogen or progesterone prescribed to males or transgender women would be categorized as MM, as the indication is feminization. Similarly, high dose bioidentical testosterone prescribed to females or transgender men would be categorized as MM.

4. Discussion

The decision criteria outlined in this article is the first step towards developing a detailed operational definition for a secondary analysis of IM activity by GPs participating in the BEACH study.²⁷ Whilst other operational definitions have been developed for other purposes such as the Cochrane Complementary Medicine Field's operational definition for systematic reviews and bibliographic research,^{10,40,41} and a common core list of T&CM for population surveys,³⁹ to the best of our knowledge, this is the first attempt to establish detailed decision criteria for defining IM that can be applied to general practice, health services research in Australia and potentially other countries with comparable health service characteristics.

Challenges with establishing the criteria for categorizing terms as IM or MM included applying high-level, theoretical definitions and descriptions to aspects of clinical practice that are legitimate components of both MM and IM. Rather than attempting to dichotomise general practice, the solution was to embrace the overlap. In this context, IM is defined as an extension of MM general practice rather than an alternative.⁴

The available terms in the two coding systems (ICPC-2 PLUS and CAPS) also influenced the final criteria. Pragmatic decisions had to be made to minimize the risk of spurious overcounting of IM practice and differentiating between IM and MM practice would not always be possible. For instance, due to them rarely, if ever being documented by participating GPs, there are no ICPC-2 PLUS terms for T&CM therapies or practitioners not already included in ICPC-2, nor various IM concepts such as nutritional insufficiency, subclinical hypothyroidism, detoxification, anti-ageing, quality of life, wellness or wellbeing that could have been used to differentiate between IM and MM indications. Other pragmatic decisions included categorizing all CAPS terms for foods, saline, and topical ophthalmic drugs, and all secondary care and non-specific ICPC-2 PLUS processes of care terms as MM.

Limitations of the proposed decision criteria include its specificity to medical practice. Different criteria and categories would be required for other types of healthcare practitioners. For instance, an additional T&CM category would be required for a study that included T&CM practitioners, as unlike medical doctors, it would be possible for these practitioners to only provide T&CM services. Additionally, the applicability of the criteria for categorizing the ICPC-2 PLUS terms is further limited to medical practice in primary care settings. Whilst informed by the available literature, the final criteria reflected the clinical discretion and expertise of the authors and was therefore subjective. We sought to ensure the research team represented different clinical perspectives, however, there is still a risk of bias that may have led to an over or under categorization of terms and concepts. We considered other methodological approaches such as Delphi surveys of a diverse range of practitioners, however, IM experts would still be expected to over include, whilst those staunchly entrenched in MM would probably recommend excluding borderline terms. Instead, prior to finalising the statistical analysis plan, we propose to use sensitivity analyses to explore the potential implications of using different criteria. Other limitations include its specificity to the BEACH study and general practice activity in Australia between 1998 and 2016. Even when the same coding systems are used by another study, the proposed criteria would need to be modified to suit the clinical and historical context of the study. For studies using different coding systems, different criteria will likely be used for the operational definition that will reflect the available terms. Notwithstanding, the decision criteria and rationale presented here lay the groundwork for health services researchers seeking to establish a detailed operational definition of IM for general practice research.

In conclusion, in the absence of an operational definition of integrative medicine in general practice health services research, we have detailed the criteria that will be used to establish the BEACH study operational definition. Differentiating between integrative and mainstream

medicine is context specific and not always possible. The criteria, definitions, principles and processes reported in this article can be applied by other researchers and health services, both in Australia and internationally.

Conflict of interests

The authors declare that they have no conflicts of interest.

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CRedit authorship contribution statement

Jennifer Hunter: Conceptualization, Methodology, Data curation, Writing – original draft. **Joanna E. Harnett:** Writing – review & editing. **Wai-Jo Jocelin Chan:** Validation, Data curation, Writing – review & editing. **Marie Pirotta:** Validation, Writing – review & editing.

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Data sharing is not applicable to this article as no new data were created or analysed in this study.

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