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Integrating Complementary and Conventional Care Using Quality Use of Medicines as a Framework

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1. Introduction

“Tis impossible to separate the chance of good from the risk of ill.”

(Hume 1998).

Complementary and Alternative Therapy (CAM) use is increasing: prevalence of use in the general population ranges between 50 and 80% globally (World Health Organisation (WHO) 2002). High CAM users include people with chronic diseases, women educated to high school level or higher, people with poor health, those who are employed and people interested in self-care (Lloyd *et al.* 1993; Eisenberg 1998; Egede *et al.* 2002; MacLennan *et al.* 2002).

Many people regard CAM as a solution to modern health and social problems such as chronic lifestyle diseases, obesity and depression. Significantly, people consider their health care options and make choices that are congruent with their life philosophy, knowledge, experience, societal norms, and culture. Depending on these factors, they may or may not choose to be actively involved in their care and/or incorporate CAM in their health care regimen.

Understanding these factors can help health professionals understand people’s health care choices, self-care behaviours, adherence to management recommendations and their capacity to be empowered. For example, there is a strong association among health beliefs, spirituality and CAM use (Hildreth & Elman 2007). In addition, there is good evidence that CAM users adopt health-promoting self-care behaviours, undertake preventative health care and believe they are ultimately responsible for their health (Kelner & Welman 1997; Garrow *et al.* 2006; Parsian & Dunning 2009).

People using CAM are largely satisfied with their CAM choices and outcomes even if it 'did not work' (House of Lords Select Committee on Science and Technology 2000). Significantly, satisfaction with treatment improves well being. However, 'satisfaction' is an elusive concept and there are many ways to define and measure 'satisfaction:' not all are objective, and some are more useful in research than for determining individual satisfaction, including with CAM.

Rittenbaug et al. (2011) developed an 18-item patient-centred CAM outcome measure to determine the multidimensional impact of CAM. The items encompass physical, emotional, cognitive, social and spiritual domains, which is consistent with holistic CAM philosophy. The psychometric properties of the tool were not reported but it is currently undergoing further testing. If it is valid and reliable, the tool could be useful in clinical care and research. It could enable meaningful comparisons to be made and might go some way towards developing a common language.

2. Integrative medicine

Some experts regard integrative medicine (IM) as a new evolving care paradigm; however, it could reflect a rebalancing process towards the system that operated before the rise of 'scientific medicine' in the early twentieth century. Research suggests most CAM users combine conventional and CAM therapies: often several CAM). Likewise, health professionals, especially general practitioners (GP) and nurses, combine both types of therapies to provide holistic care (Braun & Cohen 2010). The combination of CAM and conventional therapies is increasingly known as Integrative Medicine.

IM focuses on wellness, and the spiritual, environmental, social and lifestyle factors that enhance or compromise wellness. IM aims to provide individualised 'effective and compassionate care on many levels' (Cohen 2005). Researchers and clinicians use a variety of definitions of IM, which makes it difficult to compare and apply research findings. The definition of IM developed by the Royal Australian College of General Practitioners (RACGP) and the Australasian Integrative Medicine Association (AIMA) (2009) was adopted for this chapter because it encompasses evidence-based care, practitioner responsibility, holistic person-centred care and, is self-explanatory and practical. IM is:

The blending of conventional and complementary medicines and therapies with the aim of using the most appropriate of either or both modalities to care for the person as a whole.

Although not specifically listed in the RACGP/AIMA definition, health promotion and encouraging self-care are central to IM, as they are to CAM philosophy, and increasingly to conventional care. Significantly, IM is essentially a transformative process that has four main dimensions (Bell et al. 2002; Mulkins & Verhoef 2004):

1. Access to and availability of a range of therapies to support the individual's lifelong health journey.
2. Care that considers the individual's overall health and well being.
3. Involving the individual in decisions about their health goals and care plan.

4. A healing or therapeutic relationship between health professionals and individuals, which is essential to achieving optimal outcomes.

Bell et al. and Mulkins & Verhoef might have intended to include timely communication among health professionals and between health professionals and individuals in the fourth dimension; however, 'effective communication' could be regarded as an essential fifth dimension.

These IM definitions and dimensions reinforce the fact that IM does not aim to reject or replace either CAM or conventional therapies: it advocates combining both types of therapies when the combination is relevant to the individual's needs and is safe and evidence-based (Kotsirilos et al. 2010). Khorsan et al. (2011) undertook a systematic review of IM and identified an extensive and increasing body of literature on the subject that can be used to support practice. However, because IM is an emerging field in many countries, there may be less evidence for IM than for individual CAM.

Marshall et al. (2004) used the acronym BEECH to describe IM care:

- B: Balance between CAM modalities and/or CAM and conventional modalities.
- E: Empowerment and self-healing.
- E: Evidence-based care based following the concept 'first do no harm.'
- C: Collaboration between the health professional and the individual and among professionals, and respect for the individual's choices.
- H: Holistic multidimensional care including promoting optimal healing environments, consistent with holistic care.

Some elements of BEECH are similar to Bell et al. and Mulkins & Verhoef's IM dimensions.

3. Does integrative care exist?

The WHO (2002) described three main levels of CAM integration:

1. Integrative level where CAM is officially recognised at Government level and incorporated into health systems for example, in national medicine policies, product regulatory procedures, hospital and community guidelines and is reimbursed under health insurance systems.
2. Inclusive level where CAM is recognised and largely accepted but not fully integrated into health systems.
3. Tolerance level where CAM is not officially part of the national health system.

Level one integration is rare. For example, CAM is not formally integrated in most hospitals in Australia, although IM is becoming more acceptable/common in general practice, aged care facilities and some specialist services such as cardiology and cancer. CAM medicines are regulated under the same regulatory processes as conventional medicines in Australia but they are not funded by the government Pharmaceutical Benefits Scheme, as many conventional medicines are. However, some health benefit schemes reimburse members for some CAM therapies.

As indicated, there is a professional association for IM practitioners in Australia, AIMA, and at least two evidence-based Australian IM textbooks were published in 2011 (Phelps & Hassed 2011; Kotsirilos et al. 2011). These initiatives demonstrate a response to public demand for CAM and increasing health professional acceptance, or at least tolerance, of IM. Thus, CAM in Australia, like Canada, the USA and the UK, probably fits into the WHO integration levels two or three.

However, CAM use and IM is more structured and integrated in countries such as China, Taiwan, India, and Germany. Some developing countries include CAM within the dominant health system, but it is not necessarily systematically integrated. Many people in developing countries rely on CAM as first line treatment because conventional care is costly, inaccessible, unavailable, or all three.

In reality, many individuals self-diagnose and select management options to suit their needs and many combine CAM and conventional care. They often do not consult or inform CAM and/or conventional health professionals about their care decisions. While these behaviours are consistent with personal empowerment and choice, they can delay diagnosis or mask important symptoms and have adverse outcomes.

4. Safety, quality and IM

Safety and quality are key health care issues and need to be considered in all countries and at all levels: regulatory bodies, service providers, health professionals and individuals. The evidence-base for IM and the way it is delivered and evaluated (outcome measures) are important issues to help professionals decide what CAM/IM could meet the public demand, respect individual's choices and people's right to appropriate information to help them make informed health care decisions, but still meet quality and safety standards.

A consistent approach to delivering health care and standards of care that encompass product and professional regulation, professional self-regulation, public and professional education, and all types of rigorous research, quantitative, qualitative, evaluation, audit and translational, to generate and translate knowledge is needed (Commonwealth of Australia 2003). Table 1 provides an overview of some of the inter-related factors that affect safety.

There appear to be four key areas that need to be addressed to ensure CAM is systematically and safely integrated:

1. National policies and regulatory processes including professional regulation.
2. Processes for defining and monitoring safety and efficacy including pharmacovigilance.
3. Equitable access to CAM and conventional modalities and IM.
4. Rational use of CAM and conventional modalities (Bodeker et al. 2005).

Stakeholder collaboration/engagement is inherent in all four areas and is essential to systematically implement IM. Stakeholder consultation/engagement could include determining the priorities for action and/or for research concerning CAM and IM in relevant

countries, willingness to share and learn from each other, and willingness to undertake rigorous research to determine the benefits, risks and cost implications of IM for individuals and health systems. However, it is often difficult to assess benefit and risks from a great deal of existing research due to a multiplicity of factors such as methodological flaws, different definitions of terms and other confounding factors. Thus, it is difficult to generalise findings and/or translate them into clinical guidelines.

Inter-related factor	Factors that enhance safety
Therapies	<p>Regulatory processes: government, professional and self.</p> <p>Evidence base for safety, quality and efficacy.</p> <p>Quality control safety monitoring processes including international monitoring bodies such as the Uppsala Centre.</p> <p>Manufacturing processes including product labeling. The label must be readable.</p> <p>Appropriate storage and transport and disposal procedures.</p> <p>Adherence to conventions such as The Convention on International Trade of Endangered Wild Flora and Fauna.</p>
Health professional	<p>Education and competence to provide and/or offer advice about CAM and IM.</p> <p>Duty of care to practice within their level of knowledge and competence and regulatory framework.</p> <p>Access to relevant, accurate information</p> <p>Managing conflict of interest such as the professional prescribing/recommending and selling products at the point of care.</p> <p>Ability to reflect on attitudes to CAM, conventional and or IM.</p> <p>Ability to communicate effectively and develop therapeutic relationships with the people they care for and collegiate relationships with other professionals.</p> <p>Access to qualified health professional from a range of CAM and conventional disciplines.</p> <p>Ability to critically review research publications and determine how rigor was demonstrated in order to make informed judgments about the applicably to practice.</p>

Inter-related factor	Factors that enhance safety
Environment in which care is provided	Infection control procedures. Accessible relevant policies and guidelines. Able to ensure privacy and confidentiality of consultations. Overall staff attitudes to CAM, conventional care and IM. Well signposted. Disabled access. Meets safety standards and is visually appealing and welcoming
Individual receiving care and/or advice	Health status. Reasons/goals for using CAM or IM. Access to relevant, accurate information. Self-care capability and practices. Conventional management. Relationship with health professional. Support base. Disclosure of CAM/IM use. Health and literacy level. Access to relevant, objective information
The quality of the information provided	Relevant to the individual and their literacy level and culture. Objective Accurate. Available in a timely and accessible manner.

Table 1. Overview of some of the inter-related factors that affect safety of complementary, conventional and integrative health care.

Thus, more rigorous research to evaluate IM as well as individual CAM therapies is needed to determine safe, cost-effective models of IM and appropriate outcome measures in keeping with holistic care. In addition, individual countries may need to:

- Determine processes for funding and delivering IM services.
- Determine who could/should be responsible for coordinating IM care.
- Explore and describe health professional's roles and scopes of practice and the knowledge and competence they require to provide safe evidence based IM. Health professional's role and scope of practice influences the educational preparation required for safe practice.
- Ensure health professionals who provide CAM and/or combine CAM and conventional care are appropriately qualified. Although CAM is increasingly being included in conventional health professional education curricula, the information may not be at the level required to competently deliver CAM or IM care.

- Educate CAM users (the population) about IM so they can negotiate informed care decisions with health professionals.
- Establish and maintain effective shared documentation, communication and referral processes, including web-based and other electronic media. The social media plays an increasing role in education, communication and interdisciplinary collaboration.
- Systematically monitor outcomes including costs, benefits and adverse events.

5. Safety and risk

Many conventional practitioners believe CAM is ‘not effective’ and is ‘risky business.’ In addition, 90% of CAM users assume CAM is safe (Sharples 2003). All health care carries some risk. Currently more adverse events (AE) are reported for conventional care than CAM. Several factors could account for the difference, including different patterns of AE reporting. The same AE reporting system applies to both CAM and conventional therapies in Australia, but patients are more likely to report CAM AEs than health professionals.

Safety and risk are complex concepts and cannot be considered in isolation. Risk is inherent in everyday life: individuals determine whether they are willing to take/accept risk according to their situation and their perception of the degree of risk to *them* (Komesaroff 2003). People’s perceptions of risk are subjective and are moderated or exacerbated by past experiences, current health status, mood, information including media reports, advertising, industry, health professionals, and their health beliefs and attitudes. People accept some risk as routine, but often underestimate their personal risk (optimistic bias) (Weinstein 1982; Sharot 2011).

Health professionals’ perception of risk is usually more ‘mathematical’ than the general public because of their training. HP’s perception of risk influences the information they provide to individuals, the language they use and the emphasis they place on the risks associated with health options. However, a health professional’s perception of their *personal* risk is likely to be influenced by opportunistic bias. Significantly, individuals are unable to effectively estimate personal risk until they are in their late twenties.

6. What is risk?

Definitions and perceptions of risk change as society changes through research, technological advances and wealth, but are almost always concerned with harm to individuals (patients). The concept of health-related risk has been part of health care since it emerged in ancient cultures. For example, the Hippocratic Oath states doctors should ‘first do no harm.’ First do no harm is still encompassed in naturopathic philosophy. The 17th century *Code of Hammurabi* described punishments for ‘harmful physician errors.’ The punishment depended on to the social status of the patient.

Pliny the Elder (first century AD) suggested physicians should not learn their skills at the expense of the patient. He also introduced the concept of patient responsibility by suggesting patients were to blame if they sustained harm as a consequence of neglecting their treatment—

in modern terminology non-compliance or non-adherence. In the Middle Ages Paracelsus noted the dual nature of medicines—ability to cure and ability to kill. Paracelsus' observation could have influenced the decision to include product safety in the safety-risk matrix.

Modern concepts of risk are based on probability theory that calculates 'technical risk' objectively (Clarke 2004). Probability theory considers risk in terms of the probability of a loss and the degree and severity of the loss. Most modern definitions of risk encompass an estimation of the likelihood that an AE will occur and have negative consequences (loss) that are significant to the individual. These concepts are an important when considering informed consent and medico-legal issues.

Risk is reported as in several ways: absolute Risk (AR), relative Risk (RR), number needed to treat (NNT) or risk/benefit ratio. AR refers to the difference between the outcomes in a control group compared with an intervention group in a specified time period. RR refers to the absolute risk as a proportion of baseline. Benefits are often expressed as RR and harms as the AR. The NNT refers to the number of people who need to be treated for a specified period of time to obtain benefit.

The NNT to cause harm is the inverse of the absolute rate of adverse events occurring in a defined period of time. In order to estimate risk, the endpoints must be clearly stated. Surrogate endpoints might indicate potential benefit or potential harm.

7. Adverse events associated with CAM

The safety and risk profile differs according to the individual CAM therapy/ies, the IM combination used and the individual who uses them. Some therapies such as medicines are more likely to cause harm than others. Likewise, there is more evidence for some CAM than for others. However, it is important for health professionals to realise that lack of evidence does not mean there is no evidence, and understand that all of these issues apply equally to conventional therapies.

Estimates of safety and risk for many CAM medicines are based on a long history of safe traditional use. The term 'long traditional use' is open to interpretation: the European Directive on traditional herbal products regards use for at least 15 years within Europe and more than 30 years outside Europe as evidence of long traditional use. Most conventional medicine manufactures are not expected to fulfill such stringent duration of safe use criteria and AEs often emerge after conventional medicines are registered and used in clinical care.

In addition, modern technology and modern growing, harvesting and extraction techniques might mean modern CAM medicines have a different chemical makeup from medicines produced using traditional production processes and might be more safe or less safe, but such medicines are marketed under the 'long traditional use' mantra. These issues are rarely discussed but are worth considering and investigating systematically.

Many potential CAM/conventional interactions are theoretical (Braun 2006) and are hard to predict (Ulbricht 2012) but need to be considered as part of the overall care plan and monitoring process. People who use CAM often have several concomitant health conditions

such as atopic conditions, diabetes and kidney and liver disease that increase the risk of AEs. Table 2 outlines key issues associated with pharmacovigilance and table 3 depicts people most at risk of AEs.

Systems level	Pharmacovigilance-related processes
Health system	<p>Degree of product regulation including manufacture and pre and post marketing surveillance processes.</p> <p>Affordability and accessibility of medicines and products.</p> <p>Equitable support for CAM, conventional and IM-related research.</p> <p>Availability of evidence based guidelines to support practice.</p> <p>Systems to schedule/register and monitor medicine use including adverse events.</p> <p>Process to learn from adverse events.</p> <p>Marketing processes: in some countries conventional medicines cannot be marketed directly to the public.</p> <p>Methods of communicating important medicine-related information to the public and health professionals.</p>
Health professionals	<p>Education and competence to perform role.</p> <p>Engagement in ongoing professional development.</p> <p>Licensing, regulatory and self-regulatory processes to protect the public.</p> <p>Professional liability insurance.</p> <p>Communication, documentation, and referral processes.</p> <p>Attitudes towards and beliefs about medicines CAM, conventional care and IM</p>
Herbal medicines	<p>All of the issues covered under health system section and:</p> <p>Manufacturing practices including whether the medicine was prepared according to the traditional method.</p> <p>Processes for identifying, handling, and storing herbs including using botanical names.</p> <p>Infection control procedures.</p> <p>Processes to detect and prevent adulteration and contamination of CAM medicines.</p> <p>Informative, honest labels.</p> <p>Prescribed in appropriate dose, dose intervals and for an appropriate time considering indications for use, precautions and contraindications and considering prescribing for people at high risk of adverse events.</p> <p>Produced considering sustainable agriculture methods and follow relevant conventions such as The Convention on International Trade of Endangered Wild Flora and Fauna.</p>

Individual	Age. Physical and mental health status. Knowledge and health capabilities. Not disclosing herbal medicine use. Knows the consequences of polypharmacy. Self-diagnosis and self-treatment, which can delay treating serious problems. Method of storing and handling medicines and disposing of unused medicines appropriately. Inappropriate use of medicines and CAM e.g. sharing medicines with family members and friends. Know how to monitor defined outcomes Realistic expectations about curing or controlling diseases. Realises the cost implications of medicine use.
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Table 2. Inter-related safety and quality issues related to pharmacovigilance.

Take conventional medicines with a narrow therapeutic index such as digoxin and warfarin.
Take high risk conventional medicines such as insulin.
Have renal disease or liver damage, which compromises medicine metabolism and excretion.
Has allergies such as dermatitis and asthma.
The elderly, children, and pregnant and lactating women.
Concomitantly using five or more medicines (polypharmacy).
Uses excess alcohol or illicit drugs.
Lacks sufficient knowledge/information to make appropriate decisions about CAM use or receives inadequate or inappropriate advice about CAM.
Do not advise all the health professionals they consult about their CAM and conventional medicine use.
Acquire CAM products from the Internet or overseas that are not subject to rigorous quality control and regulatory processes. Such products may be contaminated, inadequately labeled and/or the herbs may not be correctly identified.

Table 3. Individuals most at risk of herbal-conventional-food-interactions and other adverse events.

8. Standards and regulatory processes that aim to improve safety and reducing risk

Standards and regulatory processes are important to risk management strategies. They exist to protect the public (O'Keefe & Henderson 2012). In Australia, CAM, which includes herbal medicines, homeopathy, essential oils and vitamin and mineral supplements; and conventional medicines are regulated by the Therapeutic Goods Administration (TGA); The

Office of Complementary Medicines oversees the recall of faulty or dangerous CAM medicines.

All CAM medicines are assessed for safety and the quality of the ingredients but only CAM medicines deemed to be high risk are assessed for efficacy. The TGA critically analyses clinical trial data the manufacturer supplies to support their claims of safety and efficacy. If the TGA accepts the manufacturer's evidence, high risk medicines are registered and bear the words AUST R on the label.

Manufacturers of lower risk medicines must be able to substantiate their claims that the medicine is safe risk but are not required to submit evidence of safety when they apply to have the medicine listed. Manufacturers of low risk medicines are not permitted to use terms such as cure, treat, manage, and prevent on medicine labels or marketing strategies. Listed medicines are designated AUST L on the label. Ingredients included in listed and registered medicines must be included on the list of substances approved for use in Australia. Thus, medicine labels give some indication about the level of evidence available to support safety and efficacy. Other medicine-related quality control processes include labeling, manufacturing and advertising regulations and Acts and pre and post market surveillance.

Other countries have similar regulatory process although they might classify medicines differently. Many European countries require evidence to support manufacturer's claims in order for them to be registered. Other related processes include the The WHO International Terminologies on Traditional Medicine in the Western Pacific Region (WHO 2007) and the European Parliament and Council directive on the use of traditional products, which stipulated that herbal medicines must be produced according to good manufacturing practices from April 2011 (Efferth & Greten 2011).

The European Directive contains a number of other recommendations to provide guidance for retailers, wholesalers, manufacturers and importers about requirements for medication standards about their legal responsibilities. The WHO has produced many other informative guidelines and polices to communicate and support safe evidence-based herbal medicine use which can be sourced from the WHO website,

Contamination and adulteration of CAM medicines compromises safety in many countries. The Convention on International Trade of Endangered Wild Flora and Fauna (CITES), also known as the Washington Convention, was set up to protect vulnerable species from extinction. Over 150 countries are signatories to CITES.

Health professional knowledge and competence also influence safety and quality. CAM practitioners are self-regulated and/or regulated through professional association codes, standards, policies and continuing professional development processes in most countries but few are statutorily regulated. In Victoria, Australia Chinese Medicine practitioners, Chinese herbal practitioners and Acupuncturists are required to be registered with the Chinese Medicine Registration Board: it is likely other states follow Victoria's lead.

A number of education providers in many countries, including universities and on-line education providers, offer a wide variety of CAM courses at all levels; certificates, diplomas

and post graduate degrees. In some countries course providers must meet training standards but many people attend short courses that do not adequately prepare them to deliver safe informed CAM care.

9. Quality use of medicines

Quality use of medicines (QUM) is a useful framework for determining individual treatment options and assessing and monitoring risk at all levels of medicine use (Dunning 2004).

Australia's National Medicines Policy (NMP) incorporates QUM, which encompasses conventional, CAM and non-prescription medicines. Australia's QUM processes have been adapted and are used in many other countries such as Canada. QUM essentially puts the individual at the centre of care and refers to:

- Selecting management options wisely. Significantly, QUM and IM are not concerned with either/or choices: they espouse holistic care by recommending the best options for/with the individual, which may or may not include medicines
- Choosing suitable medicines if medicines are indicated. Not everybody requires medicines to maintain health, which is consistent with CAM philosophies. Wise medicine choice encompasses, prevention, lifestyle strategies, and risk management.
- Using medicines safely and effectively' (Commonwealth Department of Health and Aging 2002).

The extent to which QUM is applied to CAM is largely unknown. Dunning (2004) developed a QUM framework for using essential oils (aromatherapy) in nursing practice. It is not clear whether aromatherapists and other health professionals are aware of or use the aromatherapy QUM framework. The framework could be adapted for CAM generally.

Although not documented in current QUM policies, QUM encompasses sustainable agricultural and carbon reduction practices, which are important considerations, given the effects of climate change and the number of endangered plant and animal species, many of which are included in CAM medicines in some countries (Taylor 1996). CITES has made a major contribution to reducing the risk and saving many endangered plants and animals. In addition to its application to medicines use, QUM could serve as a research framework to evaluate IM and other CAM. .

10. Practical ways clinician health professionals can apply QUM

Health professionals have a responsibility to individualise care, respect people's choices and be non-judgmental about the choices they make. QUM can help health professionals realise these responsibilities:

Applying QUM at the individual patient level involves:

- Developing active partnerships with individuals, effective communication and collaboration processes and using evidence based policies and guidelines to deliver consistent care and enable benchmarking.

- Engaging the individual in setting care goals and making care decisions, which includes providing objective, ethical information about medicines and other care options in a language and format the individual can understand and that is culturally appropriate.
- Pharmacovigilance, which encompasses the entire medicine pathway as well as appropriate prescribing and monitoring.
- Monitoring outcomes including the individual's medicine self-management capability and adherence, and adverse event reporting.
- Documenting CAM use.

Developing a QUM philosophy

- Be sensitive to people's philosophical and cultural views and be aware that they probably perceive risks and benefits differently from health professionals.
- Follow guidelines for using CAM where they exist or seeking and using the best available evidence and being able to justify its use.
- Being appropriately qualified and competent to use, recommend or offer advice about CAM.
- Objectively communicating risks and benefits and management options to the individual and in some cases their families or carers. If the person chooses not to follow advice, documentation should outline what information was provided and the fact the individual elected not to follow the advice.
- Developing a 'portfolio of evidence' that can be used as a reference in clinical areas.
- Adopting the QUM approach to prescribing, administering, documenting and monitoring care. This includes asking about CAM use. One of the most common reasons people do not disclose CAM use is because Health professionals do not ask about it. Ask questions should be asked in a non-judgmental way. The patient has a responsibility to disclose: health professionals can make it easier for them to do so by using appreciate body and verbal language, and effective questioning skills. For every one problem missed by not knowing, nine others are missed by not looking.
- Valuing the therapeutic relationship and doing their utmost to develop and sustain relationships.
- Considering the effect of some CAM on other staff, visitors and other people when CAM is used in health care facilities for example, vaporising essential oils and playing music.
- Knowing how to report adverse events and reporting any that occur to add to the safety and risk profile of CAM and IM. The quality of the AE report is important rather than the source of the report.
- Having processes and policies in place to clean and maintain any equipment for example, vaporizers and infection control policies.
- Documenting the type, dose and duration of the therapy, reason for use, advice given, method to monitor outcomes and the expected and actual outcomes.
- Seeking advice or referring to an appropriate person when do not have the knowledge or competence to address the issue.

11. Chapter summary

Safety and health professional responsibility are not new concepts but notions of safety and regulatory processes have evolved over millennia. QUM is a useful framework for managing CAM and IM at all levels and exemplifies person-centred care, using non-medicine options where possible and pharmacovigilance

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