Traditional and Complementary Medicine: Analysing Ethical Challenges

By

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I declare that while registered as a candidate for the research degree, I have not been a registered candidate or enrolled student for another award of the University or other academic or professional institution.

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Abstract

The use of traditional and complementary medicines (T&CMs) is both ubiquitous in low and middle income countries *and* highly contested in some sections of high income countries. Whilst T&CMs are promoted as an accessible and affordable health care system by high level health policy makers (for example, the Director General of the World Health Organization), their use is simultaneously indicted as a waste of resources, non-scientific, and unethical.

The aim of this thesis is to provide a calm, considered and well researched view on a highly emotional topic: *What is the nature of the ethical challenges for the use and practice of TCMs and how might they be addressed?*

The methodology chosen for the ambitious topic of this thesis is the Ethical Matrix as developed by Ben Mepham in the UK in the 1990s. It is founded upon a principlist approach to ethical analysis and has been used widely in decision-making for new technologies. It requires the consideration of interests of stakeholders including, but also beyond, human beings. For the purpose of this thesis four groups were selected: human users of T&CM, the environment, animals, and low and middle income countries (LMICs).

Ethical analysis reveals that:

- Most ethical concerns associated with T&CMs are related to safety issues for human users;
- there are also serious concerns about the way in which animals are routinely harmed through use in T&CM products and T&CM research;
- the production and use of some T&CMs does have damaging impacts upon the environment and,
- the ethical challenges associated with the use of T&CM in LMICs are different from those in high income countries.

Based on the analysis, the thesis provides clear steps to be taken to reduce the potential for harm from both adverse drug reactions and adverse events for humans as well as recommendations to reduce the harm to animals and the environment from use of T&CMs.

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Abbreviations

ADR = adverse drug reaction

AE = adverse event

ARRIVE = Animal research: Reporting of *in vivo* experiments

ASA = Advertising Standards Authority

ATC = Anatomical therapeutic chemical

BMA= British Medical Association

BMJ = British Medical Journal

CAM = Complementary and alternative medicine

CIOMS = Council for International Organizations of Medical Sciences

CVD = cardiovascular disease

DoH = Department of Health

EBM = Evidence based medicine

EBMWG = Evidence based medicine working group

GNI = Gross national income

HATC = Herbal anatomical therapeutic chemical

ICLAS = International Council for Laboratory Animal Science

IOM = Institute of Medicine

GDR = Generalized resource deficit

GRR = Generalised resistance resource

MeSH = Medical Subject Headings

MHRA = Medicines and Healthcare products Regulatory Agency

NCCIH = National Centre for Complementary and Integrative Health

NCCAM = National Centre for Complementary and Alternative Medicine

NC3Rs = National Centre for the Replacement, Refinement and Reduction of Animals in Research

NHS = National Health Service

NICE = National Institute for Health and Care Excellence

NLM = National Library for Medicine

NPSA = National Patient Safety Agency

OCS = Okinawa Centenarian Study

OECD = Organisation for Economic Cooperation and Development,

ONS = Office for National Statistics

RCT = Randomised controlled trial

T&CM = Traditional and complementary medicine

TCM = Traditional Chinese Medicine

THR = Traditional Herbal Registration

UMC = Uppsala Monitoring Centre

UK = United Kingdom

UN = United Nations

WHO = World Health Organisation

WHO-UMC = World Health Organisation- Uppsala Monitoring Centre

CHAPTER ONE. INTRODUCTION

The term 'complementary medicine' is broadly used in the Western world to refer to a group of therapeutic systems and interventions that exist largely outside of the established, conventional[1] healthcare system. In some countries, primarily low and middle income nations, where the use of indigenous forms of medicine is ubiquitous, it is more commonly termed 'traditional medicine'. The range of traditional and complementary medicines (T&CMs) around the world is vast and includes ancient forms of healthcare such as traditional Chinese medicine, Western herbal medicine, traditional Indian medicine (Ayurvedic), and traditional Arabic medicine (Unani), as well as more recently developed systems such as homeopathy, naturopathy, chiropractic and osteopathy. Whilst T&CMs have developed largely in their own geographic localities, and over extended periods of time, T&CM products and practices are now a truly global phenomenon (WHO 2013).

The full practical, legal and ethical implications of the wide scale use of T&CMs have only relatively recently become subjects of scrutiny. As the demand for T&CM in high income countries has expanded, education and training centres have been established to meet an increasing demand for skilled practitioners. For example, in the past it was necessary to visit China for training in acupuncture, but today courses are available all over the world. In the absence of agreed global standards, educational levels in T&CM vary considerably across the globe, from well-developed and accredited courses in universities, to short, unregulated courses available online. Whilst many countries are attempting to develop policy for and regulation of T&CM, practices are inconsistent and vary from country to country. In some countries T&CM remains completely unregulated (WHO 2013).

Many ethical challenges to T&CM have been described but few have been clearly analysed. As Ernst (2009) asserts, while a few authors have written about ethical T&CM practice they have largely only addressed ethics in the abstract and, 'the message that emerges is that, in complementary medicine, ethical issues are neglected

[1] The term 'conventional medicine' is used in this thesis to refer to the dominant healthcare system in the Western world today. It is commonly termed biomedicine, orthodox medicine, allopathy and Western medicine.

and violated on a daily basis' (Ernst 2009c, p.517). No comprehensive exploration and analysis of the potential ethical challenges to T&CM has previously been undertaken, and hence the primary aim of this thesis is to analyse emerging ethical challenges to T&CM and, where possible, to make suggestions for how these challenges might be addressed. The enquiry begins with the underlying assumption that there are ethical challenges for the use and practice of T&CM, just as there are for the use and practice of conventional medicine. The specific research question is as follows:

"What is the nature of the ethical challenges for the use and practice of T&CM and how might they be addressed?"

It is anticipated that conclusions will be highly relevant to future decision making in this field, with a view to informing:

- People working in the field of T&CM, including individual practitioners, as an aide to ensure ethical practice and avoid harm; professional bodies who establish standards of professional conduct and codes of ethics; and educators who develop programmes of education and training.
- Fund-holders and policy-makers in medicine, as decisions about priorities in healthcare, funding streams and provision must be based upon ethical considerations as well as available evidence of efficacy.
- Patients, so that information may be provided about potential harms and benefits, whilst respecting their right to make decisions about their healthcare.

1.1 Overview of the Research Process

The methodological approach for this enquiry falls within the domain of *applied ethics*, and, more specifically, the sub-discipline of *bioethics.* 'Applied ethics' is a term that broadly refers to the use of philosophical methods to examine particular issues for the purpose of moral decision-making. The particular issues in question may pertain to personal or professional life, or be related to technology, society or politics, for example. Importantly, the use of applied ethics is of notable value for informing policy and practice, a primary aim in this thesis. As Kurt Bayertz (2002) explains:

> In a remarkably short period, applied ethics has established itself as a subdiscipline of moral philosophy in both academic teaching and research. The number and variety of specialist publications expands as rapidly as the number of journals and conferences. At the same time, it has become apparent that (a) applied ethics is increasingly being integrated into the training procedures of various professions and that (b) the field is being called upon on different levels of practical decision-making, for instance, in ethics commissions or parliamentary advisory committees. Thereby, it has expanded beyond the realms of academic moral philosophy into a public role. Applied ethics has an impact not only in the form of books and essays but also in the form of practical decisions and thus action (p 32).

The field of applied ethics, as it appears today, emerged from debate surrounding rapid medical and technological advances in the early 1970s and has expanded to include a broad range of sub-disciplines such as social and political ethics, business ethics, computer ethics, medical ethics, environmental ethics, and different forms of professional ethics. Bioethics is a branch of applied ethics, which deals mostly with questions arising from the life sciences, medicine and health care. However, a broader understanding of the term adds environmental ethics and animal ethics to its scope (Gillon 2001).

An applied ethics approach to the examination of moral dilemmas can take many different forms but one of the most influential and most widely utilised approaches in bioethics and health care ethics is the four-principle approach developed by Tom Beauchamp and James Childress (1978). The four-principle approach, commonly termed ‘principlism’, entails consideration of four *prima facie* ethical principles: autonomy, non-maleficence, beneficence, and justice. These four principles form the basis of the ‘ethical matrix’, the bioethical methodology of choice for this research, first introduced by Ben Mepham in the mid 1990s (Mepham 1995, 1996). The application of principlism and, by implication, the use of the ethical matrix as a tool for ethical decision-making are not without criticism. Debate concerning the use of principlism is further discussed in Chapter 4.

This research was desk-based, involving critical thinking and conceptual, philosophical analysis as well as dialogue and exchange with other scholars through the PhD supervision process. The adoption of a desk-based approach to this enquiry enabled a holistic view of the scope of ethical challenges for T&CM as well as the detailed ethical analysis of specific significant concerns. This would not have been possible with a purely empirical approach given the magnitude of the subject area. Whilst an empirical approach is undoubtedly of value for the investigation of specific ethical dilemmas, it would not have provided the breadth needed to establish a holistic overview. Additionally, the time required for undertaking a high quality empirical investigation would most likely have restricted the research to the investigation and analysis of just one or two specific ethical concerns. In contrast, a desk-based approach can build upon the findings from multiple empirical studies, as well as existing scholarly work.

Applied ethics requires understanding of specific fields as well as the synthesis and analysis of information drawn from a diverse array of sources. The content of the examination can be extremely varied; it may be drawn from literature, empirical studies, philosophical enquiry, policy documents and so on. In addition, it often requires not only theoretical analysis, but also practical, feasible solutions. There are no set rules about how to find the relevant information, the analysis of each ethical concern may have unique requirements. This type of analysis necessitates a flexibility in approach with adaption to the specific topics of concern.

In seeking to address the research question, the following steps were undertaken in this investigation:

1.1.1 Step 1 Definitions

The main objectives of this stage were:

a. To articulate a clear working definition of T&CM to help delineate those practices to be included as the subjects of investigation for this thesis.
b. To describe the meaning of ‘health’ that informed subsequent enquiry and ethical analysis. This was highly important for this thesis since, because the selected methodology (the ethical matrix) serves primarily to highlight ethical issues and conflicts of interest, it cannot be relied upon to resolve ethical dilemmas. The established meaning of health acted as a premise upon which

argument could be based when considering ethical dilemmas that emerged from the ethical matrix. It was anticipated that from this meaning certain ethical implications for the provision of healthcare could be inferred, thus enabling conclusions to be drawn.

1.1.2 Step 2 Identification of ethical challenges and setting up the ethical matrix

The ethical matrix is a bioethical methodology that was originally designed to help evaluate complicated public policy decisions involving agriculture and food production. However, this method can be applied more widely and has proved to be a versatile tool for analysing ethical issues (Mepham 2009). The principal aim of the matrix is to facilitate rational public policy decision making by articulating the ethical dimensions of any issue in a transparent and broadly comprehensible manner (Mepham 2000).

Figure 1: The Ethical Matrix

	Wellbeing	**Autonomy**	**Justice**
Stakeholders			
A			
B			
C			

Identified stakeholders are listed on the vertical axis and the interests of each considered with respect to the three ethical principles set out on the horizontal axis.

Setting up the ethical matrix (Figure 1) concluded step 2 of the research and involved mapping all stakeholder interests identified in the literature onto the principles of wellbeing, autonomy and justice. This resulted in a complete matrix, detailing all main stakeholder concerns ordered through ethical principles.

1.1.3 Step 3 Analysis of ethical issues

This step involved critical analysis of the primary stakeholder concerns that were identified in step 2. A large number of concerns were identified across a range of stakeholders and it was not possible to analyse each in detail. Hence judgment was used

to select the issues that were deemed the most ethically challenging and these were awarded greater emphasis. Ethical analysis has resulted in considered judgements about relevant cells in the matrix. Importantly, and most challengingly, where areas of ethical conflict were highlighted, an attempt has been made to formulate strategies for resolution.

1.1.4 Stage 4 Conclusions and recommendations for policy

The final stage in the analysis of concerns for each stakeholder has been the identification of specific factors that may be relevant for policy and decision makers in the future.

1.2 Background

The wide scale use of T&CM and associated practical and ethical concerns were the focus of attention for the World Health Organization (WHO) in their traditional medicine strategy 2014-2023 (WHO, 2013). According to the WHO different forms of T&CM are found in almost every country in the world and the demand is increasing (WHO, 2013). Precise figures for global usage are elusive as demand differs greatly between regions, socio-economic groups, cultures and health complaints, even within individual countries. However, estimates suggest that usage is highest in parts of Asia and Africa where up to eighty per cent of the population rely upon some form of traditional medicine for their primary health care (WHO 2008). Elsewhere in the world there is evidence to suggest that demand for T&CM is high and is increasing, in spite of the ready availability of conventional care. Whilst the figure is not believed to be anywhere near the eighty per cent level in the United Kingdom (UK), a dramatic upsurge in popularity of many forms of T&CM over the past forty years has been well documented (Fulder 1988, Sharma 1992, Graham 1999, Ernst and White 2000, Thomas *et al.* 2001, Robinson *et al.* 2007, Posadzki *et al.* 2012b).

Potentially, there are a myriad of reasons for the popularity of T&CM, but for those in low and middle income countries it is often the case that appropriate conventional medicine is cost-prohibitive, inaccessible, or simply not available, such that T&CM treatments are the only available healthcare option. In some localities people are largely

dependent on some form of local, traditional T&CM for their primary healthcare, utilising specific types of T&CM that have a cultural connection, and are readily available and affordable. For instance, in Africa the majority of medical doctors are situated within urban areas and cities, inaccessible for those living in rural areas. Moreover, the ratio of traditional health practitioners to population in Africa is 1:500 compared to a ratio of 1:40,000 for medical doctors to population (Abdullahi 2011).

In addition to being cheaper and more accessible, there may be a distinct preference for indigenous forms of health care. For instance, traditional African healers may be sought because they offer treatments for the more intangible necessities of health and wellbeing that are not part of the conventional medic's toolkit, such as obeying instructions from ancestors, offering sacrifices to the gods and the interpretation of dreams (Omonzejele and Maduka 2011).

In China, Korea and Japan, East Asian medicine predates conventional medicine by several thousand years, is highly valued and is utilised by between forty and seventy-six per cent of these populations. In these three countries, the East Asian medicine methods of acupuncture, herbal medicine, moxibustion [2], cupping [3], and manual therapies are integrated into the national health care systems in a manner that is respectful of the historical and cultural background and allows people relatively equal access to both T&CM and conventional medicine (Park *et al.* 2012).

In regions of the world where conventional medicine is readily available and is more the norm, a substantial number of people are electing to use T&CM either as an alternative or as an adjunct to conventional care. For instance, in Australia and Europe as many as one in two adults have used some form of T&CM, and in the United States the figure is estimated at almost four in ten adults. These figures have remained relatively constant in surveys over recent years (Harris *et al.* 2012). Many reasons have been cited for the popularity of T&CM, such as dissatisfaction with conventional medicine, a lack of effective conventional medication and the presence of unwanted side effects from conventional care. However, most research evidence suggests that

[2] A traditional Chinese medicine therapy using moxa from dried mugwort (Artemisia argyi)
[3] A traditional Chinese medicine therapy using local areas of suction on the skin.

T&CM use can best be understood as a component of self-care management in general, and not as a rejection of conventional medicine (Thorne *et al.* 2002, Grzywacz *et al.* 2007, Bishop *et al.* 2010).

For those in higher income nations, the choice of health care options can be considerable. T&CM practitioners are easy to find in most countries and T&CM products are even more readily available. There is evidence to suggest that T&CM interventions are being used in high income nations for treatment of a broad spectrum of both chronic and acute health complaints including cancer (Scott *et al.* 2005, Corner *et al.* 2009), complaints related to pregnancy and childbirth (Kalder *et al.* 2011), mental health problems (Chatfield and Duxbury 2010), back pain (Ong *et al.* 2004, Lewis and Abdi 2010), addiction (Manheimer *et al.* 2003, Ashton *et al.* 2009), arthritis (Bishop *et al.* 2011, Brien *et al.* 2011), allergies (Spence *et al.* 2005), and a range of childhood complaints (Shakeel *et al.* 2007, Posadzki *et al.* 2013a).

For example, a person with a chronic complaint such as back pain might visit a practitioner such as an acupuncturist, osteopath or chiropractor, or try a range of different T&CM products, such as herbal tinctures or topical ointments, either instead of, or alongside, conventional medications. In recent years there has been a vast increase in the global market for traditional health care products and services driven, at least in part, by a desire to supplement or replace the available conventional treatments. The internet abounds with claims about the effectiveness of such treatments and many T&CM products can be obtained and self-prescribed with ease without medical advice or quality control.

The value of the contribution that T&CM makes to global health should not be underestimated, as emphasised by the WHO Director-General, Dr Margaret Chan, who, when addressing the International Conference on Traditional Medicine for South-East Asian Countries in 2013, declared that:

> Traditional medicines, of proven quality, safety, and efficacy, contribute to the goal of ensuring that all people have access to care. For many millions of people, herbal medicines, traditional treatments, and traditional practitioners are the main source of health care, and sometimes the only source of care. This is care that is close to homes, accessible and affordable. It is also culturally acceptable

> and trusted by large numbers of people. The affordability of most traditional medicines makes them all the more attractive at a time of soaring health-care costs and nearly universal austerity (As cited in WHO, 2013).

Aside from potential direct therapeutic benefits of T&CMs there are broader benefits. Herbal medicines in particular contribute directly to the development of conventional medications with as many as one-third to one half of pharmaceutical drugs being derived from plants (Abbott 2014). These include many widely used forms of medicine, for example:

- Taxol, an antitumor agent that is derived from *Taxus brevifolia* (Pacific yew).
- Morphine and codeine, widely used analgesics that are derived from *Papaver somniferum* (poppy).
- Digoxin, a cardiotonic that is derived from *Digitalis purpurea* (purple or common foxglove).
- Quinine, an antimalarial drug that is derived from *Cinchona ledgeriana* (quinine tree)

Economic benefits are significant for some countries where T&CM is an important source of income for many individuals and communities. According to the WHO (2013) the T&CM sector now plays a significant role in the economic development of a number of countries. This is highly evident in China, for example, where global promotion of TCM services and products has been used to foster economic development generating billions of United States dollars in revenue annually (Abbott, 2014).

A further noteworthy benefit, highlighted by the WHO (2013), is that T&CMs have a function in disease prevention and can enhance and maintain health. Appropriate use has the potential to make T&CMs highly cost-effective, helping to reduce pressure on health care systems by reducing overall costs. This is a particularly vital consideration given burgeoning healthcare costs and the growing need for development of sustainable forms of health care.

In spite of the potential for benefit, its widespread usage, and the apparent acceptance of T&CM by the general public, the topic of T&CM can lead to emotionally charged debates. In some parts of the world there are particularly vocal objectors to the wide scale usage of T&CM and it has variously been described as a form of 'medical heresy' (Gürsoy 1996, Stambolovic 1996), no better than 'superstition' (Singh and Ernst 2008), and 'pseudoscientific' (Beyerstein 2001, Colquhoun and Isbell 2007, Hall 2009).

1.3 Objections to T&CM

The primary objection to wide scale use of T&CM interventions focuses upon the lack of a rigorous evidence base for most types of T&CM, as is required for conventional medical health care (Ernst and Cohen 2002, K. Smith 2008, Ernst 2011). The question asked is certainly reasonable: *Is it ethical to prescribe treatments that have no scientific evidence of efficacy or safety?* No new conventional medications are introduced without rigorous testing through established scientific methods such as clinical trials.

The practice of T&CM, however, is primarily rooted in case-based, empirical evidence, passed down through generations. This form of knowledge, whether in written or purely verbal form, is subject to testing for effectiveness and safety only when applied in the real world to individuals. For some types of T&CM, such as Ayurveda, such application to individuals has taken place over many centuries.

This type of historical evidence does not satisfy those who demand that all healthcare interventions should be rooted in a scientific evidence base. In Western healthcare the introduction of evidence-based medicine (EBM) has been heralded as the most recent revolutionary phase, described as a 'paradigm shift' that will change medical practice for years ahead (Guyatt and Rennie 2001). This movement was initiated in 1992 when a group of physician-researchers, known as the Evidence-Based Medicine Working Group (EBMWG 1992) published an article urging physicians to base clinical decisions purely on evidence. In this way unreliable, intuitive judgements would be replaced with rational calculation and the use of research.

The notion of EBM is predicated upon the assumption that there is a hierarchy of evidence for medical interventions, such that certain types of evidence are deemed of greater value than others. At the top of this hierarchy are placed results from

randomised controlled trials (RCTs) and systematic reviews[4] or meta-analyses[5] of these trials. The synthesis of large amounts of clinical trial data into manageable systematic reviews or meta-analyses is meant to revolutionise medical practice and offer objective and politically transparent criteria for treatment choice and funding decisions. Proponents of EBM commend themselves on their attempt to 'realign medicine with science', whilst critics object that EBM emphasises exclusively the science of medicine whilst denying the art of medical practice (Miettinen 2001). Since the broad adoption of EBM principles, there has been increasing pressure on all forms of T&CM to provide the kind of evidence that is deemed of high value from RCTs and reviews of these trials, to enable comparative assessment of efficacy and safety. Without this type of evidence most governments are unwilling to fund provision, research or development of T&CM on anything but a small scale.

Attempts have been made to address this requirement for evidence but subsequently many T&CM researchers have described reasons why this is proving to be a challenging task (Caspi and Bell 2004, Ahn and Kaptchuk 2005, Block and Jonas 2006, Bell *et al.* 2012). Many challenges have been identified but the three most commonly cited issues can be summarised as follows:

1.3.1 Lack of effective placebo

The primary reason why RCTs, particularly randomised placebo-controlled trials, are placed at the top of the evidence hierarchy is that they are considered to be the only reliable way of establishing a causal relationship between intervention and outcomes. This type of research involves the testing of interventions against placebo and relies upon the participants in the research trial not knowing whether they are receiving active treatment or placebo. For many forms of T&CM intervention it is impossible to substitute a convincing placebo treatment, although some have tried. For example acupuncture has been tested against 'sham acupuncture' (Kim *et al.* 2011, Sunay *et al.* 2011) and chiropractic against 'sham chiropractic' (Hawk *et al.* 1999, Hannah *et al.* 2012). However, results from many of these trials indicate that 'sham' treatments often

[4] A systematic review is a means of examining results from more than one trial to look for trends.
[5] A meta-analysis takes an overall view further by performing statistical analysis on the combined results to look at the statistical significance of trends.

have an effect themselves and therefore cannot be considered effective placebos (Witt and Schützler 2012).

1.3.2 Internal / external validity problems

As reliable indicators of causality, RCTs are considered to have strong internal validity[6], but this is often created at the expense of external validity[7], as they can be a poor model of what happens in healthcare in the 'real world'. When T&CM interventions are adapted to fit an RCT model, the intervention being tested commonly bears little relationship to the way the treatment is offered in clinical practice. This is primarily a consequence of attempting to measure a complex and holistic intervention in the reductionist and linear model of the RCT (Mathie *et al.* 2014). In other words, efficacy studies for pharmaceutical drugs assume a direct, mechanistic cause-effect relationship between a specific intervention and a specific therapeutic outcome whereas T&CM practitioners do not necessarily treat a named symptom or disease directly (Bell *et al.* 2012). For example, most RCTs investigating the efficacy of homeopathic remedies for influenza have focussed on testing the effects of one homeopathic remedy, such as oscillococcinum[8], on a limited range of symptoms (Ulbricht *et al.* 2011), whereas in the real world a homeopathic practitioner is likely to select from a very wide range of homeopathic remedies for influenza, basing their prescription upon the peculiar symptoms for each individual of a mental, emotional and/or physical nature.

1.3.3 Lack of adequate funding for large scale trials

The greatest challenge for T&CM research, however, seems to be the scarcity of research funding. Government, charitable and private funding for research into T&CM is low, with the result being that research funding for T&CM is vastly out of proportion to the prevalence of T&CM use. This can be seen clearly in the United States where funding for National Centre for Complementary and Integrative Health (NCCIH) activity in 2013 amounted to 124 million dollars whilst total funding of health research and development activity in the United States amounted to 330,383 million dollars in

[6] Internal validity refers to how well an experiment is designed and conducted such that potential confounding variables (factors, other than the intervention being tested, that could also affect the outcome) are avoided.
[7] The extent to which the results of a study can be generalised to other situations and to other people.
[8] A homeopathic remedy derived from the liver and heart of a duck.

2012 (Research!America 2014), indicating that NCCIH funding is equivalent to less than 0.04 per cent of all medical research funding.

Funding for wide scale T&CM research, of the type that would be needed to develop a robust evidence base, does not seem to be available. Some argue that it would be unethical to provide funds for investigation of products and services deemed *implausible*, as funding research under these circumstances would constitute a waste of resources (K. Smith 2008, Shaw 2011). This leads to a stalemate position on the issue of evidence in T&CM; on the one hand T&CM is criticised for not having a robust evidence base and on the other hand T&CM research is not being funded to enable such research to be performed.

These challenges, together with many others, have contributed to the current situation in the UK where there is considerable debate about whether or not T&CM interventions are, or should be, an important element of health care. Argument is ongoing about what constitutes reliable evidence on this topic and how that evidence might be assembled, as can be seen in Table 1, which summarises the contrasting polarities of opinion in the debate focusing on evidence.

Table 1: Contrasting opinions on evidence for effectiveness of T&CM

T&CM is effective	T&CM is not effective
Historical and case-based evidence demonstrates clinical effectiveness.	Historical and case-based evidence is not acceptable as proof of efficacy.
People would not continue to use T&CM interventions if they were ineffective.	Perceived benefits may stem from placebo effects.
Research methods most highly placed in the evidence hierarchy of EBM (RCTs and systematic reviews) do not adapt well to complex T&CM interventions.	The only way to test an intervention thoroughly is through a randomised placebo-controlled trial.
There is a distinct lack of funding available for T&CM research.	Resources are better focussed on conventional medical research.

Distinct polarities of belief leading to a stalemate position on the issue of evidence in T&CM.

Clearly, the above two positions cannot be reconciled easily and the debate about efficacy remains unresolved in most areas of T&CM. However, if it is to be deemed unethical to use medicines and interventions that do not have a robust research evidence base then much of conventional medicine would have to be removed from use. Estimates vary widely (from eleven to seventy per cent) as to the exact proportion of conventional interventions that are robustly evidence-based (Oliver 2014).

Whilst it is obviously of ethical concern that healthcare options are effective, it is beyond the scope of this thesis to make judgements about efficacy in T&CM. Nevertheless, since the practice of T&CM (and many conventional healthcare interventions) continues in spite of scepticism about efficacy, ethical challenges about the practice, production, promotion, usage, and teaching of T&CM require attention. Whether or not the available evidence is sufficient to meet the requirements of EBM, people continue to access T&CM in growing numbers and consequently this needs to be acknowledged. At the same time, patient autonomy is highly valued in the UK, as is evidenced by the drive towards greater patient choice in healthcare (Dean 2004, Sang 2004, Bojakowski 2008, Barrie 2011). Many people choose their preferred healthcare options, using T&CM treatments either as an adjunct, or alternative, to conventional care.

In low and middle income countries many people rely upon T&CMs for their primary source of healthcare because they are culturally more acceptable and/or because they are the only form of healthcare that is affordable/available. Given that much of T&CM is under-researched, not only in terms of efficacy but also in terms of safety and cost-effectiveness, this inevitably generates ethical concerns. In addition, the practice of T&CM in the UK to date has largely existed as an independent, parallel and disparate healthcare system (Kerridge and McPhee 2004) and professional standards are extremely variable (Walker and Budd 2002, Clarke *et al.* 2004, Tyreman 2011). As the complexities of this situation become better understood, specific ethical challenges and legal issues are increasingly highlighted (Stone 2000, Ernst *et al.* 2004, Chatfield and Duxbury 2010, Posadzki *et al.* 2012c).

Such specific ethical challenges to T&CM are numerous and include issues such as safety of interventions, quality control of products, regulation and competence of

practitioners, fully informed consent, the giving of misleading information (Gorman *et al.* 2005, Cohen 2006, Ernst 2009c, Gilmour *et al.* 2011b, Posadzki *et al.* 2013b, Posadzki *et al.* 2013c), and concerns that T&CM treatment may delay or prevent patients from seeking mainstream health care such that 'the harm done by omitting evidence-based medical treatment is potentially significant' (Shaw 2010, p.130). These ethical issues clearly call into question the potential for benefit and how to avoid harm, which in turn must be considered in the light of a person's right to use their health care of choice. In addition, there are ethical considerations that extend beyond the autonomy and the wellbeing of patients and practitioners to embrace issues such as fairness and equity, and sustainability.

1.4 The Viewpoint for this Thesis

The number of potential ethical issues associated with the use of any form of medicine is vast. Furthermore, there are innumerable forms of T&CM in the world and hence it is not possible to analyse all associated ethical issues within one thesis. In alignment with my own location, this inquiry will begin with analysis from a UK perspective. The ethical issues to be examined will be drawn, at least in the first instance, from those associated with forms of T&CM that are commonplace in the UK.

Nonetheless, use of the ethical matrix as a tool for consideration of ethical issues allows for deliberation of issues related to an array of stakeholders. To a large extent, the ethical debates that are revealed by the ethical matrix are dependent upon the selection of the stakeholders. Most of the published literature on this topic considers the ethical issues as related to individual human beings. However, through the inclusion of a range of stakeholders the consideration of ethical issues in the later stages of the thesis is broadened to include global ethical concerns beyond a solely UK perspective.

It should also be made explicit here that I am undertaking this analysis, at least to some degree, from an 'insider' perspective. Prior to my current role I worked as a homeopathic practitioner for fifteen years. At the same time I was actively involved in complementary medicine research and I have since been teaching research methods to practitioners of complementary medicine for many years. My experience has provided me with a broad appreciation of the challenges that face T&CM and I hope this will

enhance the inquiry. In the following chapters I will strive for transparency of thought by detailing the flow of my argument at each stage. It begins with step 1, definitions.

CHAPTER TWO. WHAT'S IN A NAME: TRADITIONAL, COMPLEMENTARY, ALTERNATIVE?

The primary aim of this thesis is to analyse ethical issues associated with T&CM. Before embarking upon such an analysis, the adopted meaning of T&CM and the limits of what is to be considered as T&CM for the purpose of this inquiry, need to be established. The broad range of terminology used to refer to these forms of healthcare is indicative of the vast number of medical approaches around the world and it is not within the scope of this thesis to examine them all. Consequently, it is necessary to specify clearly what is under scrutiny so that the relevant ethical challenges can be identified. In attempting to describe what is meant by T&CM, the following paragraphs will first explore the origins of the most commonly used terminologies and introduce the most widely used definitions.

As the term CAM (Complementary and Alternative Medicine) is the most widely used term in the UK, I begin this chapter by making reference to CAM rather than T&CM, exploring the meaning of CAM from a Western perspective. Following exploration of the Western perspective, the discussion will be broadened to incorporate a more global viewpoint, with addition of traditional medicine to the discourse, and reference will revert to T&CM.

The term 'alternative medicine' was first popularised in the United States and Europe in the 1970s when it was noted that some people, when given the choice, were electing to use certain unconventional forms of health care, also then termed 'irregular medicine' or 'fringe medicine' (Fulder 1988). In the late 1980s the expression 'complementary medicine' was introduced in an attempt to present a more accurate reflection of the way in which most people use these therapies as an adjunct to conventional treatment (British Medical Association 1993). Currently, in the UK, the words 'complementary' and 'alternative' are often used interchangeably to describe this body of therapeutic systems (Graham 1999) which is frequently designated by the acronym CAM, complementary *and* alternative medicine, denoting usage either as an alternative to conventional treatment, or in a complementary manner (McIntyre 2001). In some circles CAM is also referred to as 'holistic medicine', 'natural medicine', or

‘integrative medicine’. Globally the term most often used is ‘traditional medicine’, denoting the cultural heritage of these forms of medicine in certain parts of the world.

2.1 Complementary and Alternative Medicine: the Western Perspective

CAM comprises a broad range of disciplines with diverse medical philosophies, diagnostic methods, therapeutic interventions, and life style approaches that are grouped collectively because they are in some way dissimilar to health care that is offered by the prevailing healthcare system (Sharma 1992). The nature of the dissimilarity is problematic to define because the range of procedures offered both within and outside the prevailing healthcare system are extremely diverse. CAM therapies may differ from conventional medicine, not only in their methods, but also in some of their underlying philosophies (Cassidy 2002). The way that many CAM disciplines define health, illness and the healing process can depart significantly from the beliefs that underlie the practice of conventional medicine (Tataryn 2002).

Whilst CAM therapies are diverse in nature, there are some common underlying assumptions that apply to most, if not all, CAMs and which differentiate them from a conventional biomedical approach. Some of the most widely accredited differences in perspective between CAM and conventional medicine are summarised in Table 2.

Table 2: Comparison of Alternative and Conventional Medical Approaches

CAM	Conventional Medicine
Takes a holistic approach to diagnosis and treatment; i.e. physical, mental, spiritual, and environmental factors are considered (Barrett *et al.* 2003).	Takes a reductionist approach to diagnosis and treatment; i.e. various specialists are concerned with individual illnesses (Milgrom 2006).
Commonly invokes an underlying vitalistic[9] doctrine (Bellavite 2003).	Based upon a biomedical understanding of the body (Colquhoun and Isbell 2007).
Treatment is tailored to the individual (Franzel *et al.* 2013).	Treatments are largely based upon what works for the 'average' person (Cronje and Fullan 2003).
Treatments are derived from, and in tune with, nature (Ostendorf 1991).	Treatments can be highly medicalised (Hughes 2008).
Cure is encouraged from within; there is high regard for self-healing (Fulder 1988).	Cure is interventionist in approach; symptoms are controlled (di Sarsina *et al.* 2012).
Commonly used to promote and maintain health, for preventative purposes (Patriani Justo and dé Andrea Gomes 2008).	Most commonly used in a reactive manner for treating existing complaints (Teixeira 2009).
High regard for autonomy; patient is active partner in the healing process (Sharma 1992).	Often criticised for taking a paternalistic approach; doctors are the experts (White 2000).

Listed here are common differences in approach that are often cited in CAM literature.

However, whilst there are many obvious differences between most CAM and conventional approaches, such as the use of acupuncture or analgesics for lower back pain relief, there are also many similarities, such as the recommendation of certain forms of exercise to improve lower back strength. Similarly, there are no clear lines drawn between those procedures that exist within and outside of the prevailing

[9] *Vitalism* is the metaphysical doctrine that living organisms possess a non-physical inner force or energy that imparts life

healthcare system. What may be considered CAM in some areas is considered as part of the established healthcare system in others. For example the use of relaxation techniques for people with hypertension is standard practice for some doctors and not for others. As well as being broad and diverse, the field of medicine is constantly changing and consequently this also contributes to the difficulty in defining CAM. Indeed, there already exists a multiplicity of categorisations for CAM, suggesting that the topic is highly problematic (Furnham 2000). As will become apparent in this chapter, the task of defining traditional/complementary/alternative medicine is highly challenging (Dunne and Watkins 1997, OAM 1997, Newman Turner 2001, Hawks and Moyad 2003, Wieland *et al.* 2011) not only because of the seemingly interchangeable range of terminology that is used, but also because the boundaries between what is considered CAM and what is considered conventional medicine are often blurred.

2.1.1 Definitions

In order to generate a meaningful definition for anything, it is naturally important that there is clarity about what constitutes a definition. The following is taken from the Merriam-Webster Dictionary:

> To define is: 'To determine or identify the essential qualities or meaning of, or to fix or mark the limits of ' (Merriam-Webster 2011).

This implies that a definition may take different forms; that the same object or phenomenon may be appropriately defined in a number of ways. An orange, for example, may be defined according to the essential qualities of oranges (citrus fruit, orange in colour) or by the limits of the group (the fruit that comes from orange trees). Whilst there may be different types of definitions, a definition, by its nature and purpose, must apply fully to all members of the class to which it applies (Clouser *et al.* 1995). This is an important point to bear in mind when examining definitions of CAM because of the diverse nature of the field.

The most prominent definitions of CAM are commonly separated into two different types of definition: theoretical definitions and operational definitions (Gaboury *et al.* 2012).

Theoretical definitions, by their nature, are based on existing theory within a field and are used to propose a way of thinking about an issue. They seek to specify precisely when a word(s) should and should not be applied. The reason such definitions are called 'theoretical' is because the definitions themselves attempt to construct theory about the nature of the thing in question. For example, a theoretical definition of 'health' would not simply tell us what health is or the way in which the word is used, but it would also propose a particular conception of health.

Operational definitions, on the other hand, are intended as a more pragmatic indicator because they are based on observable properties, behaviours or uses of an entity. They are often used in preference to theoretical definitions because they avoid the problems that are associated with attempting to define things in terms of intrinsic qualities. So, returning to the example of health, an operational definition of health might include a range of criteria that are measurable, such as blood pressure, various blood tests, electrocardiograms and so on, such that if a person has a complete set of normal measurements, then they will be deemed healthy.

Table 3 summarises the most widely referenced definitions of CAM and indicates which are regarded as theoretical and which as operational.

Table 3: Widely Referenced Theoretical and Operational Definitions of CAM

Type of definition	Reference	CAM defined as:
Theoretical: What CAM is not	(Office of Alternative Medicine 1997)	All practices defined by their users as preventing or treating illness, or promoting well-being that are not intrinsic to the politically dominant health system.
Theoretical: What CAM is not	(MedlinePlus 2010)	Medical products that are not part of standard care.
Theoretical: What CAM is not	(National Library for Medicine 2003)	Diverse medical and health care systems not considered part of conventional medicine.
Theoretical: What CAM is not	(Eskinazi 1998)	Treatments that pose challenges to societal beliefs and practices; cultural, scientific, medical and educational.
Theoretical: What CAM is not	(Benitez-Bribiesca 2000)	Healing practices compiled over the centuries through trial and error or merely by cultural and religious beliefs, not based on sound biomedical research.
Theoretical: What CAM is not & operational	(British Medical association 1993)	Forms of treatment not widely used by conventional healthcare professions AND not taught as part of undergraduate curriculum.
Operational: Defined according to specific criteria	(Wieland *et al.* 2011) (Cochrane collaboration)	1. Is the historical notion of the therapy CAM or conventional? 2. Is the use of the therapy for a particular condition currently considered to be a standard treatment within the conventional medical system? 3. In what setting is the therapy delivered and by whom?
Operational: Defined according to individual perspective	(Caspi *et al.* 2003)	Systems and modalities of health care that define and solve health problems in a context that is congruent with the person's own individual perspective, regardless of medical or social convention.

2.1.2 Theoretical definitions of CAM

There have been many proposed theoretical definitions of CAM (Barrett *et al.* 2003, Caspi *et al.* 2003). Some attempt to identify the essential qualities of CAM but, more commonly, they attempt to demarcate CAM from conventional medicine. The most widely accepted definition is that given by the Office of Alternative Medicine (OAM) expert panel at the CAM Research Methodology Conference in April 1995. This definition is as follows:

> Complementary and alternative medicine (CAM) is a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being (OAM 1997, p.52).

Currently, in the UK, the politically dominant or conventional health system is biomedicine. Hence, according to this definition, CAM in the UK is the broad domain of healing resources that are available other than those intrinsic to biomedicine. If, in another country, biomedicine is not the politically dominant health system then the range of practices that are considered CAM will be different; indeed biomedicine itself will fall into the category of CAM, when applying the above definition.

Many others have utilised a similar definition. For example, the MeSH (Medical Subject Headings) definition of CAM is as follows:

> Complementary and alternative medicine (CAM) is the term for medical products and practices that are not part of standard care (MedlinePlus 2010).

The National Library for Medicine (NLM) defines the field of CAM as:

> A group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine (NLM 2003).

The British Medical Association (BMA) carried their definition one stage further and attempted to include an operational element suggesting that CAM be defined as:

> Those forms of treatment which are not widely used by the conventional healthcare professions, and the skills of which are not taught as part of the undergraduate curriculum of conventional medical and paramedical healthcare courses (BMA 1993, p.7).

Each of these definitions are, however, disappointing as the reference criteria (conventional medicine) is rapidly changing and is not consistent. For example, use of some of the therapies historically considered to be non-conventional is growing amongst conventional healthcare professionals (such as the use of relaxation methods and meditation) and many conventional healthcare courses now offer CAM modules as part of routine training (Caspi *et al.* 2003).

Some authors, in their definitions, appear to be proposing reasons why CAM practices fall outside of conventional medicine. For example, Eskinazi suggests that there is a prejudice in regard to CAM and that a realistic definition should be:

> A set of healthcare practices (i.e. already available to the public) that are not readily integrated into the dominant healthcare model because they pose challenges to diverse societal beliefs and practices (cultural, economic, scientific, medical, and educational) (Eskinazi 1998, p.4).

Benitez-Bribiesca defines the term by distancing CAM practices from science:

> Health care services around the world can be roughly classified into two groups according to their medical orientation: scientific medicine and 'traditional medicine.' The first is based on sound biomedical research and has been in use in developed countries for a bit more than a century. The latter, however, encompasses healing practices compiled over the centuries through trial and error or merely by cultural and religious beliefs (Benitez-Bribiesca 2000, p.537).

The above theoretical definitions of CAM all define CAM in the negative, by telling us something about what it is *not*, rather than what it is. Benitez-Bribiesca tells us that it is medicine that is not scientific, Eskinazi that it is not aligned with societal beliefs and practices, and the others define CAM by reference to the 'politically dominant', 'conventional', or 'standard' healthcare system. This type of definition goes some way

to marking the limits of CAM but tells us nothing about the essential qualities of CAM. Furthermore, what is considered as scientific, acceptable, standard, dominant or conventional in healthcare differs greatly from culture to culture and over time and, as such, would precipitate continuous revision of the classification of therapeutic systems and interventions. Consequently, the practical application of these definitions would prove troublesome and they will not be adopted for the purpose of this thesis.

There are currently no widely used theoretical definitions of CAM based on the similarities existing between CAMs that tell us something about the essential qualities of the group. Whilst CAM therapies have hugely diverse backgrounds, there are some principles that most CAM therapies seem to share, as was shown in Table 2. The major similarities are examined below to see if there are any qualities that hold for all CAMs that could form the basis for a meaningful definition.

CAMs are holistic

A fundamental similarity between most CAM therapies is that they appear to apply a non-Cartesian view of health, which makes little distinction between the body, emotions, mind or spirit as separate sources of disease. All dimensions are seen to have an impact upon health and symptoms of ill health can be expressed on any level. However, a spectrum exists between reductionism and holism in both conventional medicine and CAM and both can be said to span the spectrum. Some CAM practitioners, such as chiropractors, work primarily with the physical body and ask very little about emotional and mental wellbeing, whereas some conventional general practitioners are seeking to practise in a more holistic manner (White 2000).

CAMs promote self-healing

Another possible similarity is that the emphasis of CAM treatment is often on strengthening the whole person in order to enhance their own healing response. Recognition of the *vis medicatrix naturae*, or 'healing powers of nature' is not exclusive to CAM. Indeed, the phrase is traditionally attributed to Hippocrates, but it has become more widely associated with CAM and less so with conventional medicine as technology in medicine advances. Again, however, there are examples of CAM interventions that do not fit into this category, such as the use of natural antibacterial and anti-viral supplements, which are directly aimed at killing microorganisms, just as

their conventional counterparts are. Furthermore, the prescribing of nutritional supplements to enhance health does not fall exclusively within the provenance of CAM as there are well-established conventional examples of such practice, like the use of iron supplements for patients prone to anaemia.

Individualised treatments

An attribute often emphasised is that CAM therapies take an individualistic approach to treatment, such that patients receive treatments that are tailored to their specific needs. This is in direct contrast to the conventional medical approach that generally involves prescribing a standard drug and a similar treatment regime for patients with the same underlying pathology. However, there are examples of specific therapeutic use of interventions that would generally be regarded as CAM such as the use of the herb St John's Wort for anxiety and depression and the use of the homeopathic remedy Arnica for bruising. Whilst non-specificity might be an attribute of most CAMs, it is certainly not true for all. Furthermore, with the onset of personalised medicine and the use of individual genetic profiles to determine treatment, conventional medicine is also changing its approach.

Natural medicine

One last similarity is that most CAMs would claim they fall within the category of 'natural medicines' involving the therapeutic use of natural methods and materials as opposed to human-made or chemically synthesised products. However, the claim of 'natural' is not exclusive to CAM, as many conventional interventions also involve the prescription of products from nature such as quinine, whilst many CAM products are processed.

In summary, no specific qualities that can define CAM apply equally to of all its subsets and hold over time can be identified, and a stand-alone definition of CAM cannot be derived through the identification of similarities that exist between CAMs.

Thus far, I have described problems with existing theoretical definitions of CAM and, in particular, the theoretical definitions that define CAM purely in the negative. The terms 'alternative' and 'complementary' imply an extension: a phenomenon that is not alternative or complementary in itself, but which is alternative or complementary to

something else. I have also shown how there is no widely accepted theoretical definition that appeals to the similarities between CAMs; this is unsurprising given that the CAM domain is enormously diverse as well as dynamic and changing. Hence none of the aforementioned attempts at formulating theoretical definitions of CAM have succeeded in producing a workable definition that meets the requirements of this inquiry.

Perhaps one of the main challenges in identifying a precise and universally agreed view of what CAM is, even among those desiring to pursue common goals, is that people may not be 'speaking the same language' or sharing the same meanings for terms they use, such as 'traditional', 'complementary', 'alternative' and 'medicine'. It has been suggested that it is difficult to forge appropriate language for definition and description in a field as contested, politically charged, and value-laden as CAM, because these linguistic acts presuppose a particular point of view, and often carry moral tone (O'Connor 1995). They may suggest, by their selection of words, whether the subject is to be regarded favourably or unfavourably (OAM 1997). However, in everyday life people do refer to CAM as a matter of routine and therefore it seems reasonable to postulate that there is some kind of shared understanding of the term. On the one hand we appear to have a shared understanding of what CAM means and, on the other, no defining quality that applies to all CAMs has been identified. One solution to this apparent conundrum can be found in Ludwig Wittgenstein's concept of 'family resemblance'.

A family resemblance

The notion that a definition must, by its nature and purpose, apply fully to all members of the class to which it applies was challenged by Ludwig Wittgenstein who pointed instead to 'family resemblance' as a more suitable analogy for ways in which we connect particular uses of the same word. Wittgenstein introduces the concept of family resemblances in his criticism of the traditional idea that all entities that fall under a given term must have the same set of properties or features in common. According to Wittgenstein, there is no reason to look for one essential core quality in which the meaning is located, but rather that we should think of a word's uses as 'a complicated network of similarities overlapping and criss-crossing' (Wittgenstein 1967, 66). To illustrate his point, Wittgenstein described the use of the word 'game':

> Consider for example the proceedings that we call ‘games’. I mean board-games, card-games, ball-games, Olympic games, and so on. What is common to them all? Don't say: ‘There must be something common, or they would not be called 'games' ‘-but look and see whether there is anything common to all.
> For if you look at them you will not see something that is common to all, but similarities, relationships, and a whole series of them at that (Wittgenstein 1967, 66).

Wittgenstein’s argument is that the entities under a given term need not have any one thing in common. The similarities that exist between them are like the resemblances between members of a family: build, features, colour of eyes, gait, temperament, and so on. These properties may overlap and criss-cross, but there is no one thing that is exactly the same for them all. In this way 'games' form a family and, accordingly, so would ‘CAMs’. Individual CAMs may be related to each other in ways that overlap, some of which have already been mentioned; natural, holistic, individualised, promoting self-healing, and so on.

The idea that there may be a family resemblance between CAMs helps to explain how it is possible to have a shared understanding of the term, but the boundaries between CAM and conventional medicine may still be somewhat blurred. As previously stated, what may be considered CAM in some localities is considered as part of the established healthcare system in others. Furthermore, there is a practical need for some people to decide upon what can be considered CAM for the purpose of treatment classification, health expenditure, training of competent providers, and so on. People creating databases, such as the one provided by the National Centre for Complementary and Integrative Health (NCCIH), formerly known as the National Centre for Complementary and Alternative Medicine (NCCAM), have to decide which treatments to store information about and how to categorise this information within subsets. Generally speaking, whilst conventional medical practitioners may be taught about CAM treatments, they are not normally taught how to practise interventions in the realm of CAM. Practical decisions need to be made about what is included in the education and training of health professionals that, to some degree, depends upon what is considered conventional medicine and what is considered as CAM. Recognition of the need for a pragmatic definition or description of what CAM is has resulted in the

development of some operational definitions. The most influential of these operational definitions will now be explored and their usefulness for this inquiry examined.

2.1.3 Operational definitions of CAM

The Cochrane Collaboration, established in 1993, is an international network of more than 28,000 people from over a hundred countries. Their primary aim is to create and publish a large database of reviews of the research evidence for different medical interventions so that healthcare workers can have ready access to the best available evidence. The database has become a major resource for those who endeavour to practise evidence-based medicine. To date, more than 4,600 Cochrane Reviews have been published, with almost 400 of these relating to CAM.

Whilst attempting to classify reviews as CAM-related, many challenges were encountered by Cochrane because the available theoretical definitions of CAM did not help in the operational activity of deciding which reviews to classify as CAM related (Wieland *et al.* 2011). The major problem the Cochrane team perceived, when attempting to operationalise the predominant theoretical definitions of CAM, is that the conventional medical model changes over time. Their attempts to find an operational definition of CAM failed and hence they sought to produce a standardised definition that they believed would provide an objective, reproducible and systematic method for defining and categorising CAM therapies. Ultimately, they decided to concentrate on defining the parameters of CAM from current historical and geographical perspectives of the conventional model and, in expanding and refining the CAM operational definition, they considered three criteria.

First, is the historical notion of the therapy CAM or conventional? If the historical notion is clearly CAM related then the therapy is considered CAM. For therapies that did not clearly originate outside the theories or beliefs of the conventional medical system a further two criteria were considered: (secondly) whether the use of the therapy for a particular condition is currently considered to be a standard treatment within the conventional medical system, and (thirdly) in what setting is the therapy delivered, and by whom?

The last criterion is based upon the assumption that therapies delivered by practitioners outside of the conventional healthcare system, or considered self-care, are more likely to be widely considered CAM, while therapies that are delivered exclusively by conventional healthcare workers, or exclusively within hospital settings, are much less likely to be considered CAM.

Applying their operational definition, Cochrane identified fifty-one different CAM therapies that are used in treating or preventing disease[10]. Having named these fifty-one different types of CAM, the next step for Cochrane was to determine subsets that could be used for further categorisation. For this purpose they used the subsets that had previously been identified by NCCAM (now NCCIH), the lead agency for scientific research and source of government information in the United States (NCCAM 2010).

NCCAM categorised CAM into four overarching domains:

1. Natural products such as herbal medicine and supplements
2. Mind-body medicine such as yoga, meditation and acupuncture
3. Manipulative and body-based practices such as chiropractic, osteopathy and massage, and
4. Other CAM practices which are broken down into further subsets:
    - Movement therapies such as Pilates and Alexander Technique

[10] Acupressure, Acupuncture, Alexander technique, Aromatherapy, Arts therapy (eg, dance therapy, drama therapy, music therapy), Ayurvedic traditional medicine, Balneotherapy (natural spring water bathing), Bee products(e.g. honey, propolis, royal jelly), Biofeedback, Chelation therapy (removal of toxic heavy metals from the body), Chinese traditional medicine, Chiropractic, Colour therapy , Craniosacral manipulation, Dietary supplements, Diet therapy, Distant healing, Electric stimulation therapy (e.g. TENS machine), Electromagnetic therapy (magnets), Eye Movement Desensitization and Reprocessing (EMDR) (a form of psychotherapy), Feldenkrais method (awareness through movement), Herbal supplements, Homeopathy, Hydrotherapy, Hyperbaric oxygenation, Hypnosis, Imagery, Light therapy, Magnetic field therapy, Massage, Meditation, Morita therapy (a Japanese mindfulness technique), Moxibustion, Naturopathy, Osteopathic manipulation, Ozone therapy, Play therapy, Prolotherapy (dextrose injections for non-surgical ligament reconstruction), Qigong, Reflexology, Reiki therapy, Relaxation techniques, Snoezelen (controlled multisensory environment most often used for people with learning difficulties), Speleotherapy (exposure to salt air), Spiritual healing, Tai chi, Therapeutic touch, Traditional healers and healing practices (other than Chinese), Tui na (Chinese manipulative therapy), Ultrasonic therapy (using sound waves to penetrate soft tissues), Yoga.

- Traditional healing such as Shamanism
- Energy medicine such as Reiki and healing
- Whole medical systems such as Traditional Chinese medicine, homeopathy and Ayurvedic medicine.

NCCAM acknowledged that some therapies may overlap categories and that those categorised as whole medical systems cut across all domains. Cochrane followed NCCAM's model for categories and placed each of the identified fifty-one therapies into a single group.

The appeal of organising CAM in this way is that there are overarching principles by which the therapies can be categorised (Wieland *et al.* 2011). A possible problem with this system is that someone who does not understand the language and principles of CAM might have difficulty in knowing which category a specific therapy would fall under. In some cases, even someone who is familiar with CAM would have several valid options for the placement of a therapy. Indeed, the NCCAM categorisation, originally adopted by Cochrane, has recently been modified and the four overarching domains were reduced to two: *natural products* and *mind and body practices*, with a third category of *others* (NCCAM, 2014). According to the NCCIH, natural products include substances such as herbs, vitamins, minerals and probiotics. These are widely available and often sold as dietary supplements.

Mind and body practices comprise procedures or techniques administered or taught by a trained practitioner or teacher. The third, loose category of *other complementary approaches* is reserved for approaches that do not fit neatly into either of the above two domains, such as the practices of traditional healers**,** Ayurvedic medicine, traditional Chinese medicine, homeopathy and naturopathy. Changes in categorisation in this manner serve to illustrate the subjective nature of these operational definitions.

Cochrane are careful to highlight that they do not consider their CAM field operational definition of CAM as definitive. Indeed, they question whether it is possible to identify a definitive set of therapies that are universally agreed upon as CAM, and propose that there will never be universal agreement upon CAM aside from a core set of therapies. Even this agreement, they believe, will be susceptible to change over time. However,

they are satisfied that their operational definition is transparent and they display their operational criteria on the CAM section of their website to maintain this transparency.

The Cochrane operational definition of CAM has been useful for the purpose of identifying and categorising research evidence across this vast domain. However, their definition is subject to the same challenges as the previously discussed theoretical definitions, in that what is considered as CAM varies, just as conventional medicine varies, over time and from place to place. The field of medicine is constantly changing and they will need to keep revisiting their decisions about which therapies are to be considered as CAM.

As previously mentioned, the terms ‘alternative’ and ‘complementary’ imply an extension and, thus far, the definitions examined have assumed the ‘dominant’ or ‘conventional’ medical system as this extension. The issue of the dominant practice versus ‘all others’ lies behind the whole concept of CAM and yet there is a problem with identifying the boundaries of the dominant practice because there are no clear demarcations (Cassidy 2002).

Any medicine may be ‘conventional’ or ‘standard’ in its own setting. Traditional Chinese medicine is perceived as conventional in China, and Ayurvedic medicine as conventional in India, whereas both are considered as CAM within the UK. Additionally, the image of biomedicine as a monolithic structure is inaccurate: its practice is deeply affected by cultural norms and values around the world (Payer 1988, Stein 1990).

Cassidy asserts that, if we are agreed that there are many medicines globally, with a wide range of philosophical underpinnings, cultural connotations and varying degrees of prominence, then we must come to see that *all* are alternatives, and *all* can complement others. In short, conventional medicine ought not to be treated as the standard against which all others are compared but as one among many, itself a complementary and alternative practice (Cassidy 2002). She asserts that if sorting of the different types of medicine is going to succeed we must make a serious effort to avoid culture-bound labels, and instead agree on specific identifiers.

Caspi *et al*. (2003) proposed a new operational definition that shifts focus from the traditional population-based approach to a definition that focuses upon the individual. In this way the individual acts as second referent. Their proposed definition is as follows:

> Complementary and alternative medicine includes those systems and modalities of health care that define and solve health problems in a context that is not congruent with the patient's rationale, life-world and identity, regardless of societal and medical conventions (Caspi *et al.* 2003, p.60).

In other words, people use their own internal frame of reference for judgement of what they consider to be complementary and alternative to their own beliefs. For example, for a person in the UK who considers that Traditional Chinese Medicine (TCM) is most congruent with their personal identity and beliefs, then this for them is their 'norm' against which all other forms of medicine are measured. For them all other types of therapy, such as conventional medicine, should be classified as CAM. Conversely, for a person in China, who considers conventional medicine to be most congruent with their identity and beliefs, then TCM is considered as CAM.

For Caspi *et al*., all forms of care are ethno-based and the authority for defining CAM modalities lies with individuals in alignment with their goals, objectives and beliefs. According to this definition, what is to be considered as CAM can reasonably vary between individuals, even in the same historical and geographical areas.

This proposed definition has some advantages; being person-centred and individualised, it avoids cultural, political and historical debate about what constitutes the conventional healthcare system. Furthermore, at first glance it does appear to resonate with findings from investigations into how lay people classify CAM therapies (Furnham 2000). Furnham discovered that people do indeed tend to hold different ideas about what constitutes CAM, concluding that lay peoples' perception of CAM therapies is heavily influenced by the media and does not rely simply on their understanding of the underpinning philosophies or methods. Experts may classify CAM therapies as structural, biomechanical, or psychological, for instance, while lay people seem equally happy to classify them in terms of familiarity and perceived effectiveness.

Whilst the egalitarian nature of the Caspi *et al.* (2003) definition is attractive, it does not seem to reflect the way in which people are currently using the term 'CAM'. It proposes a change in concept that would require a dramatic shift in the way in which healthcare is contemplated and provided. This person-centred, operational definition is not fully persuasive, is not helpful for those who need to classify CAMs (such as policy makers), and is not of assistance in the task of identifying those CAM therapies that should be included in this study.

Thus far, this chapter has examined the most prominent theoretical and operational definitions of CAM to date. All appear to have inherent deficiencies and consequently are inadequate for this inquiry. In fact, some authors have argued that it is futile and unrealistic to even attempt definitions of those therapies that lie outside of mainstream medicine, as CAM is nothing more than a categorical term under which hundreds of therapeutic modalities, generally sharing few commonalities, are lumped together (Ramos-Remus *et al.* 1999). Wittgenstein might say that 'CAM' is a family, as its members share a type of family resemblance, whilst others suggest that attempts to create a category for CAM can lead to harm by creating misunderstanding, prejudice and preconceptions: 'Alternative medicine is nothing more than a label; an abstract socio-cultural construct that serves the establishment and much less so the patient' (Caspi *et al.* 2003, p.59). In addition, there are some who believe there should not even be a category for CAM, such as Fontanarosa and Lundberg (1998), who state that: 'There is no alternative medicine. There is only scientifically proven, evidence-based medicine supported by solid data, or unproven medicine, for which scientific evidence is lacking' (p1618*).*

There is a particular problem when appealing to scientific proof as a measure of whether or not any individual intervention can be considered part of the conventional healthcare system. An assessment of reviews from the Cochrane Collaboration found that less than twenty-five per cent of Cochrane reviews of conventional biomedical interventions resulted in significant evidence of benefit (Ezzo *et al.* 2001). There are many therapies that are not currently accepted as efficacious, but not all of them would necessarily be considered CAM. For example, a new synthetic analgesic would not be considered CAM even if it has not been proven to be efficacious, whereas acupuncture for lower back pain would generally be considered CAM, even though there are many trials that

demonstrate efficacy in this area (Lewis and Abdi, 2010). Lack of proven efficacy is not an appropriate test for CAM.

The task of generating a broadly acceptable definition is most likely to continue to evade consensus; the CAM community has been struggling for many years to come up with a single definition of CAM agreed by all with no success (McIntyre 2001). Therefore, it seems appropriate to seek an alternative method for identifying the CAM therapies to be included in the domain of this research. It may be true that people classify CAMs in different ways (Furnham 2000), but there does appear to be some shared understanding of the term CAM, possibly due to a family resemblance, and at least a *core set* of therapies that most would agree can be classified as CAM (Wieland *et al.* 2011). If it is indeed possible to identify a core set of therapies that are broadly considered CAM, then this may be a reasonable way in which to select those that will be included in the focus of this study. Fortunately, there is a precedent for such a selection.

2.1.4 CAM in the United Kingdom

During the last twenty to thirty years of the twentieth century the dramatic upsurge in popularity of all forms of CAM was well documented (Fulder 1988, Bakx 1991, Sharma 1992, Graham 1999). This rise in popularity has been attributed to numerous different factors, including a complete shift of paradigm in the social arena (Capra 1997). However, it brought with it significant issues relating to public health policy. The issues requiring debate and resolution include matters such as training standards for practitioners, structures of regulation to protect the public, research to support claims of efficacy, and decisions about whether or not to include provision within the National Health Service (NHS). The increasing public demand for CAM, and the need to consider these issues, prompted an inquiry by the House of Lords' Science and Technology Committee who published their report in November 2000 (McIntyre 2001).

Interestingly, the Committee decided not to begin with a precise definition of CAM because of the problems they perceived with identifying one that is acceptable to all parties. Instead they began with a list of thirty-one therapies that they believed were commonly considered to fall within the field of CAM and issued this list with a call for

evidence. They justified their use of the term CAM by simply stating that it was the term used most often, and hence they adopted it for their report. They did, however, state that CAM embraces those therapies that may either be provided alongside conventional medicine (complementary) or which may, in the view of their practitioners, act as a substitute for it (alternative). Alternative disciplines purport to provide diagnostic information as well as offering therapy (McIntyre 2001).

For the purpose of their inquiry, the Committee examined written and verbal evidence about the professional organisation, patient satisfaction, the research evidence base, the delivery and the training of practitioners for all of the selected therapies. Following their investigation, they proposed that the CAM therapies be categorised into three different groups (Table 4).

- *Group 1* included the most organised professions with the greatest evidence base, that they entitled the 'principal disciplines'. They stated that each of these therapies claimed to have an individual diagnostic approach and that they were seen as the 'Big 5' by most of the CAM world. (Five therapies)

- *Group 2* contained those therapies that most clearly complement conventional medicine; these do not purport to embrace diagnostic skills. (Thirteen therapies)

- *Group 3* comprised all other therapies that purported to offer diagnostic information as well as treatment and which, in general, are indifferent to the scientific principles of conventional medicine. These therapies were split into two sub-groups:
    - Group 3a, which included long-established and traditional systems of healthcare. (Six therapies), and
    - Group 3b, which covered other alternative disciplines, which lacked any credible evidence base and hence should not be supported unless and until convincing research evidence of efficacy, based upon the results of well-designed trials, is produced. (Five therapies**)**

Table 4: CAM Therapies as Categorised into Groups by the House of Lords' Science and Technology Committee

Group	Therapies
1	Acupuncture, Chiropractic, Herbal Medicine, Homeopathy, Osteopathy
2	Alexander technique, Aromatherapy, Bach and other flower remedies, Body work therapies, including massage, Counselling stress therapy, Healing, Hypnotherapy, Maharishi Ayurvedic Medicine, Meditation, Nutritional medicine, Reflexology, Shiatsu, Yoga
3a	Ayurvedic medicine, Anthroposophical medicine, Chinese herbal medicine Eastern Medicine, Naturopathy, Traditional Chinese medicine
3b	Crystal therapy[11], Dowsing[12], Iridology[13], Kinesiology[14], Radionics[15]

This categorisation had clearly been undertaken with healthcare policy in mind and intended as an aid to decision making in this field. The categories do not take any account of similarities in philosophy or approach (as did the NCCAM categories) and it is possible that therapies will move between categories over time. It is also true that the therapies listed in each category are culturally dependent. However, this is a pragmatic categorisation that has direct practical application and is potentially of value for those involved in healthcare policy making. The very great benefit of the categorisation arising from this particular inquiry is that the Science and Technology Committee clearly identified the five most well-established and widely practised forms of CAM in the UK: acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy. In the absence of a universally agreed definition of CAM, it seems reasonable to propose analysis of ethical objections to the most commonly used CAM therapies in the UK. The five therapies in Group 1 are diverse in nature and attract a

[11] Therapists believe that crystals and stones emit unique healing energies that can stimulate a curative response.
[12] Medical dowsing is often conducted with a pendulum and used for diagnosis and making decisions about appropriate treatments.
[13] The study of the iris to diagnose disease.
[14] The use of non-invasive muscle testing to access information about a person's health and wellbeing.
[15] A method of diagnosis and treatment using specially designed instruments that are believed to emit an energy similar to radio waves.

diversity of ethical challenges. For example, herbal medicine, osteopathy and chiropractic and acupuncture are commonly accused of having the potential for harmful side effects (Pray 2006). All are accused of having the potential for adverse events by detracting people from seeking 'effective' medical care (K. Smith 2008). Analysis of the ethical challenges to these five therapies will not only cover a broad range of issues but, additionally, should be of the most practical benefit in the UK as these are the therapies most commonly utilised.

2.1.5 The Group 1 therapies: acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy

The five forms of CAM in Group 1 differ in numerous respects, originating from different cultures and different eras. They differ in their philosophies and in their methods of diagnosis and treatment. Even within each form of CAM there are conflicting schools of thought. For example, the form of homeopathy practised in France is largely dominated by the use of therapeutic prescribing, with particular combinations of homeopathic remedies being prescribed for named diseases. This is in direct contrast with the way in which most homeopaths in the UK practise, where treatment is individually tailored to the person and generally one homeopathic remedy is prescribed at a time. It is not possible to detail here all of the different forms of each of these five CAMs, and so what follows is a brief overview of the predominant features of each.

Acupuncture

Traditional Chinese acupuncture is a form of ancient Chinese medicine based on the belief that a life force ('Qi' or 'vital energy') flows through the body in channels called meridians. When Qi is not able to flow freely through the meridians, this can cause illness. There are certain points on the meridians, known as acupuncture points or acupoints that, when stimulated, can help to restore the flow of Qi, and so improve health. Stimulation of the acupuncture points is most commonly undertaken through the insertion of fine needles that can be manipulated (Pearson 1987). Western acupuncture uses a similar needling technique but the selected acupuncture points may be different and it is generally explained in a biomedical manner through reference to

effect on nerve impulses and the central nervous system rather than Qi and meridians. Both Traditional Chinese and Western acupuncture are widely practised in the UK with Western acupuncture often used in a complementary manner by conventional healthcare practitioners such as physiotherapists (Bowsher 1998, Filshie and Cummings 1999).

Chiropractic

Chiropractic is one of the more recently developed forms of CAM: the inception of modern chiropractic dates back to 1895. The Canadian Daniel David Palmer is credited with performing the first chiropractic spinal adjustment and he, together with his son, expanded the practice by establishing a school of chiropractic in Iowa. Chiropractors specialise in the diagnosis, treatment and overall management of conditions that are due to problems with the joints, ligaments, tendons and nerves, especially those relating to the spine. The main technique of treatment involves manipulation of the spine, joints, and soft tissues but advice about exercise, posture and lifestyle may also be given. Chiropractors are best known for treating back pain and mobility problems but they do also treat a number of related conditions. Traditionally, chiropractic was based upon the vitalistic notion that disease originates from subluxations (lesions or dysfunctions that affect nerve flow) of the spine, and that adjustment of these subluxations can restore health. Some modern day chiropractors still refer to subluxations, but many prefer to explain their treatment in more conventional biomedical terms (Leach 1994, Bergmann and Peterson 2010).

Herbal medicine

Also known as botanical medicine or phytotherapy, herbal medicine involves the use of a plant's seeds, berries, roots, leaves, bark or flowers for medicinal purposes. Plants have been used for medicinal purposes by cultures around the world since ancient times but the types of plants used in herbal medicine in different countries have, to a great extent, depended upon the species that are local to that region. For example, the herbs used in Chinese herbal medicine are mostly different from those used in Western herbal medicine. Herbalists can prescribe herbal remedies in a number of forms such as capsules, teas, and tinctures, from fresh or dried plants (Mills and Bone 2000).

Homeopathy

First introduced in the 18th century by German physician Samuel Hahnemann, homeopathy is based upon the principle that like can be cured with like. Substances from the natural world (whether animal, vegetable or mineral) are ingested by healthy persons in drug trials, which are known as provings, to determine their sphere of action. The symptoms produced in a proving are then listed in the homeopathic materia medica for that substance. In assessing the patient, homeopaths take into account a range of physical, emotional and mental symptoms and seek to prescribe the medicine that was able to produce similar symptoms in a proving (*similimum*) (Vithoulkas 1980). In the preparation of homeopathic medicines substances are subjected to a series of dilutions and succussions (vigorous shaking), and homeopathic philosophy teaches that the more dilution and succussion that is undertaken, the stronger the action of the medicine will be. In common with Traditional Chinese teaching, homeopaths believe in the existence of a vital energy, the 'vital force'. They use a similimum to stimulate the vital force and activate a person's innate healing capacity (Jonas *et al.* 2003).

Osteopathy

The practice of osteopathy has a similar origin to that of chiropractic, having first been proposed by Andrew Taylor Still in America in 1874 (Still 1902). Osteopaths work with the structure and function of the body, and the practice is based on the principle that the wellbeing of an individual depends on the skeleton, muscles, ligaments and connective tissues functioning smoothly together. It differs historically from chiropractic in its underlying theory in that it is the impairment of blood supply, rather than nerve function that leads to problems (Sutherland and Wales 1990). Treatment can involve touch, physical manipulation, stretching and massage in order to increase the mobility of joints, to relieve muscle tension, to enhance blood and nerve supply to tissues and to stimulate the body's innate healing ability. Practitioners may also provide advice on posture and exercise to aid recovery, promote health and prevent symptoms recurring. As with chiropractic, most people who visit an osteopath do so for back pain and mobility problems, but osteopathy is also used to treat a wide range of health conditions, including digestive problems and menstrual pain (General Osteopathic Council 2013).

Whilst there are other popular forms of CAM in the UK, such as aromatherapy and reflexology (Posadzki *et al.* 2012c), together these five forms of CAM account for the majority of CAM use in the UK. However, the situation in the UK, where CAMs are used primarily as an adjunct to conventional treatment, is not replicated in all parts of the world. Citizens in the UK have free access to conventional treatments through the National Health Service and CAM treatments do not normally form part of primary healthcare. The value, status and meaning of CAM is often very different in other countries.

2.2 A Global Perspective

As noted before, usage of complementary medicine may be as high as eighty per cent of the population in some parts of Asia and Africa where many people rely upon some form of traditional medicine for their primary health care (WHO, 2008). For many this may be because there is little choice, but for others there may be a distinct preference for indigenous forms of health care. For instance, traditional African healers may be sought because they offer treatments for the more intangible necessities of health and wellbeing such as the warding off of evil, bringing luck and good fortune, and protection against demonic attacks, which are not considered by conventional practitioners (Abdullahi 2011). In China, Korea and Japan, East Asian medicine predates conventional medicine by several thousand years, is highly valued, and is utilised by between forty and seventy-six per cent of the populations. In these three countries, the East Asian medicine methods of acupuncture, herbal medicine, moxibustion, cupping and manual therapies are integrated into the national health care systems in a manner that is respectful of the historical and cultural background and allows people relatively equal access to both traditional and conventional medicine (Park *et al.*, 2012).

Unlike most other attempts to classify and categorise T&CM the WHO distinguish between healthcare interventions that are used in a complementary or alternative manner, away from their geographical origins, and those that are rooted in local tradition and culture (traditional medicine) in their definition as follows:

Traditional medicine

Traditional medicine is the sum total of the knowledge, skills, 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.

Complementary/alternative medicine (CAM)

The terms 'complementary medicine' or 'alternative medicine' are used inter-changeably with traditional medicine in some countries. They refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system.
(WHO 2000, p.1)

Acording to the WHO, any form of healthcare that is indigenous to a particular locality can be classified as traditional medicine within that locality but, outside that locality, may be considered as complementary or alternative. Thus, acupuncture and the use of Chinese herbal medicines should be classified as traditional medicine when used within China, but as complementary or alternative medicine elsewhere in the world; what is considered traditional and what is considered complementary or alternative will therefore vary from country to country and from region to region.

This definition is not without its flaws. A major defect with the WHO definition is that it tells us nothing about how long a system of medicine needs to be in place before it is considered traditional. On the one hand, it is stated that a medicine is traditional if it is a 'practice based on the theories, beliefs, and experiences indigenous to a culture' but on the other hand it falls into the CAM category if it is 'not integrated into the dominant health care system'.

This distinction between traditional medicine and complementary/alternative medicine therefore encounters problems when attempting to classify more recently developed therapeutic systems such as homeopathy and chiropractic. Both of these systems were developed in Europe in the eighteenth century and, according to the WHO criteria, since this was after the introduction of conventional medicine, they should be classified as complementary/alternative. There is a problem with this simplistic classification,

namely that it is difficult to pinpoint exactly the beginning of conventional medicine. At the time when homeopathy was first developed the most dominant healthcare interventions in the West included blood-letting and the oral administration of herbal remedies or toxic substances such as arsenic and mercury. Edward Jenner, founder of the small pox vaccine, was a contemporary of Samuel Hahnemann, the founder of homeopathy. Many other scientists who have been credited with laying the foundations of conventional biomedicine, such as Joseph Lister, Louis Pasteur and Robert Koch, were born well after Hahnemann had proposed his system of medicine. Hence, it could be argued that homeopathy is in fact more traditional than conventional biomedicine. Since the WHO definition is suggestive of some kind of timeline hierarchy, even if a therapy is indigenous, then it should be considered as complementary/alternative if it was developed after the dominant system.

In spite of this operational difficulty, there is value in drawing a distinction between traditional or indigenous forms of healing that are rooted in local culture and tradition and those which are used, as they commonly are in the Western world, in a complementary or alternative manner. If I am to examine ethical issues in both the UK, as representative of Western culture, and low and middle income countries, it is important to acknowledge that there may be different motivations for use, different levels of reliance, and different degrees of autonomy involved in choice of healthcare. Hence, the WHO denotation of T&CM has been adopted for this thesis in consideration of both Western and global perspectives.

2.3 Summary

My investigation of what is meant by traditional /complementary/ alternative medicine has shown that existing definitions have inherent deficiencies and that, for a number of reasons, it may not even be possible to define. Consequently, a pragmatic approach has been taken to identify the forms of T&CM that will be included in the first phase of analysing ethical challenges from the UK perspective. In accordance with the 2001 report from the House of Lords (McIntyre 2001), the five therapies placed in Group 1 (acupuncture, chiropractic, herbal medicine, homeopathy and osteopathy) will be the subjects of scrutiny.

In addition, and in keeping with the intention to consider global issues, the adopted nomenclature for the thesis will be T&CM, drawing heavily upon the WHO meaning of T&CM as described in their traditional medicine strategy 2014-2023 (WHO 2013).

CHAPTER THREE: WHAT IS HEALTH?

Prior to undertaking the analysis of ethical issues associated with T&CM, it is necessary to explain what I mean by *health* as this, presumably, is the ultimate goal in health care. If we are to assume that health (or increased potential for health) is the main goal of medical interventions then it follows that we need to have some agreement about what health means in order to set relevant objectives. If health is the ultimate aim of health care then a shared understanding of what health means is necessary to reach agreement about the strategies to be put in place, and services delivered, to help achieve it. As Fiona Godlee, editor of the *British Medical Journal* remarked: '.... if health is the goal of healthcare and research, we need to know what it looks like and how to measure it' (Godlee 2011, p.1).

Perhaps those who work in healthcare might benefit from contemplating the approach of educationalists who appreciate the importance of clearly distinguishing between the identification of aims and the setting of objectives. In educational terms 'aims' are understood as statements of intent or aspiration; of what it is hoped to achieve. Objectives, on the other hand, are goals or steps that are set for meeting the aim; they are more specific and define measurable outcomes. Once the aim is identified the objectives follow; to set objectives without a clear understanding of an aim makes no sense.

This distinction between aims and objectives, as widely utilised in education, will be adopted here and applied to the concept of health. This chapter will be devoted to identification of a meaning of 'health' that will then be assumed, for the sake of argument in this thesis, as the main aim of health care. From this meaning of health certain ethical implications for the provision of health care, and setting of objectives, will be inferred.

It is anticipated that the identified meaning of health will inform argument where there are conflicting interests or opposing opinions. Consequently, an attempt will be made to propose a meaning that has broad appeal and shared understanding such that

conclusions drawn from this enquiry have real world relevance. In so doing, it is logical to begin with the examination of the currently most widely referenced definition of health; namely that used by the World Health Organisation.

3.1 The World Health Organisation's Definition of Health

Whilst there is currently a lack of broad agreement about how to define health, and a subsequent lack of a clear aim in health care, there have been numerous attempts to generate a definition of health (Balog 2005, Sartorius 2006, Van De Belt *et al.* 2010). Debate about the meaning of health and disease has been ongoing since antiquity and there have been many proposed definitions. One definition, however, stands out above all others in terms of breadth of acceptance and impact; the definition of health from the WHO, adopted by an international health conference in 1946, entered into force on 7th April 1948 and has not been altered since.

The end of the Second World War saw the establishment of the United Nations (UN) in 1945 and marked the beginning of a period of greater internationalism and internationalisation. Whilst health was not originally intended as a primary concern for the UN, intervention by Brazilian and Chinese delegates ensured that a motion to establish an international health organisation was unanimously accepted. A preliminary technical committee of eighteen health experts, who were working on emergency relief in the wake of World War II, were charged with the task of drafting the constitution of the proposed World Health Organisation, describing its operating principles and defining its functions. These proposals were then brought before an international health conference in New York in June 1946. The conference, which was representative of governments, concluded its proceedings on 19th July when the delegates of sixty-one states signed the constitution (Charles 1968). In the preamble to the constitution appeared the following:

> Health is a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity (WHO 1946).

Revolutionary in its time, this definition was intended to provide a transformative vision of 'health for all'; one that went beyond the prevailing negative conception of

health based on an ‘absence’ of pathology (Larson 1996, Horton 2009). However it has been the subject of criticism since its inception as many have struggled to understand how its meaning could be operationalised (Das 1991). It has been criticised for being too idealistic (Saracci 1997), and ‘utopian’ in nature (Garner 1979, Scully 2004), such that very few people (if any) could ever be considered healthy. Furthermore, it is now considered by some to be redundant because the WHO definition was, ‘as much a political statement as a public health statement’ (Larson 1996, p.182). In an era when there was acute awareness of the health status of whole societies it was only logical that human health be placed in a broader social context. Brock Chisholm, the first Director General of the World Health Organization (1948-1953), and member of the group who formulated the WHO definition, describes a profound pessimism about humankind and society during that period writing:

> We have responsibility for social health, for being able to live in peace and contributing to the welfare of other people. The social responsibility of the individual has never been recognized before on such a wide international basis (Chisholm 1948, p.364).

Now, however, we are no longer living in such times. Many authors have discussed the WHO definition (Huber *et al.* 2011), and opinions vary widely. The most significant objections are here summarised under the following four categories:

1. Utopian nature.
2. Medicalisation of health.
3. Wellbeing and health.
4. The changing patterns of disease.

The following consideration of these objections to the WHO definition will serve to highlight any shortcomings and, in so doing, help to achieve clarity about necessary attributes for any proposed replacement.

3.1.1 Objection 1: Utopian nature

Many have argued that inclusion of the word 'complete' in the WHO definition implies that health is a state in which everything is perfect (Garner 1979, Scully 2004). In other words, the definition is necessarily idealistic or utopian in nature. Anything less than complete absence of symptoms, and complete wellbeing on all levels, fails to achieve the requirements for health. As Bellieni and Buonocore (2009) assert, 'To define 'health' as 'complete wellbeing' would thus leave us with a 'null set' of persons as actually possessing health' (p.8). If, as proposed by Callahan (1973), the WHO definition is describing a state that is, at best, only transitory, it is difficult to imagine how an individual might relate it to their own concept of health prompting the question from Das, 'Whom then does it serve?' (Das 1991, p.923).

Most people who claim to be healthy are aware of minor complaints from time to time and subjective feelings of wellbeing vary from day to day (Richard Smith 2008). Additionally it is well known that the experience of some health complaints serves to increase health. For example, acute complaints are necessary to strengthen and develop the immune system (Holt and Jones 2000). Furthermore, it would not be considered 'healthy' for a person to maintain 'complete' mental wellbeing following a trauma such as loss of a loved one where grief would be considered a normal and healthy response. On the contrary, in such circumstances a lack of adverse effect would be a cause for concern about mental health. It is entirely conceivable that a person can be healthy without being in a state of 'complete physical, mental and social wellbeing'. As Callahan so eloquently points out, '…it is doubtful that there ever was, or ever could be, more than a transient state of 'complete physical, mental and social wellbeing' for individuals or societies; that's just not the way life is or could be' (Callahan 1973, p.87).

Perhaps it could be argued that the WHO definition is aspirational and as such represents an ideal. However, in educational circles, it is accepted that even when aims are aspirational they must also be achievable in order to set realistic and workable objectives. The WHO definition is unhelpful in practice because it is impossible to operationalise. In other words, even if we accept that the definition describes an aspirational goal, it is impossible to identify the steps needed to reach that goal, 'because 'complete' is neither operational nor measurable' (Huber *et al.* 2011, p.2). Or, as Doll puts it, 'This is a fine and inspiring concept and its pursuit guarantees health

professionals unlimited opportunities for work in the future, but is not of much practical use' (Doll 1992, p.933). We cannot possibly know which objectives to set in healthcare if the aim is unobtainable.

Necessary attribute 1: The adopted meaning of health can describe a state that is aspirational, as is common with aims, but it should be an achievable aim for which realistic objectives can be set.

3.1.2 Objection 2: Medicalisation of health

A further consequence of the inclusion of the word 'complete' is that it is indirectly supportive of the increased medicalisation of health care (Huber *et al.* 2011). As new discoveries are made, such as new ways of diagnosing potential problems or new ways of treating existing or potential problems, then the boundaries between health and ill-health are redrawn. Diseases are redefined, new drugs become available and ideas about what is healthy change accordingly: 'With the progress of medicine, individuals who are declared healthy today may be found to be diseased tomorrow' (Sartorius 2006, p.662).

For example, national guidelines on who should be prescribed one of the cholesterol lowering drugs, statins, have been subject to frequent changes in the UK. Initially statins were prescribed for people who had both high levels of serum cholesterol and a history of cardiovascular disease (CVD) (Teeling *et al.* 2005). Over time usage has been extended to include people 'at risk' of developing CVD with statin therapy recommended as part of the management strategy for the primary prevention of CVD for those at thirty per cent or greater risk of developing CVD within ten years. Guidelines published by the National Institute for Health and Care Excellence (NICE) in 2006 advised that statin therapy should be extended to include adults who have a twenty per cent or greater, ten year risk (NICE 2008). Consequently, it is estimated that approximately seven million people in the UK are currently being prescribed statins. Current guidelines (NICE 2014) have altered prescribing patterns yet again as they propose prescriptions for statins should now be extended to include those at a ten per cent or greater risk, which could see the number of people on statins in the UK double (Price and Mathews-King 2014). Statins are the most widely prescribed drug

treatment in the UK and yet the use of statins in low-risk patients without CVD remains a matter of intense debate because the exact threshold of baseline risk of CVD has not been determined (Brugts and Deckers 2010). With thresholds for interventions constantly changing, an emphasis on 'complete physical wellbeing' could lead to ever increasing groups of people becoming eligible for treatment even when only few people might benefit, resulting in higher levels of medical dependency and risk (Huber *et al.* 2011). In this way, the WHO definition could even be counterproductive, leading to practice that is driven by developments in medicine rather than by what is most beneficial for the health of individuals. Through adoption of a definition that is directly correlated with increased medicalization, we are in danger of losing sight of what a healthy person actually is.

Necessary attribute 2: The adopted meaning of health should be 'person-centred', rather than 'medicine-centred', such that its recognition is not directly dependent upon advances in medicine.

3.1.3 Objection 3: Wellbeing and health

The WHO definition equates health with a state of physical, mental and social *wellbeing*, but critics have argued that health and wellbeing are simply not the same thing. Saracci (1997) for example, asserts that the definition corresponds more closely to happiness than health, citing Freud in support of his argument who, after stopping smoking cigars for health reasons wrote:

'I learned that health was to be had at a certain cost…. Thus now I am better than I was, but not happier' (Freud, cited by Saracci 1997, p.1409).

In their report of the debate on measuring national wellbeing, the Office for National Statistics (ONS 2011) echo this thought that wellbeing is often taken to mean 'happiness' but go on to explain that happiness is just one aspect of the wellbeing of individuals. In their attempt to identify key markers for wellbeing, the ONS undertook a national research project in the UK with input from over 34,000 individuals. Results from the project indicate that, while different things matter to different people, and vary at different stages of life, there are some common themes. These include:

- the importance of health to wellbeing,

- the importance of having adequate income or wealth to cover basic needs, and
- the environment around us, and the need to connect with other people – whether partners, children, wider family, the community (local, national, faith and online), or work colleagues (ONS 2011, p.4).

According to the Organisation for Economic Cooperation and Development, when we talk about human wellbeing we are referring to the quality of people's 'experience of life' and the quality of that experience is affected by many factors, health being one of them (OECD 2013). They describe differences in what people regard as important for their wellbeing, depending on who they are, their position in society, and where they are. For example, what a young woman needs for her wellbeing in a city context is likely to be quite different to what an old man needs for his wellbeing in a rural village. Requirements for wellbeing are context-related such that, as Fulder (1998) points out, in impoverished circumstances, wellbeing might be identified as having enough to eat and easy access to clean water. Or, as Callahan describes, 'Complete wellbeing might conceivably be attainable, but under one condition only: that people ceased expecting much from life' (Callahan 1973, p.81). Furthermore, the equation of health with wellbeing is of limited usefulness to healthcare professionals. As Fulder (1998) so adequately points out, 'there are no wellbeing medicines in the pharmacopoeia' (p.151); in other words, we cannot rely upon pharmaceuticals for our wellbeing.

In 2013, a United Nations Children's Fund comparative report (unicef 2013) on the wellbeing of children in rich countries described five dimensions of wellbeing; material wellbeing, health and safety, education, behaviours and risks, and housing and environment. This report analysed objective measures of wellbeing, such as infant mortality and living circumstances, together with the subjective opinions from children from the twenty-nine included countries. The UK did not fare well in this report, being ranked sixteenth, in spite of being identified as one of the three most wealthy countries under scrutiny.

It is clear from both national and international studies that wellbeing is regarded as a complex issue with many contributing factors, including economic, social and environmental conditions as well as levels of health. Naturally those same economic, social and environmental factors can also have a direct impact upon levels of health,

but this does not imply that health and wellbeing are one and the same. Health and wellbeing are intricately linked and although there is a two way relationship between them (Department of Health 2014), they are not the same thing. Health is one of the things that people say matters most for wellbeing, but it is possible to experience high levels of wellbeing even when apparently dealing with compromised health. For example, in their qualitative study Albrecht and Devlieger (1999) confirmed previous postulation of the so-called 'disability paradox', in their discovery that people with serious and persistent disabilities can report that they experience high levels of wellbeing even when, to most external observers, these individuals seem to live an undesirable daily existence. For this investigation semi-structured interviews were conducted with 153 persons with disabilities and of these, 54.3% of the respondents with moderate to serious disabilities reported having excellent or good levels of wellbeing. Hence, there are serious problems with equating health with the notion of wellbeing.

Necessary attribute 3: The proposed meaning of health should describe a state that is distinct from wellbeing, as they are not one and the same.

3.1.4 Objection 4: The changing patterns of disease

A further objection to the WHO definition of health is that the disease burden, particularly of high income nations, has altered significantly since the definition was introduced. In the first half of the twentieth century the majority of illness resulted from infectious disease and those who did have chronic diseases could expect an early death (Huber *et al.* 2011). During the Second World War there was a peak in infant mortality rates, mainly due to increased pneumonia and bronchitis (Macfarlane *et al.* 2000). Whilst these may have been due to fuel shortages during the very cold winters of 1940 and 1941, and also to the disorganisation caused by evacuations early in the war, set against this backdrop it is easy to understand why a broad definition of health, inclusive of societal factors, would be welcomed.

However, over the course of the entire twentieth century there was a dramatic decline in infectious disease mortality. Poliomyelitis, diphtheria, tetanus, whooping cough, measles, mumps and rubella were all virtually eliminated during the second half of the

century (Griffiths and Brock 2003). This change in disease pattern has been attributed to a variety of public health measures such as improved nutrition, hygiene, sanitation and more effective healthcare interventions (Gorsky 2008). Concurrently, as mortality rates from acute diseases have declined, life expectancy has increased along with the number of people living with, and dying from, chronic complaints. The primary disease-related causes of death in the UK are currently cardiovascular disease and cancers (Murray *et al.* 2013).

In 1901, life expectancy was forty-five years for men and forty-nine years for women. By 2012 this had increased to 79.2 years for men and 83.3 years for women (Kingsfund 2012). In 1900, less than twenty-five per cent of all deaths in England and Wales occurred at ages sixty-five and over. By 2000 this figure had increased to eighty-three per cent (Griffiths and Brock 2003). Aging with chronic illness has now become the norm in the UK, with an increasing number of people living with disabilities resulting from physical complaints, such as musculoskeletal disorders and falls, as well as dementia and Alzheimer's disease (Murray *et al.* 2013). This invariably raises concerns about the WHO definition of health, as it declares all those living with chronic disease or disability 'unhealthy'. In fact, findings from studies suggest that people who live with disabilities can indeed regard themselves as healthy and this has highlighted a need for a 'conceptual disentangling' of health from disability (Drum *et al.* 2008). Changing patterns of demographics and disease in the UK demand a fresh look at the way in which health is defined, towards one in which people can aim for high levels of health and wellbeing in spite of physical or mental impairment. To do otherwise would be to label the majority (if not all) of the population as unhealthy.

Necessary attribute 4: The proposed meaning of health must allow for variations in disease patterns and demographics of the population.

In summary, the definition of health from the WHO was conceived in the aftermath of World War Two when peace and health were regarded as inseparable (Callahan 1995). At that time, widening the contemporary view of health to include the psychological and social dimensions was a major advance (Saracci 1997). However, it is clear from numerous and broad-ranging objections that this definition has limited value in current times. Nowadays, it is taken for granted that human health is affected by a wide range

of factors, including psychological and social influences, and the WHO definition of health appears to describe a state that is unachievable for most people, most of the time. The practical implications for attempting to achieve health in this sense, for all peoples, render this definition of poor pragmatic value and so, consequently, it is of limited usefulness for either healthcare professionals or individuals.

This analysis of objections to the WHO definition of health has, however, been useful for the clarification of those attributes that must hold true for any alternative definition that is proposed in this thesis.

3.2 What Does Health Look Like?

'We know it when we see it. Easy to spot, difficult to define.' (Bury 2005, p.1)

So far, in this endeavour to identify the meaning of health, pragmatic questions have been identified that might be informed by a valid definition, as well as broad attributes that the definition must exhibit if it is not to succumb to the very same criticisms as the WHO definition. However, nothing has yet been said about what 'health' actually comprises or looks like, which is, of course, the crux of the matter in hand. Hence, it seems appropriate here to ask the question, 'what does health look like'? In seeking to address this question, the attributes of certain populations, who are broadly accepted to be the healthiest communities in the world, will firstly be examined.

3.2.1 The healthiest people in the world

At seventy you are but a child, at eighty you are merely a youth, and at ninety if the ancestors invite you to heaven, ask them to wait until you are 100…. And then you might consider it.' An Okinawan proverb (Willcox *et al*. 2013)

Good health does not result exclusively from having access to the best healthcare systems. There are many factors involved, as is evident from examination of populations with apparently high levels of healthiness. In 2005, the National Geographic published an article about three distinct communities who have the greatest longevity in the world: Silanus, a mountainous region in Sardinia; a group of Seventh Day Adventists in Loma Linda, California; and Okinawa, an 800 mile long archipelago

of one large and 160 tiny islands in Japan (Buettner 2005). Although each of these communities has become a focus of study because of the tendency towards great longevity of their peoples, researchers have found that they also exhibit much lower rates of chronic disease and more years of good life. Indeed, from studies around the world, it is now widely accepted that, on average, the older people get, the healthier they have been in their lifetime (Hitt *et al.* 1999).

Silanus is located on the fringes of the Gennargentu Mountains in central Sardinia. The population is small, totalling only 2,400 people, but of the 17,865 people born between 1880 and 1900, ninety-one have lived to their hundredth birthday; twice as many as the average for Italy (Buettner 2005). Silanus is of particular interest to gerontologists because it is the only place in the world where there are as many men aged over one hundred as there are women. Unlike the other two communities mentioned here, there is substantial evidence to suggest that genetics plays an important role in the longevity of these Sardinians as approximately eighty per cent of inhabitants are directly related to the first Sardinians (Buettner 2012). Other factors implicated in their great longevity include their Mediterranean diet, active lifestyles and close family bonds.

Loma Linda in California, hosts a community of Seventh-day Adventists who, on average, live four to ten years longer than the average Californian, and have the greatest longevity of any community in the United States. Adventists have a strict health-oriented lifestyle, forbidding smoking, alcohol, meat, rich foods and caffeinated drinks (Buettner 2005). For the Adventists, health is part of their religion, along with leading active lives, and contributing to the community. They experience close social connections and are highly supportive of each other without compromising independence (Buettner 2012).

Whilst there are many differences between the two cultures, there are also many similarities between the elderly of Silanus and the elderly Adventists in Loma Linda. These include low levels of chronic complaints, high levels of energy and physical activity, faith-based cultures, strong social connections and close family ties. The elderly of Silanus and Loma Linda are remarkable in numerous ways, but even they are surpassed in apparent healthiness by the elderly of Okinawa.

In 1975, Dr Makoto Suzuki began a population-based study of centenarians, and other selected elderly, in Okinawa, Japan, which is now known as the Okinawa Centenarian Study (OCS). When Suzuki first began his studies, he found an unusually large number of centenarians, many of whom were exceptionally healthy, with remarkably low rates of heart disease and cancer (Willcox *et al.* 2001). Okinawans boast the longest life expectancy in the world, but the OCS is not just about how many years have been lived: to be considered 'successfully aging' the individual should have enjoyed a high quality of life throughout life up to, and including, a 'super-elderly' stage (Suzuki *et al.* 2004). According to Willcox *et al*. (2013, p.3): 'they (Okinawans) have slim lithe bodies, sharp clear eyes, quick wits, passionate interests and the kind of Shangri-la glow of youthfulness we all covet'. Other signs of good health in elderly Okinawans include; impressively young, clean arteries; low levels of cholesterol; a low risk for hormone-dependent cancers; strong bones; sharp minds; slim bodies; natural menopause; healthy levels of sex hormones; low stress levels; low levels of depression and excellent pyschospiritual health (Willcox *et al.* 2007). Many dietary and lifestyle factors are believed to contribute to the good health of Okinawans, including low caloric intake, high vegetables/fruits consumption, higher intake of 'healthy' fats, lower intake of 'unhealthy fats (from animal sources), high fibre intake, low body fat level, and high levels of physical activity (Willcox *et al.* 2009). However, there are other factors also at play.

The high levels of health experienced by Okinawans do not stem from stress-free lives or perfect living circumstances. On the contrary, Willcox *et al.* (2013) state that most had bounced back from significant emotional ordeals and losses including poverty, war, oppression and other hardships, with amazing resilience. A seemingly crucial factor in this ability to 'bounce back' appears to be the high levels of social support, from strong social networks and close family ties, believed by many to increase protection against illness (Willcox *et al.* 2013). In fact, many studies have demonstrated that social ties can improve the strength and resilience of the immune system. Socially connected people are less prone to stress, whilst chronic stress is believed to wear down the body over time and is implicated in, amongst other things, an increased risk of heart disease, depression, and reduced immune function (Miyazaki *et al.* 2003, Wolfer 2004, Uchino 2006, Fagundes *et al.* 2012). Elderly Okinawans, in spite of their exposure to potentially stressful situations, exhibit low levels of negative emotions (Willcox *et al.* 2013), an

attribute they share with other super-elderly. As Buettner described, ‘After interviewing more than fifty centenarians on three continents, I’ve found every one likable; there hasn’t been a grump in the bunch’ (Buettner 2005, p.26).

One last, and potentially relevant, factor about the health of Okinawans is that they incorporate both Eastern and Western healing methods into their health system. Okinawa, Japan and Hong Kong, are the top three areas of the world for life expectancy and all incorporate both Eastern and Western medical approaches (Willcox *et al.* 2013).

In summary, study of the super healthy, elderly Okinawans can teach us a great deal about health and a healthy lifestyle. The Okinawans, who have low levels of chronic disease, are characteristically of slim build; they have high levels of energy, activity and independence; they have sharp minds and they appear to cope well in stressful situations. It is believed that these factors may be enhanced by their maintenance of a positive outlook and strong social ties (Buettner 2012).

Whilst the characteristics of healthy Okinawans clearly illustrate a picture of what a healthy person may look like, it cannot be assumed that these attributes are necessary conditions for health. Indeed, these characteristics may be valuable indicators of health and a healthy lifestyle but whether or not they are all necessary for health is uncertain. However, study of the Okinawans can aid with visualisation of the potential for health. If our aim is to be aspirational but realistic, and these are whom we consider as the healthiest people in the world, then our aim should be to help people achieve a state that is similar in some way to, but not necessarily the same as, that of the Okinawans.

3.3 Towards a New Definition of Health

In December 2008, two members of the Centre for Global eHealth Innovation at the University of Toronto, Alejandro Jadad and Laura O’Grady (2008), sparked new debate about how health should be defined when they called for broad input in an editorial of the British Medical Journal (BMJ). Jadad and O’Grady created a blog on the BMJ website, inviting anyone who had internet access to comment upon, challenge, or try to enhance the WHO definition of health. Contributions to the discussion have been added from all over the world, representing a wide diversity of opinions. By March 2015 there

had been 523 comments added to the discussion that still remains open. The efforts of Jadad and O'Grady motivated the Health Council of the Netherlands and the Netherlands Organisation for Health Research and Development, to support a two-day invitational conference entitled, '*Is health a state or an ability? Towards a dynamic concept of health.*' In December 2009, thirty-eight invited participants, representing a variety of stakeholders, came together to consider whether useful descriptions of health could be found for the perspectives of the different stakeholders. The stakeholders included representatives from sectors as diverse as health promotion and disease prevention, research and research funding, health insurance, health policy and politics, international regulatory and policymaking organisations, and patients. There was broad support at this meeting for moving from the 'static formulation' of the WHO definition towards a more dynamic definition.

The outcome was a proposal for a new conceptualisation of health as:

'the ability to adapt and to self-manage' when facing physical, mental, and social challenges' (Huber *et al.* 2011, p.2).

This, state Huber *et al.*, applies to us both as individuals and as members of a community.

The proposed new definition is suggestive of a marked shift away from a disease-focussed, or pathogenic, approach in healthcare towards a more positive and proactive stance. Broad acceptance of the pathogenic model in healthcare has resulted in the assumption that disease prevention, treatment and management are the best route to better health (Becker *et al.* 2010) and, at first glance, the new definition appears to represent a radical change in thought and opinion. As Richard Smith, former editor of the British Medical Journal, observed, the pathogenic approach in healthcare is pervasive:

> But what is health? For most doctors that's an uninteresting question. Doctors are interested in disease, not health. Medical textbooks are a massive catalogue of diseases. There are thousands of ways for the body and mind to go wrong, which is why disease is so interesting. We've put huge energy into classifying

> disease, and even psychiatrists have identified over 4000 ways in which our minds may malfunction (R. Smith 2008).

Whilst the move from the WHO definition to the Huber *et al*. definition might appear radical, the new definition was not conjured out of thin air. On the contrary, it was rooted in a growing change in perspective that has been developing over a number of years. Many health practitioners had described problems with a disease-oriented approach that is necessarily insufficient if health is more than the mere absence of disease. Some had been calling for a completely new way of conceptualising health, such as Tinetti and Fried back in 2004:

> The time has come to abandon disease as the focus of medical care. The changed spectrum of health, the complex interplay of biological and non-biological factors, the ageing population, and the inter-individual variability in health priorities render medical care that is centered on the diagnosis and treatment of individual diseases at best out of date and at worst harmful (p.179).

Simultaneously, there has been a marked increase in interest and discussion about the human capacity to respond, in a positive manner, in the face of adversity. Some individuals have the ability to achieve or retain a state of health and wellbeing even when faced with stresses of a physical, mental or social nature, as is markedly apparent in the peoples of Okinawa. Many theories about health have emerged that are, in certain ways, related to this observation, three of which have been the subject of significant interest and development. These are the concepts of salutogenesis, resilience and robustness.

3.3.1 Salutogenesis

The word ‘salutogenesis’ stems from the Latin term *salus* (health) and the Greek term *genesis* (origin) and was first introduced by sociologist Aaron Antonovsky in 1979. Antonovsky spent many years studying the ways in which people respond to stress, how they manage stress and how they stay well, and observed that some people achieve health in spite of exposure to potentially disabling stress factors (Antonovsky 1979). The salutogenic approach to health and wellbeing offers a stark contrast to the pathogenic model as it is focussed upon health and looks prospectively at how best to

promote health and wellbeing. According to Antonovsky, health can be viewed as movement in a continuum on an axis between total ill health (dis-ease) and total health (ease); movement in either direction can be affected by a number of factors. People are continually exposed to stress factors termed *generalized resource deficits* (GRDs) that encourage dis-ease. The body is able to deal with most stresses without significant problems due to the *generalized resistance resources* (GRRs), the sum total of the resources that help a person cope, and which are effective in avoiding or combating the stresses in life. The generalised resistance resources are of both genetic and acquired character, as well as social and material in nature, such as understanding, intelligence, social support, family ties, culture, religion, and lifestyle factors (Antonovsky 1979, Antonovsky 1987). The ability to comprehend the situation, and the capacity to use the resources available to positive effect, is termed *sense of coherence*. This capacity is a combination of peoples' ability to assess and understand the situation they are in, to find a meaning, to move in a health promoting direction, and to have the capacity to do so (Lindström and Eriksson 2005). Stress factors (GRDs) will cause the coping mechanisms to fail whenever the sense of coherence is not robust to deal with the current situation. This causes illness and possibly even death. However, if the sense of coherence is high, a stressor will not necessarily be harmful. Ultimately, it is the balance between stress factors (GRDs) and the coping resources (GRRs) that determines whether a factor will be pathogenic, neutral, or salutary (Antonovsky 1987).

3.3.2 Resilience

The word 'resilience' stems from the Latin term *resilire* (to jump back) and the concept was originally developed and explored in agricultural and ecological systems, where it is commonly used to refer to the capacity to resist shocks and/or the speed of recovery after some disturbance or pressure (Manyena 2006, Haimes 2009). The concept has also been widely adopted in other fields including sociology and, in particular, it is commonly used in psychology, where it is taken to mean the ability of people to cope positively with stressful situations (Döring *et al.* 2013). Psychological studies of resilience in particular groups of individuals who experience stress, such as military personnel (Sudom *et al.* 2014, Ursano *et al.* 2014) and sports personnel (Belem *et al.* 2014, Sarkar and Fletcher 2014), are commonplace and the numbers of such studies are growing. Resilience is more than simply the ability to respond to stress; resilience is a

coping mechanism that helps to keep systems (including the human body) in a healthy and functioning state.

3.3.3 Robustness

The word ‘robustness’ stems from the Latin term *robustus* (hard and strong) and also describes a coping mechanism. However, this concept was originally developed and employed in engineering and biology. Robustness has been described as a property that allows a system to maintain its functions despite external and internal perturbations (Sastry and Bodson 2011). It is an emergent property and cannot be understood by looking at the individual components of an organism. Complex biological systems must be robust in order to withstand environmental and genetic perturbations, and evolution often selects traits that might enhance the robustness of the organism. Hence, robustness is ubiquitous in living organisms (Kitano 2004).

One example of how deficiencies in robustness have a direct effect on human health that is often quoted is the ability to cope with extreme weather conditions (Ivanovas *et al.* 2007). People who live permanently in more extreme weather environments seem to develop a much greater ability to cope with the extremes than people who only experience extreme weather environments on a temporary basis. For example, on average over the last decade, the average number of deaths in winter months (December to March) in England has outnumbered the average number of deaths over the rest of the year by more than 25,000 (PHE 2014). These are termed ‘excess deaths’ as they are not just deaths of those who would have died anyway in the next few weeks or months due to illness or old age. Other countries such as Finland experience lower average numbers of such deaths than England, despite worse temperatures during the winter, which is taken to suggest that some excess winter deaths could be prevented (Healy 2003).

3.3.4 Salutogenesis, resilience, robustness and health

The concepts of salutogenesis, resilience and robustness all point towards there being a dynamic internal process that is stimulated when an individual is under stress, and which serves to preserve or promote health through adaption. All three concepts are subjects of increasing interest globally, although there is variation between countries in

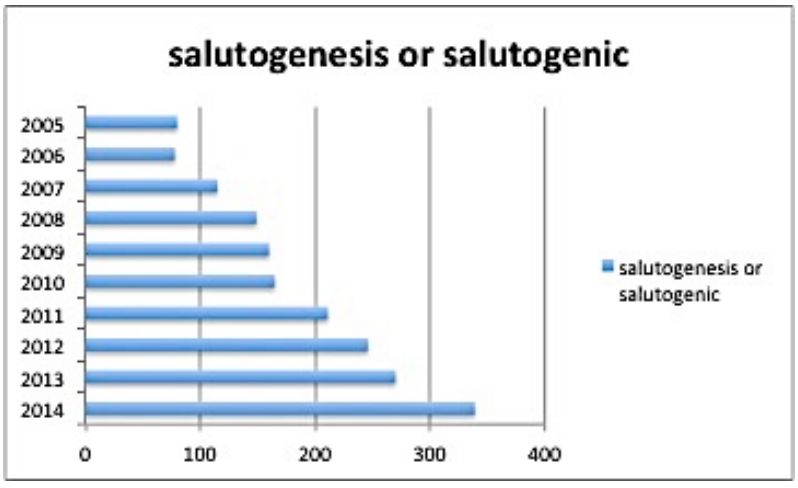
the predominance of interest in one over the others. For example, figure 2 illustrates the search interest in the UK, and shows a clear increase in searches for resilience, the beginnings of interest in salutogenesis and a maintained interest in robustness.

Figure 2: Google Search Interest in the UK for Resilience, Salutogenesis and Robustness from January 2008 to May 2015

The horizontal axis represents time (starting from 2008), and the vertical, how often a term is searched for relative to the total number of searches, globally

Academic interest in these concepts is also increasing as clearly illustrated in Figure 3, which shows the number of academic publications related to salutogenesis between 2005 and 2014.

Figure 3: Academic Publications Related to Salutogenesis Listed on Google Scholar



The year of publication is shown in the vertical axis, and the number of publications that year is shown on the horizontal axis.

3.4 Assessing the Value of the New Definition of Health

Thus far, I have outlined how the proposed new definition of health (Huber *et al.* 2011) is rooted in overlapping concepts that are receiving increased levels of interest around the world. However, for any new definition of health to be broadly accepted, it needs more than wide scale interest; it needs to demonstrate that it has real world relevance and can withstand the critique that is so heavily levied at the WHO definition of health. Hence, it is appropriate to assess the new definition of health as 'the ability to adapt and to self-manage when facing physical, mental, and social challenges' against the four necessary conditions identified earlier in this chapter.

Condition 1: The adopted meaning of health can describe a state that is aspirational, as is common with aims, but it should be an achievable aim for which realistic objectives can be set.

The concept of health as the ability to adapt is certainly achievable. It is an attribute that we can see in the healthiest people in the world; people who have a high degree of healthiness in spite of the stresses and strains of life. It does not require a *complete* absence of symptoms or *complete* wellbeing on all levels. The precise nature of the objectives that need to be set in order to facilitate adaption are yet to be established, but it is clear that they will entail a shift in emphasis away from a pathogenic approach to health care.

Condition 2: The adopted meaning of health should be 'person-centred', rather than 'medicine-centred', such that its recognition is not directly dependent upon advances in medicine.

The proposed new definition of health is clearly person-centred and is not directly linked to advances in medicine. With an emphasis on positive health, rather than disease processes, this definition is more connected to the facilitation of adaption and coping rather than treating complaints. Whilst advances can be made in how best to assess, measure and promote adaption, a concept of health as the ability to adapt requires a holistic consideration of individuals within their environments.

Condition 3: The proposed meaning of health should describe a state that is distinct from wellbeing as they are not one and the same.

As previously acknowledged, health and wellbeing are intricately linked, but they are not the same thing. It is entirely possible to conceive of a situation where health is compromised, and bodily functions are unable to adapt to physiological or environmental stress, but wellbeing is maintained. Similarly, it is reasonable to assume that a high degree of wellbeing has a positive influence on the ability to adapt to stressful situations, possibly even as a necessity, but it may not be sufficient. Hence, the proposed definition clearly fulfils this condition.

Condition 4: The proposed meaning of health must allow for variations in disease patterns and demographics of the population.

Fulfilment of this condition is obvious given the person-centred and individualised nature of the proposed definition. As longevity and numbers of people living with multi-morbidity and disability increase, so the need for change in the way we conceive of health becomes more pressing. Many people who are living with chronic complaints and disabilities consider themselves healthy (Scully 2004, Damron-Rodriguez *et al.* 2005, Drum *et al.* 2008), and have adapted well enough to live happy and fulfilling lives.

Hence, the concept of health as the ability to adapt clearly addresses the four conditions identified as necessary requirements for an acceptable replacement definition. According to this definition, health is an achievable state but it is person-centred and hence may not have the same meaning when applied to different individuals. It is also entirely possible for people with disabilities and chronic complaints to be considered as healthy if they have adapted and are coping well with their circumstances. However, for this definition to be operational we need to develop ways in which to assess and measure people's ability or potential to adapt so that there are means of assessing whether interventions are helpful.

Huber believes that the formulation 'health as the ability to adapt' could help to make health effects better measurable and assessable (Huber *et al.* 2012) and, similarly, Antonovsky believed that salutogenesis should be the theoretical basis for developing, testing and implementing plans and practices that enhance health and wellbeing. To

this end, Antonovsky developed practical scales for measuring a person's sense of coherence. These scales have been tested in practice, primarily in Scandinavian countries, and two systematic reviews of studies using the sense of coherence scales have examined the relationship between sense of coherence scales and health (Eriksson and Lindström 2006, Eriksson and Lindström 2007). Both reviews conclude that sense of coherence is a good predictor of, and contributor to, health and wellbeing. A further systematic review, limited to the use of sense of coherence scales in people aged over 65 (Tan *et al.* 2014), concluded that sense of coherence moderates stress and is associated with health, particularly mental health.

These reviews suggest that sense of coherence, at least, may be measurable, but the scales involved have not received broad based testing on a global scale. Furthermore, we need a great deal more research in order to understand how to promote a sense of coherence, resilience or robustness. Acceptance of this new definition will mean a new way of thinking in healthcare, new ways of treating people, new ways of assessing health and new ways of establishing priorities.

3.5 Implications of the New Definition of Health

The concepts of salutogenesis, resilience and robustness have been broadly accepted by those in the T&CM world because of the underlying similarities in philosophy and conception of health as a dynamic process (Fulder 1998, Kemper 2001, Bishop *et al.* 2007, Rakel *et al.* 2008, de Lacey *et al.* 2009). For example, according to homeopathic philosophy, the 'vital force' is continually acting to maintain health, responding to stresses and perturbations in life in order to preserve health. Symptoms of ill-health are only produced when the vital force is not strong enough to cope with the stresses laid upon it (Vithoulkas 1980). Hence, the proposed new definition of health is much more in keeping with the T&CM approach than the WHO definition, and adoption of this new definition has the potential to ensure that both T&CM and conventional approaches are working towards a common goal.

Currently there are some radical differences in approach between T&CM and conventional medicine that are potentially due to the differences in conceptualisation of health. For example, a practitioner of T&CM is likely to perceive a small rise in body

temperature during infection as the body's attempt to combat the infection, something to be welcomed. This contrasts with common opinion in the UK that antipyretics should be routinely used to combat fever, viewing the fever itself as a problem to be resolved (Sullivan and Farrar 2011). Indeed, studies indicate that the vast majority of caregivers would give antipyretic medication to a feverish child, even if the child appeared otherwise comfortable (Kanabar 2014). Interestingly, the most recent NICE guidelines for treatment of childhood fever state that antipyretics should only be prescribed for childhood fever if accompanied by signs of stress (Kanabar 2014), and yet they are routinely prescribed, in a prophylactic manner, with immunizations (Pedulla 2012). This leads to the situation where fever management in children, both at home and within clinical settings, does not reflect the most recent medical guidelines or research evidence (Jeong and Kim 2010). A shift in emphasis towards one that appreciates physiological signs of adaption as a sign of health, such as low-grade fever during infection, may help to change behaviour, but it will first require broad acceptance on the part of the public as well as health care professionals.

In the UK, one of the key principles for the NICE clinical guidelines is that they are: 'designed to promote good health and prevent ill health' (NICE 2013). Hence, a clear idea about what health means can only serve to improve clarity and transparency of the guidelines. The acceptance of health as the ability to adapt may require a revision of the way in which decisions are made about healthcare priorities, policy and funding, to account for the potential effects on coping and adaption of specific treatments and interventions.

From studies of the healthiest people in the world we have some indications of factors that may help to improve adaption and coping. Apart from genetic factors, there are important lifestyle aspects such as maintaining activity, feeling socially connected and having a good diet. A positive outlook also appears to be of vital importance, and given that about fourteen per cent of the global burden of disease has been attributed to psychiatric disorders (Prince *et al.* 2007), this is an issue that will need broad attention. Interestingly, 'access to the highest quality healthcare services' is not in the list of factors attributed to enhancing the health of these people, implying that the goal of achieving higher levels of health in the UK may not entail additional burden on an increasingly overstretched healthcare service.

3.6 Summary

The definition of health as *'the ability to adapt and to self-manage' when facing physical, mental, and social challenges'* (Huber *et al.* 2011, p.2) will be adopted in this thesis. This definition is in keeping with current trends in thinking across a broad domain of disciplines, including conventional medicine and T&CM. Adoption of this definition has certain implications for health care practice that will be taken into account when analysing ethical issues in T&CM. It is anticipated that this conceptualisation of health will act as a premise upon which argument can be based when considering ethical dilemmas that emerge from the ethical matrix and enabling conclusions to be drawn, where appropriate.

CHAPTER FOUR: THE ETHICAL CHALLENGES AND THE ETHICAL MATRIX

Having specified what is meant by 'health', and the extent of the T&CMs to be included in this inquiry, the next step is the identification and analysis of the associated ethical challenges. For identification of the ethical challenges, a broad-based literature search was undertaken and the resulting issues mapped onto the ethical matrix for analysis. In this chapter I will outline the steps taken to identify ethical challenges related to T&CM and the role of the bioethical methodology, the ethical matrix, in the analysis. Following completion of the ethical matrix, the full extent of ethical issues relating to a range of stakeholders will be evident and the selected concerns to be carried forward for further analysis in subsequent chapters will be identified.

I begin with an overview of the ethical matrix, including the conceptual basis, its benefits and limitations, and the structure it takes in this thesis.

4.1 The Ethical Matrix

The primary aim of this thesis is to analyse emerging ethical challenges to T&CM and, by so doing, draw conclusions that will be relevant to future decision making in this field. This involves the translation of what may currently appear as disparate, abstract theories and ideas into a form that has practical value and application. The analysis could be undertaken in many different ways but the methodology of choice for this project is that of the ethical matrix, as developed by Ben Mepham at the University of Nottingham in the mid 1990s (Mepham 1995, Mepham 1996). The ethical matrix is a bioethical methodology that was originally designed to help evaluate public policy decisions involving agriculture and food production. However, since its inception, this method has been applied widely in a number of fields and has proven to be a versatile tool for analysing ethical issues (Kaiser and Forsberg 2001, Gamborg 2002, Cotton 2009, Mepham 2009, Katrin and Ulrich 2010). The principal aim of the matrix is to assist non-philosophers in, 'rational decision making by articulating the ethical dimensions of any issue in a manner which is transparent and broadly comprehensible' (Mepham 2005b, p.316).

One advantage of using this method is that the matrix sets out a framework to help identify a broad range of ethical issues that might not otherwise be obvious. It does so by creating a formal structure for identification of the parties (stakeholders) involved in a given situation and their potentially conflicting interests. A grid for this mapping was presented in Chapter 1, formulated with the stakeholders listed on the vertical axis and the three ethical principles of wellbeing, autonomy and justice on the horizontal axis (Figure 1). The general aim is to identify and document the ethical impacts of the matter under consideration in each cell of the matrix.

4.2 The Conceptual Basis of the Ethical Matrix

The field of ethics is commonly divided into three broad areas: meta-ethics, normative ethics and applied ethics[16]. Meta-ethics concerns the status, foundations, and scope of moral values; it questions the nature, and indeed the very existence of morality.

Normative ethics is concerned with the standards and principles used to determine whether something is right or good and is itself commonly divided into various sub-branches such as: consequentialist theories, deontological theories, and virtue-based theories. Applied ethics, as previously described in Chapter One, is concerned with the moral permissibility of specific actions and practices.

Whilst these three areas of ethics appear to be distinct they are also interrelated. The use of an applied ethics approach often draws upon certain normative ethical theories such as consequentialism or deontology.

Applied ethical analysis is often conducted through the use of an 'ethical framework' because frameworks can provide a consistent and structured approach to the analysis. An extremely large number of ethical frameworks have been developed. Some are aligned with particular normative ethical theories, such as: the consequentialist framework, the duty framework, and the virtue framework (Bonde & Firenze 2013), whilst others have been developed for use within certain professions or circumstances, such as: tourism (Hultsman 1995), marketing of corporate social responsibility (Van den Ven 2008), and psychiatry (Bloch and Green 2006). The ethical framework selected for this enquiry, the ethical matrix, is an example of a cross-normative theory

[16] There are other ways of categorising the different dimensions of ethics but this is the most commonly described (Benn 1998).

framework that can be adapted for use in different circumstances and designed to reflect the concerns of different stakeholders

Ethical frameworks are most commonly employed for the analysis of specific issues but they can also provide a means of structuring and organising the information pertaining to a complex issue, such as ethical challenges to T&CM. The use of a framework in this manner serves to provide a holistic overview of the challenges as well as highlighting specific concerns.

According to Mepham, applied ethical analysis needs to fulfil three main criteria. It should be founded in ethical theory to ensure validity, broad and detailed enough to capture the main ethical concerns, and conducted in plain, user friendly language as far as possible (Mepham 2005a).

The second of these criteria has been demonstrated by widespread use of the ethical matrix, and its use has clearly shown the ability to expose a wide range of ethical considerations (Forsberg 2007, Cotton 2009). The third criterion, of user-friendly language, is largely dependent upon the people employing the matrix. The first criterion is addressed through selection of the particular ethical principles that are incorporated in the matrix. The three ethical principles used in the ethical matrix are drawn from a prominent principled approach in biomedical ethics, first introduced by Tom Beauchamp and James Childress in 1979, who stated that the following four *prima facie* principles lie at the core of moral reasoning in health care: respect for autonomy, beneficence, non-maleficence and justice. In the opinion of Beauchamp and Childress these four principles are part of a 'common morality'; an approach that 'takes its basic premises directly from the morality shared by the members of society – that is, unphilosophical common sense and tradition' (Beauchamp and Childress 1994, p.100). These ethical principles can be elucidated in slightly different ways, but the explanations provided by Beauchamp and Childress (2001) are here summarised as follows:

4.2.1 Principle 1. Respect for autonomy

This principle refers to the capacity of an individual to be self-determining and to make decisions for themselves without undue pressure, coercion or other forms of persuasion. It is contrasted with the notion of paternalism which occurs when actions of a health care practitioner override or do not seek to respect the wishes of the patient, believing that they are better able to decide what is in the patient's best interests. Whether or not the doctor knows best, s/he has no right to make important decisions on behalf of competent patients, as a general principle. Even where the doctor acts in the patient's interests, it is important that the patient's own choices and wishes be respected.

4.2.2 Principle 2. Beneficence

This principle describes an obligation to act for the benefit of others. Acting in this way might involve preventing or removing harm, or it might involve the active promotion of some good (health, for example). The aim of beneficent action is to produce the 'best' one can out of a range of possibilities. It can involve cost/benefit analysis such that the 'best' here will be the possible action in which the benefits produced maximally outweigh the costs or the risks. Put simply, it is to act always in the best interests[17] of the patient.

4.2.3 Principle 3. Non-maleficence

Duties of non-maleficence require us to refrain from causing deliberate harm or intentional avoidance of actions that might be expected to cause harm. Generally, obligations of non-maleficence are more stringent than obligations of beneficence, but again a cost/benefit analysis may need to be undertaken to identify the best possible action. In some situations harm may be unavoidable and then we must be sure that the benefits outweigh the harm.

4.2.4 Principle 4. Justice

The principle of justice requires that we do what we can to ensure that costs and benefits are fairly distributed. It is possible to obey the principle of non-maleficence and the

[17] Nowadays, the emphasis on 'best' is sometimes criticized as, for example, the second best is certainly beneficent, if it is a good solution

principle of beneficence, yet still not behave in an ethical manner, for these two principles say nothing about how benefits should be apportioned. In a given case it may well be that we can only procure a major benefit for some people by slightly harming the interests of others. The principle of beneficence may say we should go ahead, but then the benefits and costs would be unfairly distributed.
(Beauchamp and Childress 2001)

In the construction of the ethical matrix, Mepham combines the two principles of beneficence and non-maleficence into one principle, that of 'wellbeing'.

4.2.5 Derivation of the principles used in the ethical matrix

The principlist approach is derived from normative ethical theories, but it is not aligned to any one single theory. Whilst Beauchamp and Childress (2001) claim that these principles are commonly understood and accepted within society, and thus have a broad degree of support, they also assert that they are drawn from two normative ethical traditions: the duty-based moral philosophy (deontological approach) of Immanuel Kant and the outcome-based (consequentialist) ethics of Jeremy Bentham and John Stuart Mill. Mepham, in turn, extends the conceptual basis of his approach stating that the principles of wellbeing, autonomy and justice in the ethical matrix represent *three* dominant perspectives in normative ethics, namely: utilitarianism, deontology, and Rawlsian social contract theory (Mepham 2005a).

According to the approach taken by Mepham, (and in keeping with Beauchamp and Childress) respect for wellbeing corresponds to issues prominent in utilitarian theory, a form of consequentialism, which implies that the consequences of an action are of moral importance. Simply phrased, utilitarianism asserts that the moral action is the one that maximizes utility where utility, in this sense, has been defined in various ways. The founder of modern utilitarianism, Jeremy Bentham, here names happiness as the measure for utility, stating that, 'it is the greatest happiness of the greatest number that is the measure of right and wrong' (Bentham 1776).

The moral value of a particular action is to be judged upon its consequences, and the course of action that results in the most happiness/good/benefit is to be considered the

most moral. In practice, this requires the ability to predict the consequences of a particular action and to weigh up the potential for harms and benefits, but this is not an easy task. Criticisms of utilitarianism, as a workable moral theory, are extensive, not least because judgments do not take motivations for actions into account, and certain issues of justice and fairness can be overruled.

In contrast, theorists most commonly align respect for autonomy with deontological theory, which asserts that the morality of an action is based upon the adherence to rules, or acting in accordance with duty. Simply phrased, deontological or duty-based ethics holds that some acts are intrinsically right or wrong, and people have a duty to act accordingly, regardless of the consequences. One might maintain that religious rules or commandments can constitute a form of deontological ethics, but the foremost proponent of deontology, Immanuel Kant, formulated a secular deontological moral theory in the eighteenth century. Unlike religious deontological theories, the rules (or maxims) in Kant's deontological theory derive from reason. Kant's moral theory is rooted in his view that humans, as beings with the capacity for rationality, are capable of moral action. For Kant, the test of morality, and its main principle, is the 'categorical imperative', which he intended to be the basis of all other rules. Two formulations of the categorical imperative that Kant held are merely different ways of expressing the same notion, and are described as follows:

Formulation 1: '*Act as if the maxim of your action were to become through your will a universal law of nature*' (Kant 1785, 421)
Formulation 2: '*Act in such a way that you always treat humanity, whether in your own person or in the person of any other, never simply as a means, but always at the same time as an end*' (Kant 1785, 429).[18]

Kant derives the Formula of Autonomy from a combination of these two formulations of the categorical imperative because, for rational beings, 'it is precisely the fitness of his maxims to make universal law that marks him out as an end in himself' (Kant 1948, 438). In other words, if a rational being is an end in him/herself, he/she must be the originator of the laws that he/she is duty bound to obey. This, according to Kant, is

[18] Other formulations of the categorical imperative exist, but are not relevant here.

what awards him/her supreme value. All persons have dignity or special worth and they should be treated as 'ends in themselves' and never merely as a means to an end. Also known as Kant's *principle of respect*, it requires us to consider the autonomy of others in our actions. If an action would involve treating someone merely as a means and not, at the same time, as an end, then it is wrong. However, Kant's interpretation of respect for persons is quite different from the liberal individualist concept of autonomy as defined by Beauchamp and Childress [19].

For Beauchamp and Childress, respect for the individual is key as 'the autonomous individual acts freely in accordance with a self-chosen plan, analogous to the way an independent government manages its territories and establishes its policies' (Beauchamp and Childress 2009, p.99). They avoid the potential challenges of explaining autonomy as a property of individuals through description of a decision making process, detailing three qualities that the decision-maker must possess in order to make autonomous decisions. According to Beauchamp and Childress, autonomous agents are those who can act intentionally, with understanding, and without controlling influences. Within this interpretation of autonomy, the mark of an autonomous person is the ability to decide on his or her own, without undue manipulation or coercion from others because, 'personal autonomy encompasses, at a minimum, self-rule that is free from both controlling interference by others and from certain limitations, such as an inadequate understanding that prevents meaningful choice' (Beauchamp and Childress 2009, p.100).

[19] In his metaphysical account of the person Kant distinguishes between the *phenomenal* person (the empirical self perceived through the senses as individual experiences, beliefs and dreams) from the *noumenal* person (the rational self perceived through the intellect). The rationality of humans grants them access to the *noumenal* world (unlike animals who inhabit only the *phenomenal* world) and sets them aside from other species as capable of being autonomous self-legislators. Feelings, inclinations, and other individual aspects of our lives, which are all part of the phenomenal world, are not of interest or importance to Kant and must be excluded from moral decision making. As Neumann so clearly explains in his description of the practical application of Kant's categorical imperative: 'Treating your rational nature as an end in itself, I ask whether my actions towards you are consistent with the universal principles of pure practical reason. I ask whether my act could be a universal principle, and willed as such. Once I have done so, I am through with my ethical deliberation: if the act is universalizable, I perform it; otherwise not. No messy consideration of what you want as a flesh-and-blood human is required; indeed it is positively excluded' (Neumann, 2000).

In practice, a deontological approach to moral reasoning also has its shortcomings. Like utilitarianism, it has been the subject of extensive critique on many levels. For example, it offers no way of deciding how to prioritise duties, and moral dilemmas can arise when duties come into conflict with no clear means of resolution.

Mepham (2000a) aligns the third principle, respect for justice, with John Rawls' notion of 'justice as fairness', a version of social contract theory that Rawls believes provides a superior understanding of justice to that of utilitarianism, and forms the basis of modern democracy[20]. For Rawls the issue of justice is key:

> A theory, however elegant and economical must be rejected if it is untrue: likewise, laws and institutions, no matter how efficient or well arranged, must be reformed or abolished if they are unjust. Each person possesses an inviolability founded on justice that even the welfare of society as a whole cannot override (Rawls 1971, p.3).

In formulating a theory of justice, Rawls employs of a version of social contract argument to ask how society ought to be structured if it is to be considered a just society. Social contract theory can be broadly described as the view that a person's moral or political obligations are dependent upon a contract or agreement (implicit or explicit) that is established between members of the society in which they live. Rawls brings a new twist to the social contract argument[21] by asking us to consider the fundamental principles of justice from an 'original position', a fair and impartial point of view that is to be adopted in this process. In taking up this point of view, Rawls asks that we imagine ourselves in the position of free and equal persons who jointly agree upon, and commit to, principles of social and political justice. The main distinguishing feature of the original position is 'the veil of ignorance', such that those taking the stance of the original position would act as if they had no knowledge of their place in society, their worth, their assets, their intelligence, their desires and so on (Rawls 1972). Adoption

[20] To complicate matters, Rawls is generally regarded as a Kantian. Hence, one could say that only two theories form the basis of the ethical matrix. However, Rawls' treatment of 'justice' is outstanding and he is widely regarded as the most important Western justice theorist since Aristotle.

[21] Other well-known proponents of social contract theory such as Thomas Hobbes, John Locke and Jean-Jacques Rousseau did not argue from an original position.

of the veil, Rawls maintains, would lead to the acceptance of two fundamental principles:

First principle: 'Each person is to have an equal right to the most extensive basic liberty compatible with a similar liberty for others.'
Second principle: 'Social and economic inequalities are to be arranged so that they are both (a) reasonably expected to be to everyone's advantage, and (b) attached to positions and offices open to all' (Rawls 1972, p.60).

In other words, each person should be granted as much liberty as is consistent with others having the same and, secondly, the outcomes of inequalities, where they exist, are beneficial for all and do not obstruct equality of opportunity. In addition, Rawls formulated another principle in the context of inequality, namely that they are to be of the greatest benefit to the least-advantaged members of society (*the difference principle*); inequalities should only exist where their existence makes the least advantaged more advantaged than they would otherwise have been.

In everyday life, each of these normative ethical theories and positions are likely to contribute in some way to the decision making process about the best course of action in specific circumstances. It seems unlikely that anyone could consistently act purely from one perspective, either consciously or unconsciously. Indeed, the ethical matrix has been praised for its cross-ethical-theory approach, thus avoiding critique that might be levied at a single normative ethical theory whereby certain concerns may be asserted over others. The cross-theory approach facilitates analysis from a variety of perspectives (Schroeder and Palmer 2003, Cotton 2009). However, the design of the ethical matrix also has its limitations and these need to be explicitly acknowledged, along with the potential benefits, when it is being used for ethical analysis.

4.3 Benefits and Limitations of the Ethical Matrix

To date the ethical matrix has been tried and tested in a wide range of fields including: food ethics (Mepham 2000b); fisheries (Kaiser and Forsberg 2001); forest management (Gamborg 2002); animal farming (Mepham 2003); cattle transport (Whiting 2004); teaching ethics (Mepham 2005); agricultural biotechnologies (Beekman and Brom

2007); GM fish (Millar and Tomkins 2007); radioactive waste management (Cotton 2009); organic food (Katrin and Ulrich 2010); facilitating ethical reflection amongst scientists (Jensen *et al.* 2011); nanotechnology (Coles and Frewer 2013); and animal experimentation (Webster 2014). Subsequently, the philosophical and methodological basis of the ethical matrix has been extensively discussed and analysed (Kaiser *et al.* 2007).

The first people to apply the ethical matrix after Mepham were Kaiser and Forsberg (2001) in their assessment of the future challenges for Norwegian fisheries, using a participatory process. In describing their experience of the ethical matrix they list five particularly noteworthy features:

1. The method is liberal with regard to the ethical basis, and additional or different ethical considerations could be included where appropriate.
2. It provides a structured approach, explicitly identifying the most relevant considerations, allowing for focused and timely discussion.
3. It allows the users to focus upon real issues, rather than abstract philosophical terminology, through a concrete specification of topics for consideration.
4. It can help to extend democracy in decision making through broad accessibility that extends to members of the general public.
5. It reveals any conflicts of interests between stakeholders and expresses the ethical issues as the search for the optimal strategy in the light of these conflicts.

In his description of the aims and limitations of the ethical matrix, Mepham acknowledges that circumstances will frequently arise where there are conflicts between different duties and where compromises will have to be made. In these situations, ethical evaluation or judgement will require a weighing or ranking of the different impacts (Mepham 2005b). The ethical matrix has been praised for its simple design, which aids simplification and structuring of ethical discussions, but criticised for the lack of suitable deliberative mechanisms for enabling the ethical decision making needed to assist policy development (Cotton 2009). As stressed by Schroeder and Palmer in 2003, ‘The ethical matrix is helpful for fact finding in ethical debates but much less helpful in weighing the different ethical problems that it uncovers’ (p.259).

Even when faced with a completed matrix, containing all the relevant information and representation of different stakeholders, a moral judgement must be exercised. Ethical decision making remains reliant upon the competency of the users' moral judgement, provoking the question of *who should be the judge*.

When the ethical matrix was first applied as a participatory tool it was used with a multi-stakeholder group (Kaiser and Forsberg 2001, Millar and Mepham 2001).
Kaiser and Forsberg's application of the ethical matrix involved a participatory process such that relevant stakeholders were involved in the discussion and the decision making process, enabling a 'bottom up' approach to ethical analysis. Indeed, they assert that it is central to successful use of the ethical matrix that the assessment is undertaken by the stakeholders themselves as, 'the matrix can never by itself reveal the right decision' (Kaiser and Forsberg 2001, p.197). The issue of the 'top down' or 'bottom up' approach in application of the matrix has been explored by several authors, including Mepham himself, who believes the matrix can be usefully employed in both ways, depending upon the desired outcome (Mepham *et al.* 2006). Whilst advocating a bottom-up approach, Kaiser and Forsberg (2001) describe some problems arising from their experience of the participatory exercise as those involved in discussions were not automatically engaged in seeking resolution or drawing conclusions.

> What became clear to us is that ethical matrices seem to function in a participatory process only if the project leaders pre-structure the process to such an extent that some substantial issues are already pre-empted by the method. One is then vulnerable to the charge of not really being democratic, and in effect directly or indirectly manipulating the participants. The ideal of a truly bottom-up method for ethical evaluation has apparently to be compromised in order to ensure the result and usefulness of the process (Kaiser and Forsberg 2001, p.197).

The bottom-up approach is fraught with this and other difficulties, such as who can be considered as representative of each of the stakeholder groups, who is capable of exploring political and economic implications, and how we can best represent the non-human stakeholder groups such as animals and the environment. One response to these issues is that successful use of the ethical matrix is dependent upon the users being able to 'put themselves in the shoes of others' rather than being reliant upon representatives

of the stakeholder groups (Jensen *et al.* 2011). In their report of an exercise to encourage a group of scientists to reflect on ethical issues with the aide of the ethical matrix, Jensen *et al*. concluded that direct stakeholder engagement is not necessary for ethical reflection. Rather, they argue, there are other important reasons for stakeholder input but these relate more to issues of governance and social accountability.

Six years on from the first account of their experience, Kaiser *et al.* (2007) published results of an in-depth study into the potential role of the ethical matrix as a decision support framework in the fields of biotechnology and food regulation. Their conclusions were mixed; they stressed the benefits of the matrix as a practical and pragmatic tool since it allows extraction of relevant information for decision making, whilst emphasising that tools are dependent upon the competency of their users.

However, Kaiser *et al.* are appreciative of the different ways in which the ethical matrix can be used and describe how, even at its simplest level, it can be considered as a checklist of concerns, structured around ethical theory. At the very least it ensures that more than the usual narrow range of concerns are raised and considered. They also echo the opinion of Jensen *et al*. when describing how, at best, the ethical matrix helps those involved in decision making to put themselves in the shoes of others (Kaiser *et al.* 2007).

A further considerable challenge for the ethical matrix arises directly from the adoption of a principlist approach, leaving the very essence of the ethical matrix open to the same extensive critique that principlism has received (Schroeder and Palmer 2003). Principlism has been subjected to challenges since first introduced by Beauchamp and Childress in 1979. The term ‘principlism’ itself was first presented, not by Beauchamp and Childress, but by two of the most vocal critics, Danner Clouser and Bernard Gert. Clouser and Gert assert that the principled approach lacks theoretical unity. The principles lack any systematic relationship because they are drawn from conflicting moral theories, and hence often lead to conflicting conclusions (Clouser and Gert 1990, Clouser and Gert 1994).

This apparent ‘pick and mix’ selection of certain theories and principles, without an underlying theoretical basis, is a cause of great concern for Clouser (1995):

> It is a kind of relativism espoused (perhaps unwittingly) by many books (usually anthologies) of bioethics. They parade before the reader a variety of ''theories'' of ethics— Kantianism, deontology, utilitarianism, other forms of consequentialism, and the like— and say, in effect, choose whichever of the competing theories, maxims, principles, or rules suits you for any particular case. Just take your choice! They each have flaws— which are always pointed out—but on balance, the authors seem to be saying, they are probably all equally good! (p 224)

Others have objected to the choice or limitations of the particular principles, such as Herissone-Kelly (2003) who questions the argument that Beauchamp and Childress present in support of their global applicability, and Walker (2009), who believes that more principles need to be added if they are truly to represent a common sense morality. Additionally, it has been suggested, that application of a principlist approach serves to exclude the moral agent, who performs the act, from the moral judgements; in order to see what is good and not merely what are the rights involved, we must consider the virtue and intentions of the person acting (MacIntyre 1984). For example, Häyry (2003), in his scrutiny of the objection that the 'Georgetown principles'[22] are not truly representative of European values (being more aligned with Americam liberalism), points to the lack of representation of virtue ethics within their chosen principles: 'By ignoring moral (and religious) virtues, and thereby all deliberations about the ideal nature of a good, virtuous human being, Beauchamp and Childress left their views wide open to accusations of short-sighted hedonism; excessive individualism and sneaking nihilism' (p.201).

On the other hand, there are also staunch supporters of principlism such as Raanan Gillon who has claimed that the four principles can explain and justify all the substantive moral claims in medical ethics. According to Gillon, these principles provide a *transcultural, transnational, transreligious*, and *transphilosophical* framework for ethical analysis (Gillon 1994, Gillon 1998, Gillon 2003).

[22] Some writers refer to the four principles as the *Georgetown principles* in reference to the location of Beauchamp and Childress who were working at Georgetown University when the *Principles of Biomedical Ethics* was first published.

Whilst the controversy surrounding the merits of principlism is acknowledged, it is beyond the scope of this thesis to analyse in depth the pros and cons of principlism *per se*. Rather it is maintained that the adoption of principlism through the ethical matrix as the methodology of choice is entirely appropriate for two main reasons. Firstly, principlism is by far the most dominant approach to ethical analysis in healthcare today. Indeed, the book *Principles of Biomedical Ethics* by Beauchamp and Childress remains the most influential book in modern bioethics. Secondly, the principlist approach has allowed practical and applied ethical analysis during a period when rapid advances in biotechnology have generated a host of new potential ethical dilemmas. In spite of the shortcomings of using a principlist approach in bioethical analysis, the perceived benefits have been significant as evidenced by its pervasive use.

The ethical matrix is intended as a tool for mapping out the issues underpinning decision making, rather than determining ethical decisions (Cotton 2009). There may be challenges associated with the application of the matrix, for example in resolution of conflicts between different principles, and conflicts between different stakeholders, but ethical analysis is a complex and difficult task. Different individuals, even when faced with the same evidence, may draw different conclusions.

In this thesis a top-down approach to the use of the ethical matrix was inescapable. It involved the placing of myself in the 'shoes of others' as far as possible in order to appreciate the ethical issues from the perspectives of different stakeholders. It also involved the weighting of certain principles where conflicts arose, for example between wellbeing and autonomy or wellbeing and justice. This was the central task in hand. In appreciation of the limitations of a top-down approach, especially when undertaken by a single individual, I have striven to ensure that all steps taken in the analysis are explicitly justified and transparent. This was of vital importance in constructing the ethical matrix, where decisions had to be made about which principles and stakeholders to include, and what the key issues were for examination. The following section outlines my decision making process in this task.

4.4 The Ethical Matrix in this Thesis

There were four stages involved in producing the complete ethical matrix in this thesis:

1. Identifying and categorising published ethical challenges to T&CM through a broad literature search;
2. Formulating the structure of the ethical matrix, including the selection of stakeholders;
3. Mapping the identified challenges onto the ethical matrix to reveal existing areas of debate and tension; and
4. Completing the final version of the matrix in which each cell specifies the main criteria that would be met if the associated principle was respected for the associated stakeholder. This was deduced, where possible, from the mapping at the previous stage.

Each of these stages is described in more detail below.

4.4.1 Identification of the ethical challenges to T&CM

In order to capture the full extent of existing debate about ethical challenges for T&CM, a detailed literature search of published academic papers was undertaken. The search for literature on this topic has been ongoing throughout the period of study to ensure that recently emerging challenges are not omitted.

Focussing firstly on a UK-user perspective, the ethical challenges for acupuncture, homeopathy, herbal medicine, osteopathy and chiropractic, the five most commonly used types of T&CM, were identified through the systematic literature search.

In addition, and in keeping with the intention to broaden the focus of the analysis beyond a UK-user perspective, the search was then extended to look for published ethical challenges related to the use of T&CM to include concerns for practitioners, animals, the environment, sustainability and low and middle income countries. It was anticipated that this search would reveal previously identified ethical issues and ensure that the contents of the matrix are representative of a broad base of opinions and not simply my own.

Three online academic citation indexes were searched (Web of Knowledge, Discovery and Google Scholar) with combinations of the following search terms:

Complementary	Medicine Therapy Healthcare	Ethics
Alternative		Ethical
Traditional		Safety
Integrated		Adverse
Integrative		Side effects
Chiropractic		Danger
Osteopathy		Regulation
Homeopathy		Welfare
Herbal		Practitioners
Herbs		Animals
Acupuncture		Sustainability
		Environment

Numerous papers mention potential ethical issues about healthcare practice but only those that described challenges to T&CM were reviewed in detail. Unfounded assertions (such as: 'homeopaths kill people') were excluded from the findings; genuine ethical challenges were tabulated. Many repetitions of particular issues were discovered as time progressed and hence detailed records were only kept of the papers in which the issues were most clearly articulated, or that added some new perspective. Results of the literature search were organised and tabulated on an excel spread sheet with citation details, description of the challenges, type of T&CM (where specified) and related stakeholder.

4.4.2 Formulating the structure of the ethical matrix: choice of principles and stakeholders

Mepham's original matrix (1995), designed for the consideration of ethical issues associated with animal farming, maps the interests of 4 stakeholder groups (farmers, consumers, animals, environment) against the ethical principles of wellbeing, autonomy and justice (Figure 4).

Figure 4: Mepham's Original Ethical Matrix

Respect for	Wellbeing	Autonomy	Justice
Farmers	Adequate income and working conditions	Freedom to adopt or not adopt	Fair treatment in trade and law
Consumers	Availability of safe food	Respect for consumer choice	Universal affordability of food
Animals	Animal welfare	Behavioural freedom	Respect for telos
Environment	Protection of the biota	Maintenance of biodiversity	Sustainability of biotic populations

In the complete version of Mepham's ethical matrix, each cell specifies the main criteria that would be met if the associated principle (e.g. wellbeing) were respected for a particular stakeholder (e.g. farmers).

The ethical matrix for the analysis of ethical challenges to T&CM will adopt the same three principles originally suggested by Mepham (wellbeing, autonomy and justice) as there is broad agreement that they are helpful for identification of the primary ethical concerns and dilemmas. The stakeholders, however, need to be specific to the subject in hand.

The stakeholders

The particular stakeholders to be included in a matrix depend upon the issue under consideration, but the rule of thumb is that views represented in society should be reflected in the ethical matrix. Of primary importance is that those included should possess 'ethical standing'. In other words, they are subjects of ethical consideration in their own right, and not just means to others' ends (Mepham *et al.* 2006). Another factor

of importance is that the range of stakeholders is broad enough to be inclusive of all legitimate concerns. In practice this can be challenging. As the number of stakeholders are increased, the matrix can become unwieldy and overcomplicated and the advice of Mepham is that, given the practical constraints, the number of stakeholder groups can normally be kept to four (Mepham *et al.* 2006). Hence, decisions need to be made about which groups possess ethical standing, and which to include to ensure that most, if not all, concerns are captured in the matrix.

The stakeholders to be included in the matrix for this analysis are:

Humans, as they are the primary users of T&CM. The word 'humans' has been selected in preference to 'patients' in recognition of the fact that many people self-prescribe T&CM products and hence not all users have the role of patients.

Animals, as they may also be recipients of T&CM in a domesticated or farming environment. In addition, many animals and animal products are used in the production of traditional medicines and they may also be used for research purposes during development and testing.

The environment, as the production, transport and storage of medicines has direct environmental impact.

Low and middle income countries, as some forms of T&CM are relied upon heavily in less wealthy countries. Inclusion of low and middle income countries is in keeping with the intention to extend this ethical analysis beyond a UK perspective; the relationship that people have with T&CM in such countries can be quite different from high income countries because choice is more limited, regulation less well established, and healthcare may be rooted in local culture and traditions.

These four stakeholder groups were selected primarily because they were the most often mentioned in the published literature and hence they most clearly reflect the ethical challenges revealed by the literature. There are undoubtedly other potential stakeholders and some others were considered. For example, (Schroeder and Palmer 2003) recommend that 'future generations' should be included as a default stakeholder

group on all occasions because they cannot intervene in the decision making process and yet are deeply affected by the outcome. However, in this analysis the considerations of future generations are no different to those of the 'humans' group in regard to wellbeing and autonomy and would differ only in terms of justice. For future generations this would involve the right to have at least the same access to, and choice of, T&CMs as the current generation of humans and this in turn is largely dependent upon the sustainability of T&CM products and practices. As sustainability is also a major factor for consideration for the environment, I have taken the decision not to include future generations as a stakeholder group in their own right. The interests of future generations will, nonetheless, be represented indirectly through consideration of humans and the environment.

Two further groups were also considered eligible for inclusion as potential stakeholders but will not be represented in this matrix. These are *Healthcare personnel* who rely upon T&CM practice for their income and the *pharmaceutical industry*, as it has a vested economic interest in the kinds of medical interventions that are most widely utilised by a population. Whilst both of these groups can be considered as possessing ethical standing on matters relating to the use of T&CM, it is not possible to consider all interests for all groups within the scope of this enquiry. To some extent, T&CM healthcare personnel are considered in relation to other stakeholder groups. Factors associated with economics and reliance upon T&CM products for livelihood also feature in considerations of T&CM in low and middle income countries, the use of animals in production, and the safety of products for humans. The interests of the pharmaceutical industry would have been interesting to include but, given Mepham's recommendation to use no more than four stakeholders, the four previously mentioned stakeholders were considered to be more important.

Hence, the matrix in this enquiry takes the form shown below in figure 5.

Figure 5: The structure of the ethical matrix in this thesis

Respect for	Wellbeing	Autonomy	Justice
Humans			
Animals			
Environment			
Low and middle income countries			

4.4.3 Mapping of the identified challenges onto the ethical matrix

From the tabulated data produced in stage 1, each identified ethical objection was extracted and positioned on the ethical matrix with respect to the relevant stakeholder and ethical principle. This resulted in a complex matrix with the vast majority of identified ethical challenges relating to humans, particularly the wellbeing of humans, as shown in Table 5.

Where the identified ethical challenges have bearing upon more than one of the ethical principles, a decision has been made as to the most relevant position on the matrix so that the same challenges are not replicated in numerous cells. For example, the challenge 'Information on T&CM is unreliable and dangerously misleading' could be considered a threat to wellbeing, but it has also a direct bearing upon autonomy because people need reliable information for informed decision making. Hence, this challenge has been situated within the autonomy cell.

Naturally, all of the issues detailed in the cells for humans are also relevant to those in the low and middle income countries, but rather than simply replicating all concerns in both places, only those that are specific to such countries are detailed in those cells related to this stakeholder group.

From this mapping exercise, it is clear that there are a number of different ethical issues to be considered for each stakeholder group. Whilst a very large number of ethical challenges relating to the wellbeing of humans have been described, most cells of the

matrix detail a smaller number of challenges. It cannot be assumed from this that there are fewer ethical issues relating to the other groups or concerns, but rather this is simply a reflection of what was discovered in the literature search. The main benefit of the mapping exercise is that it clearly reveals the primary ethical challenges and areas of conflict to be considered.

A note about the ascription of ethical challenges to animals and the environment in the matrix

In his analysis of ethical concerns for animals in biotechnology, Mepham acknowledges that the ethical principles normally used in medical ethics need to be appropriately translated to represent the interests of non-human stakeholder groups. In consideration of animals, Mepham's (1999) reasoning runs along the following lines:

- The Kantian notion that each of us is 'an end in him/herself' can be likened to that of the Aristotelian notion of Telos[23] 'because it shares many qualities with the concept of 'intrinsic worth' or 'intrinsic value' (p.174).
- Telos is awarded paramount importance in the case of humans but it should also be extended to animals. In justification of this, Mepham quotes Holland (1995) who claims that, 'if this principle applies in the case of human relations with one another, it is hard to see why an analogous principle should not apply in the case of human-animal relations as well' (p.296)
- Respect for the telos of non-human animals extends the Kantian principle by ascribing them rights in the same (or at least similar) manner as human beings.

In the final stage of his reasoning, Mepham concludes that,

> The association drawn between the Kantian principle of respect for others as ends in themselves and the original Aristotelian notion of telos provides the basis of a coherent specification of the Rawlsian concept of justice as fairness employed in the Matrix (p.174)[24].

[23] Telos (from the Greek τέλος) for 'end', 'purpose', or 'goal'. In Aristotle's Theory of Causes the final cause (telos) is that for the sake of which a thing exists or is done, including both purposeful and instrumental actions and activities. The meaning is, in fact, quite different from Kant's notion of 'intrinsic worth' which Kant believes is a property of rational beings as ends in themselves.

[24] This final step in Mepham's reasoning involves a massive leap that is not justified with an explanation. Rawls himself argues against the inclusion of animals in justice debates by asserting that human conduct toward animals is not regulated by the principles of justice, since only 'moral persons' are 'entitled to

Accordingly, for animals treated in biotechnology, Mepham interprets respect for wellbeing, autonomy, and justice as respect for welfare (freedom from pain and stress), freedom of behavioral expression and respect for telos, respectively (Mepham 2000).

Similarly, Mepham interprets the ethical principles of respect for wellbeing, autonomy and justice for applicability to the environment, but in this case without appeal to a philosophical rationale. In the case of the environment, respect for wellbeing requires protection of the biota; respect for autonomy demands maintenance of biodiversity and respect for justice calls for sustainability of biotic populations (Mepham 1995).
Whilst considerations of animal dignity and behavioural freedom, as well as environmental biodiversity and sustainability, are considered to be extremely important, in this thesis these considerations will not be ascribed to the particular principles of autonomy and justice. Rather, it is assumed that, for the case of animals and the environment, a strictly consequentialist approach is sufficient to reveal the major ethical challenges and enable robust analysis. After all, it is possible to consider constraints upon autonomy and violations of the principle of justice under the principle of wellbeing through analysis of the potential for harms and benefits.

This approach avoids the many complications that may arise from debate concerning the application of autonomy and justice to animals and the environment, and is in keeping with an approach suggested by Häyry who found it to be more beneficial than Mepham's approach in the case of bovine growth hormone (Häyry 2000). Hence, all the ethical challenges related to the use of T&CM from animals and the environment are placed in the wellbeing cells.

equal justice'. Even if the notion of telos is extended to animals this does not, in turn, award them the status of 'moral persons'.

Table 5: Mapping Ethical Challenges onto the Ethical Matrix

Respect for:	Wellbeing	Autonomy	Justice
Humans	**Safety issues** T&CM has serious adverse effects (K. Smith 2008) **Adverse drug reactions** From herbal medicine - Toxicity (Ernst 2001, Markman 2002, Ernst 2003a, Curtis and Gaylord 2005, Ernst 2008a, Adams *et al.* 2010, Gilmour *et al.* 2011a) - Drug/herb interactions (Ernst 2001, Markman 2002, Curtis and Gaylord 2005, Ernst 2008b, Smith *et al.* 2011, White *et al.* 2014) - Allergies (Curtis and Gaylord 2005) - Contamination (Ernst 2003a, Rao and Kumar Meena 2011, Posadzki *et al.* 2013c) - Interfere with results from lab tests (Curtis and Gaylord 2005) Herbs and supplements regulated as food rather than medicine so lack the mandatory efficacy and safety assurances required of pharmaceuticals (Curtis and Gaylord 2005)	**Patient choice, education and informed consent** Many T&CM practitioners fail to gain formal consent from their patients (Ernst 2009c, Caspi *et al.* 2011) There are issues around consent when parents substitute T&CMs for conventional treatments for their children (Cohen *et al.* 2005, Shaw 2011) Consent cannot be determined because the risks are unknown (Ernst *et al.* 2004, Cohen *et al.* 2005) Effects are often not known or researched and so may violate utility in unknown ways (Ernst *et al.* 2004) Conventional medical staff's lack of knowledge and lack of support creates a significant barrier to accessing information about T&CM (Nissen *et al.* 2013) There is deliberate deception of the patients who are misled into thinking that treatments have an effect (Ernst 2008b, K. Smith 2008, Ernst 2009c, Ernst 2009b, Ernst 2009d, Shaw 2010, Shaw 2011, Smith 2011) Information on T&CM is dangerously misleading (Ernst 2008b, Ernst 2009a, Smith 2011, Smith 2012)	**Affordability and access** There is inequality and unequal distribution of T&CM (Ernst *et al.* 2004) In Europe T&CM is primarily used by educated citizens of working age and with an above average income (Nissen *et al.* 2013) Allocation of funding, research funds are scarce and should go to those areas where reasonably good evidence already exists (Ernst *et al.* 2004, K. Smith 2008) Funding should not be allocated to research of implausible treatments, waste of medical resources (K. Smith 2008, Shaw 2011, Smith 2011, Smith 2012) Use of T&CM may result in double costs: T&CM usually constitutes additional expense over and above other healthcare costs (Ernst 2008b, Shaw 2011, Smith 2011) Use of T&CM can be unnecessary and costly (Curtis and Gaylord 2005) Cost-effectiveness has not been demonstrated (Ernst 2008a) The NHS should not fund treatments that have no evidence base (Shaw, 2010)

	From homeopathy - Contaminated medications - Allergic reactions - Poisonings (Posadzki *et al.* 2012a) **Adverse events** Acupuncture has caused death and serious complications through infection and trauma (Ernst 2001, Markman 2002) Chiropractic and osteopathy – frequent mild adverse events and vertebral arterial dissection (Ernst 2001, Markman 2002, Vohra *et al.* 2007, Ernst 2009c, Carnes *et al.* 2010, Rajendran *et al.* 2012) Rejection of, or delay in access, to effective conventional care can lead to serious consequences (Coppes *et al.* 1998, Ernst 2001, Brienza *et al.* 2002, Markman 2002, Cohen *et al.* 2005, Curtis and Gaylord 2005, Cohen 2006, Vohra *et al.* 2007, Shaw 2010, Gilmour *et al.* 2011a, Shaw 2011, Smith 2011, Freckelton 2012) T&CM practitioners are denying their patients more effective conventional treatment (Shaw 2011) Homeopaths and chiropractors frequently advise against immunisation (Ernst 2001, Ernst 2009b, Ernst 2009d)	Information on T&CMs is unreliable and incomplete (Ernst 2008b, Ernst 2009c, Ernst 2009a) Claims about disease prevention are not based on science and are therefore misleading (Ernst 2009b) Much of the research in T&CM is methodologically weak (Ernst *et al.* 2004) There is a general lack of systematic reporting systems for adverse events (White *et al.* 2014) There is a widespread belief that T&CMs are safe because they are natural (Okoronkwo *et al.* 2014, White *et al.* 2014)	

	Claims about disease prevention are not based on science (Ernst 2009b) T&CM providers interfere with doctors prescriptions (Ernst 2001) **Clinical competence and regulation** There are issues associated with clinical competence of practitioners because of variable standards in education and training (Curtis and Gaylord 2005, Chatfield and Duxbury 2010, Nissen *et al.* 2013) T&CM providers are often not medically trained (Ernst *et al.* 2004) T&CM practitioners are not well regulated (Ernst *et al.* 2004, K. Smith 2008) Practitioners are often working alone, without governance measures in place (Chatfield and Duxbury 2010) **T&CM is anti-science** An attitude of anti-science is promoted leading to a general weakening of support for science-based medicine (Ernst 2001, K. Smith 2008, Smith 2011) Government registration of regulatory bodies is a tacit indication of approval (K. Smith 2008, Smith 2011, Smith 2012) Philosophies of T&CM are not based on scientific principles (Ernst 2008a)		

	Any NHS support for homeopathy could weaken patient confidence (Shaw, 2010) **Homeopathy is a threat to other T&CMs** Funding homeopathy distracts from other more effective forms of T&CM (Shaw 2010) Homeopathy promotes a weakening of support for genuine T&CMs (Smith 2011, Smith 2012)		
Animals	**Harm in the production of products** Many T&CM products are derived from animals (Adeola 1992, Still 2003, Alves *et al.* 2007, Whiting *et al.* 2013, Verma *et al.* 2014, Vijayakumar *et al.* 2015) In China more than 1500 animals are used in medicine and in India 15-20% of Ayurvedic remedies are based on animal products (Kim and Song 2013) In Brazil, at least 354 animal species are used in medicinal products of which 21% are on one or more lists of endangered species (Alves *et al.* 2013) Many animals suffer during farming processes, extraction of medicinal products and/or slaughter (Still 2003) Use of T&CM encourages unethical animal killing for products of unproven value (Rastogi and Kaphle 2011)		

	Excessive or uncontrolled hunting to secure animal products for use in T&CM has led to the extermination of some species (Still 2003) The illegal trade of animal products for medicinal use has contributed to a decrease in animal populations (Rangarajan 2005) **Harm in the testing of products** Animals are routinely used in exploratory studies, often exposed to stress, pain, artificially induced diseases and ultimately killed (Hu *et al.* 2003, Rodrigues de Almeida *et al.* 2008, Khuda-Bukhsh 2009, van Wijk *et al.* 2009, Rastogi and Kaphle 2011, Britton 2014, Bae *et al.* 2015)		
Environment	**Effects upon individual species** A growing demand for standardised herbal products is putting pressure on selected high demand species (Bodeker *et al.* 2014) Many plants and animals used for medicinal purposes are becoming extinct as a result of demand for T&CM products (Borins 1991, Still 2003, Timmermans 2003, Rastogi and Kaphle 2011) Reliance on indigenous medicines and the resulting large scale commercial		

	exploitation for urban markets are seen as a threat to biodiversity (Dahlberg and Trygger 2009) Harvesting without planting, deforestation and the increased marketing of medicinal plants have resulted in the decline and sometimes near-extinction of several valued medicinal plant species around the world (van Andel and Havinga 2008) **Other effects on ecosystems** A demand-oriented market and poor quality checks in T&CM has motivated producers to go for mass production without taking into account the finer details of plant cultivation (Rastogi and Kaphle 2011) Most medicinal plants are collected from the wild in an uncontrolled manner and cultivated plants are often considered inferior (Ncube *et al.* 2012) **Limited resources** Growing and harvesting, processing and packaging and transport of herbs is energy intensive. (McElroy 2011) In turn, climate change may lead to the extinction of species, reduction in availability, and reduction in quality (McElroy 2011)		

	In the future T&CMs may become even more expensive than conventional medicine if its resources are not readily available (Rastogi and Kaphle 2011)		
Low and middle income countries	**Same as humans plus:** **Adverse drug reactions** There is poor quality control of T&CM products and services (Okoronkwo *et al.* 2014) **Adverse events** Many users of T&CM practice self-medication without guide or supervision from licensed or certified T&CM practitioners (Van den Boom *et al.* 2004, Sato 2012, Okoronkwo *et al.* 2014) Some traditional healers are incorporating conventional medical products into their practise without proper training (Dixon 2008) Parents stop conventional medicines when children receive T&CM (Njuguna *et al.* 2015) Parents may use T&CM for children against the advice of a doctor (Njuguna *et al.* 2015) Many people do not inform their doctor about use of T&CM (Okoronkwo *et al.* 2014, Njuguna *et al.* 2015)	**Same as humans plus:** **Respect for local culture** T&CM may be preferred because it is embedded within indigenous cultural practice even without a scientific basis (Borins 1991, Macfarlane and Alpers 2009, Sato 2012, Stuttaford *et al.* 2014, Njuguna *et al.* 2015) **Community pressure** Pressure may be exerted by the community to seek T&CM (Njuguna *et al.* 2015) **Marketing pressure** Many T&CM practitioners adopt aggressive marketing strategies in print and electronic media to market their products which are freely available on the open market (Okoronkwo *et al.* 2014)	**Same as humans plus:** **Economic factors** T&CM is often the only available or affordable choice (Borins 1991, Tabi *et al.* 2006, Sato 2012, Stuttaford *et al.* 2014) Conservation policies, aimed at restricting access to certain products, may affect locals more than those who reside in other (wealthier) environments (Dahlberg and Trygger 2009) Non-sustainable harvesting not only threatens the survival of medicinal plant species, but also the people that depend on (van Andel and Havinga, 2008) **Biopiracy** Some traditional medicines have been patented without consent or compensation to their holders (Correa 2002, Timmermans 2003, Abbott 2014)

4.4.4 Completion of the ethical matrix for T&CM

Mapping of the ethical challenges onto the ethical matrix has clearly revealed that ethical considerations about the production and usage of T&CM are not limited to the interests of human users. The interests of human users need to be considered within this broader framework, and balanced against impact upon the environment or animals, for example. In the final version of the ethical matrix, each cell specifies the main criteria that would be met if the associated principle was respected for the associated stakeholder. The intention is to deduce this, where possible, from the mapping at the previous stage and this requires an appreciation of the main concerns for each of the stakeholder groups in relation to each of the ethical principles. What follows is an overview of the main concerns.

Humans

Wellbeing

Each of the five different forms of T&CM included in the search (acupuncture, chiropractic, osteopathy, herbal medicine and homeopathy) has generated concerns about safety and the potential for adverse effects. Concerns about safety can be broadly divided into adverse drug reactions and adverse events whereby adverse drug reactions are harmful side effects from use of a T&CM product. Adverse events are normally associated with practitioner errors, negligence or incompetence in application.

Reports of adverse drug reactions have included the following:

- Herbal medicine has been associated with the risks of drug/herb interactions, allergic reactions, toxicity, drug contamination, interference with laboratory tests and overdose.
- Homeopathy has been associated with a risk of allergy and drug contamination.

Reports of adverse events have included:

- Acupuncture has been associated with a risk of trauma and infection.
- Chiropractic and osteopathy have both been associated with a risk of trauma and injuries.

Additionally, and by far the most commonly cited adverse event associated with use of T&CM, is that rejection of, or delay in access to, conventional care can lead to serious consequences; the underlying assumption being that conventional care is more effective than T&CM. In addition, it is assumed that practitioners of T&CM may fail to recognise serious conditions and/or interfere with a conventional treatment approach through contradictory advice about conventional medications and immunisation.

Further concerns about T&CM for human users arise from the wide variation in standards of education, training and regulation leading to questions about the clinical competence of practitioners. In addition, harm may occur in unpredicted ways because many forms of T&CM are poorly researched for efficacy or safety.

Perhaps the most surprising challenge to the use of T&CM is the accusation that acceptance or promotion will cause harm because it is 'anti-science' and will lessen support for science-based medicine. This challenge is most commonly levied at homeopathy and this in turn leads to the challenge that support for homeopathy distracts from other more effective forms of T&CM.

Autonomy

Concerns for autonomy are particularly related to informed choice and informed consent with challenges that information is either simply not available or that it is deliberately misleading. Many people assume that T&CM products and practices are safe because they are natural and many practitioners fail to gain informed consent from their patients. There were particular concerns expressed for children whose parents may elect for T&CM treatments in preference to conventional treatments.

Justice

In the UK, most forms of T&CM are not funded by the NHS and are paid for out of pocket, leading to inequality of access. The use of T&CM can be costly and information about cost-effectiveness is scarce. Because the research evidence base for T&CM treatments is relatively small, any funding of such treatments is challenged on the grounds that funding should go into treatments where reasonably good evidence already exists. Funding for research into T&CM treatments is also challenged on the same

grounds. Indeed, it is claimed that use of T&CM increases healthcare costs as it normally constitutes additional expense over and above other costs.

Animals

Wellbeing

Many forms of T&CM are used in veterinary practice and hence carry the same potential for benefits and risks as for human users, such as the risk of infection or trauma from acupuncture or the risk of toxicity from herbal medications. However, animals are clearly harmed in the manufacture of some T&CM products as a significant number are derived from whole or parts of animals. As well as the issue of whether it is ethically acceptable to make medicinal products for humans from animals, there are also concerns about how animals are treated during farming and slaughter. Restriction of the behavioural freedom of animals may cause suffering in the farming process, and pain may be inflicted during the extraction of T&CM products. The decrease in certain animal populations and extinction of some species from over-hunting for the use in T&CM products is especially concerning.

When animals are used for research purposes in the production and testing of T&CM products, they can be exposed to stress, pain or artificially induced diseases.

Environment

Wellbeing

The production of herbal medicines, in particular, has a direct impact upon the environment as some plant species are in great demand. The growing and harvesting, processing and packaging, and transport of herbs are all energy intensive and the carbon footprint associated with production and transport contributes to climate change that in turn affects species' viability. As a result, many forms of T&CM now used may not be available in the future and others may become scarce and more costly.

The high demand for some products can motivate producers to go for mass production without regard for consequences for the environment. Many plants are harvested in an uncontrolled manner and many plants and animals that are used for medicinal purposes are becoming extinct. This results in a narrowing of biodiversity, and may alter the natural environment in an irreversible manner. On the other hand, many plants are awarded value because of their role in T&CM and direct local use can contribute to the

preservation of some species and habitats. This needs to be weighed against the harm caused by disappearance of species (animals and plants) as a result of demand for T&CM products.

Low and middle income countries

Wellbeing

Concerns about wellbeing for people who use T&CM in low and middle income countries are undoubtedly the same as those already described for humans in general. However, there are added risks associated with use in these countries where there is less quality control of T&CM products and services, and a greater reliance upon them. More people in low and middle income countries self-prescribe, presumably for financial reasons, without supervision and there seems to be a greater reluctance to inform conventional medical staff about the use of T&CM. Some traditional healers have been found to be incorporating conventional medical products into their practices without proper training and parents often stop conventional medications when their children are receiving T&CM against the advice of their doctors.

Autonomy

In low and middle income countries, where indigenous forms of medicine are commonly rooted in local culture, T&CM may be the treatment of choice. However, matters of individual autonomy can be complicated by community pressure and lack of resources to seek the treatment of choice. Informed decision making can be affected by a lack of reliable information and aggressive marketing strategies that would not be permitted in nations with higher degrees of regulation of T&CM.

Justice

The greatest challenge for those in low and middle income countries is that T&CM is often the only available or affordable choice. Even when it is not the treatment of choice, it may be used because conventional medical treatments are simply out of reach. For many households, the collection of medicinal plants for their own use is of great economic importance and conservation policies, aimed at restricting access to certain products, may have a direct impact upon them. Another significant challenge for users of T&CM in low and middle income countries is that their local products and

knowledge are open to exploitation and some traditional medicines have been patented without consent or compensation to their holders.

Having summarised the main concerns for each stakeholder group, related to each principle, it is now possible to formulate the ethical matrix for T&CM where each cell specifies the main criteria that would be met if the associated principle was respected for the associated stakeholder (Table 6).

Table 6: The Ethical Matrix for T&CM

Respect for:	Wellbeing	Autonomy	Justice
Humans	Ability to benefit from potentially helpful treatments in a safe environment. Provision of information about potential risks to health. Confidence that practitioners are properly trained, regulated and working at all times within their bounds of competence Quality assurance of the standards of products to be ingested.	Freedom to select preferred healthcare options based upon accurate information about effectiveness and potential harms/benefits.	Equal access to healthcare options. Resources in healthcare distributed through consistent, transparent and equitable processes.
Animals	Ability to benefit from potentially helpful treatments in a safe environment. Avoidance of unnecessary harm to animals in the production and testing of T&CM treatments.		
Environment	Conservation of limited resources and protection of species.		
Low and middle income countries	Ability to benefit from potentially helpful treatments in a safe environment. Provision of information about potential risks to health. Confidence that practitioners are properly trained, regulated and working at all times within their bounds of competence. Quality assurance of the standards of products to be ingested.	Freedom to select preferred healthcare options based upon accurate information about effectiveness and potential harms/benefits. Respect for local and cultural knowledge and traditions.	Equal access to healthcare options. Resources in healthcare distributed through consistent, transparent and equitable processes. Benefits from traditional knowledge, practise and products distributed through consistent, transparent and equitable processes.

4.5 The Next Steps

It is clear from this development of the ethical matrix for T&CM that most published concerns are related to human users, but the inclusion of other stakeholders has revealed competing interests. For example, there are conflicts between humans and the animals that are used in the production of T&CM products and between humans and the environment that is being harmed through the carbon footprint and reduction in biodiversity as a direct consequence of T&CM use. The aim of this analytical process is to use the ethical matrix as a conceptual tool to arrive at recommendations for public policy decisions as intended by Mepham (2009) and, as such, the next step is to undertake an in-depth analysis of the most ethically challenging features of T&CM as revealed by the matrix. Through this process, recommendations about the use of T&CM can be formulated on the basis of ethical decisions that prioritise the conception of health previously identified.

Given that the number of identified ethical challenges related to humans is vast, the analysis in this thesis will be restricted to issues related to safety, considering the potential for both direct adverse effects (adverse drug reactions) and indirect adverse events. This will be followed by an analysis of issues related to animals, the environment and low and middle income countries. The next four chapters relate to the in depth analysis for these subjects.

CHAPTER FIVE: ETHICAL ISSUES FOR HUMANS USING TRADITIONAL AND COMPLEMENTARY MEDICINES

The ethical issues related to the human use of T&CM in the previous chapter are both numerous and diverse. Previous chapters have identified issues pertaining to wellbeing, autonomy and justice which all warrant attention, but there are too many for all to be examined in detail within the scope of a single thesis. Hence, my analysis in this chapter will be restricted to the most commonly cited concerns in the literature, namely issues related to safety.

Conventional medical protocol distinguishes between two different types of adverse effects from medical interventions: adverse drug reactions (ADRs) and adverse events (AEs).

The WHO define an ADR as, 'a response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function' (WHO 1972, p.9). ADRs are characterised by the suspicion of a causal relationship between the drug and the occurrence, and are judged as being at least *possibly* related to treatment by the reviewing health professional (UMC 2013). The term ADR is often used interchangeably with 'side-effect' which is commonly used to describe any unwanted or unintended effect of a drug occurring at normal dosage. For example, penicillin can cause allergic reactions such as rashes, hives, itchy eyes, and swelling of the lips, tongue or face. In rare cases the allergy can be severe enough to cause anaphylactic shock, a dangerous condition that can be life-threatening (WebMD 2014).

In contrast, an AE involves iatrogenic harm, and can be defined as, 'any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment' (UMC 2013, p.1). AEs may take the form of temporary or permanent injuries caused by poor medical management or medical errors arising from actions or omissions, and are not due to underlying disease; nor are they expected outcomes of treatment (Tsang *et al.*

2013). AEs might result from provision of the wrong drug, an infection that is transmitted during investigation or surgery, or failure to act upon symptoms that may indicate the presence of a serious complaint.

For this analysis, I will distinguish between ADRs and AEs in T&CM, and so will consider ADRs as harmful effects caused by a T&CM product and AEs as harm that arises as a consequence of malpractice, negligence or omission. Thus, AEs may occur as a result of misdiagnosis, lack of referral or delayed access to effective care, for example. In my consideration of each of these two classes of adverse effects, I will draw, in the main, upon challenges that have been levied at one particular form of T&CM in each case. I will consider the potential for ADRs with respect to herbal medicine and for AEs I will examine such cases in relation to homeopathy. This approach has been chosen as these two forms of T&CM are by far those most commonly associated in the published literature with ADRs and AEs, respectively.

Examination of safety issues arising from the selected T&CMs will be presented in the following manner:

Safety in conventional medicine

- How ADRs and AE are identified and monitored in conventional medicine

Safety and T&CM

ADRs and herbal medicine

- What the problems are
- Summary of the challenges
- Addressing the challenges
- Ethical analysis
- Recommendations

AEs and homeopathy

- What the problems are
- Summary of the challenges
- Addressing the challenges
- Ethical analysis
- Recommendations

5.1 Safety in the Conventional Healthcare System

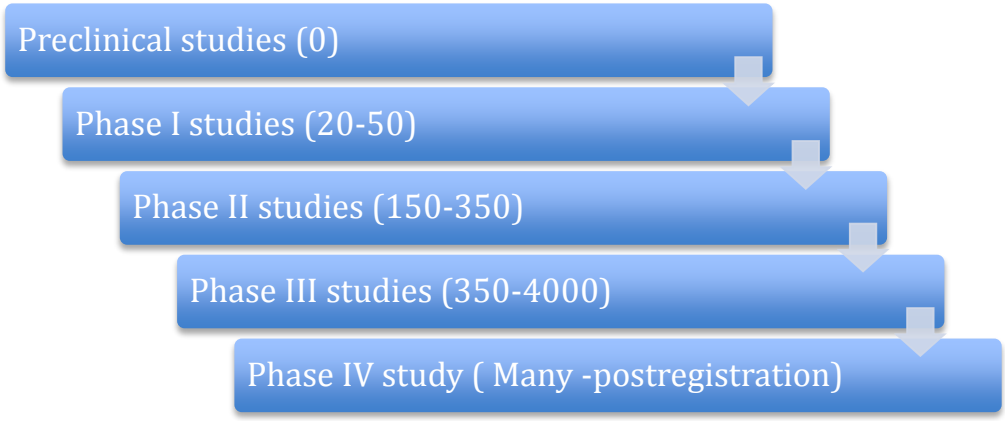
A consideration of safety in the conventional healthcare system is of value as a starting point as this provides an established context for the examination of, and comparison with, safety issues arising in the use of T&CMs.

The processes involved in the monitoring of ADRs and AEs in conventional healthcare in the UK overlap in many respects as both rely heavily upon reporting systems. Additionally, it is not always easy to determine whether an adverse effect is the result of an ADR or an AE, as the identification of an ADR involves an assessment of causality between the harmful effect in the patient and the medicinal product, and it is not always possible to determine this with confidence. Nonetheless, there are some distinct procedures in place for each and these will be outlined next.

5.1.1 Monitoring adverse drug reactions

Fairly rigorous mechanisms are in place for the ongoing detection and prevention of ADRs, collectively termed *pharmacovigilance*, and the implementation of pharmacovigilance around the world is essential for controlling the incidence of ADRs (WHO 2004). Pharmacovigilance is defined by the WHO as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem (WHO 2004). Today, the procedures involved in the pharmacovigilance of medications are generally stringent, but this was not always the case. Tightening of controls relating to drug development and drug use became a high priority in healthcare after the negative effects of thalidomide were revealed in the early 1960s in a public and high profile manner, leading to calls for greater regulation of pharmaceuticals (Heaton 1994). There are various stages involved in the clinical development of pharmaceuticals and information related to safety concerns can be collected and assessed at each stage. Following the preclinical stage, increasingly large numbers of humans are exposed to the proposed drug as detailed in figure 6 below.

Figure 6: Stage in the Development of Pharmaceutical Products



Figures relate to the number of human participants involved at each stage.

Preclinical studies

No humans are involved in this initial stage, and the approach usually consists of *in vivo* animal laboratory studies and/or *in vitro* experiments.

Phase I studies

These are the first studies of a drug on humans. They involve an initial evaluation of the effects on a small number of research participants (between twenty and fifty individuals), usually healthy volunteers, in order to assess toxicity, tolerance and aspects of pharmacokinetics[25].

Phase II studies

It is at this stage that efficacy of the drug is first tested and these studies are usually the first conducted on patients. This phase often involves the investigation of dose-response relationships and bioavailability[26]. These studies are exploratory in nature and are often used to decide which dose(s) or treatments merit further investigation. Sample sizes are often still quite low (150-350 participants).

Phase III studies

In this phase, a formal comparison of the new drug at the dose(s) chosen from Phase II is undertaken with the standard current treatment or placebo. It involves considerably

[25] The study of the absorption, distribution and elimination of a pharmaceutical in the body.
[26] The fraction of a dose absorbed by the subject and the rate at which it is absorbed.

more patients than Phase II (250-4000). The primary objective is to determine whether a drug, for which likely effective and tolerable doses have been established in phases I and II, is suitable for registration, based on its efficacy and safety.

Phase IV study

This phase involves monitoring the long-term effects of a drug, usually after registration, through its use and administration in the real world. In particular, investigation of efficacy in different populations can be undertaken and information on rare adverse effects can be gathered that have not been revealed at previous stages, in large part due to the much greater population size.

(WHO 2004)

One of the functions of clinical studies is to determine common adverse effects and these will normally be evident from studies carried out under phases I-III. However, these studies are conducted on a limited number of people who have been carefully selected for the clinical studies, and run only over a finite amount of time. This presents several obstacles to the detection of certain ADRs, in particular:

- Those that appear a long time after drug exposure, such as cancer, or those that develop after chronic use, such as the long-term ADRs of oral contraceptives that can take years to develop (Sultana *et al.* 2013).
- Less common or rare ADRs that are not revealed in the drug trials because drugs are rarely tested on more than 5,000 people before release (WHO 2004).
- Those that appear in people with different characteristics from the participants used in the trials, such as people of different ages, those with multi-morbidity, or those simultaneously consuming other medications (Scott and Thompson 2014).

Consequently, many ADRs are only detected after a product has been used by a large number of people over a long period of time, and it is essential that new treatments be monitored for their effectiveness and safety under real-world conditions following their release. This is particularly important for gathering information about use by groups underrepresented or omitted from previous stages such as the elderly, children, pregnant women and those taking other medicines. Experience has shown that the

introduction of a new medicinal product often carries unknown risks, as numerous cases have demonstrated (Council for International Organizations of Medical Sciences 1999).

Hence, in addition to the assessments made during drug development, post-market surveillance is also needed. This may take the form of individual case reports, cohort studies, population statistics and meta-analyses (Scott and Thompson 2014). Information about ADRs can be obtained through spontaneous reports from healthcare practitioners and patients or through the application of epidemiological studies of ADRs. Epidemiological studies involve the systematic collection and analysis of data from selected sources over extended periods of time (Hakkarainen *et al.* 2012).

In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) monitors the safety of healthcare products through the mediation of the 'Yellow Card Scheme'. This scheme relies upon spontaneous reporting by healthcare professionals or patients, and reports can be submitted for all medicines, including vaccines, blood factors and immunoglobulins, for herbal medicines and homeopathic remedies, and for all medical devices available on the UK market. Information is collected on suspected problems or incidents involving:

- ADRs (side effects),
- Medical device adverse incidents,
- Defective medicines (those that are not of an acceptable quality), and
- Counterfeit or fake medicines or medical devices

(MHRA 2015).

Where deemed necessary, the MHRA then reviews the product and can take action with a view to minimising risk and maximising benefit to patients.

In addition to national reporting schemes, verification of a new, potentially harmful reaction often requires the collection and review of reports from other countries, and these reports must be properly assessed and validated (CIOMS 1999). The WHO have been key players in establishing the international monitoring of ADRs through their programme for international drug monitoring.

In 1971, the WHO convened a meeting in Geneva to discuss the role of national centres in international drug monitoring. Whilst the procedures for development and the testing of drug efficacy were becoming increasingly rigorous, relatively little progress had been made in detecting and documenting the adverse effects of drugs in patients (WHO 1972). The objective of this meeting was to encourage the development of systems for detecting adverse drug reactions at national and international levels, as well as to facilitate cooperation with the WHO Drug Monitoring Project. Consequently, an international system for monitoring ADRs using information derived from Member States was established in that same year. To ensure consistency of the monitoring process, a common reporting form was developed, guidelines for entering information were formulated, common terminologies and classifications were agreed, and compatible systems were established for transmitting, storing and retrieving and disseminating data (WHO 1972). Also in 1971, the monitoring process began with ten countries that had already established national systems for spontaneous adverse reaction reporting, and who agreed to contribute data to the project.

Today, the WHO retains overall responsibility for the governance of the monitoring process but, since 1978, the administration and operation of the programme has rested with the WHO Collaborating Centre for International Drug Monitoring, Uppsala Monitoring Centre, (UMC), in Sweden. It took almost twenty-five years for the first million individual case safety reports to be entered into the database, but this has subsequently expanded rapidly over recent years since, and it now holds more than ten million records from over 130 countries (UMC 2015).

It must be emphasised that these case safety reports detail *suspected* ADRs and not actual ADRs. Before an adverse effect is classified as an ADR, the likelihood of causality between the medication and the adverse effect must be assessed. The success of pharmacovigilance is thus, to a large degree, reliant upon the assessment of causality, but this inevitably involves a subjective element of judgment on the part of the assessor. There is currently no methodology by which an assessment of causality can be undertaken in a completely objective and quantitative manner. Many tools have been developed to help objectify the assessment of causality, ranging from short questionnaires to comprehensive algorithms (WHO-UMC 2005). None of the available methods or tools provides definitive assessments, but they do help to standardise the

procedures involved. The WHO-UMC system for assessment of causality takes into account the clinical aspects of case histories and the quality of the documentation of the observation provided. Reports are classified using a range of assessment criteria to permit each case to be recorded under one of six categories that assess the likelihood of an ADR: certain; probable/likely; possible; unlikely; conditional/unclassified and unassessable/unclassifiable.

In the UK, the pharmacovigilance process begins with the patient reporting an adverse experience either to a health professional or directly to the Medicines and Healthcare products Regulatory Agency. If reported to a health professional, the onus is then upon the professional to report the adverse event. The Medicines and Healthcare products Regulatory Agency investigates reports of adverse effects and assesses them before passing them on to the WHO monitoring centre. The WHO-UMC then undertakes an assessment of causality, comparing the new reports with existing data and if, on the balance of probabilities, a new ADR is considered to hold, then the relevant information is likely to be disseminated to those who prescribe drugs, enabling them to use the information for the benefit of future patients (Stephens 2010).

Crucially, the number of reports received limits the effectiveness of post-marketing surveillance. It is estimated that, in the UK, less than ten per cent of all serious ADRs are spontaneously reported (Scott and Thompson 2014) and the UK is one of the largest contributors to international surveillance. Most ADRs are therefore unreported and hence the nature of ADRs from conventional medicine and the figures for incidence can only be approximated (Menniti-Ippolito *et al.* 2008, Luteijn *et al.* 2012).

5.1.2 Monitoring adverse events

The detection and monitoring of AEs is even more complex than the detection of ADRs and systematic gathering of data related to AEs is a more recent phenomenon. Contemporary developments were prompted at the end of the 1990s when the Institute of Medicine (IOM) in the United States issued a wake up call with its report entitled, ‘To Err is Human’ (Kohn *et al.* 2000). This report asserted that, in the United States, there were 44,000 to 98,000 preventable deaths annually arising from medical errors in hospitals. The resulting media interest brought the issues of medical error and patient

safety to the forefront of national concern. Kohn *et al.* (2000, p.4) defined safety as ‘freedom from accidental injury’ and error as ‘the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim’, citing their agreement with Reason (1990) who had distinguished between two types of errors: ‘errors of execution’ and ‘errors of planning’. Subsequently, this distinction was taken further by Leape (1994), who differentiated between errors of commission (unintentionally doing the wrong thing) and errors of omission (unintentionally not doing the right thing). Within a very short period of time, the Institute of Medicine report was credited with truly ‘changing the conversation’ and stimulating a broad array of stakeholders to engage in patient safety, as well as motivating hospitals to adopt new safe practices (Leape and Berwick 2005).

In the UK, the Department of Health responded in kind by laying out key local requirements for managing, reporting, analysing adverse events involving National Health Service patients in its document, 'Doing Less Harm' (Emslie 2001), so that lessons might be drawn to reduce such events. Subsequently, in 2004, the National Patient Safety Agency (NPSA) introduced their ‘Seven Steps to Patient Safety’. These steps were intended to help National Health Service organisations plan their activity and measure performance in patient safety so that they might meet their clinical governance, risk management and controls assurance targets. The recommended steps included building a safety culture, supporting staff, integration of risk management activity, promoting reporting, involving and communicating with patients, sharing safety lessons and implementing solutions to prevent harm (NPSA 2004).

However, implementation of these steps was not an easy process, and it required the restructuring of systems and introducing a fundamental cultural change. As recently as 2009, a report from the Healthcare Commission detailed horrendous conditions and inadequacies at a Stafford hospital where figures suggested that, because of the substandard care, five hundred more patients died between 2005 and 2008 than would be expected for the particular type of hospital. The range of problems in this large public hospital included failings in the most fundamental aspects of nursing care; ‘Patients were left in excrement in soiled bed clothes for lengthy periods; Wards and toilet facilities were left in a filthy condition; Privacy and dignity, even in death, were denied;

Staff treated patients and those close to them with what appeared to be callous indifference' (Francis 2013, p.13).

A public inquiry into Mid Staffordshire National Health Service Foundation Trust, led by Robert Francis QC, reported failures at every level up to and including the Department of Health. Altogether, these failings allowed terrible and unnecessary suffering by patients to go undetected for years. Francis uncovered a range of contributory factors, including low staff morale, a culture of bullying, acceptance of poor standards, and a disconnected management that was driven by corporate self-interest ahead of patient needs and safety (Francis 2013). The shocking revelations of the Francis report have led many within the National Health Service to question how such a situation could have arisen and how best to prevent it from happening again (Dyer 2013, Hayter 2013, Kay 2013, Kline 2013).

As part of the ongoing monitoring of AEs, the National Health Service Commissioning Board Special Health Authority now invites reporting of suspected AEs from healthcare staff and members of the public. However, as with ADRs, it is suspected that only a small fraction are captured (Rafter *et al.* 2014).

5.1.3 The extent of the problem

The limitations of reporting schemes helps to explain why there are wide variations in the estimated figures for ADRs and AEs. For example, Makeham *et al*. undertook a review of methods and measures used in assessment of safety in primary care and found that estimates of the rate of patient safety incidents ranged from 0.004 to 240 per 1000 primary care consultations, and that estimates of preventability ranged from forty-five to seventy-six per cent of all errors (Makeham *et al.* 2008). Until effective systematic methods have been developed and put in place to identify adverse events, progress in patient safety cannot be reliably measured (Rafter *et al.* 2014).

Nevertheless, there is a consensus that the figures for ADRs and AEs are unacceptably high and require reduction. The WHO estimates that, in high income countries such as the UK, as many as one in ten patients is harmed while receiving hospital care, arising from errors or adverse events. For example, of every one hundred patients hospitalised

at any given time, seven will acquire health care-associated infections even though many of these can be prevented by simple control measures such as appropriate hand hygiene (WHO 2014). In 2004, it was estimated that adverse drug reactions were responsible for 6.5 per cent of hospital admissions in the UK and that most reactions were either definitely or possibly avoidable (Pirmohamed *et al.* 2004). Apart from having a significant impact on patient morbidity and mortality, the economic burden of ADRs and AEs on the National Health Service is also high and not insignificant, drawing resources away from other areas of potential deployment and patient benefit.

It is clear from this short overview that safety assurance is a significant challenge for those in conventional healthcare in spite of the existence of clear infrastructures and procedures for the identification and prevention of ADRs and AEs. Most practices of T&CMs fall outside the procedures of the established healthcare system through their use of products that have generally not been tested in the same manner as those that pharmaceutical products are subjected to, and the lack of coherent procedures for reporting ADRs and AEs. This shortcoming in clinical governance has led to accusations of considerable risk of harm to patients (Markman 2002, K. Smith 2008, Ernst 2009c, Hunt and Ernst 2010, Shaw 2010, Ernst 2015). In the following sections I will be examining whether these accusations are justified and, if so, how they might be addressed.

5.2 Safety in T&CM

Reports of ADRs for the five main forms of T&CM under consideration in this thesis are only relevant to homeopathy and herbal medicine, as the practices of acupuncture, chiropractic and osteopathy do not rely upon the use of medicinal products. Homeopathic remedies, even though they are highly diluted (most commonly beyond the point at which they are assumed to have any biochemical action), have been associated with risks of allergy, toxicity and drug contamination (Posadzki *et al.* 2012a). However, there is very little data to analyse on the topic of ADRs from homeopathic medications, as reports are extremely rare (Bornhöft *et al.* 2006). Concerns about the safety of T&CM products are primarily focussed upon herbal products, whether prescribed by a practitioner or self-medicated, and reports of ADRs from the use of herbal medicine are far more common than for homeopathy. Herbal

products have been linked with the risks of drug/herb interactions, allergic reactions, toxicity, drug contamination, interference with laboratory tests and overdose (Posadzki *et al.* 2013b).

Aside from the potential ADRs from herbal medicine and homeopathy products, there are also potential risks of AEs, of a more intangible nature, from more widespread use of T&CMs, including the practices of acupuncture, chiropractic and osteopathy. Those revealed in the literature search include misdiagnosis, delayed diagnosis, and failure to use effective treatments with resultant unnecessary morbidity or mortality. In addition, there is the potential for practitioners to cause harm through inappropriate advice, the provision of misleading information, a lack of professional boundaries or poor standards of care. Over the past twenty years, increasing numbers of concerns about actual or potential AEs for people using T&CM treatments have been published. Some forms are deemed riskier than others, such that incompetence on the part of the practitioner could lead to serious AEs from acts of commission. For example, chiropractic and osteopathy carry a risk of trauma and injury (Ernst 2008a, Ernst 2011, Rajendran *et al.* 2012), and acupuncture carries a similar risk with an additional potential for infection (Norheim 1996, Norheim and Fønnebø 1996, Markman 2002). Herbal medicines may be misprescribed (Boullata and Nace 2000, Vickers *et al.* 2001).

However, as more information becomes available, it is becoming clear that serious AEs associated with acts of commission are not common in the UK. For instance, a systematic review of thirty-nine clinical studies of manual therapy (including chiropractic and osteopathy) revealed that *minor* AEs are common after treatment, with over half of patients experiencing short-lived reactions, but that the risk of *major* AEs was found to be very low; lower than it would be from medications (Carnes *et al.* 2010). Similarly, two prospective safety surveys from the UK, which were based on more than 66,000 acupuncture sessions, did not report any serious AEs (MacPherson *et al.* 2001, White *et al.* 2001).

By far the most common accusations of risk from T&CM concern acts of omission rather than commission. Here, the concerns arise from the potential for rejection of, or delay in access to, conventional care leading to serious consequences that otherwise may have been avoided. An underlying assumption here is that conventional care is

more effective than T&CM. In addition, it is assumed that practitioners of T&CM may fail to recognise serious conditions and/or interfere with a conventional treatment approach through contradictory advice about conventional medications and immunisation (Ernst 2001, Ernst 2009a, Ernst 2009b).

Children can be put at risk when parents opt for T&CM treatments (Ernst 2003b, Vohra *et al.* 2009, Lim *et al.* 2010), as was tragically highlighted by the deaths of four children in Australia in 2010, where the cases were reported to relate to a failure to use conventional treatment. One case involved an infant of eight months who was admitted with malnutrition and septic shock following naturopathic treatment with a rice milk diet for 'congestion'. Another death was of a child who was prescribed anticoagulants following pulmonary emboli, but who was treated with a complementary medicine instead. The child died following complications relating to a pulmonary infarction (Lim *et al.* 2011, Posadzki *et al.* 2013a).

Further concerns about T&CM for human users arise from the wide variation in standards of education, training and regulation, leading to questions about the clinical competence of practitioners (Curtis and Gaylord 2005, Nissen *et al.* 2013). Concerns about the safety of practitioners apply to all forms of T&CM and include issues such as: working within bounds of competence (Ernst *et al.* 2004), the provision of reliable information (Ernst 2008b), and integration with other forms of health care (Chatfield and Duxbury 2010). In addition, harm may occur in unpredicted ways because many forms of T&CM are poorly researched for efficacy or safety (Ernst *et al.* 2004, Smith 2012). Perhaps the most surprising challenge to the use of T&CM is the accusation that acceptance or promotion will cause harm because it is 'anti-science' and will lessen support for science-based medicine (K. Smith 2008, Smith 2011). This challenge is most commonly levied at homeopathy and in turn leads to the challenge that support for homeopathy distracts from other more effective forms of T&CM.

Both categories of safety concerns, ADRs and AEs, are equally as important; they can both lead to harm and have the potential to result in life-threatening situations. Each will be addressed here in more detail: firstly, attention is turned to an analysis of ADRs through examination of the case of herbal medicine.

5.3 Adverse Drug Reactions and Herbal Medicine

In the UK, warnings about herbal medicines are published and regularly updated on the website of the Medicines and Healthcare products Regulatory Agency (2014b). A glance at entries for T&CM products in November 2014 revealed the following examples of such additions:

Warning about Ayurvedic herbal medicine for treatment of asthmatic symptoms containing undeclared pharmaceuticals Medicines and Healthcare products Regulatory Agency is advising consumers not to use Ayurvedic Herbal Medicine Shwasa Sanjeevani as it has been found to contain dexamethasone, a prescription only medicine which has not been declared on the packaging.
Warnings about unlicensed traditional Chinese medicines containing undeclared pharmaceuticals and heavy metals The Medicines and Healthcare products Regulatory Agency is advising consumers not to use the following traditional Chinese medicines as there are concerns about possible side effects. These products are not authorised for sale in the United Kingdom and have not been found on the United Kingdom marketplace, but they could be available on the internet.
Warning about slimming pills containing undeclared pharmaceuticals Medicines and Healthcare products Regulatory Agency is advising consumers not to use specific slimming pills as these products have been found by regulators in other countries to contain prescription only drug ingredients that are not declared on the product labels.

It is clear, from these examples, that the potential for harm from unlicensed and unregulated products containing herbal medicines is pervasive and multifactorial. Potential for harmful effects stems not only from toxicity associated with poor quality or from adulterated or contaminated products, but also from the possibility of overdose,

side effects, drug/herb interactions and interference with biological tests, even from high quality herbal products. Many plants are potent or toxic and there is typically far less safety data available for herbal products than would be required for conventional medications (Werner and Soghomonyan 2014).

Many studies have suggested that herbal medicine is the most popular form of T&CM in the UK (Posadzki *et al.* 2012c), not only for adults, but also for children (Posadzki *et al.* 2013a). Herbal medicines are popular for the treatment of a wide variety of health issues including: menopausal symptoms (Posadzki *et al.* 2013), eczema (Khiljee *et al.* 2011), dementia (Tabet *et al.* 2011), obesity (Esteghamati *et al.* 2015), depression (Butler and Pilkington 2013), and even cancer[27].

Herbal treatments can be prescribed on an individual basis following consultation with a trained medical herbalist, but many herbal products are also available over-the-counter in pharmacies, health food stores and supermarkets, either as single herbs or in compound formulations. The market for complementary over-the-counter products in the UK is large. In 2009, it was estimated to be worth 213 million pounds, representing a growth of eighteen per cent between 2007 and 2009 (Mintel 2009). Herbal medication sales formed a significant percentage of this figure. In addition, a vast array of products containing herbal medications are available online, with most being sourced from outside of the UK (Morris and Avorn 2003).

A significant number of people hold the mistaken assumption that herbal products are safe because they are natural (Okoronkwo *et al.* 2014, White *et al.* 2014). However, herbal medicines have pharmacological effects, just like synthetic pharmaceuticals, including the potential for ADRs. Unlike pharmaceutical drugs, however, most herbal medicines are not taken through the same phases of development from preclinical to phase III studies before release onto the open market. In fact, most herbal medicines have been in use for substantial periods of time, perhaps even hundreds or thousands of years, before they are subjected to clinical studies, if at all. Figure 7 provides an overview of the stages of development.

[27] One study estimates that almost twenty per cent of cancer patients are using herbal medicines (Damery *et al.* 2011)

Figure 7: Stages in the Development of Herbal Medicines

These stages are representative of current day development and not the original indigenous developmental processes.

There are estimated to be more than 70,000 species of plants used in traditional medicines around the world (Chen *et al.* 2014), but only a tiny fraction have been subjected to rigorous testing under controlled conditions for efficacy and safety (Singh and Ernst 2008, Ernst 2012). The clinical studies of herbal medicines that have been undertaken vary greatly in quality and value (Posadzki *et al.* 2013b). It is only in the last thirty years or so that the risks involved in the use of herbal medications has demanded more than cursory attention.

The inclusion of herbal medicine in the monitoring processes for ADRs, both nationally by the Medicines and Healthcare products Regulatory Agency and internationally by the WHO, has helped to reveal some of the potential risks involved with using herbal medications. In the UK, the Medicines and Healthcare products Regulatory Agency has received approximately sixty Yellow Card reports each year for the past eight years, which have involved herbal medicines; forty per cent of these reports have originated from members of the general public (HMAC 2014). These figures for the reporting of suspected ADRs in the UK are very low, but when taken together with reports from other countries they become more significant.

In the period 1968-1997 a total of 8,985 individual ADRs involving the use of herbal medicines had been reported (Farah *et al.* 2000). At that time anaphylaxis, including anaphylactic shock, was the most frequently reported critical adverse reaction at 67 out of 2487 reports (2.7 per cent). Pruritus (itching skin) was the most reported non-critical reaction with 324 out of 2487 reports (thirteen per cent), followed by diarrhea, which

was often associated with the use of single ingredient herbal medications, and comprised 109 cases (4.4 per cent) (Farah *et al.* 2000).

In September 1999, the total number of reports in the WHO monitoring database was just over one million and reports of suspected ADRs from herbal medicines constituted about 0.5 per cent of all case reports.

By December 2010, there were 12,679 suspected case reports in the WHO database where purely herbal substances were involved and 21,951 reports that included both herbal and non-herbal substances (Farah 2011). The most commonly reported critical ADRs from use of herbal products are listed here in Table 7 and the most commonly reported herbal medicines associated with ADRs in Table 8.

Table 7: The Most Commonly Reported Adverse Drug Reactions Associated with the use of Herbal Medicine that were listed in WHO Database December 2010

Drug abuse (630)	Hallucination (115)
Drug dependence (274)	Asthma (111)
Hepatitis (263)	Respiratory depression (105)
Death (176)	Purpura (103)
Angioedema (169)	Prothrombin decreased (92)
Coma (162)	Aggressive reaction (89)
Face oedema (160)	Epistaxis (89)
Anaphylactic shock (151)	Hepatitis cholestatic (83)
Cardiac arrest (150)	Bronchospasm (79)
Thrombocytopenia (118)	Circulatory failure (77)
Anaphylactoid reaction (116)	Oedema mouth (77)

Table 8: The Most Commonly Reported Herbal Medicines Associated with Suspected Adverse Drug Reactions that were listed in WHO Database December 2010

Cannabis sativa L. (1057)*	*Oenothera biennis* L. (274)
Ginkgo biloba L. (960)	*Mentha x piperita* L. (205)
Hypericum perforatum L. (713)	*Citrus x paradisi* Macfad. (195)
Herbal pollen extract NOS** (690)	*Valeriana officinalis* L. (192)
Senna alexandrina Mill. (435)	*Silybum marianum* (L.) Gaertn. (174)
Herbal extract NOS (331)	*Viscum album* L. (172)
Cimicifuga racemosa (L.) Nutt. (312)	*Allium sativum* L. (162)
Echinacea purpurea (L.) Moench (302)	*Vitex agnus-castus* L. (142)
Plantago ovata Forssk. (287)	*Pelargonium reniforme* root, Curtis (130)
Serenoa repens (Bartram) Small (284)	*Digitalis purpurea* L. (129)
Glycine max (L.) Merr. (276)	*Ginseng* NOS (125)

Key:
** Species = Cannabis; specific epithet = sativa; author = L (Linnaeus); number of reported cases = 1057*
***NOS = not otherwise specified*

These figures provide an overall impression of the types of *suspected* ADRs, as well as the medicines most commonly associated with them, but they do not provide details about subsequent assessments of causality or potential mechanisms of harmful effect. In addition, they are not helpful for distinguishing between types of ADRs such as toxic effects of the herbal medicine, the potential for overdose or allergic reactions, contamination of the product, or adverse interactions with conventional drugs. Instead, they represent the early stages of an effort for global pharmacovigilance of herbal products that still has a long way to go in addressing the primary ongoing challenges. Four of these challenges are outlined below, namely hepatoxicity, herb/drug interactions, contamination of herbal products and the misidentification of herbs.

5.3.1 Herbal medicine and hepatoxicity

It may seem reasonable to assume that the extensive use of herbal medicines over long periods of historical duration should have inevitably revealed implications for their safety. Information about who might be at risk, how much to take, and potential side effects can potentially be gleaned from years of real world experience and guidance developed accordingly. This type of information evolves as it is passed down through generations and is vital to locally based, traditional forms of T&CM. However, when products are removed from their cultural and traditional roots and applied in completely different environments, under different conditions, and in different formats, the consequences of such use are unpredictable (WHO 2013). One illustration of this is the case of kava kava (*Piper methysticum).* For over three thousand years, the people of the South Pacific Islands have been using kava kava for medicinal, religious, and social purposes. There is a great local respect for this plant which holds deep cultural significance for these peoples (Cawte 1985). In Fiji, for example, the kava kava ceremony often accompanies important occasions when the root of the plant is chewed or pounded, and then mixed with water, strained and drunk. The effects of the kava kava are sedative and have been likened in some respects to alcohol (Thompson *et al.* 2004). Following reports of medicinal benefits, the leaves and the root of the kava kava plant were used to make herbal products that became popular in many other parts of the world for the treatment of anxiety, tension, insomnia and restlessness. Clinical studies backed up the efficacy claims for the use of kava kava in the treatment of anxiety (Volz and Kieser 1997, Pittler and Ernst 2000, Boerner *et al.* 2003, Connor *et al.* 2006).

In 2001, concerns were raised about the safety of kava kava after a number of cases of acute liver failure were reported, and subsequently led to restrictions, regulations and outright bans in some countries. While kava kava has the potential for beneficial properties, it appears that it also has the potential for hepatotoxic effects in certain individuals (Wooltorton 2002, Humberston *et al.* 2003, Stickel *et al.* 2003). Subsequent analysis has indicated that the majority of these case reports are probably not connected to the intake of kava kava (Teschke *et al.* 2010, Teschke *et al.* 2013), but still the potential for hepatotoxic effects has not been ruled out and internal use of the product remains banned in the UK. More research is needed to identify the precise requirements for the safe use of kava kava, despite its extensive use in the South Pacific (Anke and Ramzan 2004, Sarris *et al.* 2011).

Kava kava is not the only herbal medicine to be associated with hepatoxic effects. In their review of reports of serious hepatotoxic events, Abdualmijd and Sergi (2013) examined 254 reports of hepatoxicity involving herbs alone or in combination with other drugs. Twenty-seven herbs were subsequently identified as having a recognised potential for hepatoxic effects and the authors warned that, as the use of natural medicine increases, so will the risk of liver toxicity. The potential risk of damage to the liver from herbal medicines is now widely acknowledged. Many herbs have been recognised as potential toxins and some have been associated with significant liver injury. These include single herbs such as kava kava as well as compounds with often ill-defined ingredients (Stickel and Shouval 2015).

It is unsurprising that some herbal medicines have the potential for hepatoxic effects arising from their pharmacological action on the body, given that the liver is the main organ of drug metabolism. Foreign chemicals are transformed by metabolic enzymes in the liver and hence the liver is the major site of drug-induced damage, as is well known from the effects of alcohol on the body. However, little is known or understood about how precisely this damage is caused by herbal medications. For instance, we know that the spectrum of liver injury induced by kava kava ingestion includes hepatitis, cirrhosis, and liver failure, but the mechanism involved in kava kava hepatotoxicity has not been identified (Humberston *et al.* 2003). Immunoallergic reaction[28] and idiosyncratic reaction[29] have both been proposed (Stickel *et al.* 2003, Olsen *et al.* 2011) but neither are very helpful for the identification of those people who might be vulnerable to hepatoxic effects.

5.3.2 Herb/drug interactions

As well as being directly responsible for certain cases of hepatoxicity, some herbal medications can lead to harm in people who are simultaneously taking herbal medicines and conventional drugs, due to adverse interactions between the herbal medicine(s), the drug(s) and the human body. The relationship between drugs, dosage and reactions involves the biochemical processes of pharmocodynamics and pharmacokinetics.

[28] An immunoallergic reaction to a drug can occur in hypersensitive patients. Such reactions are normally unpredictable and can be fatal.
[29] Idiosyncratic drug reactions are adverse reactions that are not related to the known pharmacological properties of the drug and occur in only a small percentage of the population.

Pharmacodynamics is often described as *what the body does to a drug* and pharmacokinetics as *what the drug does to the body*. Pharmacodynamics refers to the movement of a drug into, through, and out of the body, and is concerned with aspects such as, the time course of its absorption, bioavailability, distribution, metabolism, and excretion (Le 2014). Pharmacodynamics involves receptor binding[30], postreceptor effects, and chemical interactions (Moroney 2007). Herbal medications can cause problems if they interfere with either one or both of these processes, thus affecting the movement of a drug through the body, or altering the effect of the dosage on the body in an ampliative or inhibitory manner.

There is considerable debate about the extent to which herbal medications can interfere with conventional drugs, which herbal medicines are most risky, which drugs most affected, the problems caused, and the mechanisms of action. Many of the studies investigating potential interactions are conducted using *in vivo* animal studies or *in vitro* laboratory experiments, and the results subsequently extrapolated for predictions of effects in humans. Within the herbal medicine community there are feelings of unjust assessment, as Josephine Briggs, director of the NCCIH points out:
'There are 11 major drug interactions with coffee, yet doctors don't tell patients not to drink coffee based on possible interactions! A lot of the fears about herbs are not founded on good meaningful accurate data' (Briggs quoted in:Tweed 2015, p.12).

However, as the number of studies increases, the picture is becoming clearer and there is certainly cause for caution with at least a limited number of herbal medications.
Following their analysis of forty-six systematic reviews of potential drug-herb interactions, Posadzki *et al.* (2013d) concluded that the majority of herbal medicine products are not associated with severe herb/drug interactions. Serious interactions were noted only for *Hypericum perforatum* and *Viscum album* and moderately severe interactions were noted for *Ginkgo biloba, Panax ginseng, Piper methysticum, Serenoa repens* and *Camellia sinensis*. The most commonly interacting classes of drugs were found to be antiplatelet agents and anticoagulants. The most serious interactions they uncovered resulted in a range of conditions that included transplant rejection, delayed

[30] A receptor is a molecule on the surface or within a cell that recognises and binds with other specific molecules, producing a specific effect in the cell.

emergence from anaesthesia, cardiovascular collapse, renal and liver toxicity, cardiotoxicity, and death. However, the authors warned that the poor quality and the scarcity of the primary data prevent firm conclusions and called for further investigation (Posadzki *et al*., 2013e). Gallo *et al.* (2014) also found problems with antiplatelet agents and anticoagulants in their recent study of 478 preoperative patients in Italy, as well as antihypertensive and central nervous system agents. Of the 478 participants in the study, forty-two were identified as being affected by a herb/drug interaction.

One of the herbal medicines identified by Posadzki *et al*. (2013c) as being capable of serious interactions, namely *Hypericum perforatum* (St John's Wort), is very popular in the UK, and is one of the oldest used and most extensively investigated medicinal herbs (Gallo *et al.* 2014). This herbal medicine is readily available over the counter and is most commonly used for the treatment of depression and/or anxiety. Indeed, there is much evidence to support this usage. A 2008 Cochrane Review found *Hypericum perforatum* to be superior to placebo in patients with depression, and as effective as standard antidepressants but with better tolerability (Linde 2008). However, this herbal medicine is often taken concurrently with conventional pharmaceuticals in potentially harmful combinations (Davis *et al.* 2014).

For instance, *Hypericum perforatum* has been found to decrease plasma concentration levels of docetaxal [31] in cancer patients, suggesting that it has an effect on the pharmacokinetics of this drug and prompting the authors to warn that concomitant use of docetaxel and *Hypericum perforatum* should be avoided to prevent potential undertreatment of cancer patients (Goey *et al.* 2014). Docetaxal is not the only drug to have its levels affected by *Hypericum perforatum*. It now appears that this herbal medicine has enzyme-inducing effects on the cytochrome P450 enzymes[32] that result in reduced efficacy of certain other medications if co-administered (Garner 2014).

Another potentially life-changing interaction that has recently come to light occurs in women who are concurrently taking hormonal contraception and *Hypericum perforatum*. In 2014, the Medicines and Healthcare products Regulatory Agency issued

[31] A chemotherapy drug.
[32] The main enzymes involved in drug metabolism.

a warning about reduced contraceptive effect of hormonal contraception when used alongside *Hypericum perforatum*. Between the years 2000 and 2013 the Medicines and Healthcare products Regulatory Agency received a total of nineteen Yellow Card reports of interaction with hormonal contraceptives. Of these suspected interactions, fifteen cases resulted in unplanned pregnancies and the remaining four cases resulted in breakthrough bleeding (MHRA 2014c).

5.3.3 Contamination of herbal products

A further potential for harm arises from the use of herbal medicines which may be contaminated, either deliberately or unintentionally, as is clear from the aforementioned warnings on the Medicines and Healthcare products Regulatory Agency website. In a recent review of twenty-six systematic reviews investigating the adulteration and contamination of herbal medicinal products, the most common contaminants were named as: dust, pollens, insects, rodents, parasites, microbes, fungi, mold, toxins, pesticides, toxic heavy metals and/or prescription drugs. A very wide range of ADRs were reported, with the most severe resulting in cases of: meningitis; multi-organ failure; arsenic, lead or mercury poisoning; malignancies or carcinomas; renal or liver failure; cerebral oedema; and coma or death (Posadzki *et al.* 2013c). The systematic reviews included reports about herbal products from all over the world and concluded that contamination was most common in traditional Indian and Chinese remedies, respectively.

There are two types of herbal products most commonly associated with deliberate adulteration: weight loss products and sexual performance enhancers. For example, Gilard *et al.* (2015) analysed 150 supplements marketed as natural products for sexual performance enhancement claiming to contain only natural compounds, plant extracts and/or vitamins. Of the 150 products analysed, sixty-one per cent were adulterated with phosphodiesterase-5 inhibitors (the active ingredient in Viagra), with twenty-five per cent of these at a dosage higher than the maximum recommended dose. An additional 5.5 per cent of products included other pharmaceutical drugs for the treatment of sexual performance. Of the whole batch, only thirty-one per cent of the samples were considered true herbal/natural products. Furthermore, a follow-up of several products over time revealed that some manufacturers make changes to the chemical composition

of the formulations so it is virtually impossible for a member of the public to have confidence in the manufacturer's description (Gilard *et al.* 2015).

5.3.4 Identification of herbs and herbal ingredients

The number of plants used for medicinal purposes around the world is estimated at more than 70,000 species (Chen *et al.* 2014). Given this vast number and the wide variation in species that are sourced, as well as variable standards of quality control and regulation of products, it is not surprising that a number of safety-related issues have emerged because of the inaccurate identification of herbal materials.

One of the most widely publicised incidents of ADR from mistaken identity of a herb was reported in Belgium in the 1990s, when at least one hundred women were believed to have developed progressive renal failure after adhering to a weight-loss regimen that included the use of Chinese herbs. Suspicion that the disease was due to the recent introduction of Chinese herbs in the slimming regimen was reinforced by identification of aristolochic acids in the slimming pills. These compounds are known to cause nephrotoxicity and carcinoma of the upper urinary tract (Grollman *et al.* 2007). In depth analysis of the pills revealed that the prescribed Chinese herb, *Stephania tetrandra* was not present in the pills at all, and in fact this had inadvertently been replaced by another Chinese herb, *Aristolochia fangchi*, in the herbal extracts used in Belgium and in France (Vanherweghem 1998). This type of induced renal disease has become known as aristolochic acid nephropathy and incidents are not restricted to the Belgian cases. Similar cases have been observed throughout the world (Cosyns 2003) and, in the majority of known cases, the cause of the problem has been the inaccurate identification of the plant ingredients (Chen *et al.* 2014). The correct identification of medicinal plant ingredients is therefore essential for their safe use.

5.3.5 Summary of the challenges

Herbal medications have pharmacological effects on the body, just as conventional medications, but they are generally poorly researched in comparison with conventional medicines in terms of their efficacy and safety (Ernst *et al.* 2004). Conventional drugs must undergo extensive testing in clinical studies, but therapeutic knowledge about

herbal medicines is gleaned in a different manner. Most of what we know about herbal medications is derived from experience of their traditional and local usage, in some cases over hundreds or thousands of years. According to the WHO, an increase in reports of ADRs associated with herbal products reflects a growing awareness that natural products may also cause harm. This, they say, may be particularly true when traditional medicines are used outside their original, clinical, cultural or pharmaceutical context, or in combination with more modern medicines (WHO 2013).

The public are often unaware of the potential for harmful effects from herbal products, assuming that the term 'natural' implies safety (White *et al.* 2014). Self-medication without appropriate knowledge can lead to harmful herb/drug interactions, overdose or toxicity (Markman 2002, Curtis and Gaylord 2005). No international standardisation guidelines for processing, manufacturing and marketing of herbal products exist (Kim *et al.* 2014) and herbal products in the UK, particularly those that are imported, may be contaminated with conventional medications, toxins, or ingredients that have been misidentified (Rao and KumarMeena 2011, Posadzki *et al.* 2013c).

Given the large number and variety of medicinal plants, the ability to distinguish them reliably from their close relatives, inferior substitutes, adulterants, and counterfeits presents a challenge that risks patient safety (Chen *et al.* 2014).

5.3.6 Addressing the challenges

In light of these challenges there are three broad requirements for reducing ADRs from herbal products. First, more safety data is needed to assess toxicity levels, appropriate dosage, the likelihood of side effects and the potential for adverse interactions with other medications; secondly, herbal products require quality control and licensing on a global scale; and thirdly, the general public and health professionals need access to the most up to date and reliable information about potential ADRs in the context of herbal medicines.

Worldwide scientific study of herbal medicines is now increasing, together with improvements in the sharing of information between regulators, and this is being driven, to a large degree, by increased public demand for herbal products in high

income countries and guided by initiatives from the WHO (WHO 2013). Safety data is growing thanks to improvements in reporting systems for ADRs on national and international levels. The WHO-Uppsala monitoring project is key in this process. As well as collecting and analysing reports of suspected ADRs, the Uppsala Monitoring Centre is also improving standards in identification of herbal materials. This is being achieved through a major project which is aimed at attaining global standardisation for herbal medicines, including their scientific names and therapeutic implications (Farah 2011). For complete analysis of reports of ADRs from herbal products, it is vital to know the exact scientific name of the plant, the part of the plant that was used and the name of the manufacturer. This is a great challenge because the information can vary widely between countries and even between districts. To this end, the Uppsala Monitoring Centre have established a classification system that is similar to the system in place for conventional pharmaceuticals (the Anatomical Therapeutic Chemical system (ATC)), known as the Herbal Anatomical Therapeutic Chemical (HATC) system (UMC 2015). This system aims to classify herbal medicines by the internationally approved Latin binomial classification of the relevant plant species and common therapeutic uses. Resolution of the existing problems requires the collaboration of botanists, phytochemists and pharmacologists and hence the Uppsala Monitoring Centre collaborates with the Department of Botany, Uppsala University, the Royal Botanical Gardens at Kew in the UK and with other international experts (Farah 2011).

In the UK, the Medicines and Healthcare products Regulatory Agency launched a registration scheme for herbal medicines in 2005 with the aim of improving the safety of herbal products that are available over-the-counter. Known as the Traditional Herbal Registration Scheme (THR), this scheme dictates which herbal medicines are available over-the-counter and sets specific standards for safety and quality. Products approved by the scheme have a ‘THR number’ on their labels and registration is only available to those medicines used for minor health conditions where medical supervision is not required (for example, colds and coughs). To be eligible for registration, the indication (the medical condition the product has traditionally been used to treat) must be agreed under legislation. For agreement of this legislation, evidence that the herbal medicinal product has been used traditionally to treat the stated condition for a minimum of thirty years (fifteen years of which must have been in the European Union) is required. Herbal

remedies which are administered by a qualified herbal practitioner, following a consultation, do not require a medicines licence, but may be subject to certain restrictions. For example, some herbs, such as aristolochia and kava kava, are deemed toxic and are banned for use in the UK under any circumstances (MHRA 2014a). The Medicines and Healthcare products Regulatory Agency are also acting to increase awareness of the potential for ADRs from herbal products (MHRA 2014b). Practitioners are informed when a problem is highlighted through the Yellow Card reporting scheme and information is made available to all on their website (MHRA 2015). Ultimately, however, the information that can be made available to healthcare professionals and the public is limited by the amount of safety data revealed through research and reporting schemes. Presumably, as this increases, so too will the quantity and quality of the available information about potential safety concerns.

On a global level, the WHO is taking a proactive role in driving forward the development of policies and regulation of herbal products. According to the WHO, most Member States now regulate herbal products, although new regulations are continually being developed, updated and implemented (WHO 2013). These regulatory approaches are aimed at protecting consumer health by ensuring that medicines are safe and of high quality. As the market is now truly international, with products often being made in a country other than that in which they are sold, it is acknowledged that it may be a challenge to ensure products are safe and of high quality. In order to address this issue, Member States and regulatory agencies are cooperating and learning from each other's experiences. Some regional bodies have been working on harmonising regulations on herbal medicines and other herbal products within their region (WHO 2013). It is therefore anticipated that over time levels of safety of T&CM products will improve.

5.3.7 Ethical analysis: adverse drug reactions and herbal medicine

For ethical analysis of issues pertaining to the human use of herbal medicines, and the associated impacts upon wellbeing, the potential for harm in the form of ADRs needs to be carefully considered alongside the potential for benefit. Examination of the ethical challenges has revealed a potential for harm from the use of herbal medications but, in the UK at least, steps have been taken to try and minimise this potential. Over-the-

counter products must be licensed and there are restrictions upon the practitioner prescription of some herbs that have been deemed risky. In addition, reporting procedures are in place for collection and analysis of safety data that can help to improve safety in the future.

The safety data available for herbal products is generally of a different quality and nature to that for conventional medications. In some respects, the long history of use of most herbal medications provides us with more realistic safety data than is available for conventional medications. Experience of use within large and diverse populations, over extended periods of time, provides valuable real-world information, whereas conventional pharmaceuticals are typically released onto the open market having been tested on a limited number and range of individuals, over a finite amount of time. However, historical usage cannot guarantee safety, as evidenced by the examples of kava kava and St John's wort.

Even so, data suggests that the number of serious ADRs from herbal medications is small (especially when compared to the number from conventional medications). In their review of fifty systematic reviews of adverse effects of single herbal medicines Posadzki *et al* (2013b) found that severe adverse effects were noted for only four herbal medicines: *Herbae pulvis standardisatus* (belladonna*), Larrea tridentate* (chaparral*), Piper methysticum* (kava kava), and *Casia senna* (senna), with three of these having been identified as potentially hepatoxic: chaparral, kava kava and senna (Abdualmjid and Sergi 2013). However, moderately severe adverse effects were noted for a further fifteen herbal medicines and mild effects for a further thirty-one herbal medicines.

Edzard Ernst, who has undertaken a considerable amount of work investigating the risk/benefit profile of herbal medications in the UK, asserts that even though herbal medicines are not devoid of risk, they could still be safer than synthetic drugs (Ernst 2003a). In support of this view, Ernst quotes Linde *et al*. (1996) who showed that the herbal antidepressant St John's wort has only half the rate of adverse effects when compared with conventional antidepressants and Schulze *et al.* (2003) who claims that even though kava kava has been banned in the UK, it is probably still safer than benzodiazepines. 'At present the relative safety of herbal medicines is undefinable, but many of the existing data indicate that adverse events, particularly serious ones, occur

less often than with prescription drugs' (Ernst 2003a, p.881). Moreover, in his analysis of the relative risks and benefits of six commonly used herbal medications[33], Ernst (2002) concludes that encouraging data support the efficacy of some of these popular herbal medicinal products, and that the potential for doing good seems greater than that for doing harm.

The potential benefits of herbal medicines are not limited to their efficacy, and other benefits could arise from their high acceptance by patients and their relatively low costs. Patients worldwide seem to have adopted herbal medicines in a major way (Ernst 2003a). In the UK, access to conventional medical healthcare is free to all citizens through the National Health Service yet many people elect to pay themselves for herbal products either instead of, or as well as, conventional products in an ongoing fashion. It is difficult to imagine why people would continue to pay out of pocket for treatments if they did not perceive some type of benefit. Indeed, Pirotta *et al.* (2014) conducted an investigation into how and why people use St John's wort for management of self-identified depression, stress or worries. Their findings confirm that while there is often a preference for more natural approaches, people experiment with different treatments and continue to use what they perceive is most effective for them.

Evidence of efficacy may be limited for many herbal medications but acceptability for them appears to be high and associated risks appear to be low, with one notable exception. It is possible to access herbal products via the internet that are neither licensed in the UK nor prescribed by a practitioner, and these products are typically prone to batch-to-batch variability in composition, concentration, contamination, and purposeful adulteration (Stickel and Shouval 2015). If people choose to use unlicensed medications obtained via the internet (especially weight loss products and sexual performance enhancers) then it would appear they are putting themselves at greater risk of suffering an ADR.

[33] Ernst examined data for the following six herbs: Ginkgo, St. John's wort, ginseng, echinacea, saw palmetto, and kava kava.

5.3.8 Recommendations for the avoidance of adverse drug reactions from herbal medicine

It is not possible to assess accurately all of the potential benefits of herbal medications from the information that is currently available, but it is possible to identify factors that may reduce the potential for harm.

For people using herbal products, the risk of experiencing ADRs from herbal preparations can be minimised if they:

- Inform their healthcare practitioners (conventional and T&CM) when taking herbal medications alongside conventional medications.
- Adhere to the instructions for dosage either on the packet for over-the-counter products or as provided by the practitioner for prescribed products.
- Use the Yellow Card reporting scheme for any suspected adverse reactions.
- Never buy unlicensed herbal medicinal products via the internet.

For practitioners, the risk of harm to their patients can be minimised if they:

- Keep up to date with safety data concerning the potential for ADRs from herbal medicines.
- Inform patients of the potential for ADRs (where known).
- Inform patients about what to do if they suspect that they are experiencing an ADR.
- Make full use of the Yellow Card system for reporting suspected ADRs.
- Ensure that patients understand how to use their prescribed herbal medications.

For patients who are concurrently using conventional medication, they should:

- Take the relevant steps needed to avoid herb/drug interaction, including referral back to the conventional healthcare professional when appropriate.

Thus, there are clear steps that can be taken to reduce the potential for harm from ADRs associated with herbal medicine. The potential for harm from AEs associated with T&CM, however, requires a completely different strategy. The risks of AEs associated with the use of T&CM are considered next through the example of homeopathy.

5.4 Adverse Events and Homeopathy

As previously mentioned, Leape (1994) distinguished between two types of medical errors: errors of commission (unintentionally doing the wrong thing) and errors of omission (unintentionally not doing the right thing). By far the most common accusations of risk from T&CM concern acts of omission. The concern that practitioners of T&CM may fail to recognise serious conditions and/or interfere with conventional treatment is commonplace (Ernst 2001, Ernst 2009a, Ernst 2009b, Gilmour *et al.* 2011a), and this leads to the accusation that, if people opt to use T&CM treatments, the rejection of, or delay in access to, conventional care can have serious consequences (Curtis and Gaylord 2005). Whilst this may be a concern for all types of T&CM, in the current literature it is most frequently levied at homeopathy. However, there are no more recorded cases of AEs from homeopathy than for other types of T&CM; the primary reason why homeopathy is the most frequent subject of this challenge appears to stem from an underlying problem that homeopathy poses for conventional science[34]. Homeopathy is often equated with being purely a placebo treatment because there is *no plausible explanation* for the mechanism of action of homeopathic remedies (Sehon and Stanley 2010)[35]. The idea that people may opt (unwittingly) for a treatment that is no better than placebo in place of 'effective' conventional medicine raises many ethical concerns (Shaw 2011, Smith 2012) because, 'patients who do not seek medical advice from properly qualified doctors run the risk of missing serious underlying conditions while they have their symptoms treated with a placebo' (Science and Technology Committee 2010, p.107).

In the UK, when the National Health Service was established in 1948, homeopathy was included as an officially approved method of treatment and there are currently still three homeopathic hospitals in the UK where members of the general public can receive homeopathic treatment from medically qualified practitioners. The National Health

[34] Homeopathic remedies are prepared from a very broad range of animal, mineral and plant substances that are serially diluted in water and ethanol. Between each dilution, the solution is succussed (shaken vigorously). Homeopaths believe that this method of preparation increases the potency of the remedies and lessens the potential for side effects. However, the process of dilution commonly exceeds the point at which any molecules of the original substance might be expected to remain in solution (as relating to Avogadro's constant), leading to the accusation that the remedies can be no more effective than water.

[35] This view has been challenged by a small number of scientists who have proposed explanations that are consistent with current scientific thinking; for example, Milgrom, L. R. (2006) 'Is homeopathy possible?', *Journal of the Royal Society for the Promotion of Health*, 126(5), 211-218.

Service spends approximately four million pounds a year on homeopathy and tens of thousands of patients are treated each year at the three hospitals (British Homeopathic Association 2015). However, the majority of homeopathy provision in the UK lies outside of the National Health Service and is primarily offered on a private basis by practitioners who do not have conventional medical training. Most homeopathic practitioners in the UK are not qualified in any form of conventional medicine (Clarke *et al.* 2004) and it is the treatment from these (non-medical) homeopaths that is mainly called into question.

Homeopathy is a controversial treatment and arguments can be vociferous between its opponents and its supporters. In 2005, when the Lancet published a damming meta-analysis of clinical trials of homeopathy compared with clinical trials of conventional medicine (Shang *et al.* 2005), it was accompanied by a short, anonymous editorial entitled 'The end of homoeopathy' that called for 'doctors to be bold and honest with their patients about homeopathy's lack of benefit' (Editorial 2005, p.690). In response, Peter Fisher, Clinical Director at the Royal London Hospital for Integrated Medicine and Physician to Her Majesty the Queen was highly critical of both the meta-analysis and the accompanying Lancet editorial commenting that, 'Regrettably, this attack will only widen the divisions. The way forward is open, transparent science, not opaque, biased analysis and rhetoric' (Fisher 2006, p.146).

Assessment of the research evidence for the efficacy of homeopathy paints a confusing picture for the general public as contradictory conclusions are frequently drawn. For example, two recent governmental reviews, one in the UK (Science and Technology Committee 2010) and one in Australia (National Health and Medical Research Council 2015), concluded that there is no reliable evidence from research that homeopathy is effective for treating the range of health conditions considered. However, the results from a Health Technology Assessment report, on behalf of the Swiss Federal Office for Public Health, concluded that effectiveness of homeopathy can be supported by clinical evidence, and also that it can be regarded as safe (Bornhöft *et al.* 2006). Clearly, the issue of whether or not homeopathy is more than placebo is not one that can be resolved within the scope of this thesis. What is of concern here is whether or not the use of homeopathy exposes people to a risk of AEs and, if so, how these can be minimised. This will be the focus of the subsequent analysis.

5.4.1 Known cases of adverse events from use of homeopathy

There have been reports of AEs with fatal consequences for users of homeopathy. Australian barrister Ian Freckelton SC, in his alarmingly entitled article, *Death by Homeopathy*, reports on four legal cases from different countries, where outcomes have been fatal (Freckelton 2012). Whilst emphasising that it is not fair to judge a profession by its worst practitioners, Freckelton believes it important to draw attention to, 'the potentially fatal consequences of undiscerning and inappropriate provision of complementary medicine, in particular homoeopathy, or of Western medicine by persons qualified in homoeopathy but not in Western medicine' (Freckelton 2012, p.457). Of the four cases that Freckelton refers to, one is from England, one from India and two from Australia.

The English case involved Dr. Marisa Viegas, a general practitioner with an interest in homeopathy who purportedly advised one of her patients against taking conventional medications and instead suggested some homeopathic remedies. The patient did as recommended by Dr. Viegas and subsequently died. The cause of her death was recorded as 'acute heart failure due to treatment discontinuation' (Chancellor 2007).

In India a claim for negligence was brought against the homoeopath, Dr. Patel, in 1996. Dr. Patel had treated a person with strong antibiotics on the basis of his own diagnosis of viral fever and typhoid fever without confirming the diagnosis through conventional testing. When the patient's condition worsened, he was admitted to a hospital but died soon after. Dr. Patel was a qualified practitioner of homeopathy but he was not qualified to prescribe conventional medications (Supreme Court of India 1996).

One of the two Australian cases involved an infant who died at the age of nine months from septicaemia following ineffective treatment for chronic eczema and associated malnutrition. The girls' father, Thomas Sam, who had qualified as a homoeopathic practitioner in India, and her mother were prosecuted for manslaughter because they had repeatedly ignored advice to seek conventional medical help for their daughter; instead they opted to rely upon homeopathic remedies alone (Smith *et al.* 2013).

The second Australian case concerned the death of Penelope Dingle who died in 2005 as a result of metastatic bowel cancer. Ms. Dingle had been diagnosed with a large

rectal tumour in 2002 and, initially, she refused conventional treatment, electing to receive treatment from homeopath Francine Scrayen instead. When Ms. Dingle eventually presented for conventional treatment in 2003 the cancer had spread widely and it was not possible to remove it all with surgery. In the surgeon's view, had Ms. Dingle followed the advice to have the tumour removed in the first place, whilst it was still contained, she would have had a good chance of curing her disease. It was reported that Mrs. Scrayen had attempted to dissuade Ms. Dingle from having surgery during her homeopathic treatment, threatening not to treat her if she elected to receive surgery. The coroner commented that: 'In my opinion Mrs. Scrayen's advising against surgery in these circumstances was an outrageous thing to do. Mrs. Scrayen had minimal medical knowledge' (Hope 2010, p.53).

Each of these cases could be analysed from a variety of legal, ethical, or cultural perspectives as well as from a medical viewpoint. There are many lessons to learn from the scrutiny of such cases and, these being the most well known cases of AEs from homeopathy, they have indeed received due attention (Condie *et al.* 2012, Freckelton 2012, Smith *et al.* 2013, Wardle *et al.* 2014). For the purpose of my analysis I wish to highlight here that these demonstrate that there are at least four well-known cases of AEs associated with the use of homeopathy. One of these cases (Patel) relates to an act of commission; it involved the inappropriate prescription of antibiotics. Three of the cases relate to acts of omission in which delayed access to conventional care resulted in fatal consequences. In one of these three cases (Viegas), the practitioner was a qualified conventional general practitioner, and hence it can be assumed there was no delay in access to conventional diagnosis. There are two cases[36] (Scrayen and Sam), which support the challenge that homeopathic treatment (by a non-medically qualified practitioner) can result in serious harm from the delay in access to conventional diagnosis and treatment.

Rather than replicating published examination of these well-known cases, for this analysis of the potential for AEs associated with the use of homeopathy, I will take an alternative approach and consider the case of the homeopathic treatment of mental health concerns. The analysis will be undertaken from a UK perspective and focus upon treatment delivered by homeopaths who are not additionally trained in conventional

[36] Obviously there may be many more cases that have gone unreported.

medicine. There are a number of reasons why this particular case has been selected for analysis here, but my primary motivation is that a study I conducted prior to this thesis revealed real-world examples of ethical challenges facing homeopaths working in mental healthcare (Chatfield and Duxbury 2010). This study took the form of a survey of homeopaths in the UK, asking about their experience of treating people with mental health complaints. The subsequent revelation of ethical challenges demands attention.

5.4.2 Mental health care and homeopathy

Following review of the global data, Becker and Kleinman (2013) concluded that 7.4 per cent of the total global burden of disease is attributable to mental illness and that, globally, the majority (seventy-five per cent) of people suffering a serious mental illness never receive treatment. Their summation is distressing:

> According to virtually any metric, grave concern is warranted with regard to the high global burden of mental disorders, the associated intransigent, unmet needs, and the unacceptable toll of human suffering (Becker and Kleinman 2013, p.71).

Estimates of the prevalence of mental health problems in the UK vary but according to the mental health charity MIND, around 300 people out of every 1,000 will experience mental health problems in Britain each year. The types of treatments sought and used can be broken down as follows:

- 230 of these will visit a GP
- 102 of these will be diagnosed as having a mental health problem
- 24 of these will be referred to a specialist psychiatric service
- 6 will become inpatients in psychiatric hospitals.

(Hatloy, 2011)

By far the most commonly experienced mental health problem is mixed anxiety and depression with an estimated prevalence figure of 9.2 per cent of adults. This is followed by general anxiety at 4.7 per cent and depression (without the symptoms of anxiety) at 2.8 per cent (McManus *et al.* 2009).

Historically, homeopathy has been used in the treatment of psychiatric conditions since its inception in the eighteenth century, and over 200 years of homeopathic literature shows that patients with a broad spectrum of mental health concerns seek homeopathic treatment. The founder of homeopathy, Samuel Hahnemann, wrote of the treatment:

> I can confidently assert, from great experience, that the vast superiority of the homoeopathic system over all other conceivable methods of the treatment is nowhere displayed in a more triumphant light than in mental and emotional diseases of long standing (Hahnemann 1842 para. 230).

However, there is limited data available to describe the full range of conditions treated by homeopaths, how commonly they are seen, or how effective treatment is. What is apparent is that many patients seek homeopathic help for anxiety and depression. For example, a study involving over 6,500 patients at the Bristol Homeopathic Hospital demonstrated that anxiety and depression are in the top ten most commonly referred conditions to this National Health Service provision (Spence *et al.* 2005). A survey of French homeopathic general practitioners also demonstrated that stress and anxiety was one of the most common complaints that clients presented with (Trichard *et al.* 2003).

5.4.3 Findings from the survey of homeopaths in the United Kingdom

The Society of Homeopaths is the largest professional organisation for homeopaths in the UK and in 2006 there were approximately two thousand practising members. One tenth of these (200) members were randomly selected from the register to participate in the survey and each was sent a questionnaire that included both open and closed questions. The open questions focused upon the views of homeopaths about their experience of treating people with mental health problems. They asked specifically for homeopaths' experiences and opinions on a number of issues such as what helped and hindered treatment, and asked them to identify any challenges that they may have encountered. Responses to the questionnaire were anonymous. Results from the quantitative part of the questionnaire provided some information about the homeopaths and presented a snapshot of the kinds of mental health problems patients seek treatment for.

Of the 200 surveyed homeopaths, 96 (48 per cent) responded. Of these, 72/96 (75 per cent) were aged between forty-five and sixty-four years; 78/96 (81 per cent) were female and most, (67/96; 70 per cent) had spent between five and nineteen years in practice. Most of those surveyed, 49/96 (61 per cent) saw no more than nine patients per week, while 62 per cent (60/96) stated that they saw patients at home, 51/96 (53 per cent) in clinic, and some at both home and clinic and 9/96 (9 per cent) in neither place.

The most commonly treated conditions fell into the categories of anxiety and mood disorders, consistent with the known prevalence of these disorders. However, the results also indicated that homeopaths were treating people with a full spectrum of mental health disorders. For example, a substantial proportion (57 per cent) stated that they had previously treated patients with schizophrenia and 78 per cent stated that they would do so in the future.

The sample of homeopaths surveyed spanned many years of experience yet no clear association was found between the number of years spent in practice and either willingness to treat each condition or the level of confidence in so doing. Over ninety per cent of the respondents stated that they would be willing to treat all disorders mentioned, except schizophrenia, regardless of their experience. Those who had treated schizophrenia in the past were more likely to say they would treat it in the future, suggesting that experience of treatment of this condition was not acting as a deterrent.

These figures and conclusions, suggest that homeopaths treat patients with mental health conditions on a regular basis, and may be alarming for people who work within conventional mental healthcare. However, they will probably not surprise most practising homeopaths, who routinely work with many different kinds of patients, presenting with many different kinds of illness, and in different circumstances. According to homeopathic philosophy, treatment is *of the person rather than the disease;* thus, conventional diagnosis and disease identification are not normally a necessary requirement for homeopathic prescription (Vithoulkas 1980). This approach to treatment inevitably raises concerns about the ability of the practitioner to maintain a practice that is wholly within their bounds of competence (Stone 2000) as patients can present for treatment with any complaint, ranging from the very mild (such as a

few warts on the skin) to others which are much more serious (such as chronic depression).

The qualitative part of the survey contained open questions that invited homeopaths to write about their opinions and experience. Amongst other things, they were asked about any challenging situations that had occurred in their practice. Despite some differences in views expressed by the homeopaths, a number of generic concerns were raised. Of particular relevance to this analysis are those issues concerning the safety of patients. In the following brief summary of the findings related to patient safety, some anonymised direct quotes from the completed questionnaires are used to illustrate some of the most typical responses.

Concerns about safety for both patient and homeopath were frequently expressed and many specific examples of challenging situations were described. These concerns were commonly intensified by frustrations regarding a lack of effective inter-professional working. Fifteen homeopaths described situations where the patient posed an actual or potential danger to themselves or others:

'I broke confidentiality with a young borderline schizophrenic and explained to him that I would do this. In my judgement he was a potential danger to himself and was exhibiting behaviour close to stalking a female neighbour.'

Nine of these fifteen homeopaths mentioned patients with suicidal thoughts and tendencies; there appears to be a lack of clarity around assessment of actual threat:

'Not being sure about the severity of patient's illness, e.g. suicidal thoughts – are they actively suicidal? At what point should others be alerted re. confidentiality.'

'I think the most difficult situation I have found myself in was when one of my patients telephoned me to say she couldn't carry on and was going to commit suicide. Luckily I persuaded her to contact other services who were very supportive and she was able to move onwards without ending her life.'

One homeopath notes the following after a patient committed suicide:

'Following the disturbing suicide of one patient with manic depression I would not want to treat this condition again;

a) For my own state of mind's sake,

b) For the patient's sake.'

From the short comments returned on the questionnaire, it is not possible to analyse these challenging situations; we do not know the precise nature of the events that led up to them or what followed. In the last case, for example, we do not know whether the homeopath was even aware that the patient was feeling suicidal or what other treatments they may have been receiving. It is clear, however, from the above examples that the conduct of the homeopath could be key in helping to avoid and/or minimise the potential for harm. In the conventional healthcare system, mental healthcare practitioners work predominantly as part of a team. They have particular expertise in the treatment of patients with mental health problems and training in how to deal with challenging situations. In contrast, the majority of homeopaths are practising outside of the conventional healthcare system, without specialist training, and without access to the standard support networks that are available to mental health care professionals.

The treatment of people with mental health disorders can generate complex ethical challenges. The National Patient Safety Agency warns that mental health service users are vulnerable to a number of potential risks often related to their own behaviour such as self-harm, aggression and violence, and sexually disinhibited behaviour (NPSA 2006). However, there is no clear cut way of assessing these risks and it is a matter that has to be judged on a case-by-case basis. Hence, it can be confusing and worrying, especially if practitioners are working alone. At the same time, it is vital that practitioners are able to respond appropriately when they believe their patients are in danger.

Obviously, the greatest potential for harm occurs when a patient expresses suicidal thoughts or feelings, particularly as the risk of suicide in patients with mental disorders is much higher than for patients without co-existent mental disorders (Raven 2006). In Western countries, approximately ninety per cent of people who die from suicide have a mental health disorder. The majority have a depressive disorder, but there are other

associations, such as bipolar disorder, alcohol, drug misuse and schizophrenia (MIND 2012). For example, suicide is a major cause of death in schizophrenic patients and studies suggest that patients with schizophrenia are at 8.5 times greater at risk of suicide than the general population (Kasckow *et al.* 2011). However, suicide risk assessment involves a judgement about human emotions, thinking and behaviours, which vary considerably with individuals depending on their age, culture, and personal circumstance; this assessment can be extremely difficult, even for those who are trained and experienced (Boyce *et al.* 2003).

There is a wide spectrum of mental health concerns, some of which are fairly moderate, such as mild anxiety, while others are much more serious and enduring, such as personality disorder or schizophrenia. Accordingly, there are many different treatment strategies and many different types of conventional drugs[37] that are used (Weich *et al.* 2011). Medications can be prescribed individually or combined with others to target a range of symptoms and these can have a variety of effects upon a patient, both desirable and undesirable. Some medications can cause extremely severe side effects whilst others are tolerated well (Whitaker and Cooper 2007). Homeopathic practitioners in the survey raised concerns about treating people who are concurrently taking conventional medications, primarily because the drugs can make it difficult to determine the appropriate homeopathic prescription:

'They are usually on very heavy chemical drugs which hinder establishing symptoms of the disease rather than of the drugs.'

But there were also safety concerns related to the management of people taking conventional medications:

[37] For example, antipsychotics are used to relieve symptoms of psychosis; antidepressants are used to relieve symptoms of depression; mood stabilisers are used to moderate extreme mood changes and benzodiazepines are used for the relief of anxiety.

'One bipolar patient on daily homeopathic prescription taking himself off lithium overnight without informing anyone.'

This situation was of great concern to the practitioner because sudden medication withdrawal can lead to seriously damaging consequences.

Additionally, the depth of mental health pathology may not be evident at first and a patient with a history of psychosis may appear to be functioning very well when first seen. However, should they decide to stop their conventional medicine, they may quickly relapse into an acute psychotic episode with serious consequences, and may require hospitalisation (Moncrieff *et al.* 2013).

5.4.4 Summary of the challenges

Mental health problems are common and many patients in the UK seek treatment from homeopaths for a wide range of mental health conditions, in particular, depression and anxiety (Spence *et al.* 2005). Homeopaths in the UK, most of whom are not medically qualified, treat people with a very broad range of conditions including a wide spectrum of mental health conditions (Relton *et al.* 2007). Homeopathic philosophy teaches that the person is an integrated whole of mind and body and as such no part should be treated in isolation (Hahnemann and O'Reilly 1996). Consequently, most homeopaths will view themselves as providers of healthcare for persons, rather than for particular types of ailments, and speciality training is rare. Few homeopaths have specialist training in mental healthcare and most work outside of the healthcare system, often on their own, and often from their own homes (Chatfield and Duxbury 2010).

The treatment of people with mental health concerns can result in challenging practical and ethical situations (Leucht *et al.* 2012). There are increased safety concerns: patients may be particularly vulnerable, at greater risk of harm to themselves (and others), and even suicidal.

Many people with mental health problems are taking conventional medications and changes to their medications can have serious consequences (Moncrieff *et al.* 2013). Homeopaths may find themselves in situations that fall outside their bounds of

competence, thus putting their patients, and others including themselves, at risk of harm. It is a major challenge for homeopaths to determine how they can assess their bounds of competence effectively (Stone 2000), whilst continually working with different kinds of patients, different kinds of illness, and in different circumstances.

5.4.5 Addressing the challenges

In the UK, there are laws regulating the practice of conventional medicine under the system of statutory professional regulation. The main purpose of regulation is to protect the public and this is overseen by nine regulatory bodies that hold registers of individuals who meet their standards of education, training, professional skills, behaviour and health (NHS 2014b). For example, the General Medical Council undertakes the regulation of doctors and only those who appear on their register are entitled to call themselves 'medical doctors' in the UK. Two of the five forms of T&CM under scrutiny in this thesis are also statutorily regulated: osteopathy and chiropractic. All osteopaths must be registered with the General Osteopathic Council and it is illegal for anyone to call him/herself an osteopath, or offer services as a registered osteopath, without registration. Similarly, all chiropractors must be registered with the General Chiropractic Council and it is illegal for anyone to call him/herself a chiropractor, or offer services as a registered chiropractor, without registration (NHS 2014a).

This is not the case for practitioners of acupuncture, herbal medicine or homeopathy. These three professions are subject to a process of voluntary registration; professional bodies exist for the registration and regulation of practitioners, but membership is voluntary. There is no protection of title for professionals who are not subject to statutory regulation; in theory, anyone can call him/herself an acupuncturist, a herbal medicine practitioner or a homeopath.

In the UK, there are several professional bodies that maintain a register for (non-medical) homeopaths. Members have to meet certain criteria: they must hold certain qualifications and agree to practise to a certain standard. However, there is no legal requirement for practitioners to join an association or to register before they start to practise (NHS 2014a). As previously mentioned, the surveyed practitioners described here were registered with the largest professional organisation for homeopaths in the

UK, namely the Society of Homeopaths. This organisation, established in 1978, maintains a register for homeopaths who meet its professional standards.

Homeopaths registering with the Society of Homeopaths agree to practise in accordance with their Code of Ethics and Practice, the National Occupational Standards and the Core Criteria for homeopaths (Society of Homeopaths 2014). The Society of Homeopaths operates a system for recognition of courses that educate professional homeopathic practitioners and graduates from these courses are eligible to apply for registration. In addition to maintenance of a register, they also act as a regulatory body with systems in place for dealing with complaints, professional misconduct and recording members' continuing professional development. The Society of Homeopaths' Code of Ethics and Practice sets out the standards of personal and professional conduct required of members and this is available to view on their website (Society of Homeopaths 2015b). Also on their website are clear instructions about what to do and who to contact if people are concerned about a member's behaviour. The information states that if members break the Society's rules they can have a formal first warning, an action plan or conditions placed on their practice. In more serious cases, members may be suspended or removed from the Society of Homeopaths' register. Adjudication findings are published on their website with the names of members who have been removed (Society of Homeopaths 2015a). This system of voluntary regulation for homeopaths is intended to protect the public from harm, helping to ensure safe and ethical practise. Undoubtedly, regulation of this kind contributes to improved standards of professional practice (Gale and McHale 2015) but standards differ between professional organisations and practitioners are not even obliged to join a professional body. Furthermore, registration with a professional body is no guarantee that practitioners will know how to respond in all challenging situations, as was indicated by some of the responses in the survey, suggesting that there is room for improvement.

The system of voluntary regulation that exists in the UK is not adopted in all European countries. In Europe, homeopathy, as a distinct system of healthcare, is recognised by law in Belgium (1999), Bulgaria (2005), Germany (1998), Hungary (1997), Latvia (1997), Portugal (2003), Romania (1981), Slovenia (2007) and the UK (1950). However, the laws in Bulgaria, Hungary, Latvia, Romania and Slovenia allow only medical doctors to practise homeopathy (European Council for Homeopathy 2015). Clearly, the restriction of the right to practise to medical doctors in some countries

avoids the challenge that practitioners are not qualified to diagnose serious conditions or manage conventional medications.

5.4.6 Ethical analysis: adverse events and homeopathy

For the analysis of ethical issues pertaining to the use of homeopathy for the treatment of mental health concerns, the potential for harm in the form of AEs needs to be carefully considered alongside the potential for benefit and the autonomous rights of the individual. Many individuals choose homeopathic treatment for their mental health problems (Relton *et al.* 2007), even though this normally incurs an out-of-pocket expense. Additionally, many say that they benefit from it. For instance, of 201 patients with depression who were treated with homeopathy at the Bristol Homeopathic Hospital, seventy-six per cent recorded an improvement in their condition following treatment, with thirty per cent of these being markedly improved. Only one per cent of the 201 patients experienced a deterioration in their condition following treatment (Spence *et al.* 2005). These figures do not prove that it was the homeopathy that caused this improvement[38], but nevertheless the majority of the patients believed that it helped them.

On the other hand, examination of the ethical challenges pertaining to AEs has revealed a potential for harm from the choice of homeopathic treatment and this needs to be carefully scrutinised to see what can be put in place in order to minimise this possibility.

Of primary ethical concern is that problems can arise when practitioners work outside their bounds of competence. Practitioners who work alone, without training or experience in working with people with complex mental health problems can be faced with challenging issues that extend beyond their normal scope of practice. As has been previously identified, this can happen with patients who are violent towards themselves or others, or patients who wish to stop their conventional medication, for example. Of vital importance to patient safety is that practitioners are equipped with the appropriate knowledge and skills. In order to minimise the risk of harm, practitioners have to be

[38] This was an observational study and the lack of a control group means that cause and effect cannot be established. Homeopathic treatment typically involves a long consultation as well as the prescription of homeopathic medications. The improvements could have been due to either of these factors, both of these factors or something else.

able to recognise situations that are beyond their competence and act accordingly. Hence, careful consideration needs to be given to the issue of competence before undertaking the treatment of patients with severe or complex illness. This should be viewed as good practice, for in such circumstances it would be unethical to continue to treat the patient regardless (Chatfield 2013). However, this is not a straightforward process. As previously mentioned, people with a very wide range of conditions seek help from homeopaths and the depth of their pathology is not always obvious when they first arrive.

Mental health care practitioners are required to undertake a risk assessment exercise for new patients. This is used to predict whether the patient is of danger to themselves or others, but the practice is widely challenged for its lack of accuracy and inherent discrimination (Scott and Resnick 2006, Kutcher and Chehil 2011). The diversity of human behaviour and experience precludes accurate and completely reliable risk assessment techniques. However, developing a greater awareness of the risk factors and potential antecedents for harm increases the likelihood that significant risk factors will be spotted during treatment (Boyce *et al.* 2003).

It is a normal part of homeopathic treatment to assess the depth of pathology and there are many factors that are known to affect prognosis. Factors such as the length of time that illness has been evident, family history, the extent to which normal life is impacted, concomitant diseases, medication use and vitality levels are some examples of indicators that the homeopath routinely uses (Vithoulkas 1980). Even without a conventional diagnosis, these indicators may serve to assess the complexity of a patient's case.

In addition to the depth of pathology, another important consideration for the homeopath is the conventional medical treatment that the patient is receiving. It has been known for patients to develop inadvertently the idea that they can cease all other medication when they begin homeopathic treatment (Chatfield and Duxbury 2010). The analysis of this issue is clear: homeopaths can be considered experts in the field of homeopathic interventions and as such qualified to give advice on this matter, but for non-medical homeopaths matters of conventional medication usage falls outside their expertise and hence it would be unethical (and in contravention of their professional

codes of conduct) to give advice on such usage. It can be viewed as part of the homeopath's ethical responsibility to refer their patient back to the prescribing practitioner for guidance.

Invariably, the consideration of such issues raises concerns about respecting the autonomy of the patient. In the UK, the National Health Service Choice Framework (2014) stipulates that patients have a legal right to choice about treatment and care. The right of the individual to self-select the treatments that they believe are right for them is highly respected in the UK. Consequently, a homeopath may find him/herself in the position of trying to treat a patient who is concurrently taking a combination of many conventional medications or, on the other hand, trying to treat a patient who wishes to stop conventional medication altogether.

Trying to respect the patient's wishes, whilst at the same time avoiding harm, can be challenging for the healthcare provider and lead to dilemmas in practice (Broer *et al.* 2010). For example, there are times when respect for patient autonomy conflicts with a health practitioner's opinion about the potential for benefit and for harm in all forms of healthcare, conventional as well as T&CM. Decisions about when it is appropriate and ethical to overrule autonomy in favour of wellbeing are complex and involve many factors; over-protection can infringe upon patient choice invoking paternalism, while under-protection can lead to harm. Advice about the best ways in which these two factors are kept in balance varies greatly (Gilmour *et al.* 2011c, Bishop *et al.* 2014, Stuttaford *et al.* 2014) but there is general agreement that, as far as possible, individuals must be informed about the likely benefits and risks of using any form of treatment, whether T&CM or conventional (Bruce and Robyn 2008).

For most forms of T&CM, including homeopathy, the shortage of data regarding efficacy and safety, together with variation in standards of education and regulation, will inevitably affect an individual's ability to make an informed choice about treatment options (Ernst 2004). Informed choice involves the exchange and understanding of relevant information so that a knowledgeable, reasoned and unpressured decision can be made (Gilmour *et al.* 2011b). It is vital that people are neither deceived nor coerced when making decisions about their health care and informed choice relies upon the accuracy and reliability of information. If there is a paucity of research evidence

available to support the use of certain treatments, then individuals need to be informed that this is the case (Gorman *et al.* 2005). The reliability of claims that are made for some T&CM products and services have been seriously questioned (Ernst 2008b), especially those advertised via the internet. A recent ruling by the Advertising Standards Authority in the UK appears to substantiate this claim. Following complaints about claims relating to homeopathy that appeared on a number of websites, the Advertising Standards Authority (ASA) conducted their own investigation to determine the acceptability of the types of claims being made, considering, amongst other things, the following tweet from the Society of Homeopaths' Twitter page:
'*Antidepressant prescriptions up by 43%. For more holistic healthcare which doesn't rely on drugs try #homeopathy'* (ASA 2013).

The Advertising Standards Authority ruled that this advertisement should not be repeated because it 'marketed treatment for depression, a serious condition for which medical supervision should be sought' (ASA 2013). The ruling prompted the Society of Homeopaths to ensure that members are conforming to ethical guidelines in their advertising. The onus must fall upon the T&CM community to improve the ways in which they inform people about its products, practices and practitioners and to avoid unsubstantiated claims.

It is clear from the findings of surveys and the analysis presented here that working with people with mental health problems can be challenging, not least because practitioners are sometimes not equipped with the relevant skills and experience that are needed to deal with problems as they arise. This is not a situation that is confined to the T&CM world; in conventional healthcare, practitioners can find themselves in comparable situations, but they have networks and support systems in place for themselves and their patients which are designed to support in these circumstances. A conventional practitioner who is concerned about a situation is not alone. As well as the support in place for patients, it can also be very important for the practitioner to feel that they have the necessary support in place for themselves. Practitioners (of any kind) who work alone with people who have mental health problems, without support systems in place for themselves or their patient, put the safety of their patients at risk because they cannot possibly be available at all times or deal with every eventuality.

One possible solution to this challenge is that the practice of homeopathy is confined to conventional medical specialists, as it is in some European countries. If all practitioners are working within the conventional healthcare system there is less likelihood that diagnoses of serious illness will be missed, or that practitioners will be working alone. Another solution would be for the practice of homeopathy to be brought under statutory regulation so that homeopathic practitioners are regulated in the same way as those in conventional healthcare. However, neither of these two options is likely to happen in the UK, at least not in the short term.

When homeopathy was first introduced into the UK, the treatment was delivered exclusively by medical doctors. However, this changed in the early 1900s when a small minority of homeopathic doctors broke away from the establishment and began to teach laypersons how to practise (Morrell 1998). Today, the vast majority of homeopathic practitioners in the UK are not trained in conventional medicine[39] and the private provision of homeopathy, and other forms of T&CM, is embedded within the British culture (Andrews 2002).

Homeopathy, herbal medicine and acupuncture bodies in the UK have all requested statutory regulation in the UK but this remains elusive. The lack of regulation is not for want of effort. There is resistance to the regulation of homeopathy by those who claim that the profession is not suitable for formal registration and regulation because such a status lend to it 'a legitimacy that it does not warrant' (Freckelton 2012).

Hence, the current situation, whereby non-medical practitioners, practising outside of a statutorily regulated system, offer homeopathic treatment to people with mental health problems is likely to continue as long as people continue to seek treatment. Thus, other ways of minimising the risk of harm need to be identified.

If health is indeed, 'the ability to adapt and to self-manage' when facing physical, mental, and social challenges' (Huber *et al.* 2011, p.2), then consideration of what is needed for this to happen is warranted. For a person with mental health problems there may be many things that help them to adapt and manage; there could be a range of

[39] This is true for most forms of T&CM in the UK.

therapies, medications, lifestyle choices, social support systems and so on, that help. This might include homeopathy or conventional medicine or both.

The need for plurality in the approach to health care is inherent within the current drive towards the provision of integrated care in the UK, which is an attempt to join up medical services offered by the National Health Service and social services offered by other bodies. The rationale behind this drive is that disjointed, uncoordinated care is not good for the patient and also leads to inefficiencies:

> Person-centred, co-ordinated care and support is essential to improving outcomes for people who use health and social care services. Reducing gaps and inefficiencies in care should also be able to offer some opportunities for financial savings (Gov.uk 2014).

Systems for integration within the National Health Service and social services are being put in place but they do not, as yet, include systems for the integration of unregulated forms of T&CM. A consequence of this omission is that patients may continue to be at risk when they seek help from practitioners who work entirely on their own. For this situation to improve, there needs to be a willingness on both sides, from practitioners of T&CM and conventional medicine, to work together for the good of the patient. Improved collaboration and integrated practice might avoid many potential problems and may be safer and more effective for the patient.

The preference for, and use of, one type of medicine over another is not in itself an ethical problem; the danger comes from overreliance on any one type of healthcare to the exclusion of all others. Many of the potential risks of T&CM stem from the notion that a particular modality can be *the* alternative, that it is the best and the only thing necessary for cure. The use of the term ‘alternative medicine’ serves to promote the idea of one alternative, in this case an alternative to conventional medicine, as something to be used *instead of* conventional medicine. The potential for harm could be reduced through the eradication of the ‘either/or’ perspective. A truly patient-centred solution might be to treat all forms of healthcare as *complementary*, such that each is viewed as having its own strengths and weaknesses, and no one type of medicine is the best for all people in all situations.

The *WHO traditional medicine strategy 2014–2023* has been developed to help countries determine how best they can promote health and protect consumers who wish to use T&CM. In their strategy, the WHO clearly specify that individual Member States will need to develop national approaches that reflect their specific needs in dealing with the most popular forms of T&CM practised in their country. Essential for this process, the WHO suggests, is that T&CMs are properly integrated into national health systems to enable consumers to have a wider choice when they wish to use such services (WHO, 2013), a vision that is, as yet, far removed from the systems in most countries. Appropriate integration of healthcare systems has the potential to offer the best of both worlds. As suggested by Dr Margaret Chan (2008), the Director General of WHO,

> The two systems of traditional and Western medicine need not clash. Within the context of primary health care, they can blend together in a beneficial harmony, using the best features of each system, and compensating for certain weaknesses in each. This is not something that will happen all by itself. Deliberate policy decisions have to be made. But it can be done successfully.

5.4.7 Recommendations for the avoidance of adverse events from homeopathy

The following recommendations apply to the homeopathic treatment of people with mental health problems by homeopathic practitioners who are not also qualified in conventional medicine.

For people using homeopathy the risk of experiencing AEs can be minimised if they:

- Consult with a conventional medical practitioner for diagnosis of their complaint before treatment, as homeopaths are not qualified to undertake clinical diagnoses.
- Are aware that anyone in the UK can legally call him/herself a homeopath and practise homeopathy, even if they have no training or experience, so it is important to ensure that their practitioner is registered with a professional body.
- Consult with a conventional practitioner on all matters concerning the use of conventional medications.

For practitioners, the risk of harm to their patients can be minimised if they:

- Always seek to work within their bounds of competence[40].
- Be prepared to seek advice from their professional body and take challenging issues to supervision.
- Never work alone.

  Ensure that patients with mental health problems have support networks in place before undertaking treatment.

  Ensure that both practitioner and patient know whom to contact when they need support/help/advice or if there is a medical emergency.
- Understand that they must take action if a patient poses a risk to themselves or others.

  Because of the potential for harm patient confidentiality may be breeched in these situations.
- Never give advice about conventional medications

  Because of the potential for harm, the patient should be clearly advised that medication withdrawal or reduction be undertaken in consultation with the person who has prescribed the medication (GP or psychiatrist).

[40] When trying to assess competence the following are all important:
- Does the patient have support networks in place?
- Are other health professionals actively involved?
- Does the practitioner feel confident and comfortable with this case?
- What else needs to be put in place?
- Is regular supervision arranged?
- Who can be asked for help when needed?

CHAPTER SIX: T&CM AND THE ENVIRONMENT

The environment is a significant stakeholder in the ethical matrix since the delivery of healthcare services can have extensive environmental impact. For instance, the production, transport and storage of medicines may contribute to the depletion of natural resources and, at the same time, accelerate pollution of the environment with by-products and waste materials.

In his application of the ethical matrix, Mepham interprets the ethical principles of respect for wellbeing, autonomy and justice, for the environment, as protection of the biota, respect for maintenance of biodiversity, and the sustainability of biotic populations, respectively (Mepham 1995). For this project, rather than attempting to apply the principles of autonomy and justice to the environment, I have opted to undertake an analysis of the impacts of T&CM on the environment solely from the perspective of wellbeing. Whilst considerations of environmental biodiversity and sustainability are important, these considerations will not be ascribed to the particular principles of autonomy and justice, but they will instead be considered, under the principle of wellbeing.

This chapter will explore the impact of T&CM upon the environment and look for ways in which harm to the environment can be avoided and/or minimised. Since the wellbeing of the environment is intricately linked to the health of living organisms, including humans, the analysis will include an examination of the relationship between the environment and health, and of the potential consequences of environmental damage upon health. Additionally, to provide context for the particular impacts of T&CM, the effects of conventional medicine upon the environment will also be examined.

6.1 Humans and the Environment

Human beings form an integral part of the global ecosystem[41] and their actions have led to profound changes in environments around the world (Wong and Candolin 2015). In the last fifty years, human activities have altered the world's ecosystems more than during any other time span in history and the consequences of these actions might well prove to be devastating and irreversible (Rodríguez *et al.* 2011). Environmental change is not a new phenomenon, and significant periods of environmental change have taken place long before humans became a dominant species. It is broadly agreed that the earth has experienced at least five periods of mass species extinction prior to the evolution of humankind, with the last of these, the Cretaceous-Tertiary extinction, taking place around sixty-five million years ago (Twitchett 2006). During this extinction, it is estimated that sixteen per cent of marine families, forty-seven per cent of marine genera, and eighteen per cent of land vertebrate families (including the dinosaurs) became extinct (Environment and Sustainability Institute 2011). Today, more than ninety-nine per cent of all species that have ever lived on the earth are estimated to be extinct (Stearns and Stearns 2000). Periods of mass extinction are characterised by a extinction rates that are markedly higher than the more normal background extinction rate, which is estimated at between ten and twenty-five species per year (Environment and Sustainability Institute 2011). With the rapid loss of species we are currently witnessing, estimated to be between 1,000 and 10,000 times higher than the background extinction rate, there are widespread claims that we are in the midst of a sixth extinction crisis (World Wildlife Fund 2015b).

The loss of species is clearly of direct harm to those species that have become extinct but it also poses a threat to those species that remain, since a reduction in the diversity of species can affect the resilience of the ecosystem. A dynamically variable range of diverse species can help to buffer ecosystems against perturbations and to maintain longer term stability (Wong and Candolin 2015). Biodiversity underpins the functioning of the ecosystems on which humans depend. A diversity of species provides humans with essential services: not only food, fuel, clothes and medicine, but also purification of water and air, prevention of soil erosion, regulation of climate,

[41] Ecosystems are collections of organisms that occur together in space and time and interact with each other and their physical environment (Wong and Candolin 2015).

pollination of crops and many more (Levin 1998, Vié *et al.* 2009). Biodiversity contributes to local livelihoods, medicines (conventional and T&CM) and economic development[42]. All human health ultimately depends on ecosystem services that are made possible by biodiversity (Patz *et al.* 2012) and the loss of biodiversity can only have a negative effect on efforts to improve health.

The WHO have long been unequivocal in their message about the interrelatedness of the environment and human health as they warned in 1986:

> Our societies are complex and interrelated. Health cannot be separated from other goals. The inextricable links between people and their environment constitutes the basis for a socioecological approach to health. The overall guiding principle for the world, nations, regions and communities alike, is the need to encourage reciprocal maintenance - to take care of each other, our communities and our natural environment. The conservation of natural resources throughout the world should be emphasized as a global responsibility (World Health Organization 1986).

Similarly, policymakers in Europe have long acknowledged that human health and wellbeing are intimately linked to the quality of the environment and this has been reflected in European Union environmental policy since the mid-1970s**.** The current European Commission's proposal for the 7th Environment Action Programme was adopted by the European Parliament and the Council of the European Union in November 2013 and covers a period up to 2020. This programme has three key objectives:

- To protect, conserve and enhance the European Union's natural capital;
- To turn the European Union into a resource-efficient, green, and competitive low-carbon economy; and
- To safeguard the European Union's citizens from environment-related pressures and risks to health and wellbeing (European Union 2013).

The programme entered into force in January 2014. It is now up to the European Union

[42] For example, local economies might be founded upon fisheries or forestry.

institutions and Member States to ensure that priority objectives are met by 2020.

The interactions between the environment and health are highly complex and difficult to assess as we do not have a clear understanding of all the relevant causal relationships (Patz *et al.* 2012). However, there are many examples of certain relationships which are well documented. Perhaps the most obvious are associated with natural disasters such as drought, flooding or other extreme weather events, which affect local environments and damage both ecosystems and the infrastructures on which life in those localities depends. The immediate impacts of such events may be obvious to the observer, but the long-term impacts are more difficult to predict because there are so many influencing variables. Whilst we cannot predict the exact consequences of natural disasters, one thing that we can be certain of is that they are occurring more often. The incidence of natural disasters worldwide has steadily increased, especially since the 1970s; there were three times as many natural disasters between 2000 to 2009, compared to those recorded between 1980 and 1989 (Leaning and Guha-Sapir 2013). According to Lenaing and Guha-Sapir (2013), the recent rapid increase in the occurrence of natural disasters is directly associated with increased rates of urbanization, deforestation, and environmental degradation. Furthermore, it is predicted that natural disasters, particularly floods and storms, will become more frequent and severe because of climate change (McMichael 2013).

Human activities are having a profound impact on the natural world as increasingly unsustainable practices are placing pressure on natural resources to meet the demands of our economies and the needs of a rapidly growing global population (Patz *et al.* 2012). Humans are held responsible for considerable damage to the environment:

> For all the wonders of modern civilization – with longevity, opportunities and high-tech solutions made available to the comfortably privileged within the contemporary world order – the impact of advanced globalized consumer culture on the environment and on the majority of humanity has been truly staggering (Poland and Dooris 2010, p.282).

According to Poland *et al* (2011) there are three major, human-induced, threats to the planet: ecological degradation, climate change and peak oil (for an explanation of what

this means, see below). Each of these threats is relevant to the current and future provision of healthcare, for both conventional medicine and for T&CM.

6.1.1 Ecological degradation

'Ecological degradation' or 'environmental degradation' are terms used to describe the deterioration of the environment resulting from such causes as the depletion of natural resources (such as water, forests, fuels and soil), the direct destruction of environments (such as through the construction of urban areas or farmland, or as a result of modern transport methods) and the eradication of wildlife. For instance, the expansion of agricultural land is considered to be a primary cause of extensive degradation, as natural habitats are directly removed through the development of farms, and the associated effects of irrigation, soil erosion, pesticides and insecticides (Sharma and Sharma 2014). Humans are the leading contributors to ecological degradation and levels are clearly affected by the growth in global population. At the beginning of the twentieth century, the global population was approximately 1.65 billion, and this has increased dramatically such that, at the beginning of the twenty-first century, there were around six billion (Chase-Dunn and Lawrence 2011). This rapid growth in population has increased pressures on natural resources, and this has the potential to result in irreversible damage to the environment. If degradation becomes sufficiently severe, a threshold is crossed beyond which ecosystems are not able to recover and return to their original state (Gao et al. 2011).

The provision of conventional medical interventions and services contributes to ecological degradation in wide-ranging ways, with the most obvious impacts arising from the pharmaceutical industry and its practices. The development and testing of new pharmaceutical drugs can take many years, and hence requires significant resources; a large percentage of products will not reach the large scale production stage (Dickov and Kuzman 2011). For those drugs that are released onto the market, the production normally comprises a series of steps, often involving multiple companies, at a number of production sites. The process usually begins with the collection and transportation of raw materials, commonly oils, plants or minerals that are required for synthesis of the drugs, other steps in the manufacturing process and packaging materials. In general, the production facilities for these materials are located at different sites from where the

drug is manufactured, and there is a risk at each stage of the production process that chemical waste will enter the environment (Larsson 2008).

In addition to direct contamination of the environment by waste arising from the production processes of pharmaceuticals, a growing body of research evidence is highlighting the problems that arise from the discharge of drug contaminated urine and faeces from both humans and animals[43]. When drugs enter the body, they are mostly metabolised and broken down into other compounds, but often a proportion of the pharmaceutical will pass through the body unchanged (Depledge 2011a). Hundreds of drugs can now be detected at significant concentrations in water, sediment and biological samples taken from the environment. Such compounds, which retain their biological activities, include antibiotics, antidepressants, analgesics and cancer chemotherapy compounds (Dietrich 2008). Furthermore, since pharmaceutical use is expected to continue to rise in the coming years, driven by the needs of the ageing population, this problem is likely to worsen (Fick *et al.* 2009). The UK Office of National Statistics predicts that the country's medicine usage will more than double by 2050 (Depledge 2011b). The extent of the ecological impacts of pharmaceutical contamination of the environment is largely unknown, and it has only relatively recently become a subject of scrutiny.

During the 1990s, in the UK, a high incidence of hermaphroditic wild fish was noted near sewage treatment works, and a nationwide investigation of the oestrogenicity of wastewater was initiated as a result. In a series of tests on caged rainbow trout, it was shown that fish held downstream from most sewage treatment works clearly indicated the presence of oestrogenic substances (Harries *et al.* 1996, Harries *et al.* 1997, Harries *et al.* 1999). Further studies identified the cause of this phenomenon to be a widely used synthetic hormone found in contraceptive pills (ethinyl oestradiol), and in some cases levels of this hormone were found to exceeded oestrogenic levels in fish by up to forty-five times (Larsson *et al.* 1999).

[43] Pharmaceuticals are also used in very large quantities as veterinary medicines, especially in the agricultural industry.

Oestrogens are known to have a multitude of effects in fish and the problem is not limited to rainbow trout. For example, Jobling *et al.* (2005) concluded that steroidal oestrogens, originating from human excretion of pharmaceutical products, are responsible for widespread endocrine disruption in wild populations of other species, such as the roach, and play a major role in causing intersex development in wild freshwater fish in rivers across the UK. Outside the UK, many other countries have now reported that ethinyl oestradiol is responsible for the feminization of male fish in other rivers (Depledge 2011a).

There are no accurate figures available for the total global use of pharmaceuticals and hence it is not possible to fully predict current or future, global environmental impacts. Consumption of pharmaceuticals varies widely from country to country in part due to variations arising from traditional and legislative influences on different health practices. For example, it is estimated that in Japan, only 0.4 per cent of women take a contraceptive pill containing ethinyl oestadiol, compared with 16 per cent in North America (Kümmerer 2008). Additionally, whilst there are a growing number of studies involving the detection of human pharmaceutical residues in the environment, there are very few that explicitly investigate other potential sources of contamination, such as waste arising from drug manufacturing processes or the waste disposal of unused medications (Larsson 2008).

In spite of all these unknowns, it is incontrovertible that conventional healthcare practices contribute to extensive ecological degradation. In the UK the National Health Service alone produces 5.5 kilograms of waste per patient per day[44] (Tudor 2013), much of which ends up in landfill sites that have the potential to pollute the environment and cause ecological degradation (Smith 2013).

6.1.2 Climate change

Over the past 150 years, human activities in industrialised nations have resulted in the release of large amounts of carbon dioxide and other gases into the atmosphere. The burning of fossil fuels, the breeding of methane-producing livestock, and the destruction of forests that naturally absorb carbon dioxide from the air, have

[44] An amount that is substantially more than health systems in France and Germany.

dramatically altered the balance of the global carbon cycle[45] (World Wildlife Fund 2015a). Extra carbon in the atmosphere is causing global temperatures to rise and provoking subsequent changes in weather and climate. Changes in levels of rainfall have resulted in more floods, droughts, or intense rain in some regions, as well as more frequent and severe heat waves. The earth's oceans and glaciers have also experienced significant changes, and oceans are warming and becoming more acidic, while ice caps are melting and sea levels are rising (United States Environmental Protection Agency 2015).

Whilst there is disagreement between experts about certain specific aspects of climate change, such as the precise thresholds beyond which change becomes irreversible, the precise timing of the major impacts and how quickly we need to implement changes in order to avoid worse case scenarios (Poland *et al.* 2011), there is a growing consensus on the central concerns. There is agreement that:

- Each of the last three decades has been successively warmer at the earth's surface than any preceding decade since 1850.
- In the Northern Hemisphere, the period 1983-2012 was the warmest thirty-year period in the last 1400 years.
- Some of the expected changes from climate change will be abrupt, leaving less time for adaption.
- A large proportion of anthropocentric climate change from carbon dioxide emissions is irreversible on a multi-century to millennial time scale (Intergovernmental Panel on Climate Change 2014).

Climate change is now anticipated to bring about more droughts in arid regions, more frequent and more intense hurricanes, typhoons and other extreme weather phenomena, rising sea levels, flooding, water scarcity in key regions, the migration or extinction of plant and animal species, and acidification of the oceans (United States Environmental Protection Agency 2015). There is also general scientific consensus that two degrees Centigrade is the largest rise in global temperature the world can afford, in order to limit dangerously disruptive impacts and that we could easily exceed this rise in

[45] The continuous process by which carbon is exchanged between organisms and the environment, including the atmosphere.

temperature by end of twenty-first century, if major action is not taken to reduce emissions (Intergovernmental Panel on Climate Change 2014).

Climate change was described in a Lancet editorial as, 'the biggest global health threat of the 21st century' (Costello *et al.* 2009, p.1693), because it has the potential to dramatically alter global health challenges in sudden and dramatic ways. We have already witnessed the impacts of an increasing number of natural disasters that are often compounded by food and water-borne disease (such as diarrhoea), vector-borne diseases (such as malaria) and malnutrition. Between the years 2000 and 2012, more than 200 million people, most of them in low and middle income countries, were hit by natural disasters each year, especially by floods and droughts (Centre for Research on the Epidemiology of Disasters 2013). Other potential effects include: changes in air pollution and airborne allergen levels; altered routes and levels of transmission of other infectious diseases; effects on food production via climatic influences on plant pests and diseases; population displacement due to natural disasters, crop failure and water shortages; destruction of health infrastructure in natural disasters; conflict over natural resources; and the direct impacts of increased heat and cold (World Health Organization N.D.).

The potential of an entity[46] to contribute to climate change is assessed through measurement of the harmful gaseous emissions (greenhouse gases) that are released into the atmosphere through activities undertaken by that entity. This has been termed a 'carbon footprint' and, in the UK at least, carbon footprint calculations are in high demand (Wiedmann and Minx 2008). However, there is currently no consensus as to how to measure or quantify a carbon footprint: some methods measure emissions of carbon dioxide alone while others include other harmful gasses such as methane (Pandey *et al.* 2011). Another key issue for debate is whether the carbon footprint should include emissions arising from the entire life cycle of products and services, or simply from the point of manufacture or delivery.

The provision of conventional medicine relies upon many different systems, products and services that contribute towards climate change. In the UK the National Health

[46] An entity here meaning anything from an individual to a large business or even nation.

Service alone accounts for twenty-five per cent of all public sector carbon dioxide emissions in England, around four per cent of total emissions (Naylor and Appleby 2013). A series of carbon footprints for the National Health Service have been published relating to years 2004, 2007, 2010 and 2012 (Sustainable Development Unit 2013b) aiding the analysis of trends over time. The National Health Service carbon footprint is measured in carbon dioxide equivalent (CO2e) and six categories of greenhouse gases are included: carbon dioxide, hydrofluorocarbons, methane, nitrous oxide, perfluorocarbons and sulphur hexafluoride. Whilst measurements are not calculated across the entire life cycles of all products and services, they do include emissions from goods and services purchased by the National Health Service, as well as those arising from building energy use and travel to and from sites. The carbon footprint of the National Health Service in England for 2012 is estimated at twenty-five million tonnes of carbon dioxide equivalents (MtCO2e). Between 2007 and 2012, there was a 5.5 per cent reduction in the carbon footprint, but the rate of reduction must be greatly increased if emissions are to meet the Climate Change Act (2008) target of an eighty per cent reduction by 2050.

It is possible to break down the total carbon footprint of the NHS to see where emissions arise within the service. Embedded carbon in overall goods and services bought by the National Health Service contributes sixty-one per cent of the total. Travel to and from National Health Service sites by patients, visitors, staff commuting and business travel contributes a further thirteen per cent, and heating, lighting and providing power for National Health Service sites contributes seventeen per cent of the carbon footprint. Health services commissioned from outside the National Health Service contribute a further nine per cent (Sustainable Development Unit 2013a). A fuller breakdown is detailed in Table 9 which provides a breakdown of the above categories into their components. This shows that the greatest single contribution to the National Health Service carbon footprint arises from pharmaceuticals at twenty-one per cent, followed by medical instruments and equipment at eleven per cent.

Table 9 National Health Service Carbon footprint breakdown

Category	Carbon emissions breakdown	2012 (MtCO2e)	%
Building energy use and direct emissions	Electricity	2.0	8%
	Fossil fuels (Gas, Coal and Oil)	2.1	8%
	Anaesthetic gases	0.6	2%
Travel	Patient	1.4	6%
	Visitor	0.4	2%
	Staff commute	0.6	2%
	Business	0.8	3%
Procurement of goods and services	Pharmaceuticals	5.1	21%
	Medical Instruments /equipment	2.6	11%
	Business services	2.0	8%
	Food and catering	0.8	3%
	Freight transport	0.7	3%
	Paper products	0.7	3%
	Manufactured fuels, chemicals and gases	0.6	3%
	Construction	0.6	2%
	Other manufactured products	0.5	2%
	Waste products and recycling	0.4	2%
	Information and communication technologies	0.4	2%
	Water and sanitation	0.2	1%
Commissioned health services	Commissioned health services from outside NHS	2.3	9%
	Total	24.7	

Figures taken from 'Carbon Footprint update for NHS in England 2012' (SDU 2013a)

Some forms of care have particularly high environmental costs. For example, one year of kidney dialysis has been equated to the environmental impacts of seven return flights between London and New York (Naylor and Appleby 2012). Metered dose inhalers, mostly used by people with asthma and chronic obstructive pulmonary disease, use two hydrofluorocarbons gases as aerosol propellants. Both of these gases have over one thousand times the impact on global warming that the same weight of carbon dioxide gas (National Atmospheric Emissions Inventory ND) has. Another significant contributor to the carbon footprint stems from use of anaesthesia. Anaesthetic gases are potent greenhouse gases, with between 130 and 2000 times the impact on global warming compared with the same weight of carbon dioxide gas. Anaesthetic gases and vapours are primarily eliminated through exhalation without being metabolised in the body and so most anaesthesia systems transfer these gases as waste directly into the atmosphere (Andersen *et al.* 2010, Ishizawa 2011).

6.1.3 Peak oil

'Peak oil' is a term used to describe the pattern of production of crude oil as one that grows, reaches a maximum (peak), and then gradually declines to zero. Marion King Hubbert, a geoscientist and employee of the Shell Company, first introduced the notion in 1956 (Aleklett 2012). He proposed that the production pattern of oil forms a symmetrical, bell shaped curve with the peak occurring when about half of a non-renewable resource is extracted (Bardi 2009). Hubbert's work sparked debate on the topic of peak oil that continues to this day. Whilst there is agreement that petroleum production will peak, there is disagreement about specifics such as the peak's timing, the shape of the production curve around the peak, and the post peak rate of decline. Estimates regarding the timing of the peak vary between the first decade and the third decade of the twenty-first century, but recent reports argue that the peak of world petroleum production is imminent (Schwartz and Parker 2011). In spite of this potentially imminent challenge, the concept of peak oil has to date had virtually no influence on public health or health care delivery policy.

Across the globe, economic growth is largely dependent upon fossil fuels, most importantly oil. As the supply of cheap, crude oil is depleted, oil supplies will become increasingly more expensive and extraction techniques potentially more damaging to

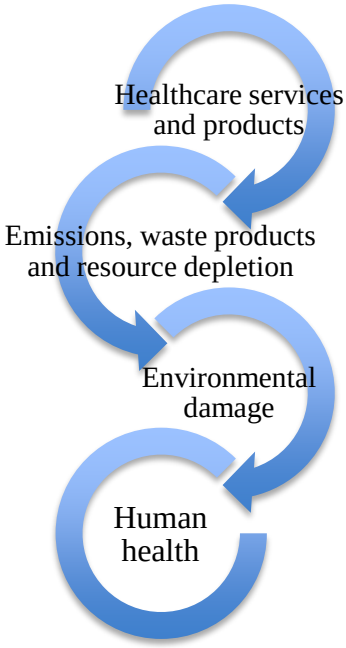
the environment. This situation creates a system of feedback effects that have been described as an 'economic growth paradox': increasing the oil supply to support economic growth will require high oil prices that will undermine that economic growth (Murphy and Hall 2011). Increasing scarcity and rising costs of petroleum will have far-reaching impacts on health because petroleum is currently fundamental to the provision of healthcare services (Frumkin *et al.* 2009). Some effects will be direct, such as rising health care costs. Others will be indirect in nature, such as changes in transportation and agricultural practices, or arising from the potential for economic hardship and geopolitical conflict. Health impacts will range from local to global, and vulnerable populations will be disproportionately affected (Frumkin *et al.* 2011). The transition of health care systems to other energy inputs will be highly challenging.

Conventional healthcare practice relies upon the ready availability of petroleum in many ways. A large number of pharmaceutical drugs are derived from petrochemicals as are plastics, resins, solvents, textile fibers, lubricants, and cleaners, which are also used in health care. Many medical supplies contain plastics derived from petroleum and much of modern antiseptic practice depends on the use of disposable plastic materials. For example, amongst many other things, petroleum is required to make lubricants, syringes, birth-control devices, rubbing alcohol, gowns, toothbrushes, bandages, hearing aids, heart valves, splints and prosthetics (Frumkin *et al.* 2009).

Aside from the reliance upon petroleum for medical supplies and equipment, a shortage will greatly affect transportation, as petroleum currently accounts for more than ninety per cent of transportation fuel, in the form of petrol, diesel and jet fuel (Energy Information Administration 2015). Shortages in petroleum supply will impact upon functions such as the transport of supplies, the transport of healthcare workers and patients, the provision of ambulances (including air ambulances) and public health services, such as community based health visitors and public health inspectors (Frumkin *et al.* 2011). It is impossible to predict precisely the extent of the problem, because the impacts are potentially so far-reaching. For example, changes to the transport of supplies may affect the whole supply chain of many pharmaceutical products, from the point of sourcing raw materials to the point of prescription.

Consideration of the effects that the provision of healthcare has on the three major, human-induced, threats to the planet of ecological degradation, climate change and peak oil, serves to exemplify the tension that exists between the wellbeing of humans and the wellbeing of the environment. However, it is also clear that the health and wellbeing of humans is dependent upon a healthy environment and it is in the interests of humans to protect the environment. Paradoxically, healthcare systems that are intended to improve human health also contribute to environmental damage (Figure 8).

Figure 8: Relationship between human health, the healthcare system and environmental damage



Healthcare systems intended to improve human health contribute to environmental damage that in turn has a negative effect on human health.

In many countries, human activities have resulted in great benefits for human health and wellbeing, in particular through increased access to medicines, welfare and global food production. These positive impacts, however, have not benefited everyone and unsustainable use of ecosystems has resulted in irreparable loss and degradation, with negative consequences for health and wellbeing (Patz *et al.* 2012).

6.2 The Impacts of T&CM on the Environment

Thus far, discussion of the impacts of healthcare services on the environment has focused entirely upon conventional healthcare and it is clear that the wellbeing of the environment is adversely affected by many damaging consequences of conventional healthcare. An appreciation of the impacts of conventional healthcare services is helpful for contextualization of the subsequent analysis of the impacts of T&CM upon the wellbeing of the environment. The need for all forms of healthcare to mitigate harmful effects caused by their interventions will inevitably increase as natural resources decline and the problems associated with climate change increase. It is anticipated that this will ultimately demand scrutiny of practices down to the finest detail. However, it is not currently possible to provide an accurate and detailed description for every aspect of production and delivery of T&CM, as the information needed to do so is simply not available. Instead, the following sections aim to provide an overview of the main environmental impacts, and analysis will take into consideration the three major human threats to the planet: ecological degradation, global warming and peak oil. Each of the five types of T&CM identified in chapter two (osteopathy, chiropractic, acupuncture, homeopathy and herbal medicine) will be considered in respect of:

- the effects of provision upon ecological degradation,
- the production of harmful emissions that contribute to global warming and,
- the reliance upon crude oil and petroleum products.

Osteopathy and chiropractic will be considered first, and will be examined together as they have very similar requirements for their provision.

6.2.1 Osteopathy and chiropractic

In the UK, osteopaths must be registered with the General Osteopathic Council and there are currently around 5,000 on their register (GOsC 2015). Chiropractors in the UK must similarly be registered with the General Chiropractic Council, and there are currently around 2500 registered (GCC 2015). Most osteopaths and chiropractors are self-employed and work in the private sector, with a smaller number working in multi-disciplinary environments within the National Healthcare Service and private companies (British Chiropractc Association 2010, General Osteopathic Council 2015).

Back and/or neck pains are the most common reasons for people to visit a chiropractor or osteopath and a patient's experience with either may seem very similar. Both systems use palpation and visual inspection for diagnosis, both treat the same areas of the body and both use comparable manipulative techniques. Occasionally, other diagnostic procedures can also be used or referred to, such as X-rays, MRI scans and blood tests. The differences between chiropractic and osteopathy may seem subtle in practice, but they originate from a difference in philosophies. In general, chiropractors tend to concentrate on the spine for diagnosis and treatment, whereas osteopaths focus more on restoration of blood flow through work on the soft tissues as well as the joints (Sutherland and Wales 1990, Bergmann and Peterson 2010). However, the individual methods used by practitioners can vary widely, even within the same discipline, as a result of their training and experience. Common to all is the aim of alleviating pain symptoms, including back pain, neck pain, joint pain and other musculoskeletal conditions (Ong *et al.* 2004).

Chiropractors and osteopaths rely upon few resources, other than their own skills, for the treatment of patients. The primary piece of equipment for both is a treatment table that can vary in design according to need, but is commonly constructed from a welded steel base with a polyurethane foam topping. The main ongoing environmental impacts arise from energy consumption for travel (practitioners and patients) and from premises used for business.

Ecological degradation

The primary contribution to ecological degradation from the delivery of chiropractic and osteopathy arises from the manufacture of treatment tables, and the associated consequences of steel and polyurethane production. Steel is an alloy of iron and other elements, primarily carbon, and it is widely used in construction because it has high tensile strength and a relatively low cost. Steel is the world's most widely used metals but steel making impacts on ecological degradation through the depletion of non-renewable resources, depletion of land resources and the depletion and acidification of water resources (Singh *et al.* 2007). The mining of any product has environmental impact through the erosion of land, the formation of sinkholes and contamination of soil, groundwater and surface water from the chemicals used in the mining processes, with the potential for a concomitant loss of biodiversity. Up to ninety-eight per cent of

mined iron ore is used in steel making and the majority of the world's iron ore presently comes from four countries; Australia, Brazil, China and India. Current forecasts indicate that known Australian and Brazilian iron ore reserves are likely to be exhausted by the years 2044 and 2050, respectively. The situation is not as clear for China and India, where new reserves are still being discovered, but so too are their population sizes and their reliance upon natural resources that are necessary for economic growth (Yellishetty and Mudd 2014). A further problem for the mining of iron ore is that the quality or grade of the ore declines as mining proceeds because the high grade ore tends to be mined first. Consequently, mining requires increasing levels of energy and water, and creates more waste as time proceeds (Mudd 2010).

As well as being the most widely used metal, steel is also the most widely recycled. Metal recycling helps to minimise the use of limited natural resources and it also directs waste away from landfill sites, thus reducing the potential for pollution. Most of the steel that is produced today is recycled, but there is still a small percentage reaching landfill. Over time, this amount will become more significant, suggesting a potential need to 'mine' landfill in the future (Yellishetty *et al.* 2011).

The contribution of polyurethane to ecological degradation stems mainly from its disposal as foam is normally disposed of via landfill. A switch to more natural fibre cushioning could mitigate this (Glew *et al.* 2012).

Climate change

Harmful greenhouse gasses are released during the production of both steel and polyurethane. It has been estimated that the amount of iron ore used to produce one tonne of steel contributes to an average of two tonnes of emissions. This is partially due to mining and transportation, but mostly arises from the smelting and refining processes (Yellishetty and Mudd 2014). The use of recycled products can greatly reduce carbon dioxide emissions, as the production of steel through this route consumes approximately one third of the energy that is needed for production from ore (Yellishetty *et al.* 2011).

Polyurethane can also contribute to greenhouse gas emissions at various points during its lifecycle. Fossil fuels provide an energy source during its production and the blowing

agents[47] required can act as potent greenhouse gasses. In recent years, this has been recognised as a problem and alternative blowing agents are being sought, while the most polluting agents (chlorofluorcarbons and hydrofluorocarbons) are being phased out.

Improper disposal or burning of polyurethane foam can release a number of dangerous toxins into the air. During fires, polyurethane foams burn rapidly and produce dense smoke, toxic gases and intense heat. Carbon monoxide is the most common gas produced, but the smoke also contains benzene, toluene, nitrogen oxides and hydrogen cyanide, all of which are damaging for the environment (Glew *et al.* 2012).

Aside from the equipment used by osteopaths and chiropractors, the running of premises and the travel needs of practitioners and patients all contribute to climate change through the gaseous emissions arising from energy production and the use of fuel. Chiropractic and osteopathy are both 'hands on' treatments, and treatment cannot take place remotely. Patients and practitioners must come together for the consultations. As with all forms of T&CM in the UK, practitioners work predominantly in private practice, often working alone. The relative number of osteopaths and chiropractors to the general population is very small when compared with the number of General Practitioners in the UK. As of July 2015, there were 64,923 registered General Practitioners in the UK (General Medical General Medical Council 2015), each responsible for between one and two thousand patients (GP 2014). In contrast, the combined number of osteopaths and chiropractors is around 7,500 and many people have to travel some distance for treatment, because practitioners are not evenly distributed across the country.

Peak oil

Transportation involved in the production and delivery of steel and polyurethane, and the travel of patients and practitioners, all rely upon crude oil based fuels. In addition, polyurethane foam has traditionally been made from the combination of two types of liquid chemicals, isocyanates and a polyol, and both are derived from crude oil distillation. However, increasing amounts of polyurethane are now being produced

[47] Blowing agents use a foaming process to create a cellular structure in the foam.

from renewable resources, such as lignin (Xue *et al.* 2015), castor seed oil (Imasuen *et al.* 2014) and biodiesel-derived glycerol (Hu *et al.* 2015).

In summary, the main piece of equipment used by osteopaths and chiropractors, the treatment table, is associated with damaging environmental impacts, but these have the potential to be mitigated to a large extent. Through the use of recycled steel and the proper disposal of tables to recycling, rather than to landfill, the effects on ecological degradation and climate change from the use of steel can be minimised.

The production of polyurethanes from renewable resources would serve to minimise the contribution to peak oil, but would not address the problem of potentially damaging effects from emissions during disposal (Hu *et al.* 2003). A better solution would be to seek an alternative natural fibre to use in place of polyurethane foam (Glew *et al.* 2012).

It should also be noted that treatment tables have a long life span enabling their use for thousands of patients. Whilst the production of treatment tables bears an environmental cost, the costs of seeking a different treatment may be even higher. Osteopathy and chiropractic treatments could potentially reduce the need for pharmaceutical drugs, hospital stays and surgical interventions (Erwin *et al.* 2013, Meeker *et al.* 2014). As one osteopath opines: 'one of the things I love about osteopathy is the principle that the body 'has its own medicine chest'…I feel there are still many conditions that can be helped and even cured by …'hands on' gentle readjustment of soft tissues and joints, which is about as carbon-neutral as it gets!' (Hunter 2015).

Undeniably, however, environmental damage also accrues from the running of premises and the transport of practitioners and patients. This is a challenge for all types of T&CM in the UK, especially in cases where practitioners are sparsely located, often working alone. The most obvious solution to this challenge would be to locate practitioners within existing or newly designed community health centres. Locating a range of practitioners and health services in the same premises would help to minimise environmental damage, as patients would not have to make separate journeys for each separate service. If treatment centres were additionally eco-efficient and well placed, with good links for public transport, this would offer a best-case scenario from the perspective of the environment. However, this would require a major shift in attitudes

about healthcare, T&CM and the environment; the location of practitioners of T&CM is not currently driven by what is best for human health or consideration of environmental wellbeing.

6.2.2 Acupuncture

In the UK there are two distinct types of acupuncture that are available: Traditional and Western Medical practices. The practice of Traditional acupuncture is predicated upon the philosophical principles of Traditional Chinese Medicine with the concept that *Chi* (life force) circulates through *meridians* (channels) in the body, and can be accessed at certain points (acupoints) through the incision of acupuncture needles. In contrast, Western Medical acupuncture is embedded within a conventional medical understanding of the body and is practised only by conventional medical practitioners, such as doctors, physiotherapists and nurses, who also use needling methods as an adjunct to their professional practice (British Acupuncture Council 2015).

The British Acupuncture Council is the largest self-regulatory body for the practice of Traditional acupuncture in the UK with around 3000 members (British Acupuncture Council 2015). Practitioners of Western Medical acupuncture are overseen by the British Medical Acupuncture Society, and there are currently around 2000 registered doctors and allied health professionals who practise acupuncture alongside more conventional techniques (British Medical Acupucture Society 2015).

In common with chiropractors and osteopaths, most Traditional acupuncturists are self-employed and working in private practice. Consequently, their practices will be subject to the same ongoing environmental concerns arising from the use of premises and travel. Also in common, most acupuncturists work with treatment tables, but the bases of their treatment tables can be manufactured from materials other than steel, such as aluminium or wood. The primary difference in equipment stems from the use of acupuncture needles in treatment. Acupuncture treatment (Traditional and Western Medical) involves the insertion of ultra-fine, sterile, disposable needles into selected acupuncture points on the body. It is estimated that over four billion acupuncture needles are used globally each year, with an annual increase of five to ten per cent per year (China National Institute of Standardization 2014). Single use, disposable acupuncture needles were introduced in the UK following concerns about the potential

for infection and transmission of agents between patients, and the British Acupuncture Council stipulates that only single use, pre-sterilised, disposable needles can be used in practice (British Acupuncture Council 2010). Needles are either individually packaged or packaged in small numbers (commonly five or ten) intended for use on one patient. Multipacks of five, ten or more needles must not be used or stored for use after each session. There are many different types of acupuncture needles, but they normally have a stainless steel needle with a handle made from copper, plastic or steel. Some come with a plastic tube as a guide for insertion (Journal of Chinese Medicine 2014). In addition, Traditional acupuncturists may also use moxabustion[48], cupping therapy[49] or other forms of physical stimulation such as massage.

The following analysis of the impacts of acupuncture upon ecological degradation, climate change and peak oil will detail only those aspects that differ from osteopathy and chiropractic.

Ecological degradation

The primary contributions to ecological degradation from acupuncture stem from the use of treatment tables and acupuncture needles. Both can produce potentially harmful effects at different stages of their life cycles. Many acupuncturists use treatment tables with a base made from aluminium, a metal that is lighter and more portable than steel.

The main source of aluminium is bauxite, a naturally occurring mineral that is surface mined in many different countries around the world, the most significant of which are Australia, China, India, Brazil and Russia. Alumina (aluminium oxide) is extracted from the bauxite and transformed into aluminium through electrolytic reduction. Aluminum is a versatile metal and has become the world's second most commonly used metal, after steel. Over the past fifteen years, the world's output of both bauxite and alumina has almost doubled. In 2014, two hundred and thirty-four million megatonnes

[48] Moxabustion involves the burning of moxa, a dried herb, *Artemisia vulgaris*, which is a very common plant that grows like a weed on uncultivated areas, such as waste places and roadsides. Its use poses no current concerns for the environment.

[49] Cupping is the term applied to a technique that uses small glass cups or bamboo jars as suction devices that are placed on the skin to draw the blood flow towards the surface.

of bauxite were produced globally, from which 108.4 million megatonnes of alumina were refined (Walker 2015). The processes involved in the production cause significant environmental degradation and use a substantial amount of fossil fuels (World Aluminium 2015). Aluminium production is an energy intensive process (Walker 2015), with the largest percentage of electricity (more than ninety-five per cent) used in the electrolysis process. Electricity production contributes between twenty-five and eighty per cent of the total environmental impact of aluminium production, with the highest values associated with coal based electricity production, which is most prolific in China.

Aluminum is one hundred per cent recyclable (Ioana and Semenescu 2013) and the recycling of aluminum requires only five per cent of the energy to produce recycled metal as compared to production from raw materials. In addition, recycling eliminates waste, saves energy, conserves natural resources and reduces the use of landfills (World Aluminium 2015). As well as reducing harmful environmental impact, increased levels of recycling will extend the life of the world's bauxite reserves considerably.

Most of the acupuncture needles used in the world are manufactured in China and the vast majority of these have copper coil handles. According to Zhang *et al.* (2014), a conservative estimate is that around one hundred tonnes of copper coil is used in the production of acupuncture needles each year. As with the production of steel and aluminium, copper production is not an environmentally benign activity. During the stages of mining, processing and refining, copper production has significant adverse impacts on air quality, surface and groundwater quality, and the land around the mining and production sites (Northey *et al.* 2013). One advantage of using copper is that it can, in theory, be recycled indefinitely and copper's recycling value is so great that premium-grade scrap normally has a minimum of ninety-five per cent of the value of the primary metal from newly mined ore. However, it is unlikely that the copper used in acupuncture needles is produced from recycled sources, as most copper wire production uses newly refined copper (Copper Development Association 2015).

The disposal of acupuncture needles can also contribute to ecological degradation as the copper and steel materials used in acupuncture needles are rarely recycled. As with all needles used in healthcare, once they have been contaminated through use, they pose

a health risk and must be disposed of in specially designed sharps disposal containers immediately after use (Zhang *et al.* 2014). These containers are dealt with in accordance with local environmental health department guidelines (British Acupuncture Council 2010). According to the Environment Agency (2011), used acupuncture needles are considered 'bio hazardous waste' and should be either incinerated or steam treated in autoclaves, followed by maceration and removal to landfill. Either way, the metals used in the production of acupuncture needles are not normally destined for recycling and are completely lost as a resource.

Aside from the environmental costs associated with the acupuncture needles themselves, there are also problems associated with the use of plastic for tube guides and the packaging of the needles. Most plastics are petroleum based. They are cost-effective, versatile, lightweight and an ideal material for many disposable applications. Over 300 million metric tons of plastics are produced in the world annually and about fifty per cent of this volume is used for disposable applications; products that are discarded within a year of their purchase (Halden 2010). The disposal of plastics is a major cause of ecological degradation. The utility of plastic in contemporary society is undeniable but the perceived benefit of single use, throw away products and packaging is accompanied by persistent waste as plastics degrade extremely slowly. Disposal of plastics in landfills diminishes land resources (North and Halden 2013) and a significant amount of disposable items, such as plastic bags, bypass legitimate disposal and enter the environment, resulting in widespread, long-term pollution. Plastics pollute natural habitats creating problems for wildlife from ingestion or entanglement in plastic, the leaching of chemicals from plastic products and the potential for plastics to transfer chemicals (Thompson *et al.* 2009). This is not just a threat to the land: plastic pollution is now ubiquitous in aquatic environments, posing a major threat to aquatic life (Eriksen 2014).

In theory, the recycling of plastics represents a plausible solution to many of these problems but, in practice, there are numerous logistical challenges, including the lack of effective sorting techniques, since the mixing of different plastic source materials has a significant impact upon the quality of the resultant recycled materials. Increasing the use of biodegradable plastics could also help to reduce impacts upon ecological

degradation; however, it can do so sustainably only if these alternatives are made from non-fossil resources using renewable energy (North and Halden 2013).

Climate change

Harmful greenhouse gasses are released during the production of aluminium, copper and plastics.

In the production of aluminium, the largest greenhouse gas contributions are attributed to alumina refining and electrolysis unit processes. Electricity production for electrolysis is the largest contributor (fifty-six per cent of the total) with thermal energy production for direct use in alumina refining contributing thirteen per cent of the greenhouse gases (Norgate *et al.* 2007). Apart from emissions relating to energy production, other significant influences (fourteen per cent of greenhouse gases) result from direct emissions produced by the electrolysis process, during which several perfluorocarbons, a group of potent greenhouse gases with long atmospheric lifetimes, are released (United Company RUSAL ND).

The aluminium industry is taking steps to reduce associated harmful emissions. The quantity of carbon dioxide produced by the industry depends in large part on the type of energy used to fuel the process of electrolysis, and electrolysis can be fuelled using electricity from non-fossil fuel sources. For example, in Canada, Brazil, Norway, and Venezuela, the primary source of power is hydroelectricity, rather than fossil fuels. In addition to consideration of power source, recycling is a key strategy for minimizing the harmful effects of aluminium production on the environment. The recycling of aluminum requires only five per cent of the energy to produce recycled metal and generates only five per cent of the greenhouse gas emissions (Ioana and Semenescu 2013).

A recent study of copper mining shows that mining, milling and smelting are the processes responsible for the majority of the copper mining carbon footprint (Memary *et al.* 2012). The greenhouse gas emissions from these stages of copper processing are each dependent on the source of energy used in that stage: diesel and electricity are used in mining stage; coking coal and natural gas are the main energy source in smelting, and electricity is the main energy source used in refining (Mudd *et al.* 2012).

As with aluminium, the carbon footprint of the electricity used in the process depends on the power for source of electricity generation, which could be coal, diesel, natural gas, hydro or other renewables (Northey *et al.* 2013).

Whilst the recycling of copper is cost-effective and more energy efficient, with much less of an impact upon climate change, this is not relevant to the production of acupuncture needles, since they are neither made from recycled copper and nor are they recycled themselves.

The production of new plastics is energy intensive. It has been estimated that the production of one kilogram of plastics from crude oil requires between 62 and 108 megajoules of energy, compared with 20-25 megajoules for iron (from iron ore); 18-35 megajoules for glass (from sand) and 20-50 megajoules for steel (De Decker 2013). The resulting carbon footprint for plastic is around six kilograms of carbon dioxide per kilogram produced (Rohrer 2011). Additionally, disposal through incineration results in the release of high levels of carbon dioxide and other greenhouse gases (North and Halden 2013).

Peak oil

Transportation involved in the production and delivery of all materials used in acupuncture practice, including steel, copper, aluminium and plastics, and the travel of patients and practitioners, all rely upon crude oil based fuels. Of particular concern is that the current production of plastics from crude oil is not sustainable. Currently, around four per cent of the world's oil is used as the raw material for plastic production each year, and a similar amount is used to provide the energy needed for plastic production (Thompson *et al.* 2009). Given the declining reserves of oil (and other fossil fuels), its use for the manufacture of non-recyclable goods is not sustainable. There is pressing need to increase the recycling capacity of products and develop suitable plastics (or plastic alternatives) from renewable sources (Sabaliauskaitė and Kliaugaitė 2014).

In summary, the treatment tables and acupuncture needles used by acupuncturists are associated with damaging environmental impacts, some of which can be mitigated. Through the use of recycled aluminium and the proper disposal of tables to recycling

rather than landfill, the effects on ecological degradation and climate change from the use of aluminium can be minimised.

The production and disposal of acupuncture needles is a more challenging concern. The current requirement for sterile and single use needles has implications for the consumption of natural resources (steel, copper and oil), the production of greenhouse gases and pollution of the environment arising from disposal. The lack of recycling of used acupuncture needles results in a permanent loss of these materials as a resource; this practice is a problem for the future sustainability of acupuncture and will require addressing.

6.2.3 Homeopathy

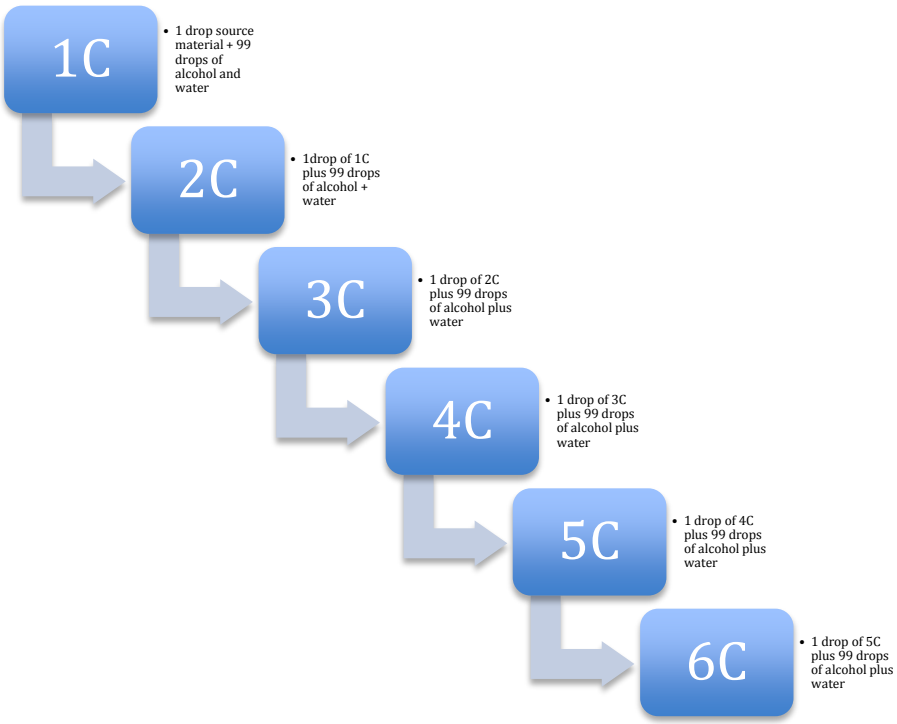
There is no legal requirement for homeopaths in the UK to be registered with a professional organisation, and hence it is not possible to determine the exact number of practitioners. However, there are currently around 3,000 homeopaths who are registered with one of four homeopathy associations (Norland and Parkinson 2015). Three of these associations, the Society of Homeopaths, the Alliance of Registered Homeopaths and the Homeopathic Medical Association are voluntary registering bodies for professional homeopaths. The fourth, the Faculty of Homeopathy, is a membership body for statutorily regulated doctors, nurses, midwives, dentists, pharmacists, podiatrists, osteopaths, chiropractors and veterinarians who incorporate homeopathy into their day to day professional practices. Some of these doctors and nurses work within National Health Service clinics or at one of the homeopathic hospitals in the UK in Bristol, Glasgow, Liverpool and London (British Homeopathic Association 2015). The majority of homeopaths in the UK work in private practice, commonly on their own (Chatfield and Duxbury 2010) and hence their practices will be subject to the same environmental concerns relating to the use of premises and travel as apply to other forms of T&CM. Within consultations, homeopaths seek to determine which homeopathic medication(s) most closely mirror the symptoms of the patient and small doses of that medication will then be prescribed. Homeopathic medications can, in theory, be made from anything, but are most commonly derived from plants and minerals. A smaller number are made from animal products (Castro 2003). There are

two principles in homeopathic philosophy that are directly relevant to the environmental impact of homeopathic medications.

Firstly, homeopaths believe that medications can be made more potent, and cause fewer side effects, when they are prepared in a special way through serial dilution and succussion[50] of the source product in water and/or alcohol. Secondly, homeopaths work with the principle of the 'minimum dose'; the notion that medications should be given in the smallest possible dose needed to stimulate the healing response of the body. Sometimes this can be as little as one or two tablets (Vithoulkas 1980).

The ratio of solute to solvent per dilution, and the number of dilutions undertaken, is indicated in the 'potency' of the medication. For example, a 6C potency, where the letter 'C' is derived from the Roman numeral for 100, denotes that the ratio of solute to solvent for each dilution was 1:100 and the '6' tells us that this was repeated six times as illustrated in figure

Figure 9: The serial dilution process for a homeopathic potency of 6C.



Succussion of the solution takes place between each step

[50] Vigorous shaking that takes place between each dilution.

For a 6C potency, the source product or 'mother tincture' is diluted: 1/100 X 100 X 100 X 100 X 100 X 100 which is equal to 1 part in 100,000,000,000. A potency of 6C is considered as low by homeopaths (Jütte and Riley 2005) and many use much higher potencies with a greater number of dilutions, such as 30C (30 dilutions), 200C (200 dilutions) or 1M (1000 dilutions). Once the dilutions and succussions have been undertaken, the resulting liquid is termed a 'medicating potency' and it can be stored indefinitely in dark glass bottles without refrigeration, but away from sunlight and strong smells. A few drops of the medicating potency can be used to medicate a whole bottle of inert tablets (normally made from lactose or sucrose) or it can be added to water to make a homeopathic medication (Close 2009).

Because of the way in which homeopathic medicines are made and prescribed, only tiny amounts of source materials are required for the supply of hundreds or even thousands of practitioners (Morgan 2014). Similarly, the amount of lactose or sucrose that is used is also very small, sometimes as little as one or two tiny pills per patient. Hence, collection and use of the source materials, and the use of sucrose or lactose tablets, have minimal environmental impact. The other main materials used by the homeopath, namely glass bottles and alcohol (ethanol), each have a degree of environmental impact, and are considered below.

Ecological degradation

There are many different types of glass, but the type most commonly used for the production of bottles and jars is composed of three main components; silica sand, soda ash and limestone. The use of glass bottles leads to a number of detrimental environmental impacts from transportation of the raw materials, production of the glass containers, transportation to the pharmacy, transportation of the filled bottles to the consumer, transportation of the empty bottles for disposal or recycling and recycling of the bottles. Glass manufacturing is among the most energy-intensive of industries (United States Energy Information 2013). The production stage of the glass bottle has the highest environmental impact because very high temperature furnaces (up to 1,200 degrees centigrade) are used and have very high energy requirements for the melting of raw materials to form glass. Road transport has the second highest effect and is higher than for other types of containers or packaging because of the relative weight of the glass (Banar and Cokaygil 2008). In addition, there can be localised environmental

degradation around glassworks arising from fresh water use, water pollution and dust (Gander 2008).

On the positive side, glass is totally recyclable and can be recycled an infinite number of times without loss of quality (Gander 2008, Blengini *et al.* 2012). The use of recycling avoids landfill disposal and, for a glass manufacturer, the use of cullet (recycled glass) is extremely beneficial. Aside from savings in virgin raw material consumption, around three per cent in energy savings can be achieved for every ten per cent of cullet that replaces these raw materials, because no 'reaction energy' is needed to melt cullet (British Glass 2013).

The ethanol used in homeopathic medications is produced through the fermentation of natural sugars with yeast. A synthetic form of ethanol can be produced from petrochemicals but this is never used for human consumption. Most of the world's bioethanol is produced from crops such as sugar cane, sugar beet, corn, rice and maize, and vegetable waste is commonly used in animal feeds. In the UK, there was no bioethanol production prior to 2007, but there are now several industrial sites producing ethanol from sugar beet and wheat (Alberici and Toop 2013). Still, much of the ethanol used in the UK is imported from Europe or the US where the primary source material is corn (Hofstrand 2009a).

Changes in land use, where crops are grown for ethanol production, can cause substantial ecological degradation through an increase in tillage[51] intensity, use of fertilizers and pesticides, depletion of soil minerals, water-induced soil erosion and greenhouse gas emissions (Larson *et al.* 2010).

Much of the electricity used in the production of ethanol comes from fossil fuels, with only a small portion coming from renewable sources such as wind (Hofstrand 2009b). Recent advances in biotechnology have led to the development of a process to produce ethanol from waste biomass using bacteria. In this process, genetically engineered strains of *Escherichia coli* are used to convert plant sugars into ethanol. This allows ethanol to be produced from waste, while the main crop can be grown as a food source.

[51] *Tillage* is the agricultural preparation of soil by mechanical agitation of various types.

The use of waste to produce ethanol may also help with disposal and reduce the practice of burning crop residues (Larson *et al.* 2010).

Climate change

The major contributors to climate change arising from the production of glass are the carbon dioxide emissions that result from the combustion of the fuels used to fire the furnaces and from associated road transport (Nilsson *et al.* 2011). In addition, carbon dioxide is also produced by the decomposition of raw materials during the melting. This is the only greenhouse gas emitted during the production of glass (AGC Glass Europe 2012).

Recycling can reduce these carbon dioxide emissions, just as the use of cullet decreases the energy required in production and the amount of carbon dioxide released during melting (British Glass 2013).

The production of bioethanol is a source of greenhouse gasses at various different points along the life cycle. Carbon dioxide emissions result from the combustion of fossil fuels on the farm that are directly related to crop production. Off the farm carbon dioxide emissions are released through the use of fossil fuels for the manufacturing and transportation of inputs such as fertilizers, pesticides and seeds (Larson *et al.* 2010). Crop production also results in a substantial amount of nitrous oxide, a powerful greenhouse gas, estimated to be 289 times as powerful as carbon dioxide. The large increase in the use of nitrogen fertilizer for producing high nitrogen consuming crops like corn has increased nitrous oxide emissions (Hofstrand 2009a). In addition, the manufacture of fertilizer and lime is also a large source of nitrous oxide emissions (Hofstrand 2009b). A switch to renewable sources of energy and a reduction in the reliance upon nitrogen fertilizers are needed to reduce the impact that ethanol production has upon climate change.

Peak oil

The transportation needed for the production and delivery of all materials used in homeopathy practice, as well as the travel of patients and practitioners, all rely upon crude oil based fuels.

In summary, the environmental impact of homeopathic medications stems primarily from the use of ethanol in production, the glass bottles used for storage and the associated transport requirements. These can be minimised through the production of ethanol from waste biomass, powered by renewable sources of energy, and the efficient recycling of glass.

The impacts associated with running premises and the travel of practitioners and patients could, in theory, be minimised with increased use of remote consultations. Homeopathy is not a hands-on treatment and many practitioners are already offering consultations online (Treuherz 2015). This is especially helpful in remote areas where people may otherwise have to travel long distances for treatment.

6.2.4 Herbal medicine

In common with homeopathy, there are no legal requirements for practitioners of herbal medicine to be registered with a professional body; there is only a process of voluntary self-regulation, meaning that anyone can call himself or herself a herbalist. Consequently, it is not possible to establish the exact number of working as medical herbalists in the UK, but there are around 640 practitioners registered with the leading professional body, the National Institute of Medical Herbalists (2015a). Most medical herbalists work in private practice. Unlike homeopaths, medical herbalists sometimes undertake a physical examination of their patients and hence face-to-face consultations are the norm. Herbal treatments are derived from plants and may be prescribed in many different forms. Most prescribed herbal medicines are administered in the form of a liquid tincture, but patients may also be given herbal tea, tablets, ointments, creams or lotions (Casey *et al.* 2007). Ethanol is commonly used for the extraction and preservation of herbal products to form tinctures and the tinctures are typically stored in brown glass bottles. Hence, some of the environmental impacts arising from the production of herbal tinctures are similar to those for homeopathic medications, but the quantities of glass and alcohol needed for herbal medications are much larger. Whereas homeopathic medications are highly diluted and prescribed in tiny amounts, herbal tinctures are often prescribed in amounts of five to ten millilitres of tincture, twice per day (National Institute of Medical Herbalists 2015b). Over-the-counter herbal products are most often sold in the form of tablets or capsules in plastic containers (De Bolle *et*

al. 2008). Aside from the environmental impacts of ethanol, glass and plastic production, the wide scale use of plants in medicine also has a direct impact upon the environment, as some plant species are in great demand. The environmental impacts of T&CM that were revealed in the construction of the ethical matrix related exclusively mostly to the practice of herbal medicine, suggesting that these impacts are greater and/or more obvious than for other forms of T&CM.

Ecological degradation

Many plants used for medicinal purposes are under threat of extinction as a result of the demand for herbal products (Bodeker *et al.* 2014), and the primary causes of this loss of medicinal plant biodiversity are the destruction and over-collection of plants in their natural habitats (McKenzie *et al.* 2009). Harvesting without replacement planting, deforestation and the increased marketing of medicinal plants have resulted in the decline and near-extinction of many valuable medicinal plant species around the world (Dahlberg and Trygger 2009). Most medicinal plants are collected from the wild in an uncontrolled manner, and cultivated plants are often considered inferior to their counterparts (Ncube et al. 2012). Botanic Gardens Conservation International, a plant conservation charity based in Kew Gardens, London, estimates that about twenty one per cent of the total number of medicinal plants species (approximately 70,000) may be threatened (Hawkins 2008). In the United States, the origin of many well known medicinal plants, a significant number have been overcollected almost to the point of extinction in their natural habitats, including the pacific yew, ginseng, goldenseal, black cohosh, and echinacea (McKenzie *et al.* 2009).

The high demand for some products can motivate producers to engage in mass production without regard for the environmental consequences or for the finer details of plant cultivation (van Andel and Havinga 2008). Both the large-scale cultivation and the wild harvest of medicinal plants can lead to loss of genetic diversity within that species. A diverse gene pool contributes to the ability of species to maintain resistance to diseases and to adapt to a changing climate, but intense cultivation from a limited stock can lead to monocultures which are especially susceptible to plant diseases and pests, especially when grown in high densities (Hawkins 2008).

The environmental impacts of herb production differ greatly between species in accordance with demand, availability and their growing requirements. For instance, the bulk of Echinacea, currently the most popular herbal remedy in the United States and UK, is derived from two different Echinacea species, each with distinct growing requirements. Both *Echinacea angustifolia* and *Echinacea purpurea* species grow wild only in North America and there is a great demand for wild-harvested plant material, especially roots of *E. angustifolia*. Whilst *E. purpurea* is relatively easy to cultivate, *E. angustifolia* is difficult to grow due to its greater susceptibility to fungal diseases, and the plant requires two to three years growth before it is harvestable. The lag time between demand and harvest can create unanticipated surpluses, or unpredictable prices and hence *E. angustifolia* is primarily obtained through wild harvesting (Kindscher *et al.* 2008). Traditionally, many Native American tribes used the roots of *E. angustifolia*, but the quantities involved were relatively small. As the popularity of Echinacea products increases, so do concerns that unregulated harvesting will decimate wild populations (Kindscher 2006). When the price of wild Echinacea roots is high, harvesters can decimate supplies in a relatively short amount of time (Kindscher *et al.* 2008) and Echinacea harvesting has been likened to a 'gold rush' scenario (Crawford 1999).

On the other hand, many plants are awarded value because of their role in T&CM (Timmermans 2003) and direct local use contributes to the preservation of species and habitats (Brown 1992). Wild harvest gives an economic value to ecosystems and habitats and thus provides an incentive for protection. The involvement of local people in sustainable management practices increases both their desire and their ability to protect wild populations from over-exploitation (McKenzie *et al.* 2009).

Climate change

The growing and harvesting, processing and packaging, and transport of herbs are all energy intensive; the carbon footprint associated with production and transport contributes to climate change that in turn may lead to the extinction of species, reduction in their availability and also reduction in the quality of the resultant products (Rastogi and Kaphle 2011).

Many herbs are harvested from diverse geographic locations and the transport requirements from source to market may be very significant, including transport from source to raw material wholesalers, to manufacturers for processing, to wholesale warehouses and finally to practitioners, clinics and retail outlets (McElroy 2011). Similarly, the processing of herbs may have many different requirements depending upon the final product, including drying, milling, encapsulating, pressing and percolation (*ibid*.), each of which has requires energy that is usually derived by fossil fuels.

Peak oil

The transportation needed for the production and delivery of all materials used in herbal medicine, as well as the travel of patients and practitioners, all rely upon crude oil based fuels. In particular, the packaging of herbs is oil intensive. Plastics are extensively used for storing and packaging of bulk herb material and also for the final packaging retail products (McElroy 2011).

In summary, the environmental impacts of herbal medicine can be damaging in a number of ways. Aside from those impacts arising from associated materials, such as glass, ethanol and plastics, the energy requirements for production and transport of the herbs themselves are also high. The harvesting of medicinal plants, especially those in high demand, can lead to the degradation of land and the loss of biodiversity (Rastogi and Kaphle 2011). There are concerns that many herbal products in use now may not be available in the future and that others may become scarcer and more costly. A growing demand for standardised herbal products is putting pressure on selected high demand species (Sustainable Development Unit 2014). Additionally, if oil prices rise, this will lead to the decreased availability of herbs from overseas and increased costs of transport and packaging (McElroy 2011).

The environmental costs associated with herbal medicine are recognised by many in the field (Hawkins 2008, Kindscher *et al.* 2008, McKenzie *et al.* 2009, McElroy 2011). Many potential solutions have been proposed and some action is already being taken. For example, Botanic Gardens Conservation International has conservation projects all over the world. They believe that botanic gardens are the most important agencies for the conservation of native medicinal plants, since plants are not often the priority of

other conservation bodies, especially those of undetermined economic use (Hawkins 2008).

Through consultation, Botanic Gardens Conservational International have identified that a multi-method approach to conservation is needed including the following key factors:

1. Research

   It is essential to collect accurate data regarding plant population density in the wild, the current commercial demand and future projections, methods of collection and threats to these plants.

2. Education

   The benefits that could be attained through better management of ecosystems must be clearly demonstrated in different ways.

3. Collaboration

   Botanic gardens are well placed to facilitate collaboration and add both botanical knowledge and knowledge about local people, industries and landscapes.

4. Conservation

   Plant and seed collections must be maintained as a conservation resource.

5. Preservation of indigenous knowledge

   Reduction in biodiversity is accompanied by a cultural diversity crisis and concomitant loss of indigenous knowledge. Botanic gardens are able to collect, maintain and promote indigenous knowledge.

6. Development of alternatives to wild harvesting practices

   Offering of training initiatives to provide communities with valuable horticultural expertise and market information.

7. Ensuring sustainable wild harvests

   Wild collection is sustainable as long as the amount of medicinal plant material of a given species collected each year in a certain region does not exceed the annual, natural increase of the species in the same location.

   (Hawkins 2008).

In addition, there are areas where the herbal medicine industry could take more responsibility for their ecological footprint, such as the use of recyclable packaging materials and increasing the use of locally sourced supplies. For example, in the UK, Rutland Biodynamics, a producer of organic herbal products, aims for complete for traceability and sustainability. To this end they conduct a total audit of the environmental impact of all activities, from raw materials (land, seeds and packaging) through to composting and drainage (Rutland Biodynamics 2015). They take proactive measures to offset their contributions to environmental damage, such as ensuring that everything they send out is recyclable, and the planting of thousands of new trees. It is now estimated that their activities absorb more greenhouse gases than are generated (*ibid.).*

The environmental impacts of herbal medicine may be extensive in some respects but it appears that measures can be taken to mitigate these successfully. Given that a large percentage of the global population rely upon herbal medicines for their primary healthcare it is essential that this is addressed for the sake of humans as well as for the wellbeing of the environment.

6.3 Future-proofing T&CM

Health expenditure in the UK and in all other high income countries around the world has been growing unchecked for decades (Britton 2011) and, until recently, without consideration for the effects that services have upon the natural environment. Now that the environmental impacts of the healthcare system and the potential health co-benefits of minimising these impacts are recognised, plans are being put in place to try and address this growing problem. A Sustainable Development Strategy for the Health, Public Health and Social Care System 2014-2020 was launched in the UK in January 2014, and it describes a vision for a sustainable health and care system that can be achieved by reducing carbon emissions, protecting natural resources, preparing communities for extreme weather events and promoting healthy lifestyles and environments (Sustainable Develeopment Unit 2014). Developing a more environmentally sustainable approach to health and social care will require substantial changes at a number of levels, and the scale of the environmental challenge means that a fundamental transformation in service may be necessary (Naylor and Appleby 2013).

The majority of National Health Service organisations now have strategies for environmental sustainability, but tangible action appears to be slow and inconsistent. The slow pace of change has been associated with various challenges such as: a lack of leadership and ownership of sustainable development principles at senior levels; resistance to change among front line social care staff, and a financial climate that precludes the up-front investment that some sustainability initiatives require (Evans *et al.* 2012).

In the light of the immense challenges that face the current and future provision of healthcare and the urgent need to reduce the environmental fallout, the issue of whether T&CM can contribute to a more environmentally friendly healthcare system is worthy of consideration. According to the WHO, the predominance of curative, hospital-based, disease-oriented services are 'top-heavy' and responsible for huge inefficiencies that could be redirected towards achieving universal health coverage (World Health Organization 2013). The current provision of conventional medicine is undoubtedly vastly more damaging than the provision of T&CM in terms of energy use, reliance upon oil and pollution of the environment, but direct comparison is not feasible for all services. For example, there is no form of T&CM that could serve as an alternative to the intensive care treatment required for those who have suffered traumatic injuries. However, there are some potentially comparable areas. For instance, the environmental impacts of osteopathic and chiropractic approaches to the treatment of musculoskeletal problems can be directly compared with a conventional approach. So too for many other conditions that are treated with T&CM, including both acute and chronic conditions. Additionally, it is broadly agreed that prevention must be at the core of sustainable health care; the most sustainable approach being one that minimises care needs by preventing ill-health and supporting people to manage their own health as effectively as they can (Naylor and Appleby 2013). Here, there is obvious congruence with the underlying philosophies of many forms of T&CM, as well as with the notion that health is rooted in the ability to adapt and respond.

It is a fundamental precept of most forms of T&CM that they work 'with nature' and, indeed, T&CM is often referred to as 'natural medicine'. However, this analysis has shown that all forms of T&CM are harming the environment to some extent; in particular, herbal medicine. There are steps that can be taken to minimise harm to the

environment whilst continuing to deliver T&CM treatments. Since human health is inextricably linked with the health of the environment, it is essential that all forms of health care are respectful of environmental wellbeing and actively take steps to mitigate any damage that is caused.

6.3.1 Recommendations for T&CM and the environment

The suggestions and recommendations made in this chapter, in relation to all five forms of T&CM, are numerous and detailed. Rather than repeat them all again, the overarching principles for minimising risk to the environment and, in turn, ensuring the sustainability of T&CM, are summarised in Table 10.

Table 10: Recommendations for minimising the risk of damage to the environment from T&CM

Risk of damage to the environment from T&CM can be minimised if:
• All products used in practice are assessed for their contribution to environmental degradation, climate change and peak oil, and replaced with more environmentally friendly options where possible • Multi-method conservation approaches are adopted and implemented globally to ensure the sustainability of plant sources • T&CM practitioners are more centrally located, in places that are easier for people to reach and less environmentally costly to run. • Opportunities for the use of telemedicine are explored.

CHAPTER SEVEN: ANIMALS AND T&CM

The top-down approach of the ethical matrix demands that I place myself in the 'shoes of others' as far as possible in order to appreciate the ethical issues from the perspectives of different stakeholders. Animals were identified as important stakeholders because many forms of T&CM are used in veterinary practice and hence carry the same potential for benefit and risk as for human users, such as the risk of infection and trauma from acupuncture, or the risk of toxicity from herbal medications. An additional concern, however, is that many T&CM products are derived from animal sources. Animals are clearly harmed in the manufacture of some T&CM products since a significant number are derived from whole, or parts of, animals, many of which are endangered species. A further cause of concern is the use of animals for research purposes in the production and testing of T&CM products, whereby animals can be exposed to stress, pain, artificially induced diseases and/or ultimately killed.

For the application of the ethical matrix Mepham asks us to consider the ethical dimensions of a particular issue in accordance with the three principles of wellbeing, autonomy and justice, and to consider issues from the perspectives of the identified stakeholders (Mepham 1995, Mepham 2000a). Mepham suggests that the principles of autonomy and justice should be applied to animals and, in so doing, he equates autonomy with 'behavioural freedom' and justice with 'respect for telos' (Mepham 1995). This interpretation of autonomy and justice is difficult to justify, as aforementioned in Chapter four, and there is considerable debate about whether or not these principles should even be applied to animals (Elliot 1984, Garner 2003, Lund and Forsberg 2009, Aerts *et al.* 2012).

Beauchamp and Childress define autonomous actions in terms of agents who act intentionally, with the benefit of understanding, and free from controlling influences that determine their actions (Beauchamp and Childress 2001); this definition would clearly need to be reconsidered or reinterpreted for its application in the case of animals. It has been suggested that respect for autonomy with respect to animals could be interpreted as 'respect for preferences' (Regan 1987), as preferences can be identified

in many animals, although their preferences are largely governed by their instincts and animal instinct doesn't normally count as self-legislation (Lund and Forsberg 2009).

Similarly, there is debate about whether or not the principle of justice can be straightforwardly applied to animals. Rawls himself argues against the inclusion of animals in justice debates by asserting that human conduct toward animals is not regulated by the principles of justice, since only 'moral persons' are 'entitled to equal justice' (Rawls 1972, p.504). However, a number of other political theorists believe that it is entirely appropriate and useful for animals to be a subject of the principle of justice (Garner 2003), and suggest there are no good reasons for disallowing the possibility that the individuals under the veil of ignorance turn out to be non-human animals (Elliot 1984).

Contentious debate about the applicability of the principles of autonomy and justice to non-human animals is enduring. Even between those who support such an application there is no clear agreement as to how the principles should be interpreted for non-human animals. Consequently, the inclusion of these principles in the analysis of ethical challenges for animals would be similarly contentious and open to broad-based criticism. Hence, for animals, a strictly consequentialist approach is adopted here. The attributes that Mepham equates with autonomy and justice, namely 'behavioural freedom' and 'respect for telos' can still be considered through this analysis but only insofar as they impact upon wellbeing. In so-doing, a significant strength of the cross-principle approach of Mepham's matrix may not be fully realised. However, this approach avoids the complications that may arise from debate concerning the application of autonomy and justice to animals, whilst still allowing for robust analysis of ethical issues associated with animals and T&CM[52].

Hence, this chapter will adopt this approach to explore the potential harms and benefits for animals arising from T&CM, and analyse potential impacts upon their wellbeing.

Consideration of the major harms to animals requires that I extend my perspective

[52] It is not inferred that this approach is superior to Mepham's cross-principle approach for non-human animals. It is simply less open to interpretation and less contentious.

beyond the UK since much of the harm to animals arising from their use in T&CM products, and in related research, occurs largely outside of the UK. In order to capture the primary threats to animal wellbeing, I must consider a broader range of T&CM practices than previously, and hence consideration of potential harms for animals will not be limited to the five types of T&CM identified in Chapter two. However, before I describe these harms, I first provide an overview of the ways in which T&CM is used for the benefit of animals in the UK.

7.1 Animal benefits from T&CM in the United Kingdom

In the UK, all five primary forms of T&CM examined in Chapter 2 are used, to some extent, in the treatment of animals. Only veterinary surgeons can use acupuncture, herbal medicine or homeopathy to treat animals, and they must retain their professional membership of the Royal College of Veterinary Surgeons in order to practise with these methods. It is illegal, in terms of the Veterinary Surgeons Act 1966, for non-veterinary surgeons, however qualified in the human field, to treat animals, and it is the responsibility of the veterinary surgeon to ensure that they are adequately trained in the application of those treatments that they offer (Royal College of Veterinary Surgeons 2015). It is, however, permitted for qualified osteopaths and chiropractors to practice on animals, provided that the animal has first been seen by a veterinary surgeon that has diagnosed the condition and decided that it should be treated by 'physiotherapy'[53] under his/her direction.

The main uses of each of the five types of T&CM in veterinary medicine are outlined below.

7.1.1 Acupuncture for animals

The Association of British Veterinary Acupuncturists was formed in 1987, and there are now several hundred registered members offering veterinary acupuncture to a

[53] 'Physiotherapy' is interpreted here as including all kinds of manipulative therapy. It therefore includes osteopathy and chiropractic but would not, for example, include acupuncture or aromatherapy.

variety of animal species for a range of conditions (Association of British Veterinary Accupuncturists 2015). According to the Association, acupuncture is mostly used to treat birds, cats, dogs, farm animals and horses. For example, in horses acupuncture can be used to treat neck and back pain, lameness, chronic obstructive pulmonary disorder, chronic gastrointestinal disease, post viral fatigue, paralysis, muscle spasm, behavioural problems (frequently associated with undiagnosed chronic pain) and infertility. In birds, it is used for behavioural problems (such as feather plucking and repetitive behaviour), chronic infections, reproductive problems and locomotor problems (such as paresis / 'wing droop', tendon injuries and wing/leg stiffness).

7.1.2 Herbal medicine for animals

The British Association of Veterinary Herbalists is much smaller by comparison, with only seventeen members currently listed (British Association of Veterinary Herbalists ND). However, there may be many more veterinarians using herbal medicines in practice since registration with the British Association of Veterinary Herbalists is entirely voluntary. According to one of their members, the treatment of dogs and cats makes up the bulk of their work, but they also treat horses, ponies, goats, donkeys, mules, cattle, pigs, sheep, llamas, alpacas, buffalo, rabbits, ferrets, guinea pigs, lizards, terrapins, tortoises, snakes, raptors and a range of other birds (Alternative Veterinary Medicine Centre 2007a). The list of complaints that they treat in these animals is extremely long, suggesting that herbal medicines are used to treat just about every health problem that they encounter.

7.1.3 Homeopathy for animals

The British Association of Homeopathic Veterinary Surgeons was formed in 1982, and lists forty-six practices around the UK that offer homeopathy for animals (British Association of Homeopathic Veterinary Surgeons ND). According to one of their members, all species and all types of animals respond well to homeopathy, and they treat all types of animals including cats, dogs, farm animals, horses, ponies, wild animals, buffalo, goats, birds, reptiles and fish. Homeopathy is used in animals for complaints ranging from mild acute diseases to long-term chronic conditions. It is popular with organic farmers who may choose to use it for their animals because it does not give rise to drug residues in meat, milk or eggs and it is also used with competition

horses and dogs without risk of contravening competition 'doping' rules (Alternative Veterinary Medicine Centre 2007b).

7.1.4 Osteopathy for animals

The Society for Osteopaths in Animal Practice (2015) has around sixty members in the UK, and these treat a range of animals including dogs, cats, horses, farm animals and some species of wildlife. According to the British College of Osteopathic Medicine (2015), the provision of osteopathic care for animals is a rapidly developing sector within osteopathy. The main complaints treated fall under the categories of minor joint strains, ligament sprains, osteoarthritis, development growth problems, post-surgery problems, neck and back problems, and lameness of mechanical origins.

7.1.5 Chiropractic for animals

The British Veterinary Chiropractic Association currently has around fifty registered members throughout the UK who mostly work with dogs and horses (British Veterinary Chiropractic Association ND). Chiropractic is used to treat a range of health and performance problems including musculoskeletal problems, tension or stiffness, and offer chiropractic as a prophylactic treatment to maintain fitness or to enhance the performance of animals for sport. It is also offered as a complementary treatment for chronic lameness or tendon problems in horses and for osteoarthritis and tendon problems in dogs.

Interest in the use of these types of T&CM for animals is increasing in the UK, as is evident from the development and growth of their relevant registering bodies. Just as some people choose to use T&CM for their own treatment, they also choose it for the treatment of their animals (Wynn and Fougere 2006, Ivemeyer *et al.* 2012, Merwe and Gehring 2012, Bergenstrahle and Nielsen 2015). The potential for benefit of T&CM use in the treatment of animals is largely unexplored; research in this field is still in its infancy. However, the growing interest in organic foods is to some extent driving an increase in uses of some forms of T&CM amongst livestock, particularly in dairy and egg production, and especially through the application of homeopathy (Kijlstra and Eijck 2007, Ruegg 2009).

Whilst animals may benefit from use of these T&CM treatments, they will be subject to the same concerns that were identified for humans in Chapter five (adverse drug reactions and adverse events). However, I will not be entering into an analysis of these issues in this chapter, as there are far more serious issues relating to the wellbeing of animals from their use in T&CM products and research. My analysis of these concerns begins with an overview of the role and use of animals in conventional medicine in order to provide background context and to explain the guiding principles and regulations that have bearing upon such usage in the field of medicine.

7.2 The Role of Animals in Conventional Medicine

Many conventional medications either contain animal products or are derived from animal sources. In their 'Guidelines for the use of medicines/pharmaceuticals of animal origin', the Queensland Department of Health (2013) list pharmaceutical products known to be of animal origin. These include fifteen drugs derived from pigs, fifteen from cows, ten from mice, ten from chicken eggs, thirty-six from Chinese hamster ovary cells, thirteen from horses and a further twenty from a range of other sources, such as chondroitin that is derived from bovine or shark cartilage and Digibind that is derived from sheep. Production of some of these drugs involves the killing of animals. For example, heparin, an injectable anticoagulant, is derived from the tissues of slaughtered animals, mainly pigs. Attempts have been made to produce heparin synthetically but, as yet, this approach does not offer a viable alternative approach to produce a drug that is in high worldwide demand (Pavão and Mourão 2012).

Many of the drugs that are derived from animal products do not involve the slaughtering of animals, such as herceptin. Herceptin inhibits the proliferation of human tumor cells under certain conditions and is commonly used in the treatment of patients with metastatic breast cancer. This drug is produced by a cell line[54] that is derived from the ovaries of a Chinese Hamster. These cells are the most commonly used mammalian sources for the industrial production of therapeutic proteins (Omasa *et al.* 2010).

[54] A cell line is a population of cells descended from a single cell and containing the same genetic makeup. The cells are reproduced in the laboratory.

One particular pharmaceutical drug of animal origin has received a considerable amount of criticism and is the subject of ongoing debate. The derivation of its name, Premarin, stems from its source in 'pregnant mares urine', and is manufactured from conjugated oestrogens obtained from the urine of pregnant horses. It is taken by millions of women worldwide to treat the symptoms of menopause either during natural menopause or after induced menopause in the cases of women who have undergone hysterectomy. Most of the world's Premarin is derived from the urine of approximately two thousand pregnant horses kept on twenty-six ranches in North Dakota and Canada (North American Equine Information North American Equine Ranching information Council 2015). Opponents of Premarin production claim that both the pregnant mares and their foals suffer greatly:

> For most of their 11-month pregnancies, the horses are confined to stalls so small that they cannot turn around or take more than a single step in any direction. The animals must wear rubber urine-collection bags at all times, which causes chafing and lesions, and their drinking water is limited so that their urine will yield more concentrated estrogen. Once the foals are born, the horses are impregnated again, and this cycle continues for about 12 years. Some of the thousands of foals born on (Premarin) farms each year are used to replace their exhausted mothers. Some are offered for adoption, but the remaining foals—along with worn-out mares—are sold at auction, where most are purchased by buyers for slaughterhouses (People for the Ethical Treatment of Animals 2015).

To many horse-lovers, the nature of this industry is considered cruel and profoundly disturbing (Andersson 2004), but the North American Equine Information Council, representing ranchers involved in the collection of pregnant mares' urine, takes a different view. They point out that all ranchers must adhere to the '*Recommended Code of Practice for the Care and Handling of Horses in PMU Operations'*, which specifies standards for nutrition, watering, exercise, and barn environment, among other requirements. Furthermore, they claim that equine ranching is the most highly regulated horse ranching activity in North America (North American Equine Ranching Information Council 2015).

As well as their use in pharmaceutical products, many animal tissues and their derivatives are used in medical devices. These materials can comprise a major part of the device, such as bovine/porcine heart valves or bone substitutes for use in dental or orthopaedic applications or they may be used as a product coating, as is the case with collagen or gelatine. Some other biochemicals obtained from animal sources are used in the device manufacturing process, such as stearates[55] from animal fats, or foetal bovine serum[56] (Silver 2012). European regulations governing the production of animal-derived products and devices are largely concerned with human safety issues and risks to those that use them. For example, European Union Regulation 722/2012, which covers medical devices that use animal tissues, requires device manufacturers to ensure adequate risk management and controls to prevent spreading certain animal-borne diseases to human users of their products. However, manufacturers are also required to provide a justification for the use of animal tissues or derivatives, specifying animal species, tissues and sourcing and taking into account the clinical benefit, potential residual risk and suitable alternatives, such as lower risk tissues or synthetic alternatives (European Union 2012).

A further source of controversy for conventional medicine concerns the role of animal experimentation in drug development and testing. The number of animals used in research worldwide is impossible to specify exactly, because many countries do not publish data about the numbers of animals involved. In the UK, vertebrate animals, such as mammals, fish and birds, are protected by law; the numbers of these animals used for research purposes are counted by the government each year. Invertebrate animals, such as fruit flies or worms, are also used in large numbers for research purposes but are not protected by the law or counted (Understanding Animal Research 2015b). The most recently published figures available relate to the year 2013, when there were just over four million (4,121,582) scientific procedures using animals in the UK (Home Office Statistics 2014). The number of animals used will be slightly less than this because some animals are included in more than one procedure. The figures show that the annual number of animal procedures increased by one million (over one

[55] Stearates are commonly used in the production of medicines as a lubricant. It prevents the ingredients from sticking to the manufacturing equipment.
[56] Foetal bovine serum is the most widely used growth supplement for cell cultures.

third) in the twelve years from 1997 to 2009. The use of genetically modified mice models are largely responsible for recent increases (Ormandy *et al.* 2009). A known and consistent genetic profile of the animals used in a study is often of advantage, as it can reduce variability in the experiments arising from genetic variation in the animal samples studied, and can also increase the reproducibility of the results (Office International des Epizooties 2014). In 2013 alone, genetically modified mice were used in 2,511,929 scientific procedures, representing sixty-one per cent of the overall total in the UK (Home Office Statistics 2014). This trend will continue as genetic techniques are more widely applied to the pharmaceutical and biomedical industries.

Whilst we cannot determine the exact number of animals used worldwide in research, the global figure has been estimated at between fifty and sixty million animal procedures per year (Understanding Animal Research 2015b). This figure is based in part upon some published data for the following countries:

USA (about 20 million procedures),
EU, including the UK (about 12 million procedures),
Japan (about 5 million procedures),
Canada (2 million),
Switzerland (less than 1 million) and
Australia (less than 1 million).

The number estimated for the rest of the world is approximately ten million, so the total is unlikely to exceed sixty million. Moreover, the number of animals used in research continues to rise in many countries (Schuppli *et al.* 2015) and, as in the UK, the recent rises in animal procedures are mainly attributed to the increased production and use of animals with genetic modifications or defects.

Most of the animals used in research in the UK are rodents, followed by fish and birds. Taken together, dogs, cats and monkeys represent two in every one thousand animals used. The following figures relate to procedures on animals in the UK in 2013:
Rats, mice and other rodents (all purpose-bred laboratory species) 84.5 per cent
Fish, amphibians, reptiles and birds 16.3 per cent
Sheep, cows, pigs and other large mammals 1.5 per cent

Dogs and cats (all bred for research, no strays or unwanted pets can be used) 0.12 per cent

Primates (mainly marmoset and macaque monkeys) 0.07 per cent

(Home Office Statistics 2014)[57].

Animals are used for many different purposes in medical research and testing. Most are used in the research and development of medical and veterinary drugs, including vaccines for humans and other animals (Royal Society for Prevention of Cruelty to Animals ND). There are four main points that are commonly cited as reasons for using animal research (Animal Research Info ND):

First, to advance the scientific understanding of how living creatures function; the study of animals is viewed as a vital part of this process as many basic processes are the same in all animals.

Secondly, as models for the study of disease processes, because humans and animals share many illnesses in common. For example, dogs suffer from cancer, diabetes, cataracts, ulcers and bleeding disorders such as haemophilia, and rabbits suffer from atherosclerosis, arthritis and obesity.

Thirdly, animals are used in the development and testing of potential forms of treatment, especially pharmaceutical drugs. Drugs are invariably tested on animals in preclinical studies and data from animal studies is viewed as essential before new therapeutic drugs and procedures are tested on human patients.

Lastly, animals are used for assessment of safety; new treatments are tested in suitable animals to reveal any potentially harmful effects (*ibid.).*

As well as the obvious benefits to humans, medicines and vaccines for pets and livestock also rely upon animal research and the majority of the medicines used for animals are derived from those used in humans. In addition, there are some treatments that are used exclusively in veterinary medicine. For example, Pasteurellosis, a severe

[57] The actual declared numbers were: Mice = 3,045,690, Rats = 262,641, Fish (mainly zebrafish and trout) = 501,841, Birds (mainly chickens) = 138,287, Pigs, goats, sheep & cattle = 14,500, Guinea pigs = 26,342, Rabbits = 11,895, Amphibians (e.g. frogs) = 4,286, Dogs (mainly beagles) = 3,554, Primates (macaques & marmosets) = 2,202, Reptiles = 696, Ferrets = 430, Cats = 109, Horses and other equines = 330, Others = 4,955

respiratory disease, used to be common, and affect around twenty per cent of cattle. Vaccine development involved research on about 450 calves, but it is estimated that the vaccine has prevented around twenty million cases of the disease (Understanding Animal Research 2015a). The Royal Society for Prevention of Cruelty to Animals highlights the ethical dilemma this can generate:

> The Society is opposed to all experiments causing pain, suffering or distress, yet advocates vaccination of companion animals to protect them from disease – and vaccines are currently developed and tested on animals (Royal Society for Prevention of Cruelty to Animals ND).

Ethical guidelines and regulations for the use of animals in medical research vary widely between countries. There are currently no overarching global standards to guide practice. The following describes the efforts of various bodies to address this deficiency.

7.3 The Regulation of Animal Use in Medical Research

Most existing animal research policy around the world is concerned with animal welfare and is underpinned by the notion of the 'three Rs': replacement, reduction, and refinement, first proposed by William Russell and Rex Burch in 1959 (Russell *et al.* 1959). Replacement refers to the idea that, wherever possible, the use of animals should be replaced with other methods that do not employ sentient creatures. Reduction concerns the lowering of the numbers of animals needed in experiments and procedures to obtain meaningful results, while refinement refers to any factors that can decrease the incidence or severity of inhumane procedures for the animals that are used.

Attempts to apply the three Rs have revealed that replacement is not always possible because molecular, cell, tissue or organ models are highly simplified when compared with whole animals or humans; reduction depends primarily on improved research methods and better statistical analysis; and the notion of refinement has been broadened to include all aspects of the life of a laboratory animal, from birth to death (Smith 2001).

In the UK, the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) leads the discovery and application of new technologies

and approaches to replace, reduce and refine the use of animals for scientific purposes. Central to their activities has been the development of the ARRIVE (Animal Research: Reporting of In Vivo Experiments) guidelines that have been widely adopted by academic journals to improve transparency and quality in the reporting of research involving animals (Kilkenny *et al.* 2014).

The three Rs also provide the foundation for European policy. On 22 September 2010, the European Union adopted Directive 2010/63/EU on the protection of animals used for scientific purposes, which took full effect on 1 January 2013. The Directive stipulates measures that must be taken to replace, reduce and refine the use of animals in scientific research. Amongst other requirements, it lays down minimum standards for housing and care and regulates the use of animals through systematic project evaluation that requires the assessment of pain, suffering, distress and lasting harm caused to the animals (Understanding Animal Research 2015a).

On a global scale, however, there is substantial variation in the ways in which different countries document the numbers and types of research animals used, making it difficult to determine whether the Three Rs are being implemented consistently (Ormandy *et al.* 2009). For example, in many parts of Asia, there are few or no guiding principles or regulations and levels of accountability, transparency and responsibility can be poor (About Animal Testing 2015).

In recent years there have been attempts from different organisations to develop global frameworks. In 2012, the International Council for Laboratory Animal Science (ICLAS) and the Council for International Organizations of Medical Sciences (CIOMS) updated their 'International Guiding Principles for Biomedical Research Involving Animals' (CIOMS & ICLAS 2012). These principles also incorporate the Three Rs and are intended to serve as a framework of responsibility for all countries, including those with emerging research programmes.

At the same time, the Basel Declaration Society, an organisation based in Europe, is calling for all countries to sign up to their Declaration and to adopt one set of universally agreed principles. The aim of the Basel Declaration is to bring the global community of scientists together to ensure the application of ethical principles whenever animals

are being used and to call for more trust, transparency and communication on the topic of the use of animals in research (McGrath *et al.* 2015). So far, the Declaration has been accepted in many European countries and it is hoped that it will eventually be accepted by the rest of the world in the same way as the Declaration of Helsinki (The Basel Declaration Society 2014).

It is against this backdrop, in an era when there is growing awareness of the need for global ethical standards regarding the use of animals for medical purposes, that the use of animals in T&CM medications and research is now examined.

7.4 The Role of Animals in T&CM

The traditional practice of using animals or animal-derived products for medicinal purposes has been termed 'zootherapy' (Costa-Neto 1999) and appears to have deep historical origins in many different countries around the world. Many T&CM products are derived from animals (Adeola 1992, Still 2003, Alves *et al.* 2007, Alves *et al.* 2013, Whiting *et al.* 2013, Verma *et al.* 2014, Vijayakumar *et al.* 2015) and investigations have been undertaken in a number of regions where zootherapy is commonplace in order to document usage. These investigations most often take the form of interviews, discussions or focus groups with traditional healers to elicit information that is customarily passed on through an oral tradition from generation to generation. The results from these ethnographic studies are helping to build a picture of global usage: which animals are used, how the animals are obtained, what parts of the animals are used, and for what ailments. Table 10 summarises the findings from the most recent of these studies in India, Brazil, Korea and Mauritius.

Table 11: Summarised findings from zootherapy studies in regions of Korea, India, Brazil and Mauritius since 2011

Author	Region	Animal species	Part used	Medical conditions treated	Most commonly cited animals
(Kim *et al.* 2014)	Korea	77 species including: Fish (36.4%) Mammals (19.5%) Molluscs (16.9%) Arthropods (10.4%)	Whole animal (25.8%) Bones (15.8%) Larva (14.7%) Gallbladder (10.7%) Animal faeces (9.4%) Meat (7.0%) Fat (7.0%)	53 conditions including: Lumbago (11.1%) Bone conditions (8.3%), Fever (7.7%) Lethargy (6.6%) Common cold (6.2%) Burns (5.1%)	Horse Korean Horse Cicada Chicken Centipede
(Vijayakumar *et al.* 2015b)	Tamil Nadu, India	46 species including: Mammals (30.43%) Birds (23.92%) Insects (15.21%) Spiders (8.70%) Ray finned fish (8.70%) Reptiles (6.53%) Amphibians (4.34%) Gastropods (2.17%)	Includes: Whole animal (most frequently used). Also: butter, meat, milk, bones, horn, musk, skin, fin, tail, excrement, bile, liver, honey, mucus, eggs and legs.	163 conditions including: Aphrodisiac ailments Dental care ailments Endocrine disorders Hair care ailments Oncology Orthopaedics	Deer Golden eagle Indian flapshell turtle Green pigeon Chicken
(Vijayakumar *et al.* 2015a)	Kerala, India	69 species including: Mammals (29%) Birds (28%) Insects (17%) Reptiles (10%) Ray finned fish (4%)	34 parts including: Whole animal (19.42%) Meat (17.47%) Fat (6.80%) Blood (5.82%) Eggs (5.82%), Feathers (4.85%)	85 conditions including: Cough (5.03%) Earache (3.77%) Asthma, rheumatism, wounds, diarrhoea, eye diseases, fever and tuberculosis (each 2.51%)	Indian flapshell turtle Honeybee Chicken Black vulture Earthworm
(Sajem Betlu 2013)	Dima Hasao, India	34 species including: Mammals (17.5%) Birds (7.2%) Reptiles (5.2%) Insects (2.6%) Gastropods (2.6%)	Flesh (34%) Gall bladder (22%) Fat (14%) Whole animal (8%) Blood, fur and paws(Each 2%)	34 conditions including: Diabetes Jaundice Malaria Impotence Hernia Epilepsy Burns	Not identified but includes many rare, vulnerable and endangered species: Asian elephant Hoolock gibbon Sloth Bear Black bear Silvered leaf monkey

(Chakravorty *et al.* 2011)	North-East India	36 vertebrate species including: Mammals (50%) Birds (22%) Fish (17%) Reptiles (8%) Amphibians (3%) (Use of invertebrates was not documented)	Includes: Claws and nails, skin, feathers, mucus, fins, fat, flesh, bone, bone marrow, stomach, intestine, testes, gall bladder, umbilical cord, blood, horns and antlers.	20 conditions including: Fever Pain Digestive disorders Tuberculosis Malaria Typhoid Smallpox Dysentery Jaundice Burns and wounds	Not identified but includes: Deer Bear Tiger Leopard Cobra Python Owl Eagle Goat Wolf
(Barros *et al.* 2012)	Brazilian Amazonia	31 species including: Mammals (39%) Birds (26%) Reptiles (16%) Fish (10%) Amphibians (6%) Insects (3%)	Includes: Fat, bile, bones, feathers, teeth, nails, beak and penis	28 conditions including: Snakebite Pneumonia Asthma Earache Rheumatism Bleeding Indigestion	White-lipped peccary Razor-billed curassow Grey tinamou Giant armadillo Lowland tapir
(Alves *et al.* 2011)	North-East Brazil	51 species including: Birds (33%) Mammals (33%) Reptiles (12%) Arthropods (12%)	Includes: Flesh, bone, cartilage, skin, tail, fur, feather, teeth, nails, head, tongue, stomach, viscera, liver, bile, milk, fat, rattle (from rattlesnakes), spine, shell, abdomen and body secretions	68 ailments including: Infections and parasitic diseases Respiratory Musculoskeletal Mental disorders Poisonings, wounds and burns	Chicken Lizard Domestic goat Rattlesnake Armadillo Iguana Cattle
(Mootoosamy and Fawzi Mahomoodally 2014)	Mauritius	31 species including: Ray finned fish (22.6%) Mammals (19.4%) Insects (12.9%) Birds (9.7%) Annelid worms (9.7%) Reptiles (6.5%)	Includes: Whole animals (most frequently used) Also: meat, milk, bones, horn, musk, skin, fin, honey, mucus, eggs and legs.	44 conditions including: Endocrine Nutritional and metabolic disorder Diseases of the circulatory system	Cattle Honeybee Chicken Snail Bombay duck (lizardfish)

From the combined findings of different researchers, together with information already in the literature, it is possible to estimate the number of species of animals that are used in T&CM products in certain regions. For instance, Alves and Alves (2011) have determined that, in Latin America, 584 animal species have been reported as used in traditional medicines; 354 of these in Brazil alone (Alves *et al.* 2013). These numbers are probably an underestimate of actual usage, since it is unlikely that all uses have been documented. In India, where there is an immense biodiversity of fauna, accounting for ten per cent of the reported biological species on the planet (Kim and Song 2013), there is documented evidence for 351 medicinal uses of animal and animal parts (Sajem Betlu 2013). However, in the case of China, where the use of animals is long established in Traditional Chinese Medicine, no documentation of an ethnographic nature on the use of animals could be found[58]. However, numbers have been postulated using information drawn from ancient and current textbooks of Traditional Chinese Medicine and it is estimated that as many as 1500 animal species are used in T&CM (Still 2003, Kim and Song 2013).

Traditionally, numerous animal parts have been claimed to have medicinal properties and the use of medicines obtained from animals is suggested as traditional cures for a wide variety of ailments. Some of the relevant animal species are critically endangered. For instance, one of the most highly prized animals is the tiger, sought for the use of various body parts, especially the bones, but also the hair, teeth, skin and many other organs (Still 2003). These tiger parts are used to treat a number of disorders; examples include the use of the eyeballs for epilepsy; of the whiskers for toothache; of the urine for rheumatism; of the bones for joint problems and hemiplegia; of the brain for laziness and pimples; and of the tail for skin diseases (Still 2003, Athiyaman 2008).

Tigers were classified as globally endangered in 1986 and, following this, an international treaty banned cross-border trade in tiger parts (International Union for Conservation of Nature 2011). In the past, tigers inhabited an area that stretched from Pakistan to the Far East of Russia, with an estimated population of 100,000 just one hundred years ago. In 2014, there were believed to be approximately 3,200 wild Tigers in Asia, with fewer than 2,500 breeding adults (World Wildlife Fund 2015b). Tigers are now found only in thirteen countries: Bangladesh, Bhutan, Cambodia, China, India, Indonesia, Laos, Malaysia, Myanmar, Nepal, Russia,

[58] The search precluded any publications not written in English.

Thailand and Vietnam; all of these countries have endorsed 'The Global Tiger Recovery Program' and pledged to improve cross-border cooperation to curb the illegal smuggling of tigers and other endangered animals. However, in spite of tiger hunting now being declared illegal everywhere that tigers persist, the killing of wild tigers continues (Wiersema 2013). Prices for tigers, dead or alive, continue to soar as the size of tiger populations decrease and poaching, driven by the demand for T&CM products, is a primary threat to their survival (Winter and Guynup 2013). Between the years 2000 and 2014, parts of 1,590 tigers were seized, an average of two tigers per week (TRAFFIC 2015).

Tigers are not the only endangered animals used in T&CM; the illegal trade of animal products for medicinal use has contributed to a decrease in numbers for many animal populations (Rangarajan 2005). Rhinos, once common throughout Eurasia and Africa, are now found almost exclusively only in national parks and reserves. Two species of rhino in Asia (the Javan and Sumatran rhinos) are classified as 'critically endangered' (WWF 2015b). The decline in rhino numbers is undoubtedly linked to its use in T&CM. Virtually every part of the rhino is used: the horn for alleviating fever, the skin for treating skin disease, the penis as an aphrodisiac, the bone to treat bone disorders and the blood as a tonic for women who are suffering from menstrual problems (Still 2003). The smaller Asian rhino horns are more highly prized than African rhino horns because it is believed they will be more potent. Animal studies undertaken in the UK and South Africa found no pharmacological basis for the claimed effects of rhino horn, or any other animal horns (Abraham 2014).

The use of non-human primates in T&CM is also widespread and has been recorded in fifty-one countries, mainly in Latin America, Africa and Asia. According to Alves *et al.* (2010), the trade in these products is encouraging the commercial hunting of primates, and threatening them on a scale they have never faced before. Of the 101 species of primates recorded in their review, Alves *et al.* found that twelve species were classified as 'Critically Endangered', twenty-three as 'Endangered', twenty-two as 'Vulnerable' and seven as 'Near Threatened'.

Another large mammal that is in demand for its supposed medicinal properties is the bear. Bear bile has been prescribed in Traditional Chinese Medicine for centuries and it is used to treat a range of complaints including inflammation, bacterial infections and pain (Still 2003). Widespread illegal killing of bears is contributing to declining numbers, especially in Southeast Asia and China (International Union for Conservation of Nature 2011). In the 1980s, with

numbers of wild bears in decline, the practise of bear farming was established and today there are approximately 13,000 bears on Asia's bear farms (Kikuchi 2012). There have been many concerns expressed about their welfare (Yibin *et al.* 2009) as the bears are commonly kept for years in tight cages; their teeth are broken, their claws are pulled out and the bile collection process can cause severe pain through use of a catheter or implant into the bear's gall bladder. When the bears cannot produce sufficient bile they are often left to die of starvation (Kikuchi 2012). The most important component of bear bile is ursodeoxycholic acid and this has been shown to be effective against many complaints including liver and gall bladder ailments (Challem 2007), but this chemical can be synthesised artificially (Still 2003). Indeed, the synthesised version is commonly used for the treatment of cystic fibrosis, gallstones and biliary cirrhosis (Electronic Medicines Guide 2015).

In Latin America, where zootherapies form an integral part of the local culture, many of the animal-derived medicines include threatened species (Costa-Neto 1999). For instance, of the 354 animal species known to be used in Brazil, twenty-one per cent are on one or more lists of endangered species (Alves *et al.* 2013). Most of the medicinal animals used in Brazil are wild and although Brazilian legislation forbids commercial use of wild fauna, medicinal products and derivatives made from animals, including species that are on the list of endangered species, are commonly traded in Brazilian markets (Alves 2009). This trade occurs illicitly and without due monitoring by competent environmental agencies (Ferreira *et al.* 2013); in Brazil, the trade of medicinal animals is a well organised practice (Ferreira *et al.* 2015).

Given this situation, the desire to investigate alternatives to the use of animals in medicine appears to be growing and suggestions have been made for the substitution of the use of threatened animal species with medicinal plants or domestic animals (Luo *et al.* 2011, Kikuchi 2012, Ferreira *et al.* 2015). This is a complex process because there is currently little overlap between the use of medicinal plants and animals or the use of wild and domestic animals (Ferreira *et al.* 2015). The use of animals for medicinal purposes can be related to a host of factors including biological, cultural and socioeconomic aspects (Rastogi and Kaphle 2011).

Medicinal products derived from animals are not just used for human health care, but they are also used as veterinary medicines in some regions of the world. For instance, Souto *et al.* (2011, 2012) recorded the use of zootherapy in veterinary medicine in North Eastern Brazil and found many parallels between human and animal uses. Zootherapeutic medicines are commonly used

with livestock and pets in the same way as with humans, especially when being treated for the same diseases. This is possible with mammals such as cattle, sheep, goats and pigs, because they can suffer from many of the same health problems as humans (Alves and Alves 2011).

Aside from their use in T&CM products and treatments, animals are used in T&CM research in the same way as they are for conventional medicine. Animals are routinely used in exploratory studies, and are often exposed to stress, pain, artificially induced diseases and ultimately killed (Hu *et al.* 2003, Rodrigues de Almeida *et al.* 2008, Khuda-Bukhsh 2009, van Wijk *et al.* 2009, Rastogi and Kaphle 2011, Britton 2014, Bae *et al.* 2015). Animal experiments are undertaken for the development and testing of many types of T&CM, including acupuncture (Hyojung Lee *et al.* 2015, Xin *et al.* 2015); Ayurvedic medicine (Aggarwal *et al.* 2014, Bakrania and Patel 2015); herbal medicine (Bae *et al.* 2015); homeopathy (van Wijk *et al.* 2009) and Traditional Chinese Medicine (Tejedor Garcia *et al.* 2012).

The vast majority of these experiments are conducted on rats and mice but other animals are also used such as: rhesus monkeys (He *et al.* 2015); baboons (Gauthaman and Ganesan 2008); capuchin (Leal *et al.* 2012); pigs (Shuzhen *et al.* 2009); rabbits (Sien-Hung *et al.* 2013); guinea pigs (Pohanka *et al.* 2012); and frogs, fish, sheep and chickens (Bonamin *et al.* 2015).

Many of the experimental designs necessitate harm to the animals in order to determine the effects of treatment. For instance, for testing the Ayuervedic drug, Baharer Nani, commonly used for wound healing, an eight millimetre diameter hole was punched into Wistar rats (Gangopadhyay *et al.* 2014). For the testing of the active ingredient in *Hemidesmus indicus*, hyperlipidaemia was first induced in Wistar rats through the daily induction of large quantities of ethanol over a period of 30 days (Saravanan and Nalini 2007). Wistar rats were also used to evaluate the anticonvulsant activity of *Gmelina arborea* bark against experimentally induced seizures. Convulsions were induced either through drugs or electric shocks and the anticonvulsant effect was measured by the duration of hind limb extension, muscular spasms and stupor phase (Shinde *et al.* 2013).

We do not have statistics for the total number of T&CM studies that use animals, but Tejedor Garcia *et al.* (2012) have estimated that of the 29,319 references for Chinese herbal medicine on MEDLINE for the period between 2000 and 2011, around twenty-five per cent involved animals (8952 animal studies). Furthermore, the number of studies of Chinese herbal medicines

has increased significantly in the past fifteen years. According to Tejedor Garcia *et al.* this is due to an increasing demand for scientific proof of efficacy. The adoption of Chinese medicine (and other forms of T&CM) in Western countries is impeded because there is limited knowledge on chemical composition, pharmacokinetics, pharmacodynamics, efficacy and safety. Hence, the view of many is that the same type of research evidence is needed for T&CM products as is required for conventional drugs and this therefore must include animal studies (Nayak and Nayak 2010, Tejedor Garcia *et al.* 2012, Medagama and Bandara 2014, Bae *et al.* 2015, Hyojung Lee *et al.* 2015).

7.5. Ethical analysis of the role of animals in T&CM

A range of serious concerns for the wellbeing of animals has been described here and in depth ethical analysis of each would involve lengthy debate. Consideration of exactly how the interests of animals should be represented, awarded value and weighed against the competing interests of humans could easily fill several theses. Hence, although the following ethical analysis may appear to be brief in nature, it will nevertheless serve to expose specific points of contention and reveal useful recommendations for practice.

The idea that animals should be awarded moral consideration was greatly advanced in utilitarian ethics; as the founder of modern utilitarianism, Jeremy Bentham, famously quoted: 'The question is not, Can they *reason*? nor, Can they *talk*? but, Can they s*uffer*?' (Bentham 1823 p.144 Footnote). Bentham was not against the use of animals for food or experimentation but he expounded the view that suffering should be avoided and that animals should only be used if there was a realistic potential for good (of humanity). In other words, the potential for good to humans would need to outweigh the potential for harm to animals. Sensitivity towards the suffering of animals was also advanced by the work of Charles Darwin who starkly challenged the notion that humans were created by God in his own image: 'Man in his arrogance thinks himself a great work worthy the interposition of a deity. More humble, and I believe truer, to consider him created from animals' (Darwin 1838 pp196-197). Darwin was resolute in his opinion that many animals, just like humans, are sentient beings:

> The lower animals, like man, manifestly feel pleasure and pain, happiness and misery. Happiness is never better exhibited than by young animals, such as puppies, kittens, lambs, &c., when playing together, like our own children. (Darwin 1871 pp 39-40)

In more recent years two ground breaking and highly influential books concerning animal ethics have dominated discussions in this area; *Animal Liberation* by Peter Singer (1975) and *The case for Animal Rights* by Tom Regan (1987). Regan claims that sentient beings who are able to see themselves as 'subjects of life' have 'inherent value' which awards them defensible moral rights and that this in turn implicates *prima facie* duties for human beings towards animals. Singer, on the other hand, argues for utilitarian based animal ethics grounded in the notion of 'equal consideration of interests'. Equal consideration of interests requires us to give equal weight to similar interests, regardless of species. Preference for the interests of one species over another constitutes 'speciesism', a prejudice that is held no more justifiable than sexism or racism. A key point in Singer's argument is that equal consideration of interests is necessary for *sentient* beings that are capable of feeling pain and suffering.

Given that I am taking a consequentialist approach to the analysis of ethical issues associated with animals and T&CM, coupled with the requirement to place myself in the 'shoes of animals', it seems fitting to follow Singer's line of reasoning in this analysis. Maintenance of sensitivity towards speciesism should help me to avoid anthropocentric bias in the weighing of the potential harms and benefits necessary for this consideration of animal wellbeing.

7.5.1 Using animals in the production of T&CM products

There is obvious harm to many animals that are used in T&CM medicinal products. Many wild animals are hunted and killed and excessive or uncontrolled hunting has led to the extinction or near extinction of some species. Others, who are not killed, may suffer great distress and pain, such as the bears that are kept on bear farms for their bile.

Most animal-derived T&CM products are intended for human use and human benefit. Some are used in veterinary medicine to treat pets and livestock, but the medicines are not normally used for the treatment of the animal species from which they are derived. Moreover, humans are the ultimate beneficiaries of healthy livestock.

Medicinal benefit from animal-derived products (for humans or animals) is far from certain, even for the most expensive and widely used products. Most have never been tested for efficacy; some that have been tested show no benefit (like rhino horn). Hence, in the main, animals are being harmed for the manufacture of products of unproven value.

There could be other ways, aside from medicinal effects, in which humans benefit from the use of animal-derived T&CM. Zootherapy may be an important and integral part of a traditional healthcare system with cultural and economic significance.

However, the killing and/or suffering of animals to make T&CM products for the benefit of humans is inherently speciesist. If we award the bear equal consideration of interests to the human recipient of bear bile, then it is clear that the painful extraction of bear bile is not justifiable because the bear's interests are sacrificed to serve human interests. This is especially difficult to justify when there is a readily available synthesised version of the active ingredient of bear bile that could be used as an alternative. The acquisition of bear bile causes pain and suffering. The manufacture of a synthesised equivalent does not.

From a utilitarian perspective, it can be argued that potential benefits to a large number of beings might justify the humane killing of one or a few beings. For example, the preparation of the homeopathic medication, *Apis melifica*, requires the killing of one honeybee, but the resultant medication can be used to treat thousands of humans and animals. Not many would argue that this is unethical. The principle of equal consideration of interests does not apply if a being is incapable of suffering or feeling pain or happiness. Bees are not considered to be sentient creatures and hence, in this case, there is no competing interest to take it into account.

However, the killing of a tiger, a member of an endangered species, for treatments that are of dubious medicinal value, is hard to justify, even if the resultant products are distributed to many. There is a quantitative and qualitative difference between the killing of a bee and the killing of a tiger.

According to Singer, we must take care when we compare the interests of different species. In some situations a member of one species will suffer more than a member of another species. In this case we should still apply the principle of equal consideration of interests, but here we must give priority to relieving the greater suffering (Singer 1993). This seems to suggest that it may be acceptable to use some animals in T&CM products if the suffering of the used animal(s) is less than the suffering that the potential recipients would experience without this medication. However, the weighing of relative degrees of suffering between individuals is extremely difficult, and even more so when they are of different species.

It is clear that the use of animals in T&CM products is rarely (if ever) undertaken in the interests of animals. Here, the ethical matrix exposes a conflict between the wellbeing of animals and the wellbeing of humans. Given that there may be some circumstances in which the use of animals in T&CM products is justifiable (when interests have been awarded equal consideration) and there is no easy way of weighing relative degrees of suffering, it may be helpful to apply the broadly accepted principles that have been developed to protect the welfare of animals in animal experimentation. Application of the Three Rs to the use of animals in T&CM products would require analysis of the following:

Replacement: Can the animal product be replaced with any other medicinal product? Sentient animals must be replaced in all possible circumstances. Replacement of an animal-derived product with a herbal product, conventional drug or even a product that is derived from non-sentient animals would reduce suffering.

Reduction: How is the need for the T&CM medication being measured and what is the minimum amount required to meet the real need? In order to reduce the number of animals being used the actual need for a product must be explicit and quantified.

Refinement: What measures are in place to minimise the pain, suffering, distress or harm to the animals? In the cases where a real need has been demonstrated and there is no possibility of replacement, then suffering to the animal must be reduced and welfare maximised.

Whilst application of the Three Rs may not be a perfect substitute for the weighing of relative interests, it does ensure that the interests of animals are given due consideration. In addition, there is no good reason why, if it is a requirement for the use of animals in experimentation, that it should not also be a requirement for the use of animals in the manufacture of T&CM products. The fact that this notion is readily accepted within animal research, but not even discussed in regard to use of animals in the production of T&CM medicinal products, is a clear example of double standards.

7.5.2 Using animals in T&CM research

The ethical issues concerning use of animals in T&CM research are similar to those described for use of animals in T&CM products. The inclusion of animals in research can be justified on

a utilitarian basis if, for example, the use of a small number of animals in experimentation could lead to benefit for a greater number of animals or humans. Such was the case for the research on 450 calves that led to the development of a vaccine for Pasteurellosis. As previously described, there are existing guidelines that serve to protect animal welfare in experimentation but there are two major problems with the current guidelines:

First, there is no one set of guidelines that has global acceptance. This means that standards vary between countries and what is routine practise in some countries may be considered unethical in others. A move towards the establishment and acceptance of global guidelines appears to be gaining momentum but this is unlikely to be fully successful until all academic journals apply uniform standards. At present, many academic journals have a policy of accepting the ethical standards 'local' to the author (McGrath *et al.* 2015). This can result in animal research deemed unethical in the UK being published in a UK journal. Provision of a platform for such research can only serve to perpetuate unethical practice. Besides, not all animal research is undertaken by researchers keen to publish and some research in industry, for instance, can therefore not be governed through journal standards.

Secondly, existing guidelines provide poor guidance on species selection. Guidance from the Animals Scientific Procedures Act (2014) is to use animals with the 'lowest degree of neurophysiological sensitivity'. As we have seen, most animal research in T&CM is undertaken on rats and mice. The same is true for animal experimentation in conventional medicine. The British public have a particular fondness for cats, dogs and horses and this preference, rather than any objective measurement of 'neurophysiological sensitivity' seems to be at the root of the Animals Scientific Procedures Act stipulation that project licences authorising the use of cats, dogs and equidae will only be granted if:

> ….the programme of work to be specified in the licence can be achieved—
> (a) only by the use of cats, dogs or equidae; or
> (b) only by the use of cats, dogs, equidae and other animals which it is not practicable to obtain.
> (Animals in Science Committee 2014)

However, current evidence appears to indicate that similar responses to pain are seen in most mammals, birds and fish and, as such, it would appear to be unjust to distinguish between classes of sentient animal in terms of neurophysiological sensitivity (Webster 2014). The

preference for use of rats and mice over cats, dogs and horses is a clear example of speciesism in animal research.

This brief ethical analysis has revealed many problems with the use of animals in both the manufacture of T&CM products and in T&CM research. However, it has also revealed opportunities for steps forward as detailed in the following recommendations.

7.6 Recommendations for the Use of Animals in T&CM Products and Research

- The same ethical standards should be applied to both the use of animals in research and the use of animals in the manufacturing of T&CM products.

  There may be differences in how the standards are applied but the principles should be the same. For example, the principle of 'Reduction', one of the three Rs, is intended to minimise the number of animals used. In research this would involve an understanding of methodological design and statistical analysis; in the manufacture of products this would involve an accurate assessment of the actual need for a product.

- Ethical standards for the use of animals need to be globally agreed and applied consistently. The current movement towards global standards for animal experimentation should be encouraged and developed further.

- Guidelines should reflect current scientific understanding that similar responses to pain and suffering are present in mammals, birds and fish. Any distinction between species for experimentation or use in products needs to be justified on other grounds.

- Academic journals need to adopt guidelines for publication that require the highest ethical standards, rather than accepting those local to the authors in order to promote ethical practice and discourage unethical practice in animal research.

CHAPTER EIGHT: ETHICAL ISSUES FOR T&CM IN LOW AND MIDDLE INCOME COUNTRIES

As specified in Chapter one, consideration of the ethical issues associated with T&CM is broadened in the final sections of this thesis to include ethical concerns that extend beyond a United Kingdom perspective. This was necessary for consideration of the ethical issues associated with animals and T&CM in the previous chapter, and in this chapter it is vital for consideration of ethical issues related to the final stakeholder in the ethical matrix, low and middle income countries (LMICs).

The World Bank classifies countries as low, middle and high income according to the value of their gross national income (GNI) expressed per capita, an approach that takes into account the dollar (US) value of a country's annual income and the number of its inhabitants. Gross national income does not inform us about the distribution of wealth within a country, but simply reflects the average income of a country's citizens. In 2014, low-income economies were defined as those with a GNI per capita of 1,045 dollars or less; middle-income economies as those with a GNI per capita of more than 1,045 dollars but less than 12,736 dollars; and high-income economies as those with a GNI per capita in excess of 12,736 dollars. Middle-income countries are further divided into lower-middle-income and upper-middle-income categories, with the demarcation between these sub-classes set at a value of 4,125 dollars GNI per capita (The World Bank 2015a). Of the 215 countries listed, 80 are currently classified as high income countries and 135 are classified as LMICs.

In many LMICs, some forms of T&CM are relied upon for the primary source of healthcare. Consequently, the relationships that people have with T&CM in such countries can be quite different from those of people in high income countries, in part because choice may be more limited and professional regulation less well established, but also because the healthcare is often rooted in local cultures and traditions. As we have seen, the WHO distinguishes between healthcare interventions that are used in a complementary manner, away from their geographical origins (complementary medicine), and those that are rooted in local tradition and culture (traditional medicine). Acording to the WHO, any form of healthcare that is indigenous to a particular region can be classified as 'traditional medicine' within that locality, but outside that region it may be considered as 'complementary' (WHO 2013). In the high income UK,

most T&CM is used in a complementary manner; the National Health Service provides access to conventional healthcare for all citizens and people who can afford to pay for additional T&CM services can also choose from a broad range of privately delivered treatments. In LMICs, the types of T&CM that are available may be completely different to the five that have been identified as the primary focus in this thesis. With an emphasis upon *traditional* usage rather than *complementary* in LMICs, it is important to acknowledge that many forms of traditional medicine are region-specific. The types of T&CM that are available in LMICs are largely dependent upon the accessible flora, fauna and other local resources, as well as the local traditions. Hence, this stage of the analysis should be inclusive of a broader range of T&CMs than the five primary systems selected for previous chapters of this thesis, in order to consider more fully the ethical issues from a LMIC perspective. However, given the large number of T&CMs applicable globally, and the enormous diversity of practice in different LMICs, it is not possible to analyse all potential ethical issues with respect to all T&CMs in all LMICs. In this chapter I will, therefore, focus upon a specific topic, within a specific region, identified following an overview of the scope of ethical issues concerning use of T&CM in LMICs.

8.1 The Scope of the Challenges in LMICs

There are many potential ethical concerns relating to the use of T&CM in LMICs. Given that the types of T&CMs used, and the ways in which they are accessed, varies greatly between individual LMICs, it is important not to generalise these concerns and hence imply they were the same in all regions. What we can be sure of is that the ethical issues for human users of T&CM that were described in Chapter five could also apply to people living in LMICs. However, there are many additional concerns that are specific to the inhabitants of such countries, some of which were highlighted in the ethical matrix in Chapter four. In order to provide some indication of the scope of the ethical issues that are particular to LMICs, the following synopsis of the main issues, pertaining to wellbeing, autonomy and justice, draws upon published examples from a range of LMICs.

8.1.1 T&CM in LMICs: Wellbeing

The number of experiences of adverse drug reactions or adverse events from the use of T&CM is greater in LMICs than in high income countries, simply because there are more users of such healthcare systems. With up to eighty per cent of populations depending upon T&CM for

primary care in some regions (WHO 2013), the number of users of T&CM is significantly larger than it is in most high income countries. In addition, there are often fewer or poorer quality control procedures in place for T&CM products and services (Okoronkwo *et al.* 2014). Lack of infrastructure for the regulation and/or quality control of T&CM products can lead to many problems such as the adulteration of traditional preparations which in some cases includes potentially harmful ingredients (Isah *et al.* 2012). To take one study of relevance as an example, the analysis of samples taken from twenty different herbal remedies, obtained from randomly selected outlets in southeastern Nigeria, showed that more than ninety-eight per cent of the herbal remedies did not comply with international safety limits for heavy metal content. Apart from zinc, all heavy metals detected (particularly cadmium and lead) exceeded the limits for safety levels, suggesting strongly that users of these herbal products are inadvertently exposed to heavy metal poisoning (Nwoko and Mgbeahuruike 2011). Similar findings for herbal medicines have been well documented in other studies (Rao and KumarMeena 2011, P. Posadzki *et al.* 2013c, Kim *et al.* 2014).

A further source of concern is that conventional drugs can be added to T&CM products by traditional healers who lack proper training in conventional medicine. This type of syncretic healthcare has been reported in Ghana (Dixon 2008) and elsewhere in Africa. One such instance resulted in large amounts of non-steroidal, anti-inflammatory medicines being given to older patients without medical supervision until adverse drug reactions (such as gastrointestinal bleeding) developed (Isah *et al.* 2012).

A large number of people in LMICs self-medicate, using a variety of T&CMs without guidance or supervision from licensed T&CM practitioners. Many use a range of products simultaneously and this type of polypharmacy bears the potential for harmful drug/herb interactions (Van den Boom *et al.* 2004, Sato 2012, Okoronkwo *et al.* 2014).

An analysis of the use of T&CMs by cancer patients at the University of Nigeria Teaching Hospital in Enugu found that, out of 160 patients who were interviewed during the study, 104 patients (sixty-five per cent) had used some type of T&CM at some time during their cancer illness. Of the users, 21.2 per cent reported some type of adverse effect. Most of the named adverse effects could not definitively be linked to the specific T&CM used by individual patients, but at least two cases involved the development of ‘full thickness chemical burns following the application of herbs on the skin’ (Ezeome and Anarado 2007, p.33). A larger

study, in the same Nigerian region, investigated patterns of T&CM use, the perceived benefits, and potential for associated harm amongst adults. Of the 732 participants that were interviewed, 84.7 per cent had used T&CM at one time or another. The majority (70.3 per cent) did not experience any adverse effect after using T&CM products, whilst 184 others (29.7 per cent) reported a range of different adverse reactions, including dizziness (seventeen people) and body weakness (fifteen people) after taking herbal remedies (Okoronkwo *et al.* 2014). Significantly though, a large majority of the participants (78.6 per cent) stated that they had benefitted from T&CM use (*ibid*).

In addition to the potential for adverse drug reactions, the customary patterns of health seeking behaviour in LMICs can also lead to an increased chance of experiencing an adverse event. As many people use T&CMs for primary care, the potential for adverse events from delayed access to conventional care is greater. In Kenya, Njuguna *et al*. (2015) conducted interviews with the parents of seventy-five children attending hospital for cancer treatment. As many as ninety-five per cent of the parents reported use of T&CMs for their children, some against the advice of their conventional doctor, and some reported having stopped conventional medicines for their children whilst they received T&CM treatment (Njuguna *et al.* 2015). With delay in access to care and abandonment of cancer treatment cited as common reasons for cancer treatment failure in Africa and other low-income countries, this situation is clearly of concern (Ezeome and Anarado 2007, Hadley *et al.* 2012, Magrath *et al.* 2013).

As described in Chapter five, many countries have established systems for the reporting of adverse drug reactions and adverse events; national regulations for quality of medicinal products and services; and structured models for implementation of legislation. However, in many LMICs, these systems are not well developed or implemented. Of the 135 countries that are classified by the World Bank as LMICs (2015a), only seventy-two are participating in the WHO Programme for International Drug Monitoring as full members, although the number is slowly increasing (WHO-UMC 2015). There is evidence that the regulation of T&CM in LMICs is improving, but efforts are often slow. For example, the Nigerian National Agency of Food and Drug Administration and Control was first established in 1993 but, of the numerous herbal medicines in circulation in Nigeria, only about twenty have so far been registered (Nwoko and Mgbeahuruike 2011).

8.1.2 T&CM in LMICs: Autonomy

In LMICs, where indigenous forms of medicine are commonly rooted in local culture, T&CM may be the treatment of choice for a variety of reasons (Borins 1991, Macfarlane and Alpers 2009, Sato 2012, Stuttaford *et al.* 2014, Njuguna *et al.* 2015). For example, in Nepal, analysis of opinions about traditional herbal medicine has revealed that it is often considered by the populace as:

- the main lifeline,
- the first choice,
- less expensive,
- more culturally acceptable,
- with fewer side effects, and
- available through practitioners who possess greater patience and tolerance.

(Kunwar *et al.* 2010).

Various forms of T&CM are practised in Nepal, most with significant differences as a result of their distinctive influences. For instance, the Amchi health care system, found in the mountainous districts of Nepal, is rooted in Tibetan Chinese medicine, while the Baidhya healing system, prevalent in western Nepal, is influenced by Ayurvedic medicine. Spiritual beliefs, customs, livelihood strategies and the resources available have influenced the nature of each of these healthcare systems and, because of their prolonged use in their respective regions, these systems are inseparable from their local cultures (Kunwar *et al.* 2013).

In Kenya, Njuguna *et al.'s* interviews with parents of children with cancer also revealed a broad range of reasons for these parents in choosing to use T&CM, which included:

- hope in a cure,
- a perceived helpfulness,
- a recommendation from others,
- allowing the child to stay within the family and not have to remain in hospital,
- the avoidance of side effects, and
- a fear of surgery.

(Njuguna *et al.* 2015).

However, different types of T&CM are used in Kenya compared to those employed in other countries, and the majority of the parents in this study reported using spiritual help. It was explained by the author that most people in Kenya are deeply religious, that communities adhere strongly to their traditional practices, and illness is commonly viewed as having a spiritual component. Similar customs have been noted in a number of African nations (Omonzejele and Maduka 2011) and this plays a significant part in the choice of treatment.

Despite the high usage of T&CM in Africa, various studies have indicated that most people never discuss its use with conventional doctors (Bodeker and Burford 2007, Ezeome and Anarado 2007, Okoronkwo *et al.* 2014, Njuguna *et al.* 2015). Indeed, many people are told not to use T&CM by their doctors (Njuguna *et al.* 2015), suggesting that there can be a disregard for patient autonomy and/or potential conflict with their doctor's opinions about possible harms and benefits.

Impacts of community values may be seen in the way that decisions about healthcare are made in cultures where individual autonomy is not always regarded as paramount. Many African cultures operate through tightly bound communities that have their own core values and their own *modus operandi*. Osuji (2014) describes how, in some African community settings, the sick patient rarely goes unaccompanied to the doctor or traditional healer. Generally, when someone is ill the head of the family and relevant community members consult amongst themselves to decide upon a course of action. If the person is able, they may be involved in these discussions, but decisions are reached by consensus, rather than by the individual alone. The elders of such communities are often the holders of such power and make decisions on behalf of, and for the good of, the community as a whole. In some cases, pressure may be exerted by the community to seek T&CM treatments, as Njuguna (2015) explains can happen in Kenya. Here, when community members believed that the children with cancer were bewitched, parents were advised to stop conventional treatment at the hospital and seek T&CM care instead.

Understanding and interpretation of autonomous choice in African healthcare may be quite different from the liberalist view that defines autonomy as a property of self-determining individuals, able to make decisions for themselves, without any form of persuasion. Osuji (2014) asserts that this African form of consent does constitute legitimate informed consent, if we accept the notion of 'relational autonomy'. The concept of relational autonomy is premised

upon the notion that people are relational beings who are socially embedded and who interpret their autonomy through their relationships with others.

Regardless of whether decisions about healthcare are made by an individual or on a collective basis, a primary limiting factor for choice is undoubtedly the economic implications of the available treatments, and this is in turn related to the principle of justice.

8.1.3 T&CM in LMICs: Justice

In most countries, regardless of whether they are categorised as high, middle or low income, people pay out of pocket for T&CM treatments (Bodeker *et al.* 2005). In high income nations, T&CM use is primarily associated with higher income and educational levels within the populations (Harris *et al.* 2012). By contrast, in LMICs, use of T&CM is more often associated with lower incomes and rural living (Tabi *et al.* 2006, Sato 2012, Stuttaford *et al.* 2014). Equity issues associated with T&CM are a cause of concern chiefly because patient choice is severely limited by availability and affordability. For people in LMICs, T&CM is often the only affordable healthcare choice and access to conventional forms of healthcare may involve travelling long distances, even if it were affordable in itself. Even for those with a preference for T&CM, the costs of seeing a qualified practitioner may be too high.

In Kenya, Njugana *et al.* (2015) found that most of the families they interviewed had no regular income (sixty-three per cent), and that the vast majority (eighty-nine per cent) reported financial difficulties. Treatment costs prohibited access to certain aspects of prescribed conventional treatment (twenty-eight per cent) and some families (twenty-nine per cent) expected to be unable to complete treatment due to financial problems. Aside from the direct costs of treatment, travel costs were also seen as a major problem with fifty-two per cent citing high travel costs as the main reason for not being able to attend hospital appointments (Njuguna *et al.* 2015).

In rural Nepal, Kunwar *et al*. (2010) found that traditional herbal medicine flourished in rural areas, whereas conventional healthcare was scarcely accessed as a result of the high cost and long travel time to health centres. Mwaka *et al.* (2015) reported similar findings for Uganda. The majority of participants in their study also reported that most public health facilities are located far from their homes and that people hence had to travel long distances to access

conventional medical services, whereas traditional practitioners were located within the communities and were easy to access. Lack of money for transport and the unaffordable cost of healthcare in modern health units were repeatedly given as key reasons for choosing to use traditional medicines.

The ratio of traditional healers to population is often significantly higher than the ratio of doctors to population in LMICs. For instance, in Africa, the ratio of traditional healers to population is 1:500 compared to a ratio of 1:40,000 medical doctors to population. Furthermore, the majority of medical doctors are situated within urban areas and cities, inaccessible by those living in rural areas (Abdullahi, 2011). In Nepal the ratio of traditional healers to population is 1:100 compared to a ratio of 1:20,000 medical doctors to population (Kunwar *et al.* 2010).

In LMICs the poor may sacrifice basic needs such as food and education in order to pay for health care (Bodeker and Kronenberg 2002) and those who cannot afford to pay for properly regulated treatments may be forced to purchase unregulated products from unlicensed vendors (Bodeker & Burford, 2007). The prohibitive costs and difficulties with access may explain why self-medication is the first-line approach to treating common diseases in rural areas, with traditional healers or doctors consulted only after home remedies have failed (Bodeker *et al.* 2005).

A further concern for LMICs is the potential for exploitative trading. For instance, *Artemisia annua* is grown in Tanzania and exported to Europe for processing into anti-malarial drugs. The resultant medicinal products are reimported for sale at over six dollars per dose, which is out of reach of most of the people who need them (Bodeker & Burford, 2007). Consequently, there has been a drive towards greater protection of traditional knowledge and products, although this is proving problematic. Modern notions of intellectual property often conflict with traditional systems of knowledge, as legal ownership and current intellectual property regimes were not designed to accommodate traditional knowledge. Many experts have claimed that conventional patent laws are inadequate to protect traditional knowledge and biodiversity (Abbott, 2014).

The WHO (2013) stresses the importance of the need to protect intellectual property rights of indigenous peoples and local communities, and their health care heritage, whilst ensuring

access to T&CM and fostering research, development and innovation of healthcare. They advise that adequate protection of T&CM through conventional intellectual property or *sui generis* rights can help prevent its unauthorised use. As well as encouraging innovation, this in turn, they say, is likely to protect traditional knowledge that might otherwise be lost.

8.2 The Focus of Ethical Analysis

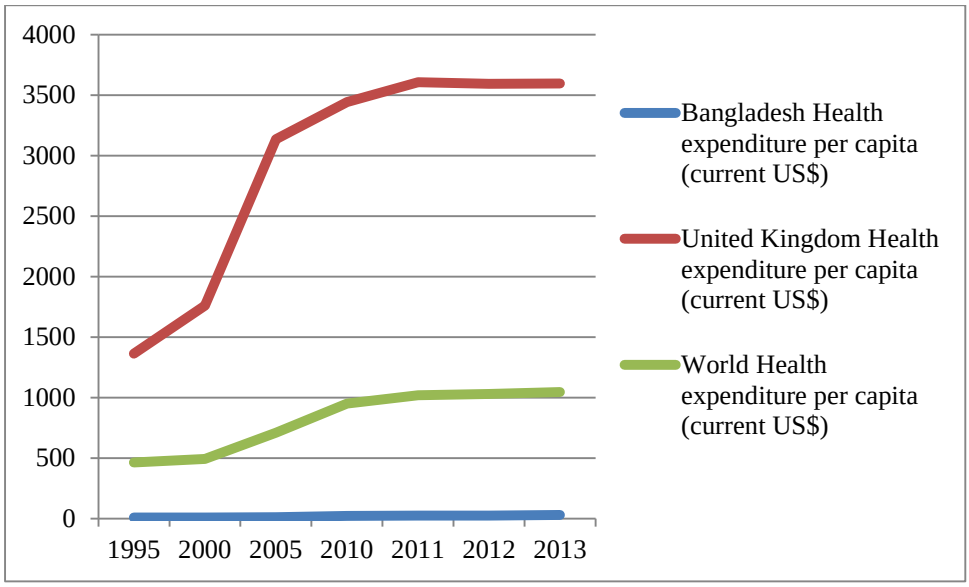
From this brief synopsis it is clear that there are numerous ethical issues pertaining to the use of T&CM in LMICs that demand attention. Many issues are region-specific, as the types of T&CM that are used vary greatly between regions, as do the local traditions, regulatory systems, availability of healthcare resources and economic factors. Given that it would be impossible to undertake an evaluation of ethical concerns for all people in all regions, I will focus my analysis upon a specific topic within a specified country.

The country I have chosen to consider in greater detail is Bangladesh, the eighth most populous, and eleventh most densely populated country in the world; it is a low-middle income country, with a high use of T&CM. Bangladesh is an interesting country to examine because it has been praised for making 'remarkable progress in health and human development' within a health system that is 'frequently characterised as weak, in terms of inadequate physical and human infrastructure and logistics' (Ahmed *et al.* 2013).

A glance at the figures for per capita health expenditure in Bangladesh (Figure 10) help to visualise the stark contrast between the amount of government funding for health in Bangladesh and that available in a high income country such as the UK. Even when compared with the world average, the health expenditure in Bangladesh is extremely low. In 2013, this was estimated at just 31.63 dollars per capita, whereas the figure for the UK was 3997.92 dollars per capita and that for the world average was 1047.81 dollars per capita (World Health Organization 2015).

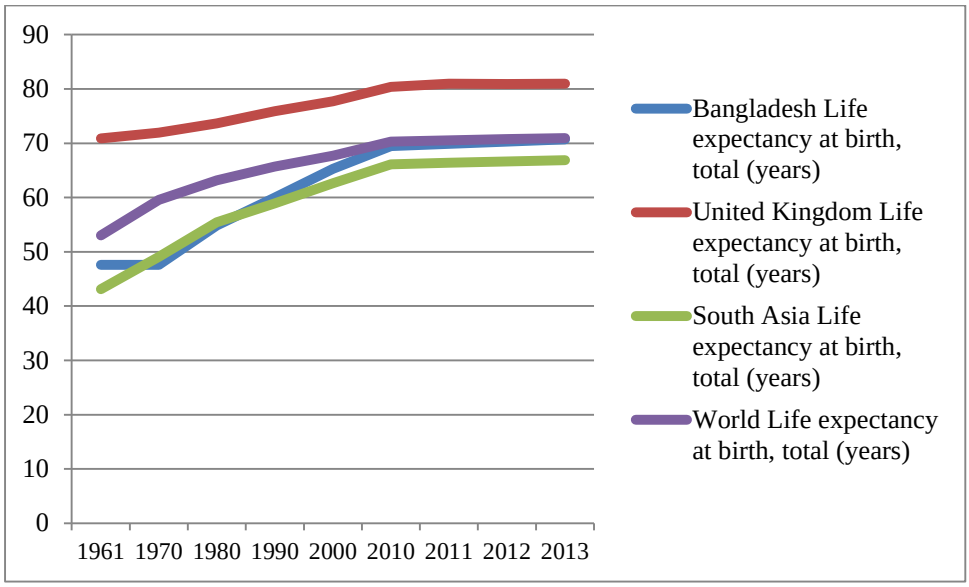
In spite of the low health expenditure, great improvements in health have been made in Bangladesh in recent years. Figure 11 shows how the life expectancy at birth for people living in Bangladesh has risen from approximately forty-eight years in 1970 to around seventy-one years in 2013, a figure that is higher than in all other South Asian countries (The World Bank 2015b).

Figure 10: A comparison of health expenditure per capita between Bangladesh, the United Kingdom and the world average



Values for Bangladesh are below 32 dollars per capita.
Figures are drawn from the World Health Organization, Global Health Expenditure Database (2015).

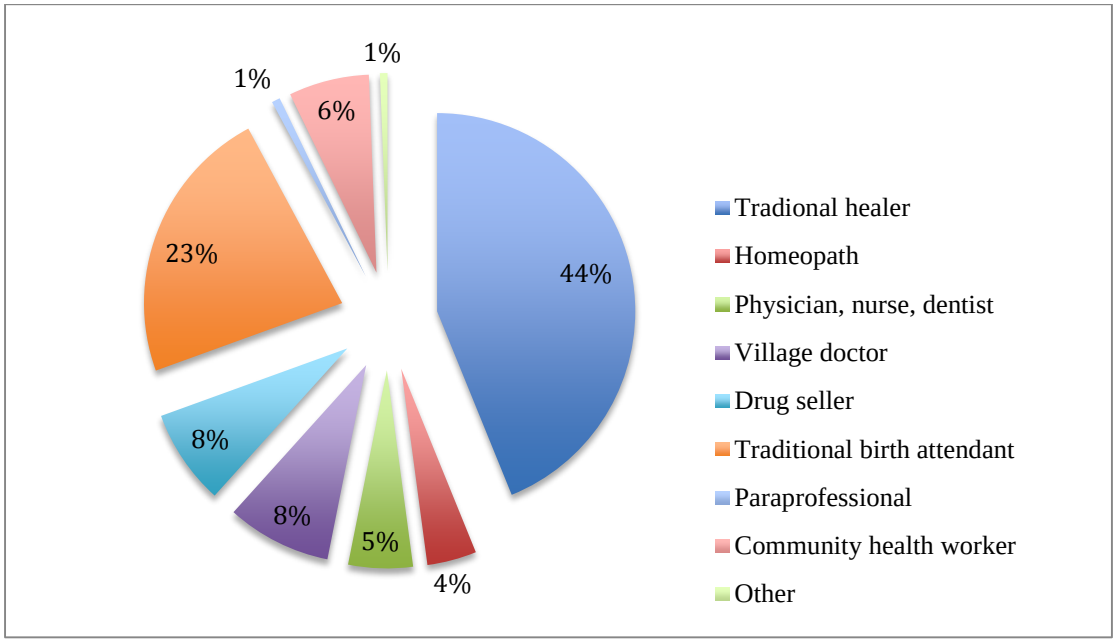
Figure 11: A comparison of life expectancy at birth between Bangladesh, South Asia, the United Kingdom and the world average



Figures are drawn from the World Bank (2015)

Many people in Bangladesh rely upon T&CM for their health needs and traditional healers are the most prevalent of all health care providers in Bangladesh (Figure 12)

Figure 12:Density of healthcare provider per 10,000 population in Bangladesh



Most traditional healers fall into one of three categories:

- Kabiraj, whose practice is based on diet, herbs and exercise;
- Totka, practitioners, who combine Ayurvedic, unani, and conventional medicine; and
- Faith healers who use a range of rituals including sanctified water, oil and chanting.

Other important providers of care are the traditional birth attendants (including both trained and non-trained providers) who provide a home-based delivery service; homeopaths, some of whom possess recognised qualifications from government or private homeopathic colleges (Ahmed *et al.* 2009); and village doctors, who are untrained providers of conventional medicine (Mahmood *et al.* 2010).

The pluralistic nature of healthcare delivery in Bangladesh is quite typical for many LMICs where conventional healthcare is not the dominant, or most widely used, form of medicine.

The ethical matrix highlights concerns relating to three ethical principles: wellbeing, autonomy and justice. In previous chapters I focussed primarily upon matters of wellbeing for the

stakeholders under consideration but the issue I have chosen to examine in relation to Bangladesh, as an LMIC, concerns the principles of autonomy and justice.

Briefly stated, the principle of autonomy refers to the capacity of an individual to be self-determining and to make decisions for themselves without undue pressure, coercion or other forms of persuasion and the principle of justice requires that we do what we can to ensure that costs and benefits are fairly distributed (Beauchamp and Childress 2001). The literature has clearly revealed an apparent conflict between autonomy and justice in health seeking behaviour for many people in LMICs and while this conflict is alluded to frequently, it has not been explored thoroughly. Clearly, there are barriers to access of conventional medicine for a number of reasons in LMICs but, equally, there are a number of reasons why T&CMs may be preferred. Hence, this analysis will focus upon the following question:

To what extent do people in Bangladesh use T&CM because they want to (autonomous choice) and to what extent do they use T&CM because it is the only readily available form of healthcare (justice in provision)?

This question is important because the findings could potentially influence future decisions about priorities, spending, structures and regulation in healthcare. If people are primarily opting for T&CM because they have little choice, then conventional medical provision should be prioritised and expanded. If, on the other hand, there are deeply felt reasons for using T&CM, then this must be respected equally. A further possibility is that there are particular circumstances in which one or other form of healthcare is preferred. If this is the case, then appreciation of these circumstances could help to target resources in ways that are aligned with patient preference and need.

Despite the significance of this question, it is a difficult one to address because there are many complex issues involved in people's healthcare choices. Moreover, for the top-down approach to use of the ethical matrix it is crucial that I find a way of 'putting myself in the shoes' of others and, for a person in my position, with a comfortable life in a high-income country, it might appear as rather arrogant that I should be making judgements about the healthcare choices of people in LMICs. However, through careful evaluation of the findings from existing studies, I believe it is possible to extract and analyse data that is relevant to this topic, as outlined below. This process will hopefully help to shed some light upon the question in hand.

8.3 A Meta-Ethnographic Analysis of Health-Seeking Behaviour in Bangladesh

A number of empirical studies have sought to investigate the 'health-seeking behaviour' of people in Bangladesh. These studies provide us with information about the types of health care that different groups of people use and the data is often correlated with socio-economic and demographic data to help determine the various influencing factors. Many of these studies are very large, cross-sectional studies[59] (Amin *et al.* 2010, Najnin *et al.* 2011, Chowdhury *et al.* 2015) that are useful for telling us about patterns of behaviour. A meta-analysis of these large surveys would be very helpful for telling us *what* people do, but would be much less helpful for telling us *why* they do what they do. In order to gain a deeper understanding of the reasons why people make the choices that they do, other studies have used qualitative, rather than quantitative methods, to seek the participant's perspective.

Qualitative research methods are concerned with looking for meaning, rather than dealing with numerical data. In contrast to quantitative methods that generally concentrate on the 'how', 'how often' and 'how many', these methods are used to investigate the 'why' in human behaviour (Silverman 2011). Qualitative methods are typically used in the social sciences to further and deepen our understanding of the social world, but have also been widely used in anthropological research and are becoming increasingly important in health care research (Holloway and Wheeler 2010). Essentially, qualitative methods are used to investigate the views of participants, with methods that seek, 'to enter into the inner world of another person and to gain an understanding of that person's perspective' (Johnson and Christensen 2008, p.207). The researchers who have used qualitative methods to investigate health-seeking behaviour in Bangladesh have, at least to some extent, attempted to place themselves in the shoes of the participants. In examining the findings from these studies I too must try to adopt this perspective to represent the interests of these stakeholders in the ethical matrix.

[59] Cross-sectional studies capture a snapshot of the issue or outcome under investigation, at a specific point in time. Data can be collected on individual characteristics, opinions and life style etc. to look for associations with the issue or outcome. They normally involve the use of surveys, sometimes with a very large population.

Because of the nature of qualitative investigation and analysis, it is impossible to avoid the influence of the researcher's prior conceptions and bias completely. Hence, qualitative findings are often referred to as a 'co-creation' between the researcher and participants (Pope and Mays 2000). For this reason, and because the numbers of participants in each study is normally quite small, it has been broadly accepted that the findings from qualitative investigations should not be generalised to wider populations. However, recent years have seen an increasing interest in combining the findings from qualitative studies to inform health-related policy and practice (Thomas and Harden 2008, Ring *et al.* 2011). Consequently, a range of different methods for synthesising qualitative research findings (metasynthesis) has been developed.

The first people to highlight the benefits of synthesising results from qualitative studies were Noblit and Hare, who introduced a method for the synthesis of ethnographic research findings termed 'meta-ethanography' (Noblit and Hare 1988). This method has since been adapted for many other forms of qualitative studies beyond ethnography but, in essence, all adaptations have involved the identification of key concepts from the various studies and 'translating[60]' them into one another. Explanations or theories associated with these concepts are also extracted from the studies and an attempt is made to pull corroborating concepts together in order to draw conclusions that go above and beyond those of the original studies. The notion of 'going beyond' the primary studies is a critical component of metasynthesis and is what distinguishes this method from a simple summary of findings that might be found with a traditional literature review (Thomas and Harden 2008). For the purpose of this analysis, a meta-ethnographic study was undertaken, in the style of Noblit and Hare (1988), to investigate the health-seeking behaviour of people in Bangladesh. This involved synthesis of the results from the available qualitative studies as detailed in the following steps.

8.3.1 Search strategy

The first stage in this meta-ethnography was to identify the relevant studies for inclusion in the analysis. For reliability of results it is important that as many studies as possible are included in a meta-ethnography, but also that it is limited to those that are relevant to the question in hand. For this question: 'To what extent do people in Bangladesh use T&CM because they want to and to what extent do they use T&CM because it is the only readily available form of healthcare?', the following key terms were selected: 'Bangladesh', 'health seeking',

[60] The term 'translating' here refers to the process of identifying similar concepts from different studies that may not be expressed with identical words.

‘healthcare seeking’, ‘patient choice’ and ‘patient preference’. They were applied through the academic databases Academic Search Complete, CINAHL, Science Direct and MEDLINE, as well as through Discovery and Google Scholar search tools.

For the sake of relevance, the date of publication was limited to papers from 2010 onwards as it was considered that older texts might not capture current preference trends. The way in which healthcare is delivered in Bangladesh has changed significantly in recent years, as is evident from the marked increase in life expectancy.

Full texts for each potentially relevant study were obtained and papers were examined in detail to ensure that all key studies were included according to the inclusion and exclusion criteria detailed below.

8.3.2 Inclusion/exclusion criteria

Papers were included if they:

- Sought to document reasons for choice in health care;
- Included mention of T&CM; and
- Included a qualitative component.

Papers were excluded if they:

- Were purely quantitative or
- Did not mention T&CM choice

8.3.3 Data analysis

The papers were synthesised using a three-step process of inductive thematic analysis. Stage one involved coding of the text from the original papers. Similar phrases or words were labelled with similar codes and these were repeatedly refined using an iterative process until all relevant data had been labeled with an applicable code. This process was undertaken with NVivo software, which is very helpful for the organisation of the data and structuring of the coding framework. Stage two involved the development of 'descriptive themes', whereby the coded data was organised into such themes, and stage three involved the generation of 'analytical themes'. The process of translating (Noblit and Hare 1988) is normally used in stage three, and not earlier, because it facilitates the analysis of themes across the papers. Whilst the descriptive themes remain close to the primary studies, the analytical themes represent a stage of

interpretation whereby the reviewers go beyond the primary studies and generate new interpretive constructs, explanations or hypotheses (Ring *et al.* 2011).

8.3.4 Findings

A total of twenty-two studies were found to have documented health-seeking behaviour in Bangladesh since 2010. Of these, twelve met all of the above criteria for inclusion and were included in the analysis. These twelve studies used a range of methods for data collection, including interviews, focus groups and observation techniques, as detailed in Table 11.

Table 12: Study Characteristics

Author(s)	Aim	Sample	Methods	T&CM use
(Aktar 2012)	To explore the behaviour of women seeking health care for safe motherhood in rural Bangladesh.	118 married women aged between 15 and 45 years, from 3 rural villages	Naturalistic observations, unstructured interviews, and a questionnaire that contained both closed and open-ended questions.	Most of the rural women (88.1%) did not have regular medical check-ups of any kind during their pregnancy. 88% had untrained birth assistants during delivery. 42.28% had consulted providers after abortions. Of these, 21% were homeopaths and 47.52% were kabiraj.
(Billah 2015)	To explore the dynamics of healthcare seeking practices of people living with HIV (PLHIV) and to examine the major socio-demographic factors determining their healthcare choices.	Purposive snowball sampling was used to identify 100 people living with HIV infection. Participants were aged 17 to 58 years old and attending clinics in Dhaka clinics. 67 were male and 33 respondents were female.	Mixed methods enquiry. All participants were interviewed and 20 case studies undertaken to explore the meaning, context and reasons for healthcare choices.	The health seeking practices of PLHIV are highly influenced by NGO services. Aside from conventional help, 14% saw homeopaths and 18% saw traditional healers. Many (47%) also used homeopathy and herbal medicine for prevention.
(Choudhury and Ahmed 2011)	To explore maternal care practices among women who participated in a grant-based livelihood programme for the ultra poor.	20 women, comprising 12 lactating mothers and 8 currently pregnant (who had had at least one previous childbirth) in Rangpur and Kurigram urban districts. 15 out of 20 were in their twenties, and two were below 20 years of age, while 3 were in their thirties.	A qualitative exploratory framework was used to collect maternal care practice from women in ultra-poor households. Data were collected through in-depth interviews using a flexible interview guide.	Cultural beliefs and norms have a strong influence on maternal care. Most of the deliveries took place at home (19 out of 20) with a traditional birth attendant being called after the onset of strong labour pains.

(Chowdhury *et al.* 2011)	To investigate three kinds of health behaviours: treatment-seeking behaviour during sickness, self-medication, and noncompliance of both prescription and over-the-counter drugs.	1,809 non-medical dorm students of Dhaka University and Jahangirnagar University (in Savar). 77% of the students were in the age-group 21 to 31 years, and the rest were less than 21 years; 89% of the students were male.	Interviews were conducted with every available and willing student at the residential halls	In spite of the availability of free conventional treatment at the university health centres many students opted for self-medication or private T&CM treatments.
(Ferdous *et al.* 2014)	To understand mothers' perception about signs and symptoms, causes, and healthcare seeking behaviours related to pneumonia when their children had pneumonia.	24 mothers from a sub-district of rural Bangladesh, whose children were hospitalized in a charitable institution providing low-cost health services to the surrounding rural population.	Exploratory study utilising focus groups. Mothers were asked to share their knowledge and perception about pneumonia and especially of health care seeking behaviour. 7-8 mothers were invited to participate in each session.	58% of parents first sought medicines from a local drugstore before coming to the hospital. Of these, 2 parents gave just traditional treatments and the rest gave a mixture of conventional, herbal and homeopathic medicines to their children.
(Hossain *et al.* 2013)	To characterise the perceived aetiology and care-seeking patterns for 'jaundeesh' (hepatitis).	One hundred people who self-reported jaundeesh and who lacked symptoms of yellow eyes or skin were randomly selected from a larger scale study in rural Bangladesh.	Formative part of a larger epidemiological study consisting of 100 in-depth interviews.	Jaundeesh patients primarily sought folk and spiritual remedies from informal care providers, with only 19% visiting conventional care providers. Kabirajs are the main care providers for jaundeesh and offer multiple treatment options such as amulets, ritual hand washing, and bathing with herbal medicines.

(Hossen and Westhues 2012)	To gain a deeper understanding of the use of traditional and modern medicine among older adult women living in rural Bangladesh.	17 women aged from approximately 60 to 75 years. 15 lived with their extended family in rural locations.	A feminist phenomenological approach using qualitative, in-depth, face-to-face interviews, typically 2 to 3 hours long. A semi-structured interview schedule established a general direction for the interview.	The women used a diverse range of treatments for different reasons with the most common being faith healers and herbalists. They distinguished between mild and severe illnesses and normally only resorted to conventional treatment for severe illness.
(Nahar 2010)	To document the health seeking behaviour of childless rural poor women and urban middle class women in Bangladesh.	20 rural poor (in Mymensing district) and 11 urban middle class (in Dhaka), childless women were recruited through snowball sampling methods.	An ethnographic approach. To gain insights into individual experience, life-history interviews were conducted face to face.	Local healers in the informal sector were found to be the most popular health service option among the rural childless women. Urban childless women predominantly sought expensive Assisted Reproductive Technologies (ART) treatment, which is available only in the formal sector, in private services. Despite their choice of conventional treatment, many urban childless women return to, or simultaneously pursue, various traditional, spiritual or folk treatments.
(Rahman *et al.* 2012)	To explore the context, reasons, and choices in patterns of healthcare-seeking behaviour of the hill tribal population of Bangladesh to present the obstacles and challenges faced in accessing healthcare provision in the tribal areas.	218 men, women, adolescent boys, and girls belonging to nine different tribal communities in six rural districts.	Participatory tools and techniques, including focus-group discussions, in-depth interviews, and participant-observations, were used. Data were transcribed and analysed using narrative analysis.	Traditional healers are very popular among the tribal population. The Baddya are the most common source of care for the tribal people for most illnesses. Homeopathic practitioners were the most common healthcare providers for women and children, together with traditional birth attendants.

(Rashid *et al.* 2011)	To document common sexual and reproductive health problems and use of providers.	312 women aged 15–49 from two rural and one urban area of Bangladesh. At least 100 respondents from each of three selected sites: Chittagong (urban), Rangpur (rural) and Sylhet (rural), which were chosen to represent a range of different poor populations in Bangladesh.	Face to face interviews using a questionnaire with both closed and open questions.	Both informal and formal markets played an important role in treating these problems, including for the poor. Of the total number, 65% reported taking conventional drugs, 35% used herbal medicine and other traditional remedies, and 10% used homeopathy.
(Sikder *et al.* 2012)	To describe care-seeking behaviour among women of reproductive age who died from fatal non-communicable diseases as recorded in northwest rural Bangladesh.	250 women who had died from a non-communicable disease were identified from a much larger study (125,000 married women aged 14 to 45 years). All lived in the rural district of Gaibandha.	Qualitative textual analysis of verbal autopsy narratives. Allowing for a four-week mourning period, conduct verbal autopsy interviews were conducted face to face by research physicians.	Of the 250 women, 71% first sought treatment from non-certified practitioners. Most of these however switched to certified providers when their condition did not improve. Some delayed seeking treatment because: they didn't realise how sick they were, the costs were high or the services far away. Of those women who were told they could not be cured, many used homeopathy for palliative care.
(Uddin *et al.* 2014)	To determine the consequences of hypertension and COPD[61] on daily functioning of patients, healthcare-seeking behaviour, and provider responses.	24 hypertension and 24 COPD patients, stratified by gender, income status and age. They were from two study sites, one rural (Matlab) and one urban (Kamalapur).	Part of a mixed methods, population-based, cross-sectional survey. All patients identified with hypertension and/or COPD were interviewed. Face to face, in-depth interviews were conducted in their own homes.	The primary source of care for those in urban areas was conventional medicine, with many more seeing qualified doctors than in rural areas. Those in rural areas are most likely to visit local providers for their treatments, typically pharmacies/drugstores and a range of informal providers from traditional healers to semi- or untrained village doctors.

[61] Chronic obstructive pulmonary disease.

8.3.5 The participants

In total, the twelve studies included 3,047 participants with a large number (1,809) coming from one study of university students (Chowdhury *et al.* 2011). The participants spanned all age groups, from infants to the elderly and included a wide range of health complaints including mild, short-lived acute problems (such as colds and coughs), and both life-threatening communicable diseases (such as pneumonia and AIDS/HIV infection), and life-threatening non-communicable diseases (such as chronic obstructive pulmonary disorder and hypertension).

Of the 3,047 participants, 1,004 were female and 1,677 were male. Gender was not specified for the other 366 participants. The gender balance was greatly affected by the number of male university students in the Chowdhury (2011) study as eighty-nine per cent of the interviewed students were male.

Two of the studies did not specify how many participants came from urban or rural areas. Students in the Chowdhury (2011) university study were drawn from both, as were the participants in the Billah (2015) study, who were seeking treatment at an HIV clinic in Dhaka. The remaining ten studies indicate that around 979 participants were from rural areas and around 159 from urban areas.

8.3.6 Emergent themes

Three key themes emerged from the final stage of analysis: *limitations of choice, mutual respect* and *exercising selectivity.* These were further subdivided into subthemes as listed in Table 12.

Table 13: Key themes and subthemes of healthcare seeking behaviour in Bangladesh

Key Theme	Sub themes
Limitations of choice	Structural constraints Cultural constraints
Mutual respect	Respect for patients Respect for practitioners
Exercising selectivity	Assessment of likely effectiveness Degree of severity Quality of care

The themes and subthemes are presented below using quotes from the participants and interpretations of the findings of the original authors, together with my own overarching analysis.

Limitations of choice

A large number of limiting factors for choice in health care were identified in the papers, assigned here to the categories of *structural constraints* and *cultural constraints*.

Structural constraints

Structural constraints include those practicalities that have direct impact upon the accessibility of healthcare provisions. These were reported in the majority of studies and clearly had an impact upon choice, especially for those who were poor and/or lived in rural communities.

For those in rural districts, travel requirements had a major influence on where people sought care for their health problems. The distance from the home to the practitioner, the poor quality of the roads, the lack of transportation or the high cost of hiring transportation all made travel highly challenging. During the monsoon season, such factors could be exacerbated as many roads and rivers become impassable for months at a time. Sometimes this would prevent people from seeking essential care, as exemplified by one woman, who said:

'I have recurrent abdominal pains on one side of my body. I need to go for an X-ray examination to know what is wrong but such facilities are far away and I do not have the money for transportation and the examination itself '(Hossen and Westhues 2012).

Another woman described how a visit to the hospital could be an arduous task for an elderly woman living in a rural area:

'The people in town can go in the afternoon. We in the village get up at 6 a.m. to take the bus. We arrive. We go to the doctor at the hospital. You arrive at 10 a.m. You are stuck there until the afternoon, without eating, without being able to drink water. You spend hours and hours and get hungry. You have to go back before the doctor has seen you. You miss the bus. You have to go however you can, so you can get home, even walking' (Hossen and Westhues 2012).

Rahman *et al.* (2012) also found this a major challenge for rural tribal members who cited transport costs, travel time, and distances as important barriers to seeking conventional healthcare.

Lack of finances was another limiting factor; Aktar (2012) described how, in families with a low income level, pregnant women simply could not afford to consult qualified doctors for their physical problems and illness. For some people, the consequences of poverty are fatal. Sikder *et al.* interviewed the families of one hundred women of childbearing age who had died from non-communicable diseases, enquiring about their treatment before death. Of these, seventy per cent of respondents reported poverty was the reason for not seeking medical treatment, or a lack of compliance with prescribed treatment. Additionally, many of the women had been referred to other clinics because of the nature of their complaints but these were unaffordable for the woman and her family (Sikder *et al.* 2012).

For others, both distance and finance were problematic. When parents of children with pneumonia were asked for the reasons why they did not seek treatment sooner, a number of practical reasons were proffered, including lack of money for treatment of their child, long distances to be travelled, poor road conditions causing travelling to be difficult or time consuming, and long waiting times in hospital (Ferdous *et al.* 2014).

Cultural constraints

Aside from the structural constraints upon choice in healthcare, cultural constraints were also frequently mentioned across the studies. The major cited difficulties affected women in particular. For instance, purdah[62] prohibits women from travelling alone, and presents a further obstacle to those women needing to seek health care outside their own locality (Hossen and Westhues 2012). Mothers were delayed in seeking hospital care for their children with pneumonia because they could not bring their children to the hospital alone and had to wait for another person to accompany them (Ferdous *et al.* 2014). Girls needed to be accompanied by a male relative to visit health centres, thus requiring support and valuable time from a male family member, who often needed to curtail employment with financial loss as a result (Rahman *et al.* 2012). As one elderly woman commented:

'It is not easy to go to the hospital when you cannot walk by yourself. You have to hire a tempo or vhotboti (locally made pull cart) in order to get there. And who is accompanying and staying with you there?' (Hossen and Westhues 2012).

In addition, Sikder *et al.* (2012) found that women seldom made their own health care choices, but rather that their families made all major decisions regarding their treatments. Rahman *et al.* (2012) noted the same thing. In spite of the major contribution that women make to local economies, men generally had control over finances and all major decisions made at the household level, including the choice and timing of healthcare treatments. Hospital care was not available in the villages and required permission from husbands or a male relative before a woman could access it. To go to hospital, a woman commonly had to find someone to accompany her, and then locate the money to pay for her care, arrange transportation and find somebody to do her household chores (Rahman *et al.* 2012). Monetary constraints and restrictions on the movement of women were also cited as reasons for not accessing antenatal care (Choudhury and Ahmed 2011).

[62] Purdah is the practice of screening women from men or strangers.

Mutual respect

The importance of mutual respect appears to be a crucial factor in the healthcare decision making process. People want to be treated with respect by their practitioners and they also want to feel respect for the practitioner.

Respect for patients

A recurrent view from participants suggested that people commonly felt conventional doctors lacked respect and understanding for them (Rahman *et al.* 2012). The problems with lack of respect were acutely highlighted in the accounts of experiences with publicly funded hospitals. People living with HIV and AIDS described feelings of discrimination arising from the attitudes of public health practitioners. As one participant commented:

'Doctors in public health centres do not show any interest for touching us, let alone mental support and requisite counselling. It seems to me that we are really neglected and helpless in regard to treatment seeking' (Billah 2015).

In contrast, their experience of treatment by health practitioners in the nongovernmental organisations (NGOs) was completely different and most of the respondents reported that they were highly satiated with the treatment and counselling of care givers of NGO clinics (Billah 2015).

Women from poor households seeking maternal care expressed similar opinions about public health facilities, describing usage of abusive language, denial of services, lack of compassion and a refusal to assist properly. One seventeen year old described her visit thus:

'I went to government facility for antenatal care. The concerned person told me I might need caesarean, and I would die if I did not go to the hospital. Are these words good to tell someone who is pregnant?' (Choudhury and Ahmed 2011)

Older women in Hossen and Westhues' (2012) study also described a perceived lack of respect in the modern health care system. One woman explained:

> Whenever you go, doctors will ask, 'ki shomoshaya' (what's wrong with you?) Well, I have been suffering from lower abdominal pain. 'Well take these pills

> and that's that.' They don't let you to talk with them. You may have other concerns to talk about but they become rude. You can never be satisfied with this kind of service (Hossen and Westhues 2012).

In addition, they described a form of discrimination based on age, class and gender. The services that are most needed by the older women, such as laboratory testing, gynaecological examinations, treatment for menopause, and breast cancer services are only found in large hospitals and clinics in urban areas. As one participant mentioned,

'In the clinic you will not get anything for senior people. The clinics are only dealing with children and family planning issues' (Hossen and Westhues 2012).

In contrast, Hossen and Westues (2012) observed a bond of trust and faith between their participants and their traditional healers. The women in their study mentioned that they felt more comfortable asking questions and talking about their illness and treatment with someone who, 'shares the same cultural heritage, is female and who speaks their native language' (p 338) They quote one participant as explaining,

'*We go to a mohila (female) kabiraj. She talks with us, prepares medicines, explains everything properly and nicely. She never charges us too much. If it is midnight you can call her. She does not mind'* (Hossen and Westhues 2012).

Respect for practitioners

When practitioners showed respect for their patients, in turn patients respected them more highly, as the last quote in the previous section indicated. Rashid *et al.* (2011) found the same applied to the women in their study. Informal providers were preferred because of the absence of class differences and existing social relationships. Most are deeply embedded in rural communities and are called to visit homes for treatment, reflecting a high degree of community trust. The treatments prescribed by kabirajs were also highly respected because they have been in use for hundreds, if not thousands, of years (Hossain *et al.* 2013). Whilst their traditional healers lacked medical training, tribal people demonstrated a high degree of trust and faith in the healing skills that had been passed down from the ancestors. Consequently, they sought treatment from them for a wide range of illnesses, such as orthopaedic problems, mental health issues,

infections, and common cough and cold (Rahman *et al.* 2012). Traditional health care providers were aware of local beliefs and customs and were trusted because they lived in the community (Hossen and Westhues 2012). Nahar (2010) highlighted the importance of having a shared explanatory model for health and disease. In her study of the health seeking behaviour of childless women, Nahar found that, according to the traditional healers, infertility is caused by spiritual reasons and therefore it can only be treated by spiritual means, not by any biomedical procedures. The rural women that she interviewed shared the same explanatory model. As this woman explained,

'Childlessness is a condition that can be treated by a kabiraj as they understand better. This is not a condition that doctors can treat. The kabiraj knows better about childlessness' (Nahar 2010).

Exercising selectivity

Selectivity is used here to mean: '*the quality of carefully choosing someone or something as the best or most suitable'*

Even within the confines of limited choice, people move between traditional herbal, conventional treatments (including self-medication from drug store), homeopathy and religious healers, depending upon their availability and perceived suitability for their problems (Nahar 2010). The findings of these studies suggest that people have fairly well structured frameworks for healthcare decision making, based upon three main factors:

- Assessments of likely effectiveness
- The degree of severity of an illness
- The quality of care

Assessments of likely effectiveness

In most high-income countries, where conventional medicine is dominant, there is an overwhelming demand for medicine to be 'evidence-based' and for decisions to be based upon reliable research evidence (Evidence Based Medicine Working Group 1992). However, this conceptualisation of evidence is not helpful for many people who

live in Bangladesh, without access to the results of medical research, and who are using traditional treatments that have very rarely been subjected to testing. Even so, assessments about effectiveness are not random; they appear to be made on the grounds of personal experience, on the basis of fit with their own explanatory model, and on advice from trusted persons.

To a large extent, personal experience shapes opinions about effectiveness, as described by this woman:

'I had been suffering from insomnia. The kabiraj gave me some herbs to boil and take before I slept. I was dubious about the effect of the kabiraji medicine until I tried it. Now I don't have any problems sleeping. It was great and effective. I was surprised by the efficacy' (Hossen and Westhues 2012).

Sometimes, different forms of treatments are tried and the results are compared, as shown by the comments of the mother of a three year old boy with reported jaundeesh, who said:

'In the hospital, the doctors did blood tests and said my son had jaundeesh. They gave him vitamin drops and told us to come back in four days. I did not go back since my child was not improving with hospital treatment. To cure my child, I had to visit the kabiraj, and he got better treatment compared to the hospital' (Hossain *et al.* 2013).

There is broad acceptance that different types of medicine are needed for different concerns, and that T&CM treatments are believed to be more efficacious for certain types of complaint. Jaundice is one such example:

'If you have jaundice a doctor cannot cure you, you have to go to a kabiraj' (Hossen and Westhues 2012).

Particular kinds of treatment can also be believed to be more efficacious for particular people. For example, homeopathy is the most frequently used treatment for women and children in the tribal communities that Rahman *et al.* (2012) studied.

A widely held belief is that diseases with a spiritual component are beyond the scope of conventional medicine. For example, illnesses believed to be caused by the wind (dushito bayu) and the evil eye (nazar laga) are not considered curable by conventional means. As one woman explained,

'The Imam has special understandings about some special sicknesses which a doctor could not even diagnose. I was possessed by a djin (spirit). The doctor did nothing but I was cured by the Imam' (Hossen and Westhues 2012).

A shared explanatory model for the underlying causes of disease appears to be very important in the assessment of whether a treatment is likely to be of any use.

Lastly, opinions about effectiveness are guided by respected members of the family and community (Ferdous *et al.* 2014), who can pass on their own experience and discuss the suitability of the potential providers. Provider reputation can play a major role in treatment-seeking decisions (Rashid *et al.* 2011) as stories of their successes and failures are passed quickly between members of a community.

The degree of severity of an illness

Across the studies, there is an emergent consensus that hospital treatment is needed for severe and life-threatening diseases. For people living in rural areas, the first line of treatment is self-care involving either conventional or traditional preparations (Chowdhury *et al.* 2011) or a visit to a local healer. Only later, if this approach does not work, is the more expensive and less convenient option of conventional treatment considered. This pattern of behaviour was obvious across several rural communities and is well illustrated by this mother's account:

'Elderly people told that tulshi leaf (herbal medicine) with breast milk is good for cough and cold, so first I gave tulshi leaf with breast milk to my child; but once I observed that his condition is getting worse, and I stopped giving breast milk. However, my baby suddenly developed convulsion, and I took him to the hospital immediately' (Ferdous *et al.* 2014).

Another mother had a similar story:

'My child had symptoms like running nose, cough, and cold. Initially, I gave him herbal medicine (lemon juice and extracts of tulshi leaf with lukewarm water) three to four times per day and I also bought medicine from local drug store, but my child did not get well. Then I took him to the hospital' (Ferdous *et al.* 2014).

Rahman *et al.* (2012) noted that people with illnesses that seemed less serious or were perceived as lacking a direct 'natural' cause (for example, headache, pains, rashes, etc.) preferred traditional healers whereas people of all ages suffering from diseases perceived as 'serious' and as caused by 'natural' elements (malaria, jaundice, etc.) were taken to facilities offering conventional treatments.

Likewise, Hossen and Westhues (2012) tell how their participants distinguished between soto khato (mild sickness) and marattak oshuk (severe sickness). Soto khato (mild sickness) was considered normal, tolerable, and could be cured by self-medication or consulting a faith healer or herbalist. For marattok oshuk (severe sickness), a doctor's support was necessary. One participant described this as follows:

'It depends on how unwell I am and what the problem is. For minor problems like headache and runny nose, we can use pura pani (water blessed by the Imam). If this does not work I would go to see a doctor. If it is heart attack or diarrhea you have to go directly to hospital' (Hossen and Westhues 2012).

Another participant reinforced this message stating:

'If you don't feel well, like matha zim zim kora (dizziness), hozomer beram (indigestion), rat jaga (insomnia) you can go to the Imam and get pura pani or jhara (verses to chant from the Quran) and become well. If the disease is minor you can go to the Imam. But if it is amarattok oshukh (major disease) like a heart attack you need to go to the hospital. Some illness can be cured by doctors and some can be cured by the Imam' (Hossen and Westhues 2012).

The quality of care

One final concern that appeared to be important for selectivity was the quality of the available care. This point is perhaps most evident from comments about publicly funded healthcare which is often not accessed even though it represents a much cheaper (or even free) healthcare option. Money, it seems, is not always a limiting factor:

'To treat complicated diseases (surgery cases), we had to sell our valuable properties' (Rahman *et al.* 2012).

According to Rahman *et al.* the fees for service providers were not the most significant determinant of choice for healthcare provider. The participants in his study of tribal communities were willing to pay larger sums for care, even for T&CM care, if they felt that the services they received were of high quality, efficient, and respectful of their cultural differences. For example, regardless of their distance and the costs that the Christian missionary hospitals charged for their services, the tribal people who had access to the hospitals appreciated the quality of services, cleanliness, and polite behaviour of the health staff working there. In emergency situations, the respondents communicated their preference for the missionary hospitals or private practitioners over the public-health facilities (Rahman *et al.* 2012).

8.3.7 Discussion

Meta-ethnographic studies are limited by the characteristics and findings of the original studies selected for scrutiny (R. P. Lee *et al.* 2015). Whilst twelve studies would normally be considered a good number for the general application of meta-ethnography, given that I am seeking views that are representative of an entire population (i.e. of Bangladesh), more studies would have been preferable, as the results are decidedly skewed towards the opinions of those who are less wealthy, and those who live in rural areas. The opinions of more wealthy individuals, who predominantly live in urban areas, are not well represented in the analysed papers and hence are under-represented in the subsequent analysis. A large proportion of the participants came from the Chowdhury *et al.* (2011) study, which surveyed university students, and, whilst they may have come from urban areas, this paper was not rich in qualitative information. In addition, the health-seeking behaviour of students was mostly concerned with the

treatment of minor complaints. With this in mind, no conclusions will be drawn about the opinions of urban-dwelling Bangladeshis. However, we do know from a number of quantitative studies, that people living in urban areas of Bangladesh are more likely to have higher incomes and more likely to use qualified providers, especially registered physicians (Anwar *et al.* 2008, Mashreky *et al.* 2010, Nahar 2010, Hamid *et al.* 2015). This trend has been found in other LMICs (Zere *et al.* 2010, Saxena *et al.* 2013, Devkota and Upadhyay 2015).

It is also worth noting that, of its population of approximately 160 million (World population review 2015), around ten per cent reside in the twenty largest cities[63]. Thus, while urban and better income individuals are largely absent from the selected studies, the majority of the population in Bangladesh falls into the rural and low income sectors.

The emergence of clear themes from the meta-ethnography carried out here suggests that opinions and patterns of health-seeking behaviour are similar across some communities, and hence we can assume, with a degree of confidence, that the findings are representative of a significant number of people in rural Bangladesh.

The health system in Bangladesh is a pluralistic system and delivery occurs via three key sectors:

1. The public healthcare system
2. The private healthcare system
3. The non-governmental organisations (NGOs)

The public healthcare system has limited capacity and provides only basic services. The quality of these services is reported as being fairly poor (Ahmed *et al.* 2015) and this was corroborated by the experiences of many participants in the meta-ethnography. The private healthcare system consists of a wide range of formal and informal services, both conventional and T&CM. The formal sector consists of conventional and some T&CM services (unani, ayuvedic, homeopathy) delivered via clinics and hospitals, while the informal sector consists mainly of untrained providers of conventional or T&CM. In

[63] Dhaka is by far the largest city in Bangladesh with a population of just over seven million. Chittagong and Khulna the next largest with 2.6 million and 660,000 citizens, respectively.

the informal sector, village doctors comprise some sixty per cent of those healthcare providers practising conventional medicine, even though they lack formal training (Kabir *et al.* 2014). Hence people in rural Bangladesh may have ready access to many conventional drugs but rather poor access to conventional health services, trained doctors and other healthcare workers.

Formal healthcare workers are mostly concentrated in the urban areas of Bangladesh and people in rural areas are primarily served by health care providers in the informal sector (Ahmed *et al.* 2015). Supplementing these two sectors are the services provided by NGOs, which seek to promote people's welfare through grassroots initiatives and development programmes (Ahmed *et al.* 2013).

Over the last decade, Bangladesh has seen significant improvements in health outcomes even though it is a resource-poor country (Chowdhury *et al.* 2015). Most gains have been attributed to improved public health services, such as increased coverage of immunisation, improved antenatal care and mass mobilisation for oral rehydration therapy to combat childhood diarrhoea and tuberculosis control (Uddin *et al.* 2012, Khan *et al.* 2013, Rahman *et al.* 2014). Despite this, there are obvious inequalities in health care utilisation between different groups, as is clear from the experience of people living in rural communities. Income and availability matter in shaping the way that individuals use different kinds of care and the stage at which they are chosen: the rich have greater opportunities to seek conventional care, and do so sooner than the poor, who are more likely to rely upon traditional forms of care, especially in the early stages of treatment (Sato 2012).

People in rural communities are not well-served by the formal health sector in Bangladesh and the majority of the country's population (up to 80 per cent) seek their primary care from informal healthcare providers: traditional healers, faith healers and community health workers (Chowdhury *et al.* 2015). Whilst this is a typical situation for the poorer members of society in LMICs, little has been written about the precise way in which T&CMs are utilized, how they might be contributing to health and wellbeing and to the improving longevity of the population.

The purpose of this meta-ethnography was to inform the question: 'to what extent do people in Bangladesh use T&CM because they want to and to what extent do they use T&CM because it is the only readily available form of healthcare?' Whilst the question cannot be answered precisely, it is obvious from the findings that there are constraints upon people who live in rural areas that affect their choice of healthcare provision. Economic factors and the challenges involved in having to travel long distances for care are highly influential. For women in rural areas, there is an additional obstacle to overcome, because they may need to be accompanied. However, people living in rural areas still demonstrate selectivity in their treatment choices. There is general agreement that serious complaints need to be treated with conventional care, from formal providers. Other complaints are commonly dealt with through self-care or by visits to local practitioners. There are clear preferences for local T&CM providers, an important factor being the perceived mutual respect, which often appears to be lacking with public healthcare.

Another notable consideration is that health, for these people, is not just about the treatment of mental and/or physical complaints. For many, there is a spiritual component to health that simply cannot be treated with conventional approaches. Additionally, as we have seen in chapter three, strong social ties make a positive contribution to resilience and the way in which traditional healers are embedded within the community may help to promote this. The value awarded to the giving and receiving of respect and the need to feel cared for by someone with a shared understanding may well be important requisites for feeling socially connected.

Clearly, there are perceived spiritual and social benefits from the use of T&CM treatments, but what this study cannot tell us is whether there are physiological benefits from using herbal treatments or homeopathy or any other indigenous medications. There are indications that some T&CM treatments are viewed as being more effective than conventional options. For instance, T&CM treatment was believed to be more efficacious than conventional alternatives in the treatment of hepatitis (Hossen and Westhues 2012, Hossain *et al.* 2013). It is possible that many traditional treatments have medicinal value but this is largely unexplored.

From the small number of studies that investigate the health-seeking habits of people in urban Bangladesh, it is apparent that even when conventional treatments are readily available, people use T&CM treatments alongside or instead of conventional care (Nahar 2010, Chowdhury *et al.* 2011), just as they do in the United Kingdom (Posadzki *et al.* 2012c). When given the choice, it appears, many people in urban areas still select T&CM and it remains an important component of their health care.

8.3.8 Recommendations arising from the meta-ethnography

Many suggestions have been made for ways in which inequalities and inequities in the healthcare system in Bangladesh could be addressed (Najnin *et al.* 2011, Rahman *et al.* 2014, Ahmed *et al.* 2015, Hamid *et al.* 2015). In recent years, government and donor-funded initiatives have made significant inroads but the logistics involved with delivering effective, high quality and culturally acceptable services to a largely rural population are complex and challenging.

Two of the reviewed papers suggested that inclusion of kabirajs and other traditional health practitioners in health education and training programmes could help to advance primary care services. If local healers were integrated into the public health system, this could greatly increase access to appropriate care through newly created referral processes (Hossen and Westhues 2012, Hossain *et al.* 2013). Such an initiative would clearly be aligned with the WHO recommendation that Member States should develop national approaches that reflect their specific needs in dealing with the most popular forms of T&CM by properly integrated them into national health systems (WHO, 2013). The words of Dr Margaret Chan (2008), the Director General of WHO, have direct relevance here, just as they did when considering issues related to wellbeing in Chapter five:

> The two systems of traditional and Western medicine need not clash. Within the context of primary health care, they can blend together in a beneficial harmony, using the best features of each system, and compensating for certain weaknesses in each. This is not something that will happen all by itself. Deliberate policy decisions have to be made. But it can be done successfully.

Lastly, on the topic of effective healthcare delivery for people living in rural areas, many advances have been made in recent years, through use of telemedicine. A number of studies have investigated the use of telemedicine in various locations around the world and found it to be especially helpful for people living in rural areas (Nakashima *et al.* 2013, Bifulco *et al.* 2014, Goozner 2015, Menon *et al.* 2015, Yang *et al.* 2015). Telemedicine can be used for consultations but it can also be used for education and training of local practitioners and groups. Women in Bangladesh, in particular, may benefit from telemedicine options, given the concerns about travelling alone. With the number of mobile phone subscriptions at 128.769 million (July 2015), representing around eighty per cent of the population, and the number of internet subscribers at 50.707 million, representing around thirty-two per cent (Bangladesh Telecommunication Regulatory Commission 2015), this could be a viable option.

CHAPTER NINE: CLOSING CHAPTER

At the onset of this undertaking, I was aware of ethical concerns about T&CM (traditional and complementary medicine) practice, such as inconsistencies in the reporting of adverse effects and deficiencies in the training and regulation of practitioners, but my perspective was based on my experience in the United Kingdom and in Europe, and was also largely anthropocentric. I could not have imagined, at that stage that I would be delving into topics as diverse as steel and copper production, zootherapy and access to healthcare in rural Bangladesh.

In this closing chapter, I will summarise the main points of my learning at each stage of this thesis.

My first task was to establish the limits of my enquiry through the identification of what is meant by the terms ‘traditional’, ‘complementary’ or ‘alternative’ medicine. These terms are often used interchangeably to describe a range of health care approaches that do not fall under the umbrella of conventional medicine, but the range is so diverse that it was not possible to define clearly what it is that describes a treatment approach as T&CM. The way the WHO distinguishes between treatments that are used in a complementary manner and those that are deeply rooted in local culture and traditions was key in my decision to adopt the nomenclature ‘T&CM’. For many people outside the UK, T&CMs are their primary source of healthcare, and not just something that is used to supplement conventional medicine.

My second task, that of trying to define ‘health’, also proved complex and challenging. My first point of learning was that health is not just about the absence of symptoms and neither is it about complete wellbeing, as is stated in the most widely referenced definition employed by the WHO (1946). Instead, consideration of the healthiest populations in the world provided a vibrant picture of what health can look like, and enabled insight into how it might be achieved. The high levels of health that are experienced by the Okinawans, for instance, do not stem from access to expensive, high tech medical systems, but rather, their health can be attributed to a variety of simpler

measures, such as a healthy diet, staying active into old age and having a strong sense of community. This community spirit, or 'yuimaru', as it is termed in Okinawa, is widely credited as an important factor for longevity and health into old age (Willcox *et al.* 2013). Significantly, it is seen as enabling autonomous living into old age (Franklin 1996). At the age of ninety-five, Okushima explains why she would not leave her home to live with her family, 'I have friends and neighbours here. On summer evenings we walk along the beach until after seven or eight at night. We dance, we drink awamori, we talk and talk and talk for hours. All this enjoyment ' (Franklin 1996).

In 2011, a group of health workers and academics came up with their own definition of health as, 'the ability to adapt and to self-manage when facing physical, mental, and social challenges' (Huber *et al.* 2011, p.2). This definition reflects the resilience of the Okinawans who, in spite of their exposure to potentially stressful situations, exhibit low levels of disease, and live long and active lives (Willcox *et al.* 2008, Buettner 2012). It also reflects a convergence of thinking across various disciplines, such as psychology and environmental science, and is in direct alignment with the way in which many T&CM philosophies describe health.

Development of an ethical matrix for T&CM revealed that most published ethical concerns were related to human users, and primarily those who use it in a complementary manner. Given the large number of identified ethical challenges related to humans, the analysis of ethical concerns for human users in the UK was restricted to those issues related to safety, and focussed on the potential for direct adverse effects (adverse drug reactions) and indirect adverse events. Scrutiny of these two safety issues was in turn limited to the examination of adverse drug reactions arising from herbal medicines and adverse events relating to the use of homeopathy for the treatment of mental health complaints.

My analysis revealed that there are clear steps that can be taken to reduce the potential for harm from adverse drug reactions associated with herbal medicine, as outlined below.

For people using herbal products, the risk of experiencing ADRs from herbal preparations can be minimised if they:
• Inform their healthcare practitioners (conventional and T&CM) when taking herbal medications alongside conventional medications. • Adhere to the instructions for dosage either on the packet for over-the-counter products or as provided by the practitioner for prescribed products. • Use the Yellow Card reporting scheme for any suspected adverse reactions. • Never buy unlicensed herbal medicinal products via the internet.

For practitioners, the risk of harm to their patients can be minimised if they:
• Keep up to date with safety data concerning the potential for ADRs from herbal medicines. • Inform patients of the potential for ADRs (where known). • Inform patients about what to do if they suspect that they are experiencing an ADR. • Make full use of the Yellow Card system for reporting suspected ADRs. • Ensure that patients understand how to use their prescribed herbal medications.
For patients who are concurrently using conventional medication, the risk of harm can be minimised if they:
• Take the relevant steps needed to avoid herb/drug interactions, including referral back to the conventional healthcare professional when appropriate.

Similarly, analysis of the potential for adverse events arising from using homeopathy for mental health complaints revealed that there are practical measures that can be put in place to reduce the likelihood of such events, as follows:

For people using homeopathy the risk of experiencing an adverse event can be minimised if they:
• Consult with a conventional medical practitioner for diagnosis of their complaint before treatment, as homeopaths are not qualified to undertake clinical diagnoses. • Are aware that anyone in the UK can legally call him/herself a homeopath and practise homeopathy, even if they have no training or experience, so it is important to ensure that their practitioner is registered with a professional body. • Consult with a conventional practitioner on all matters concerning the use of conventional medications.

For practitioners, the risk of harm to their patients can be minimised if they:
• Always seek to work within their bounds of competence. • Be prepared to seek advice from their professional body and take challenging issues to supervision. • Never work alone. Ensure that patients with mental health problems have support networks in place before undertaking treatment. Ensure that both practitioner and patient know whom to contact when they need support/help/advice or if there is a medical emergency. • Understand that they must take action if a patient poses a risk to themselves or others. Because of the potential for harm, patient confidentiality can be breeched in these situations. • Never give advice about conventional medications.

In Chapter six I explored the impacts of T&CM upon the environment. Climate change is considered the greatest challenge to healthcare of the twenty-first century (Costello *et al.* 2009). Together with increasing ecological degradation and the inevitable onset of peak oil, these are major threats to the environment and to the health of all living beings. There is an urgent need for health care services to respond to these threats and to prepare for the challenges that the future holds (Naylor and Appleby 2013). Conventional healthcare services contribute to environmental damage on a scale that is unsustainable (Verkerk 2009), and there is a need for all aspects of health and social care to examine their own contributions to such damages in a critical fashion. My analysis of ethical concerns, pertaining to the environment issues inherent in the use of T&CM, involved detailed scrutiny of the environmental impacts of the five main types of T&CM identified in the UK. This analysis revealed that there are damaging environmental impacts arising from each of these five types of T&CM, but that these could be reduced or mitigated in various ways. Whilst the impacts from chiropractic, osteopathy and homeopathy are comparatively small, there is significant cause for concern about the use of copper and steel in the manufacture of acupuncture needles, because they are not recycled, and there are further concerns about the sourcing of plants for herbal medicines.

My recommendations for each type of T&CM are too numerous to list here but the overarching themes were as follows:

Risk of damage to the environment from T&CM can be minimised if:
• All products that are used in practice are assessed for their contribution to environmental degradation, climate change and peak oil, and replaced with more environmentally friendly options where possible • Multi-method conservation approaches are adopted and implemented globally to ensure the sustainability of plant sources • T&CM practitioners are more centrally located, in places that are easier for people to reach and less environmentally costly to run. • Opportunities for the use of telemedicine are explored.

In Chapter seven, consideration of animal wellbeing revealed a potential for benefit in the UK from use in veterinary practice that appears to be growing in popularity. However, a global perspective revealed that animals are being routinely harmed through use in T&CM products and research. In many countries, legislation for the use of animals in T&CM and in associated research projects is not implemented effectively. Additionally, protected and endangered species are hunted for their use in T&CM products (Still 2003, Chakravorty *et al.* 2011). My ethical analysis revealed many problems with the use of animals, but it also revealed steps that could be taken to address these. The recommendations are as follows:

Recommendations for the use of animals in T&CM practice and research
• The same ethical standards should be applied to both the use of animals in research and the use of animals in the manufacturing of T&CM products. (There may be differences in how the standards are applied but the principles should be the same. For example, the principle of 'Reduction', one of the three Rs, is intended to minimise the number of animals used. In research this would involve an understanding of methodological design and statistical analysis; in the manufacture of products, this would involve an accurate assessment of the actual need for a product.) • Ethical standards for the use of animals need to be globally agreed and applied consistently. The current movement towards global standards for animal experimentation should be encouraged and developed further. • Guidelines should reflect current scientific understanding that similar responses to pain and suffering are present in mammals, birds and fish. Any distinction between species for experimentation or use in products needs to be justified on other grounds. • Academic journals need to adopt guidelines for publication that require the highest ethical standards, rather than accepting those local to the authors in order to promote ethical practice and discourage unethical practice in animal research.

The last stakeholders I considered were LMICs. There are numerous ethical challenges associated with the use of T&CM in LMICs, but for reasons given I examined an issue related to autonomy and justice for people living in Bangladesh. Through the use of meta-ethnography, which provided insights into the opinions of the study participants, I sought to address the question: 'to what extent do people in Bangladesh use T&CM because they want to, and to what extent do they use T&CM because it is the only readily available form of healthcare?'

From that analysis, it was clear that, in spite of the many constraints upon access, people in Bangladesh still expressed selectivity in their choice of healthcare provision. There was a clear preference for T&CM for certain types of complaints, as well as recognition that other, urgent and serious, complaints may need conventional care. Even those who resided in urban areas still opted to use T&CM as well as conventional treatments, suggesting that conventional medicines do not supply them with all the tools they want or need for their health care.

The aforementioned recommendations for each of the stakeholders have emerged from applied ethical analysis of challenges for T&CM and they are intended to be informative rather than prescriptive. Given the broad-ranging topics that have been covered, the recommendations have not been designed for one specific body. Rather, they could be helpful for a range of purposes and a variety of organisations. For example, the recommendations from analysis of the potential for adverse events in humans are helpful for the homeopathy profession and indeed they have already formed the basis of guidelines for homeopaths working with people with mental health complaints (Chatfield, 2013). Analysis of the ethical challenges associated with the use of T&CM for animals resulted in a recommendation that journal editors review their publication policy for research involving animal experimentation and, as a direct result, one of the most highly respected T&CM peer-reviewed journals is currently developing new policy and author guidelines. Whilst some of the recommendations may have local or profession-specific impact, others may require national or even global action. For example, analysis of the ethical challenges associated with the use of T&CM for the environment will provide individual professions with information and recommendations that may help to increase the sustainability of their practices but it will also enable legislators and policy-makers to make more informed decisions about

the potential place of T&CM within sustainable healthcare systems. Undoubtedly, my recommendation that use of animals for the production of T&CM products should be subjected to the same ethical requirements as animal experimentation will require multi-national willingness and effort for implementation.

Whilst I did not set out to undertake an in-depth critique of the ethical matrix *per se*, my prolonged application of this ethical framework over the course of my PhD study has inspired me to reflect upon the usefulness of this approach to ethical analysis.

Discovery of the ethical matrix, and its application to T&CM, had a significant effect on my perspective, and has enabled me to identify a broader range of ethical concerns, and then to consider these in new and productive ways. Before I even began this analysis, the need to think about whom to include as stakeholders in the ethical matrix set my thoughts on a trajectory that stretched beyond humans and beyond the UK. However, I believe the primary benefit from use of this methodology was realised through a 'top-down' approach. The top-down application necessitated a 'walk in the shoes' of the various stakeholders, because they are unable to represent their own interests. In so doing, I attempted to view ethical concerns from the perspective of animals and from that of the environment, as well as of human beings in the UK and in LMICs. This approach to the analysis encouraged sensitivity towards the interests of the stakeholders, which, in turn, facilitated subsequent pragmatic analysis, rather than limiting my endeavours to that of a purely theoretical exercise.

My application of the ethical matrix has differed from that of Mepham in two significant ways:

Firstly, the ethical matrix was originally designed for consideration of particular and specific issues, such as cattle transport or radioactive waste management. I, however, have applied the ethical matrix in a more holistic manner to create an overview of ethical concerns for a very large topic and then considered specific issues arising from this perspective. Whilst this differs from Mepham's approach, he is clearly of the opinion that the matrix can be adapted for use in a wide variety of situations (Mepham 2005a) and I believe that my application in this more holistic manner has been particularly helpful for appreciation of the scale and scope of the ethical challenges for

a range of stakeholders and for the organisation of the existing ethical challenges found in the literature.

Secondly, for the analysis of ethical challenges for animals and the environment I have applied only the principle of wellbeing and have not attempted to apply the principles of autonomy and justice. I appreciate that this has confined my analysis to a consequentialist approach thereby limiting the cross-normative theory approach to ethical analysis. I do not doubt that a cross-normative theory approach to ethical analysis could, in theory, be applied in the case of animals and the environment, however, I have concerns about doing so within the context of the principles that are identified in Mepham's ethical matrix. The ethical matrix is founded upon the four principles introduced by Beauchamp and Childress (1994) for analysis of ethical issues in healthcare and whilst these are claimed as prima facie principles for humans, their application to non-human animals is not at all straight-forward. Application of these principles for animals and the environment is open to a range of unresolved conjectures (for example, what is an autonomous animal?), which are almost as limiting as using consequentialism alone. My decision to undertake a purely consequentialist approach for the case of animals and the environment has, nevertheless, resulted in a robust ethical analysis and generated many relevant recommendations.

My final comment on the ethical matrix is more of a recommendation. As previously stated, when using a top-down approach to the ethical matrix it is important to try and step into the shoes of the stakeholder under consideration. This may involve new and creative approaches such as the method I have used for the analysis of people living in LMICs. Qualitative research is used to highlight the subjective perspective of research participants and meta-ethnographic studies can enable inferences to be made from the combination of results from similar studies. Where qualitative studies have been used to reveal the perspectives of a particular stakeholder group, the findings from these empirical studies can help to bring the voice of the stakeholders to the ethical analysis. This may be a useful method for increasing authenticity when using a top-down approach in ethical analysis.

Given the theme and results of this PhD study, it is appropriate to conclude with a few thoughts on resilience. In the literature, reference is being made increasingly to the notion of a 'resilience toolkit'; one that contains the tools for ensuring resilience. This

has been applied in a number of fields, including community resilience[64] (Pfefferbaum *et al.* 2015), mental health resilience (Southwick 2011) and climate change resilience (Engle *et al.* 2014). It is premised upon the assumption that, for effective resilience or adaption, people need to have the necessary resources in place.

If health can indeed be equated with the ability to adapt, then it should be possible to imagine what a resilience toolkit for health might look like, to question which resources are the most vital and to examine the place of T&CM within that toolkit. Obviously, the basic building blocks for health; food, clean water, shelter and so on, will be essential ingredients of the toolkit, as well as the public health interventions that have made such a difference in Bangladesh. Aside from this, the Okinawans might tell us we need a good deal of yuimaru (community spirit) to stay active and to maintain our autonomy into old age. For some, their resilience toolkit may include T&CM if it can be used as a resource that helps them to stay well. The challenge for legislators and policy-makers is to ensure that this resource can be used in a safe manner, without undue harm to the environment, to animals and in an equitable fashion. It is hoped that the recommendations from this PhD study will facilitate the development of policy in this area.

[64] Community resilience can be thought of as 'local disaster readiness'.

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