

# The Evidence Base for Holistic Medicine

## A Discussion Paper

### The difference between holistic and conventional medicine

#### Introduction

*In this document we will discuss the evidence-base for holistic medicine. We will start with the issue of definition of terms for the different forms of medicine, and then explore the divergent approaches to health and well-being that they represent. Different forms of medicine require different measures of effectiveness and we make the point that it is this issue which is crucial to understanding the science behind holistic medicine. This issue often creates strong feelings about appropriate means of evaluating health outcomes from both conventional and non-conventional forms of intervention, and we argue for the development of consensual methods of measuring effectiveness as a way forward, so that the health benefits of holistic and integrated healthcare can be more accessed within public health systems.*

#### Terminology

The terms “holistic“, “alternative“, “complementary“, “traditional” and “non-conventional” have all been used over the last twenty years to describe a popular form of medicine outwith that usually delivered within GP practices and hospitals.

Each term has attracted both supporters and detractors and there is not one term that is universally used throughout the various modalities. This does result in a problem in defining our field of work in an acceptable way for everybody concerned.

Each term captures something of the sense of this form of medicine, i.e. that it is not part of conventional healthcare as represented by doctor based medicine and usually provided for by the public purse. Whilst each individual term portrays some of the quality of a holistic approach to medicine one term alone cannot do justice to the widely different forms of non-conventional medicine.

There are also important differences in the use of these alternative names which have within them both points of agreement and contradiction (which we cannot discuss easily within this limited format) so we have mainly opted for the term holistic to convey what we mean. However, sometimes other terms may offer a

better nuanced, or more precise meaning apropos our discussion. At those times we will use the term that most captures the sense of what we are seeking to convey.

Perhaps the best definition of what we do is those forms of medicine which are not conventionally taught within medical schools, or practised within public health settings. The world of holistic health lies largely outside of formal teaching establishments and formal western medical practice and belongs to a richer, diverse culture and heritage than formalised western medical knowledge.

Every culture in the world has developed forms of healing that have maintained a sense of the process of human health and healing being a wider activity than taking medicines and performing surgery.

Sometimes the cross-over from these forms of healing into doctor based medicine conventional medicine is obvious and mutually beneficial e.g. some herbs, plant based medicines and physical based medicine like massage, exercise and physiotherapy. At other times the world of conventional healing finds it hard to comprehend that people can find relief or healing with practices that are outside of conventional medical knowledge e.g. acupuncture and homeopathy.

This difficulty in terminology is present throughout our discussion and underlies a profound difference of approach used by the holistic community. This split continues to be a problem in how we think about medicine and well-being, and how we go about the practise of generating knowledge and information about the benefits of alternative healing methods and practices.

Similarly when talking about the National Health Service (NHS) we use the terms 'western scientific medicine' and 'conventional medicine' interchangeably to distinguish between the holistic approach and doctor or hospital based medicine. When we talk about conventional medicine we use the term globally to describe the form of medicine as endorsed by the large organisations governing or representing the National Health Service (BMA, GMC, etc). We are aware that there are exceptions to the dominant view even within conventional medicine (eg The British Holistic Medical Association and the College of Medicine), but that they are a minority and they too struggle to find a voice within that system. We would regard those individuals and groups as our natural allies in the endeavour to maintain an open dialogue about new ways of health creation.

## **A recent split**

The holistic approach to medicine has always been a fundamental component of healthcare since antiquity, and it is only relatively recently that this holistic practice of health and healing has become so radically divorced from the practice of western scientific medicine. The way that modern western medicine has evolved means that it is primarily about caring for advanced states of disease manifestation. By turn this drives the delivery of the service, attracts a certain kind of pharmaceutical research, dictates medical training and monopolises public funding on health. Modern

medicine has willingly separated itself from simpler processes of health and healing.

Conventional medicine as a whole (with notable individual exceptions) offers hardly any input into holistic health in relation to diet, exercise and movement, relaxation, life-style, personal responsibility, stress management, coping with the demands of modern life (work-life balance etc), psychological and emotional health. Furthermore, collectively it has little to say about spirituality and health or the socio-cultural-political determinants of health like food values, pollution and inequality.

It is as if modern medicine is conducted in its own bubble divorced from any consideration of the social context in which it works. It could be argued it has contributed to most of its problems by cultivating a culture of belief in doctors infallibility and the myth of delivering ever more potent potions for ailments (the-pill-for-every-ill mentality), and technological advances and surgical procedures that can cope with every malfunction of the body (eg replacement, repair, and radiation). This culture has not been helped by a mind-set often in denial about the need for accountability and more open access to all available information about medical performance and safety.

### **The over-medicalisation of health**

Paradoxically, whilst shielding itself from the socio-cultural-political reality within which it practices modern medicine has insinuated itself into every aspect of life and been allowed to colonise vast areas of human experience like birth, death and mental and emotional functioning as if they are medical problems.

That modern society has allowed many areas of life to be medicalised has benefitted the pharmacology industries but done little to shed light on the causes of many of our health problems like pollution, inadequate consumer protection and advice about poor food quality, break up of community structures, break-down of personal responsibility in society, social inequality, poor personal coping skills, and inadequate education about diet and life-style choices. It was only a hundred years ago that women were routinely operated on for hysteria by having hysterectomies. Whilst we no longer live in those times, the same privileged mind-set dominates medical practice and distorts debate about the best way of coping with modern health problems, often with severe cost issues for the public purse and for individuals who are not adequately informed of the choices they have or the risks associated with either drugs or surgery.

A case in-point is the long struggle to develop access to psychological based therapies in GP surgeries. There has been a gradual shift to allow patients with mental and emotional problems a chance to explore their problems through psychological therapies and counselling as opposed to pharmaceutical prescriptions; in other words to de-medicalise an area of human suffering.

This has been a long battle that has not been entirely won. Mental health budgets are still inadequate and mental health practitioners within the NHS do not share the same status, pay or career structures as GP's or psychiatrists though they are often the better choice for distressed patients. Psychological therapies within the NHS are still largely under the control of a medical practitioner, a sign of how their use is perceived within medical services.

The difference between psychological and medical intervention, is reflected in the difficulty in researching the effectiveness of psychological therapy in terms acceptable to the sceptical scientific medical mind. Psychological therapy cannot be double-blinded, placebo controlled, (the classic RCCT), or have a standard dose or procedure, so technically it is outside of the remit of the classic RCCT format. However, this does not mean it cannot be tested for effectiveness, rather that new ways of measuring outcomes have to be created fit for that purpose, and consensus created about appropriate measures for non-drug oriented medicine.

At the heart of the holistic response to health and healing is seeing health issues as a product of the total socio-cultural-political environment in which we live. In many ways holistic practitioners fill the gap left by modern medicine which (with notable exceptions) cannot break out of a narrow interpretation of healthcare i.e. end state disease management, or emergency provision requiring medical intervention. Data gathered at this end of the health spectrum, i.e. when there is a definite disease manifestation, will always bias the medical profession as that is where they ply their trade.

### **Different forms of medicine and healing require different forms of research and evaluation**

Holistic practitioners work with the person not the disease, and this position requires different forms of interrogation in terms of effectiveness i.e. new ways of assessing outcomes across a wider social dimension and time-frame. We view our work as a totality and cannot divide it into 'specific therapy effects' and 'non-specific effects' without destroying the integrity of what we do.

This view of research and data collection is alien to the medical mind. Deliberate inclusion of the non-specific elements of treatment is to the medical mind non-scientific practice at best, and quackery and charlatanism at worst. Hence, we in the holistic world are in an impasse with medical science and it is an impasse in which there is minimal engagement between conventional and holistic practitioners. Recent material on the integrity of the placebo effects within all medicine (Wallach 2009, Zollman and McPherson 2009) would advocate care in designing out this ingredient.

Although the holistic approach is criticized for lack of evidence, in reality the evidence base for holistic approaches to health is older, wider, has more depth and is more time tested than most of modern medicine as practised in GP surgeries and hospitals. It taps into modern neuro-science, brain research, endocrinology,

immunology, cellular biology, evolutionary psychology, human genome research, nutritional science, high-tech human energy field research, embryology.

It is also more sophisticated in the questions it asks about the processes and possibilities of human healing. We use a wide-range of concepts to understand and explain human disease processes and health creation, including systems theory, complexity theory, quantum physics, the mind-body link, evolution theory and notions of tensegrity and homeostasis. This is because the nature of human beings is complex, evolutionary and to a certain extent ineffable to science as we know it; it requires a broad multi-disciplinary approach to capture that complexity.

Holistic Medicine's scientific endeavours are part of a collective urge to move towards greater understanding of our human journey. Whilst disease is an important aspect of this journey, so too is health creation and well-being. If the findings of modern science, in all its manifestations, is not an active part of the 'scientific medical' mind-set, then we must ask why are contributions from the wider human sciences and humanities not utilised? And request that a space be made for greater dialogue across all the disciplines in our mutual quest for health.

The means of enquiry to show processes and effects within human tissues, structures and emotions range from laboratory assays, individual case-studies, MRI scans, EEG's, ECG.s, longitudinal studies, pathological reports, patient reports, qualitative and quantitative measures, validated outcome measures, observational measures, behavioural measures, trans-generational studies, ethnographic studies, social- group analyses, high-tech measures of changes in human energy fields, cost-benefit analysis, and risk-benefit analysis.

Also within this array of respectable scientific research are random controlled clinical trials (RCCT), meta-analyses and replicated studies. Somehow, the whole of this range and depth of forms of scientific evidence gets overlooked in the narrow focus on RCCTs. This is like playing poker with a straight flush to be beaten by someone who is playing lowest hand wins and has managed to convince everyone that is the only game to play.

## **The common ground**

The most effective medicine has always been a combination of the scientific evidence, craft based knowledge, skilful human observation, palpation and communication, medical expertise, best practice and patient centred participation, backed by careful study, analysis and observation of change. Furthermore, there is no argument between physicians of whatever code that the aim of medicine is to get the right treatment to the right patient at the right time in order to gain the most clinical benefit with the least risk at the least cost.

Within most medical practices the promotion of good health, the prevention of disease and the amelioration of chronic and relapsing conditions are seen as part of the role of the physician. Whilst embracing all of these ideas, holistic medicine

would add in patient empowerment and the need to enhance understanding and informed choice as part of good practice.

## **Distinguishing holistic practice from conventional practice**

Western scientific medicine as practised today in hospitals and most GP surgeries is driven by an ageing population and growing use of accident and emergency services. Consequently, it has become concentrated on the late stage of disease manifestation, or emergency intervention in disease or accidents. The wider tasks of prevention, health promotion, amelioration and understanding the complex causation of modern diseases has been left to non-medical agencies, including public health bodies and academic research. These areas of health do not attract the same level of funding or research as pharmacology, and therefore have not developed the same level of research activity or output.

The vested interests in medicine, GPs and hospitals and the pharmacological industry have been remarkably silent on wider public health issues. They seem largely content to preserve a status quo that sees disease at an individual level, and they tend to ignore the social and environmental influences on public health. For example, the connection between environmental pollution and diseases like cancer; or the connection between life-style issues, food quality and health problems of epidemic proportions like diabetes and obesity.

Despite an abundance of evidence about these kinds of health issues there has been no demand from the conventional medical profession as a whole for appropriate research or public education about these issues. They appear largely content on perpetuating the myth of medical infallibility and a 'pill for every ill'.

The fact that these wider issues of public health, pollution, food quality, life-style and education are not researched in the same way as drug based medicine raises the question why certain forms of health research and information are prioritised over others. The random controlled clinical trial (RCCT) in particular is promoted as the gold standard for intervention and public funded health activity, but as we will hopefully show this is but one method of demonstrating clinical relevance.

From our perspective it seems this distortion of concern about health issues has been perpetrated on the public by the political assertions of those with most to gain from maintaining that status quo i.e. those from within the medical fraternity, and big pharmacology companies, who appear largely indifferent to the wider aspects of public health and well-being.

Public health as an issue goes beyond what doctors do, say or think, and if that profession cannot or will not embrace the modern scientific, social and environmental context of health then there is a need to develop a different kind of debate about the evidence we need to inform public health systems.

## **The medical sleight of hand**

To define health as 'what we do as doctors' and conjure out of the picture the wider issues of health in our society is a remarkable sleight of hand perpetuated by the medical profession. Further, to decry those who wish to open up the medical discourse, and deny the need to develop a different scientific base for evaluating the contribution of different approaches to modern health is in essence an act of political ring-fencing by the profession. In this process, the rules, procedures and questions about evidence and appropriate modes of enquiry are fixed in favour of the incumbents.

We believe that in a modern democracy that this is not good enough. There has been a culture of protectionism for too long within medicine which has had severe negative implications for public safety. At its worse it has made possible the perpetuation of numerous public outrages by members of the medical profession which could have been avoided, or at least ameliorated, had there been a more open culture of information and accountability and the enforcement of adequate methods of clinical governance, audit, and evaluation. This culture of protectionism has only recently been addressed internally by the profession but it has required legislation to protect 'whistle-blowers' within public health and care organisations.

There is now a need for an informed debate about measuring the social and medical risks and benefits of different forms of medical intervention so that society can make the best choices about priorities in public health expenditure.

## **The effectiveness of holistic and conventional medicine**

### **Is there a hierarchy of evidence?**

Assessing and measuring the effectiveness of holistic and conventional medicine has always been a controversial issue. It is often suggested that there is a hierarchy of evidence with the random controlled clinical trial (RCCT) as the "gold standard" (Ernst 2002; Thomas and Fitter 2002) and more recently (Dawes BMJ 2011). However, it is a view that can be interrogated in the name of the practicalities of delivering modern medical services where more patients are seen with complex, chronic diseases requiring individualised programs of care (Zollman and McPherson 2009) and where ill health is linked not to individual pathology but social and environmental factors.

Common sense tells us that some forms of medicine cannot easily fit into the RCCT model, e.g. surgery, any of the psychological therapies and physical modalities, care of the elderly or chronically affected, whereby the necessary conditions for the RCCT (including double-blinding, placebo control, standardisation of dose, and randomisation) cannot be designed into the testing process in any meaningful way without radically changing the nature of the intervention beyond its normal

application. That is, the therapy being trialled in these RCCT conditions bears no relation to the treatment as actually practised in a real clinical context.

This does not mean that these procedures cannot be tested scientifically, but that different forms of evidence have to be gathered as appropriate to the practice of that form of medicine. The fact that a therapy cannot be appropriately tested by an RCCT does not render that therapy beyond scientific evaluation, or mean that there is 'no evidence' to support its clinical use. This assertion is critical to the evidence base debate. We put 'no evidence' in commas as the medical convention is to only allow RCCT data the status of evidence and relegates any common sense meaning of the word irrelevant in medical discourse. This appropriation of the word evidence for a limited use is misleading and has enormous implications for assessing the benefit of any therapy.

The case of surgery is an interesting comparison with holistic medicine. There are no RCCTs for surgery as we do not have any controlled studies where a placebo has been offered or could ethically or meaningfully be conducted. What a surgical placebo would look like is beyond the imagination of this writer. However, surgery is a significant part of modern medicine, yet the fact that it operates outside of the much vaunted RCCT 'gold standard' and for which therefore there is technically 'no evidence' is a compelling argument that we need a range of appropriate forms of evidence for different forms of intervention. Furthermore building on this argument, we cannot have different standards operating across the whole practice of medicine. This somewhat obvious statement indicates the depth of the double standards being used within the evidence base debate.

Holistic medicine has always been so much more than the provision of specific treatments, and as such does not, and should not, fit into the narrow constraints of conventional scientific medicine. As with GPs in practice, the majority of patients that a holistic practitioner sees do not fit into the neat disease categories of clinical trials and they need treatments packages that fit their personal predicament. That is, we may use a number of elements within our treatments as we judge them to be appropriate, the end result being a synergetic mix of therapeutic interventions to match the requirement of individual patients. We operate idiopathically, and we quite correctly say we treat the person not the disease.

However much we would wish it differently, the arguments about evidence-base quickly stray into deep philosophical issues of 'evidence hierarchies' and 'interpretation of evidence' that require advanced knowledge of the field, and this often leaves the interested lay person deeply confused by the conflicting reports and accounts from within the medical establishment from so-called experts. To simplify the argument we need a level playing field to make any judgement at all!

Unfortunately, the skills to evaluate medical evidence are not widely available amongst conventional medical practitioners, the popular press, holistic practitioners or public health commissioners. Furthermore, until there is a consensus about appropriate forms of evidence for the practice of different forms of medicine or

therapy (E.g. spinal surgery versus conservative forms of physical therapy for back pain) then we will be in this difficult area of critical discourse for some time.

We need to go beyond the mantra of the RCCT as 'gold standard' and accept the need to balance the contribution of many sources of data and information including the human sciences, medical research evidence, clinical judgement and individual choice. Holistic medicine uses a more diverse and pluralistic evidence base. The field is necessarily complex and at times diffuse, so the challenge is to map the clinical relevance of the various sources of evidence that we have, and this surely is the task for the next few years for the holistic community.

The accusation of being non-scientific or anti the scientific process (e.g. Diamond 2001 Dawkins 2001) is a gross falsification of our position, a mischievous misreading of the difficulties inherent in the researching the area, and a false polarisation between ourselves and conventional practice. The position lacks any sense of serious engagement with the problem of medical proof. This situation has prevailed for some 30 years and is still being promoted today (Wallach 2009). For example Murcott (2009) in reviewing Singh and Ernst's book 'Alternative Medicine – Trick or Treat' in the periodical *Nature* makes the point that the level of hostility towards alternative medicine in the book 'mirrors that of the proponents of alternative therapies, leaving each position as entrenched as ever' we are in danger of creating an environment where any non-medical contribution to the evidence debate is seen as a form of heresy, and in riposte merely adds fuel to the fire; and any potential gain of learning from the wider use of holistic medicine is lost from view.

To emphasise this point Edzard Ernst, formerly professor of Complementary Medicine at Exeter University, an outspoken critic of much of the holistic movement (Ernst 2001), champion of the RCCT as gold standard (Resch and Ernst 1996), self-appointed scourge of all supporters of Integrated Medicine CAM (like the newly formed College of Medicine), recently surprised himself when reviewing his own appraisals of the complementary therapies that he had evaluated (Ernst 2010): 53% were deemed to be positive, 40% were deemed to be neutral, and 7% seen as negative.

In comparison, in a recent survey in the BMJ journal *Clinical Evidence*, on therapies (including CAM) that cannot be tested through RCCT's (the full list interestingly included many psychological, surgical and medical interventions) 11% were seen as beneficial, 23% likely to be beneficial, 51% not enough known about them, a further 8% unlikely to be harmful and 8% probably not useful.

An earlier review of Ernst's work (Donnelly 2002) estimated that, of the complementary therapies reviewed by Ernst in terms of the evidence available at the time, 15 of 19 of the therapies were deemed either 'positive', 'better than placebo' or 'encouraging of further research'. Although there has been a gradual accumulation of positive data that has stood up to hostile scrutiny for over a decade there is a reluctance amongst our detractors to accept that there is any evidence base at all for the use of holistic medicine within public health systems.

So even though there is a level of quality data from even our fiercest critics, and that there is evidence to show that holistic therapies can withstand this level of medical scientific scrutiny and show consistently high levels of effectiveness there is no let up in the invective against holistic approaches (Wallach 2009, Ash 2011).

We would be the first to say that we want more rigorous holistic investigation methods to mirror the holism of our treatments, and are not satisfied with the state of play as it is, but to say that there is 'no evidence' for what we do is clearly a wrong statement.

A more common sense, simpler way of thinking about forms of evidence in medicine is to consider scenarios where there is a lack of RCCT evidence in terms of published academic research, but there is a fund of information on well - known and used remedies and procedures i.e. established custom and practice. The question is would you wait until there was definitive RCCT evidence, or act on best available information?

Probably the more urgent, or unknown the situation the more relaxed you would be about the lack of formal evidence and be more open you to consider other forms of evidence that emphasised best practice, user feedback, or service evaluation to inform your decision i.e. what is known to have worked in the past from personal practitioner experience, peer experience, review articles, and patient outcome studies.

The most graphic example of this is the decision whether to use a parachute to jump from a falling aeroplane. There is never likely to be an RCCT trial of parachute effectiveness, but would that mean there was 'no evidence' the parachute was your best chance of survival? In the narrow world of scientific medicine where intervention can only be based on RCCT evidence the only scientifically justified action is to not use the parachute and take your chances. Your sure death would have been a testament to your scientific purity and probity, but think of the gains had you temporarily acted with best expert judgement rather than statistical proof!

Accumulated clinical experience filtered through training, evaluation and peer communication, service user feedback and outcome studies is much like the parachute. We sometimes know things work from pragmatic knowledge rather than academic research. Practical medicine must be a blend of the pragmatic and the proven (in the sense of RCCT level information).

## **Evidence based medicine (EBM)**

So how else can we assess and measure the effectiveness of holistic and conventional medicine? Recently the case was made for using a process called "Evidence Based Medicine (EBM)" (Sackett 1996), and this is still a useful yardstick as recommended by the BMA.

The whole point about EBM is that it does not equate with random controlled clinical trials (RCCT's). In the words of its early champions (Sackett et al 1996) EBM was defined as :

*'The conscious explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice'*

And also crucially . .

*'Evidence based medicine . . .requires a bottom up approach that integrates the best external evidence with clinical expertise and patients choice, it cannot result in slavish, cookbook approaches to individual patient care'(Sackett et al 1996)*

The use of the term 'evidence-base' requires some in-depth understanding of the different forms of evidence from different forms of scientific and medical enquiry. For example, lab tests are one form of information as opposed to random controlled trials, outcome studies or pragmatic trials or peer reviewed journal articles. There is a false sense of hierarchy in the explanatory or clinical significance of these different forms of evidence and much of the evidence base of holistic medicine is downgraded by comparison.

Over the last few years the evidence base for holistic approaches to health, disease and well-being has been increasing steadily and surely. However, instead of steady progress towards more informed debate about appropriated healthcare for everyone, the debate has been hi-jacked and been over-politicised by those who have tried to reduce the debate to "quack-busting" (Ernst 2011, Singh 2009, and Colquhoun website).

The field has become so polarised that rational scientific debate has become difficult (Muttoff 2010) and disempowers patients from making informed decisions about their own healthcare. By uncritically accepting the hubris of the bio-medical model (that there is a medical solution to the diseases of modern society) allows the assertion that it is only a matter of time before medical science delivers us free from disease to stand unchallenged. This is a very dangerous assumption to make given the catalogue of similar promises since the advent of pharmacological medicine and the existence of very real and present environmental hazards.

TSHP feels that we are part of a movement towards greater understanding of health, healing and well-being and the quest for appropriate testing for medicine of whatever modality. This is important so that both the individual patient and society as a whole can better understand the procedures and processes being proposed and assess the risks and benefits associated with them. TSHP would hope to fill a role as a portal into this debate for those who want to develop some understanding of what is at stake.

## **In summary so far**

We believe that public debate about the evidence base for holistic medicine is a vital public issue with profound significance for the practice of every form of public health. It is of such a complex nature that it requires to be conducted in a dispassionate and informed manner to enable all stakeholders (e.g. GPs, commissioner, and patients and tax payers) to become fully aware of the comparative risks and benefits attaching to all forms of medicine.

In the current climate of non-existent and sometimes hostile dialogue across the modalities (Ash 2011, Wallach 2009) the space for respectful reflection and mutual learning is not easily found within public health discourse (Donnelly 2002, Lewith 2009, Ash 2011). Consequently, the possibility of achieving a consensual approach to creating common ground between different health practices is almost impossible to achieve.

By default the two codes of medicine as we are defining them (holistic and conventional) are falsely polarised. Conventional medicine is depicted as being practised according to an 'evidence base', and therefore worthy of backing by the public purse. By assumption therefore, almost all forms of holistic medicine are characterised as operating outside of a formal evidence base (Singh 2007, Ernst 2002, Dawkins 2001), and so are not worth funding publicly and amount to a conspiracy perpetrated on the public as consumers.

I wish that I was making this up but even a cursory foray into either Ernst's or Colquhoun's websites and related twitter feeds will verify the ferocity of the language used in discussing unconventional forms of medicine. Images of 'witch-finder' generals are not far away when reading this material. At this moment in time with the NHS under so much strain it is deeply worrying that such literature will have a stifling affect on the evolution of holistic and integrated healthcare and the future of medical training.

This polarity is unjust, inequitable and untrue and can often mask deep problems within the practice of conventional medicine such as unreported negative drug trials; suppressed evidence of the side effects of drugs (Lazarou 1998); the inherent risks of medical procedures (Null et al 2006), unnecessary drug prescriptions (Agger 2002, Barker et al 2002, Nash et al, Schindler et al 2003), unnecessary hospitalisation (Siu 1990, Erickson et al 1999) and procedures (Leape 1989, US Congress 1976, Suh 2000) unreported adverse incidents (Leape 1994, Stenson 2003, Bates 1995, Dickinson 2000), medically caused injury and death (Null et al 2006, Lazarou et al 1998 ); lack of longitudinal research on medical procedures (Johnson 2002) and the practice of off-label prescribing (NBC Dateline programme 2006). All of which procedures are daily occurrences within public health systems internationally (Null et al 2006), and goes largely unremarked upon by the medical fraternity or medical press.

This catalogue of documented concerns over 20 years, which has been replicated internationally (Schindler et al (2003), Coste et al (1995), Blendon et al (2002) and periodically updated (US Institute of Medicine 2008) and Health Grades report (2010). The relative lack of response from the medical profession is alarming.

Null and colleagues did much to collate this data from US data sources in 2006 and it was updated in 2009. This evidence suggests that **hospitals are some of the most unsafe places** on the planet causing between 44,000 and 98,000 deaths in the US (more than those killed in motor accidents), personal injuries affecting 8.9 million people, at a cost of between \$17 and \$29 billion per year in terms of insurance, lost income and production, cost of disability and healthcare, most of which could have been avoided by exploring safer procedures for patients (Kohn et al 1999).

In the UK, Lewith (2009) cites that between 4% and 7% of surgery results in mistakes, hospital acquired disease contributes to 15% (ie not the disease you came in with) of all diseases and that the NHS spends over £2 billion a year on compensation claims. It is in this context that holistic medicine's contribution to safer, more patient centred and effective medicine is being denied.

### **A level playing field as a minimum requirement**

Until all the available information about both conventional and holistic is acknowledged and acted upon proportionately we do not have a level playing field to assess the comparative risks and benefits of either form of medicine. Some movement towards accommodation with the practicalities of research in this area has been provided by the Medical Research Council (2000) framework for clinical evaluation of complex conditions which encourages researchers to identify specific patient populations, and design specific interventions with agreed outcome measures for that group. In this way, we could work towards consensual measures for different disease manifestations.

As well as the evidence cited above concerning the dangers inherent in modern medicine our argument can go even further. Medical researchers for sometime have noticed that most medicine has no evidence base according to narrow RCCT criteria. The estimates range between 50% (Jonas 2001) and 21% (Peters et al (2002) and as low as 10% according to Chalmers (1998). In a more recent British Medical Journal article only 13% of medicine as practised in GP surgeries has an evidence base and 43% has no evidence base at all (BMJ 2009). Why this is a sum total of the categories of intervention already mentioned where either no RCCT's are available, are unsuitable or just not carried out e.g. surgery, use of untried technology, off-label prescribing, multiple pharmacological intervention, unnecessary prescription, or procedure, or prescribing for chronic, complex conditions or where there is no known diagnosis (e.g. Medically Unexplained Conditions)

Sadly, repeated legal reviews and Audit Activity fails to eradicate the problems which have been consistently documented internationally. The depth of and

persistent nature of these problems does not compare with anything that the regulated complementary health professions report through their own audit activity.

One example of the assessment of risk within these professions is that the professional indemnity for a regulated osteopath is around £300 per annum, for a herbalist it is £100. However, the corresponding fee for an obstetrician is £30k per annum these are decisions taken by professional risk assessors within the insurance industry surely a profession not swayed by political rhetoric.

When there is the occasional admission that the drugs don't work – such as the astonishing admission in 2004 that 90% of all prescription drugs are effective for only 30% to 50% of those who use them (made by Allen Roses, a senior executive of Europe's largest drug manufacturer Glaxo-Smith-Kline) – it is met not by a universal outcry to stop prescribing drugs that are at best useless and at worse harmful. Rather, we are promised that the pharmaceutical companies will not make the same mistakes again, and that the next generation of drugs will be smarter, better and more effective. That this promise is made by the same people who sold, the problematic drugs to the medical profession in the first place is accepted without question.

The scale of risks associated with a pharmacological and surgical approach to healthcare and well-being far outstrips any risk factor associated with regulated professional holistic healthcare. Simply put we do not injure or maim people, or create chemical dependency to the extent that conventional medicine does. There is a need for the medical profession to put its own house in order before it attacks practise it does not understand.

That is not to say that holistic therapies do not need rigour in their audit and evaluation processes, but that those processes will be fit for the purpose of assessing differing interventions and which will necessarily be different from the practices of conventional medicine i.e. prescribing drugs and surgical procedures.

### **Good evidence should drive good practice**

Similarly where there is clinical data that simpler, cheaper, more holistic approaches to health are possible, for example Dean Ornish's work (Chainini et al 2011) on reversing heart disease by holistic methods there is no rapid take-up of the methods within conventional medicine. If it were true that medical practice was driven by evidence these holistic approaches would be routinely appraised and offered to patients as part of a duty of care and informed choice. This does not often happen. Where effective treatment is denied because of prejudice, misunderstanding or a lack of adequate methods of disseminating good practice outside of the dominant medical scientific model then there is cause for concern and an issue to be addressed by conventional medicine.

## **Reader beware**

We believe that the debate is serious and is full of deep contentious and often controversial issues. In confronting the often misleading information in the press, the holistic health camp must expect more deliberate confusion and obfuscation from current vested interests in health and healing. So reader beware, this is not an easy area, and however much we endeavour to navigate it carefully and responsibly there are fundamental differences between proponents of conventional and holistic health that perhaps can never be fully breached.

Reaching accommodation on this issue is not a compromise of standards but an attempt to create a debate in which the public can trust the judgement of the providers of health whether they are conventional or holistic practitioners. TSHP wishes to be part of that debate on behalf of our potential users.

## **Where do we go from here?**

The debate about evidence has been systematically distorted towards conventional medicine, particularly drug therapy and surgical intervention. As we have already said a level playing field is badly needed to assess different levels and types of information to allow for a full comparison to be made about the effectiveness, safety, cost, ethics and sustainability of healthcare practices.

The implications for establishing this level playing field for evidence are wide ranging and would not only question much of public medicine as practised in hospitals and GP surgeries today, but also apply pressure to revise priorities in current public expenditure on public health systems.

The endeavour to develop a unified evidence base has the capacity to transform healthcare as we know it, and for that reason it is a debate that we must engage with. However, the path to that even playing field is full of difficulties as it would require, alongside all the evidence from holistic practitioners, all unpublished drug trial data from the pharmacology industry, all hospital performance data, and long term follow-up data about medical interventions and adverse incidents and side effects from treatments and medication. This demands far more transparency and honesty from all the vested interests in the debate than has been forthcoming up to now.

Where we enter the debate is that we agree that the current environment of public medicine requires that medicine as practised either within the public sector or private provision should be safe, effective, cost-effective and engage patients in the process of understanding and managing their conditions.

In this respect holistic medicine like any other form of medicine needs to consolidate the evidence for each specific aspect of its activity, and where there is sufficient evidence, to promote these practices within public health services.

However alongside this duty, as part of the professional activity of all healthcare professionals, we believe that we also need to establish some common ground for evaluating the contribution of all the different modes of practice and approaches to health. We need to be able to make long term comparisons between therapies of whatever derivation, through the establishment of full, transparent, and exacting evidence bases which can be openly interrogated by an informed public. This is the essential backdrop for all public medicine as practised today.

Furthermore where the holistic approach is proven to be effective, safe, cost-efficient has patient support and shows superiority on those counts to conventional medicine we would should require that public health systems to respond positively and incorporate these advances in patient choice.

Until that has been established we will continue to place the best available information in the public domain to adjudge the relevance of holistic approaches to public health issues.

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