

Primum non nocere: thoughts on the need to develop an 'adverse events' register for complementary and alternative therapies

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Building a body of knowledge to support the efficacy and practice of complementary and alternative therapies is an imperative that should be fully embraced by all those involved. Additional endeavours to monitor adverse events related to complementary and alternative therapies should also be pursued. The history and extent of medical iatrogenesis is briefly outlined, as is the literature on adverse events related to complementary and alternative therapies. Allopathic medicine is slowly realising the negative impact of iatrogenesis and is starting to develop systems to monitor such events in order to reduce or eliminate their existence. It is suggested that a similar development is needed in complementary and alternative therapies, so that it can be ensured that, at a minimum, *primum non nocere*, the therapy should firstly do no harm. © 2002 Elsevier Science Ltd. All rights reserved.

INTRODUCTION

The need to establish evidence to support the efficacy of complementary and alternative therapies is quite correctly urgent, particularly in an age that is paying increasing attention to the need for safe high-quality practice that is evidence based. However, building such a body of evidence to support the practice of complementary and alternative therapies may be perceived to be difficult to achieve, primarily because of the difficulties of designing research studies that would conform to the randomised control design gold standard of the evidence-based practice movement. It is quite likely that the 'sledge hammer' of even the most carefully constructed experimental design research is unlikely to reveal the subtleties of some of the more mysterious processes that would appear to emerge from the potentially therapeutic effects that occur as a result of complementary and alternative therapy encounters. Despite this, it would be far from

sensible to dismiss randomised control design research entirely, as it has the potential, often already realised, to reveal significantly beneficial physiological and other processes. It would be far better to include it in an armoury of research approaches that should also include qualitative research designs. These designs, that include amongst others, grounded theory, narrative and phenomenology, have a far greater potential to illuminate aspects of the intrapersonal and interpersonal processes such as 'how therapeutic engagement can improve outcomes' (Reilly 2001) and other 'non-specific benefits' (Reilly 2001) that would seem to play such a central part in determining the increasing popularity of complementary and alternative therapies. These are not really new issues; they have been identified in the literature elsewhere (Ersser 1995, Richardson 2000) and the subject will no doubt continue to be debated well into the future.

There is another option that may be available to those who have an interest in exploring the

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beneficial, or other effects, of complementary and alternative therapies. This option, rather than asserting a need to establish the beneficial effects of complementary and alternative therapies, would seek to explore the opposite; in other words, to establish, systematically, whether there are any harmful effects of complementary and alternative therapies. Such an approach would be based on the premise that, at a minimum, complementary and alternative therapies should, as the title of this paper suggests, *primum non nocere*, cause an individual no harm. There is a need to establish this as much as there is a need to establish the efficacy of complementary and alternative therapies.

ALLOPATHIC IATROGENESIS

Probably popularised by Illich (1976) in his seminal and, for some, controversial work 'Limits to Medicine', the concept of medical iatrogenesis, or the diseases and disorders that arise as a result of medical treatment, and Illich's central assertion that medical care is often harmful at clinical, social and cultural levels, has been receiving increasing attention in the medical arena in recent years. It could be argued that medical care has not really contributed to the improved health status of the (Western) population in general, and that most of the improvements that have been seen have happened as a result of reductions in infectious disease and alterations in nutrition, behaviour and the general environment (McKeown 1979). How much this situation has changed as a result of advances in medical science in fields such as, for example, critical and acute care, oncology and genetics in the 20 years or so since this assertion was published, could be the subject of a separate paper. Whatever the situation, there is evidence to suggest that modern, highly technological and chemical medical care is only achieved at considerable personal cost and risk to some individuals.

Such cost and risk is manifest in the literature as reports and studies of adverse events (AEs), adverse drug reactions or events (ADRs or ADEs), medical errors and a variety of further nomenclature. The House of Lords Select Committee on Science and Technology (2000) identified that:

many conventional medical and surgical interventions, as well as effective synthetic drugs, and even some of herbal origin, produce in some patients troublesome and distressing side-effects which may occasionally even have fatal consequences.

A brief and superficial literature review revealed the significance of the problem of medical iatrogenesis. For example, Pouyanne et al.

(2001) found that just over 3% of patients who were admitted to a series of hospitals in France were there because of adverse reactions to drugs, a figure that is similar to those found in Australia and the United States of America. The authors extrapolated the French results and estimated that throughout the whole of France, nearly 135,000 patients would be admitted to hospital annually as a result of adverse reactions to drug treatments. Elsewhere, serious drug-related errors have been found in 6.7% of patients in two hospitals in America (Bates et al. 1995), and that adverse drug reactions were the cause of 5.1% of hospital admissions (Lazarou et al. 1998) and that 10.9% of patients would develop adverse drug reactions while in hospital (Einarsson 1993). A systematic review of ADRs in paediatric in- and out-patient care found an overall incidence of 9.53% (Impicciatore et al. 2001). A recent report by the Audit Commission (2001) 'A Spoonful of Sugar: Medicines Management in NHS Hospitals' suggested that over a 1000 deaths occurred in England and Wales due to medication errors or ADRs. It is thought that 'over 120,000 Americans die each year as a result of preventable errors in their hospital care' (Berwick & Leape 1999). In a large-scale Australian study, it was found that adverse events occurred in 16.6% of 14,179 hospital admissions, and of this 16.6%, 51% events were thought to be preventable, 13.7% resulted in permanent disability and 4.9% in death (Wilson et al. 1995), and it is thought that in Australia there may be as many as 18,000 deaths per year due to medical errors (Kohn et al. 1999). The kind of errors from which such statistics are constructed include drug treatment complications, inappropriate prescriptions and mistakes in administration, missed, incorrect or delayed diagnosis and errors or adverse events that arise from surgical procedures (Weingart 2000). For example, from a random sample of 30,195 patient records, 1133 (3.7%) patients were found to have suffered from iatrogenesis, with the most common caused by adverse drug reactions (19%), wound infections (14%) and technical complications (13%; Leape et al. 1991).

The reason for including such statistics here is to show that the subject of medical iatrogenesis would appear to be taken very seriously by the medical profession who have identified 'startling levels of risk and harm' (Berwick & Leape 1999). Although adequate epidemiological information is limited (Weingart et al. 2000), the medical profession has studied the subject extensively and is systematically beginning to produce a body of research that can identify areas where patients may be at increased risk of AEs. Such knowledge can then be used to plan risk reduction or elimination procedures. A similar system of AE reporting and the development of risk reduction

or elimination procedures needs to be adopted by practitioners of complementary and alternative therapists. From this, it would be impossible to prove the efficacy of such interventions, but at least it would begin to systematically reveal and subsequently reduce any substantial dangers or risk that may be encountered in a complementary or alternative therapy consultation.

WHAT RISK?

It is not the intention to provide an extensive review of the literature on the risks of being the recipient of complementary and alternative therapies, nor to analyse the nature of those risks, which may be indirect, that is, financial and exploitative, there being no perceivable therapeutic benefit for the recipient, or delaying allopathic consultation. Direct risks arise from the complementary and alternative therapy consultation and treatment themselves, such as the ingestion of toxic substances, negative interactions with allopathic medicines, or physical adverse events such as acupuncture-related pneumothorax. For example, in a systematic review of homeopathic treatment, Dantas and Rampas (2000) found that, out of a sample of 53 papers that met the inclusion criteria, 36 reports did not mention any adverse effects, and of those reports that did, they were noted to be nothing more than mild and transient in nature and were more often than not simply temporary exacerbations of existing symptoms. In relation to hypnosis, Gruzelier (2000), who was examining the subject in experimental, clinical and entertainment settings, found a wide and worryingly common variety of resultant negative physiological and psychological effects. Although most were short-lived and minor, they also included two cases of 'first episode schizophrenia... seizure, stupor, and spontaneous dissociative episodes' (p. 163). In a study of acupuncture that was carried out in Japan, 391 consecutive patients who were treated during a four-month period over a total of 1441 sessions and with over 30,000 needle insertions, a variety of mild and transient unwanted effects were discovered (Yamashita et al. 2000). These effects included a variety of infrequent minor local reactions such as needle insertion pain, minor bleeding on needle withdrawal and haematoma. More frequent and significant systemic adverse events included tiredness (8.2%), drowsiness (2.8%), dizziness and nausea and chest pain (0.3%). These adverse effects of acupuncture are less severe than those that can be found elsewhere. For example, in a systematic review of the adverse effects of acupuncture, Ernst and White (1997) found a risk of infection with hepatitis B and C, HIV, bacterial endocarditis and staphy-

lococcal septicaemia that was usually related to the improper handling or sterilization of needles. If that was not serious enough, the traumatic effects of acupuncture included over 60 cases of pneumothorax, cardiac tamponade, and one death. Another complementary and alternative therapy intervention where there might be a risk of significant injury is chiropractic. It is thought that up to 50% of all chiropractic consultations may result in mild and transitory pain (LeBoeuf-Yde et al. 1997, Senstad et al. 1997). However, more severe consequences of treatment that have been reported include the possibility of cerebrovascular accidents, disc herniation and a variety of other complications (Assendelft 1996). Finally, in this brief attempt to show that there are risks associated with complementary and alternative therapies, Ernst (1999) has identified that although St John's wort (*hypericum*) appears to act as a highly effective antidepressant with fewer side-effects than its synthetic counterparts, there may still be risks associated with its use. He recommends that doctors should be aware that its use with prescribed medications may alter normal blood concentrations of the latter, that users should be made fully aware of the potential consequences of taking such a drug, and that the subject of the regulation of herbal remedies needs to be carefully re-examined.

REPORTING ADVERSE REACTIONS

After a comprehensive review of non-medical near-miss reporting systems that examined procedures from a range of industries, including aviation, NASA, petrochemical processing, steel production and the nuclear industry, Barach and Small (2000) concluded that:

Non-punitive, protected, voluntary incident reporting systems in high risk non-medical domains have grown to produce large amounts of essential process information unobtainable by other means. [They]...have evolved over the past three decades to emphasise near misses, in addition to adverse events, to encourage confidentiality over anonymity, and to move beyond traditional linear thinking about human error, to analyses of multiple causation at the level of systems (p. 763).

These authors go on to state that similar near-miss and adverse effects reporting systems could be applied in health care, where systems should be established to allow complete confidential and objective reporting (Barach & Small 2000) at a national level (Alberti 2001, Vincent et al. 2001). This may be easier said than done. In hospitals and other such health care establishments, there may be a strong culture of blame (Alberti 2001), scape-goating, punitive and litigious behaviour that would restrict the reporting of adverse events and near misses (defined as 'any event

that could have had adverse consequences...and was indistinguishable...in all but outcome'; Barach & Small 2000). In addition to this, allopathic medicine is often practiced within the context of large, complex organisations where systems failure, rather than an individual's inadequacy in any given situation, can be seen to be at fault (Neale et al. 2001). For complementary and alternative therapists, the problem of reporting adverse events may be compounded, or paradoxically enabled, by their often independent or isolated and multivariate practice. For some complementary and alternative health care practitioners who work within orthodox allopathic health care environments (such as those who work primarily as nurses or midwives but use complementary and alternative therapies as adjunctive interventions), the issue of reporting adverse events and near misses is a matter of positively addressing and eliminating punitive responses and their own employers and professional bodies making sure that local and/or national reporting procedures are in place and are operating effectively. For nurses and midwives and other practitioners who are working outside orthodox allopathic health care environments, in for example, independent private practices or in alternative healing environments, not only do they have direct financial concerns which may, but should not, negatively impact upon adverse event reporting, they will also have to deal with the absence of local policy and the probability of the absence of any national, umbrella policy and procedure capable of producing accurate and reliable data.

Given that there may be as many as 50,000 complementary and alternative practitioners in the UK, and another 10,000 registered health professions delivering complementary and alternative therapies (many of whom are members of a very wide range of voluntary and statutory professional bodies), and as many as 5 million people who are regular recipients of such therapy, it would appear to be quite a considerable job to create an adverse events register. However, this could be achieved by making it an operational requirement of the voluntary and/or statutory professional bodies such as the British Acupuncture Council and the British Acupuncture Accreditation Board, the Aromatherapy Organisations Council, the European Herbal Practitioners Association, the Society of Homeopaths, the Reflexology Forum, the General Osteopathic Council and the General Chiropractic Council. Alternatively, complementary and alternative therapists could be encouraged to participate in the new Health Professions Council, or amalgamate with one of the more generic, umbrella professional bodies such as the Institute for Complementary Medicine or the British Complementary Medicine Association. It has

been acknowledged that part of the role of statutory bodies is to take 'action to protect patients from serious adverse outcomes of care when such circumstances arise' (Budd & Mills 2000). Creation of a national adverse events register would go some of the way to achieving this. 'Factors in clinical practice...that predispose to adverse events' (Neale et al. 2001) can then be identified and the potential risks of complementary and alternative therapies subsequently minimised.

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