The "therapeutic footprint" of medical, complementary and alternative therapies and a doctor's duty of care

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The increasingly high profile of complementary and alternative therapies is undeniable.[1,2] By spending billions on therapies that rarely have strong evidence of efficacy,[3] or have been disproven,[4] patients clearly are seeking something different to standard medical care, without demanding the kind of information about efficacy and risk now routinely requested of doctors.

There are complex societal factors influencing the use of complementary and alternative therapies.[5] Reasons for their popularity include a pragmatic pursuit of better outcomes for chronic health problems,[6] which may relate to "effectiveness gaps" in medical care;[7] a preference for self-care, and "holistic" or "natural" approaches to health;[8,9] and beliefs about disease causation that differ from the medical paradigm.[10]

The use of complementary and alternative therapies mostly occurs in parallel with medical care.[2,11] It can be viewed as a form of health consumerism.[12] Health consumerism has interlinked facets, which include a market-based approach promoting individual choice; advocacy for the inclusion of consumer perspectives within health care;[13] and formal mechanisms for protecting consumers' rights.

Increasingly, health consumerism may not just challenge the doctor–patient relationship, but sidestep it altogether. This occurs when medications are sold directly via the Internet, or "natural" health products and do-it-yourself diagnostic kits are bought over the counter or in supermarkets. Many consumers have misplaced expectations about consumer protection mechanisms and assume (wrongly) that these products are independently tested for efficacy before being marketed.[2] These developments create new challenges — how is a doctor's duty of care for his or her patients affected when patients "treat" their health problems outside the medical setting?[14]

Here, we explore the doctor's role in the dichotomy between the doctor–patient relationship within standard medical care, and consumers taking non-prescribed complementary or alternative treatments outside the medical setting. We propose the concept of the "therapeutic footprint" in which the balance between potential risks and the evidence supporting a treatment allows standard medical care to be compared with complementary and alternative therapies — approaches that are otherwise "incommensurable".[5]

ABSTRACT

- Complex societal factors unrelated to evidence of efficacy influence the increasing use of complementary and alternative therapies, which can be viewed as one form of health consumerism.
- The "therapeutic footprint" is a conceptual model that "plots" medical therapies and complementary and alternative therapies in relationship to one another and to their levels of risk and supporting evidence, acknowledging that medical therapies also entail risks.
- Philosophies about management of risk and adverse effects differ between complementary and alternative therapies and standard medical care, due to fundamental differences between professionalism within medicine and the demands of health consumerism.
- In standard medical care, patients' risks are mediated prior to treatment via the doctor–patient relationship and informed consent. With complementary and alternative therapies, protection mechanisms for consumers come into effect mainly after a problem has occurred. Understanding this difference helps doctors whose patients are using complementary or alternative therapies to define the boundaries between these therapies and professional medicine and provide appropriate disclosure of risks.
- Discussing complementary and alternative therapies and how they differ from standard medical care can provide opportunities to explore patients' concerns and improve the therapeutic relationship.

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Complementary or alternative?

Complementary and alternative therapies include a diversity of practices.[15] However, we should not lose sight of the distinction between the concepts "complementary" and "alternative". The often-used acronym "CAM" (complementary and alternative medicine) obscures important differences between therapies that are *complementary* to medicine (eg, aromatherapy to lessen discomfort after surgery) and therapies that are used as *alternatives* or substitutes for medical treatments (eg, a diet recommended as a treatment for cancer instead of undergoing chemotherapy for a chemoresponsive cancer). Ultimately, however, the intention of the provider and/or user of a therapy may determine whether a treatment is complementary or alternative. Alternative therapies that *replace* conventional medical care, and are promoted as such, present specific risks and problems, which vary according to the health context of the user.

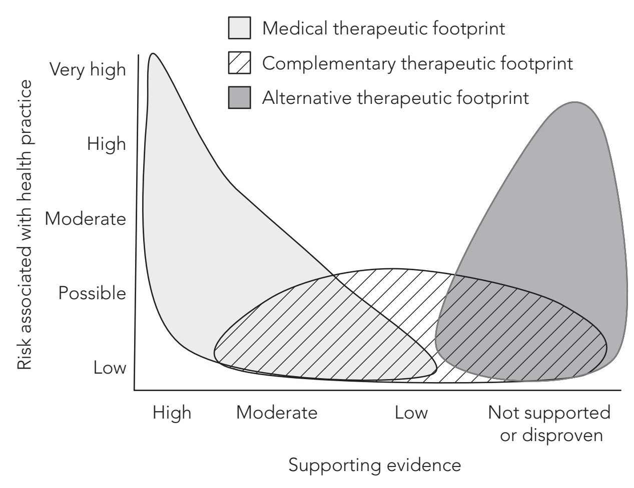
The "therapeutic footprint"

The therapeutic footprint is a conceptual model that "plots" medical therapies and complementary and alternative therapies in relationship to one another and to their levels of risk and supporting evidence. The balance between evidence and risk (Box 1) distinguishes standard medical practice from complementary therapies and even more so from alternative therapies. While risks associated with complementary and alternative therapies may be minimal,[16] even a low risk of a severe adverse event is less acceptable if related to a treatment whose benefits are small or unproven.[17] The model acknowledges that any discussion of risks of complementary and alternative therapies would be disingenuous without including the hazards associated with standard medical care.

Medical therapeutic footprint

Few medical treatments are without risk. Medical practice includes some ultra-high-risk therapies (for instance, bone marrow transplantation) as reflected in the medical therapeutic footprint. Many common treatments, like anticoagulation, carry significant potential for harm. The principle permitting risk exposure in medicine is informed consent, based on the best available evidence about the risks and benefits of treatments, accurate medical contextualisation of the problem, and acknowledgement if evidence is lacking. While broad commitment to evidence-based medicine exists, some well established practices (for instance, the widespread use of aspirin in older people who are well) may never be able to be subjected to rigorous scrutiny, and thus lie towards the outer right edge of the medical therapeutic footprint — substantially overlapping with complementary therapies. The extent to which doctors actually translate evidence-based knowledge into practice varies; however, doctors offering high-risk treatments without supporting evidence, outside a clinical trial, fall into the practitioner profile associated with alternative therapy.

1 The "therapeutic footprint": a theoretical model of standard medical care compared with complementary and alternative therapies



Complementary therapeutic footprint

Complementary therapies are frequently "high touch, low tech" (lots of personal contact and little use of high technology products)[18] and inherently less risky, as the complementary therapeutic footprint suggests. Nonetheless, ingested products[19] and unusual diets have quantifiable potential risks, as do physical therapies like chiropractic or acupuncture. Negative outcomes are generally less frequent and severe than many of those associated with medicine.[16] Methodological, economic and cultural issues related to studying complementary therapies mean that, despite investment in research, evidence for the efficacy of complementary therapies will continue to be incomplete.[20] Increasingly, however, rigorously generated evidence exists for the efficacy of specific complementary therapies, assisting their integration into standard medical care.[21]

Alternative therapeutic footprint

The alternative therapeutic footprint may be either low risk, or associated with significant risk — especially when therapies are invasive, or preclude proven treatments, like some alternative cancer therapies. Risky alternative therapies are frequently unproven, or disproven,[4] but maintain market share because they promise to cure disease. Examination of Internet sites promoting alternative therapies (easily found by searching the Web for "cancer treatments") reveals common features that magnify risk (Box 2). In our experience, patients consulting alternative practitioners whose practice has these characteristics often tolerate significant physical and financial burden in the hope of relief or cure.

Consumerism meets professionalism

In evidence-based medicine, the skills involved in weighing risks against benefits, and assisting patients to make individual choices, are central to clinical practice. The professional relationship between doctor and patient defines the parameters for decision making according to ethical principles. The duty of care to patients is further defined by professional standards and legal sanctions. In Australia's largely publicly funded health care system, doctors act as gatekeepers to health resources, and management decisions must be clinically justifiable and socially responsible.

Complementary and alternative therapies respond to consumer demand. When people choose to use these therapies outside a medical setting, their rights and responsibilities are not defined by the doctor–patient relationship, but by protections and safeguards for consumers. They are buying a product, and the only limitation is their capacity to pay. Some health-specific protections exist — for instance, regulation by the Office of Complementary Medicines within the Therapeutic Goods Administration[22] — but these barely keep pace with the growth in complementary and alternative therapies. Consumerist mechanisms protect choice, but result in greater risk being borne directly by the consumer. Consumers are protected by a safety net, which mainly comes into effect after a problem has occurred, eg, via complaint mechanisms and product recalls. In contrast, informed consent is proactive — identifying and deciding about the degree of risk or burden patients are likely to encounter or willing to accept if they elect to have a particular treatment. One reason for the success of complementary and alternative therapies is that, because a culture of informed consent is lacking, consumers believe they are inherently safe,[18] compared with medicine where risk is appropriately brought to the foreground.

2 Characteristics of alternative therapy practices likely to magnify consumer risks

- Focus is on cure — this is regardless of the disease being treated; the therapy may be presented as a universal panacea
- Denial of responsibility — promotes treatments in terms of inherent goodness, naturalness or safety without acknowledging any potential for risk or treatment failure. Adverse effects or failure of therapy may be explained as patients' failure to follow the therapy regimen properly or starting therapy too late
- Exclusive relationships — highlights opposition of standard medicine to alternative therapy and discourages use of some or all standard medical care
- Exploitative relationships — encourages psychological dependence in treatment users
- No objective scrutiny of outcomes — existing evidence about the therapy is discounted and the "medical model" and its basis in scientific knowledge is discredited ◆

3 Doctors' duty of care towards users of complementary and alternative therapies — four clinical scenarios, related issues and key medical responsibilities

Scenario 1

Patient requests advice about options for complementary or alternative therapy

- What level of knowledge can reasonably be expected of doctors?
- How much responsibility do doctors have to advise their patients regarding non-medical treatments?
- Should doctors be expected to provide information to allow patients to give informed consent to non-medical treatments?

Key medical responsibilities

To advise patients of the different approaches underlying medicine and complementary and alternative therapies and their implications

To advise patients about the limitations of the evidence and/or of the doctor's own knowledge

To refer patients to good quality information sources (eg, National Center for Complementary and Alternative Medicine <http://nccam.nih.gov/>)

Scenario 2

Patient presents with adverse effects possibly due to use of complementary or alternative therapy

- To what extent are doctors responsible for the detection, monitoring and outcomes of non-medical treatments?

Key medical responsibilities

To provide medical care for any health problems

To report possible drug interactions or side effects

To exercise pharmacovigilance in all clinical situations, recognising the prevalence of use of complementary or alternative therapies

Scenario 3

Patient requests that an investigation be ordered for use by complementary or alternative therapists

- Can the investigation be clinically justified?

Key medical responsibilities

To apply usual clinical decision-making criteria to patient requests for additional investigations

To provide results to patients if requested and contextualise the information

Scenario 4

Patient requests that the doctor provides intravenous access to be used for unproven treatments (eg, vitamin C infusions)

- To what extent is the doctor then responsible for any treatment given via that route, and for any associated risks, complications, and outcomes?

Key medical responsibilities

To counsel about the risks associated with invasive alternative treatments and not participate in their provision

To review patient expectations of goals of medical and non-medical treatment

To clarify the differences in approach to management of risk between medical and alternative therapists

To suggest questions to ask the alternative therapist so that the patient can make a more informed choice ◆

Doctors as alternative therapists

Doctors practising as alternative therapists may have stepped outside their professional boundaries, as their medical status may gain credibility for alternative therapies. Doctors who provide or endorse unproven or unorthodox treatments have the same duties and responsibilities as those in standard medical care,[23] and thus consumers harmed by these treatments have more avenues for redress than those treated by non-medical therapists.

However, the push to professionalise specific complementary therapies is likely to redefine practitioners' responsibilities, creating an ethical context closer to that of medicine in terms of informed consent, provider accountability, and potential for redress if harm results from a treatment.[24]

The integrative medicine movement

The integrative medicine movement argues for complementary therapies to be blended with standard medical care where sufficient evidence exists to support particular practices. Integration further implies that these practices can be incorporated within a professional model of health care, and that usual professional responsibilities would then apply. Boundaries between medicine and complementary therapies are being continually redefined, and the process by which therapies are accepted as part of standard care is subject to debate, particularly regarding what kinds and levels of evidence are acceptable.[25]

Recognition that there is considerable overlap between the therapeutic footprint of standard medical care and that of complementary therapies suggests that the gap is not always as large as might be thought. Research that contributes to establishing the place of those complementary therapies already in common use is valuable. However, research into patterns of marketing and use of alternative therapies and their associated risks is also needed.

The challenge for doctors

The prevalence of complementary and alternative therapy use presents doctors with significant professional challenges (Box 3). Problems often relate to boundaries between complementary therapies and standard medical care. Discussing these issues with patients can be challenging. However, these conversations provide opportunities to explore patients' concerns, and discuss and review goals of treatment. This in itself is a valuable outcome with the potential to improve the therapeutic relationship.

In an age of consumerism, doctors' professional roles are evolving. In responding to patients' wishes and to competition from other providers, doctors should not lose sight of their responsibility to guide patients' decision making, applying medical knowledge in the patient's best interests, using standards for which they are professionally accountable. This is not paternalism: we need to recognise that being a patient is not the same as being a customer.

Competing interests

None identified.

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