Regulation:

Principles, issues, perils and prospects

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In determining whether a given approach to knowledge can arrive at 'respectability', the following criteria seem relevant, if not exhaustive: it must be precise in its approach, rigorous in its procedure and honest in its reporting; as a discipline it must proceed with integrity. (Petranker, 2003 p 12).

The use of complementary and alternative therapies is rapidly increasing in the United States. . . Along with the increasing popularity of CAM, there is the need to generate scientific studies that examine the efficacy and safety of various CAM therapies. (Zick and Benn in 'Alternative Therapies in Health and Medicine', May/June 2004 p 50).

The principal purpose of regulation of any healthcare profession is to protect the public from unqualified or inadequately trained practitioners. The effective regulation of a therapy thus allows the public to understand where to look in order to get safe treatment from well-trained practitioners in an environment where their rights are protected. It also underpins the healthcare professions' confidence in a therapy's practitioners and is therefore fundamental in the development of all healthcare professions. (Select Committee on Science and Technology: Sixth report. Chapter 5: 'Regulation').

The public needs protection from untested alternative remedies and rogue practitioners of complementary medicine, but no one is providing it - a House of Lords committee said. (Report by the Health Editor of 'The Independent' 29 November 2000).

. . . regulation, especially in the form of statutory self-regulation (SSR), is not a panacea. Regulatory mechanisms are only effective if they are relevant, up to date, and properly enforced. While some CAM practitioners view statutory regulation as a means of enhancing their profession, others see it as a slippery slope to unwanted control and interference by the government. Unless sensitively managed, the transition from voluntary self-regulation (VSR) to SSR may alienate the fundamental membership of a CAM therapy. (Lee-Treweek et al 2005 pp 54-56).

The Shiatsu Society is actively engaged in the process of regulation and protection of the public as more access to complementary therapies becomes available on the NHS. A shiatsu regulatory forum is a forum for different shiatsu associations involved in registering practitioners in this country. The purpose of such a forum is to explore the latest government requirements for the regulation of complementary therapies and create a unified body for the different shiatsu organisations in order to facilitate compliance with government directives. Shiatsu Society website accessed on 14 September 2006.

Abstract

Regulation is not for its own sake. Regulation provides a form of validity. The aims of regulation ought to be: the protection of the public; making it clear to the public that there are rigorous and transparent theoretical constructs allied to relevant research methodologies; clarity and justification as to the boundaries of effectiveness of a therapy; the responsible exercise of a duty of care and the building of trust in therapies which are offered for the public benefit rather than trust being assumed. An overarching principle is that of informed consent. Regulation would also have the benefit of improving public assurance at a time when increasing use of CAM therapies is in parallel with 'which?' and 'what for?'. Regulation would therefore improve transparency and accountability. The only ethical justification for offering therapeutic intervention is that it is demonstrably for the public benefit. This paper explores the terms in the title in both ethical and practical respects and makes suggestions as to how principles can be identified, issues addressed, perils avoided and prospects improved.

Aim

The main aim of this paper is to identify and explore some principles, issues, perils and prospects in the context of regulation.

Introduction

I am not a practitioner of any CAM therapy. I am very familiar with counselling and psychotherapy and used to practise the former. I was centrally involved with the university validation of postgraduate courses in counselling and psychotherapy. I have experience in designing regulatory frameworks in both university and private sectors.

In a sense I am addressing the title of this paper as an interested and thoughtful member of the public. I do not represent the point of view of any organisation. I am a member of the Alternative and Complementary Health Research Network (Manchester). I have good friends who are experienced CAM practitioners. I also have a friend who suffered from gross negligence at the hands of a CAM practitioner and who needed emergency medical intervention as a result.

I also want to emphasise that I appreciate that the issue of regulation is both contentious and complex. It may well be the most complex undertaking that any organisation might contemplate. It's certain that any organisation will undergo significant changes even in the preparation for the process of regulation.

There are increasing public expectations for transparency, accountability, regulation and indeed litigation. These may be linked with increasing scepticism towards any who set themselves up as experts based on self-established expertise. Self-asserted expertise can be delusory and dangerous. There is also the fact that increasing numbers of people use CAM therapies.

My own general standpoint is that any formal offer of service to the public, be this therapeutic, educational, legal, gas fitting, financial services, vehicle repairs and maintenance, should be subject to formal regulation.

Six related processes are implied in any form of regulation:

1 scrutiny and validation
2 responsibility and accountability
3 transparency
4 monitoring and review including procedures for removal from the register
5 user-friendly complaints procedures
6 unification rather than fragmentation within and between therapies

It is no longer appropriate, if ever it was, to offer therapies or services to the general public for payment on the basis of implicit and unaccountable trust. I think that is irresponsible. It puts the already vulnerable user into an even weaker position.

The inclusion/exclusion of CAM therapies in relation to what slowly became orthodox therapies, both historically and currently, is mixed and varies in different countries. Any orthodoxy is, almost by definition, defensive. Open-minded orthodoxy is an oxymoron. (See Saks 2003 for a historical overview and discussion).

This leads me to the broad view that the extent to which either statutory or self regulation are resisted, the opportunities for CAM therapies to be included or excluded on the basis of mere whimsicality and prejudice are considerable. On the other hand, if one is determined to be excluded then there are many conservative and dominant forces which will support that exclusion.

So much for a brief general background.

I want to frame this paper with two very broad, opening questions:

What is the formal attitude of the official body of your form of therapy towards statutory regulation of its training and practice ?

What is the attitude of the membership and how was this discovered ?

I shall leave those questions hanging in the air and will not address them directly. That is not to diminish their significance.

I now state what I think are *seven principles* on which any therapeutic intervention which is offered to the public should be based. These principles are consistent with either *formal self regulation* or *formal statutory self regulation*. They apply with equal force to orthodox as well as to CAM therapies. I would expect my GP to be operating within these seven principles.

I would need to be convinced that these principles could be adopted and effectively practised *without* some form of regulation. In the absence of regulation how could the public know whether and what principles were being adopted and practised ?

Obviously all seven ***principles*** have within them a range of ***issues,*** various ***perils*** and a variety of ***prospects***. I shall now explore some of these.

1 The protection of the public.

An *issue* here is the obvious one: therapeutic intervention should not be so uncertain in its outcomes as to create the likelihood of damaging the mental or physical health of the patient. The other side of this issue is that there is no such thing as a risk free intervention. Life itself is one big risk. Although I sense that as a society we have perhaps become excessively risk sensitive, there is nevertheless an obligation on those who offer therapy to be risk sensitive and for risks to be made clear to clients. Risks should not be ignored.

Another protection *issue* is that there should also be clear procedures to mitigate any damaging effects arising from therapeutic intervention. Referral to a medical practitioner might be one such. Referral to a senior CAM practitioner might be another. I sense that there are sensitivities around the issue of referral. It's not a simple issue, but I think it's an important one.

A potential *peril* is that therapists fail to mention risks out of a defensive attitude which perhaps indicates a lack of confidence. Secrecy is defensive. The consequence is that the public might be put at risk.

A *prospect* within this principle is that protection for the public becomes a central and guiding principle in the training of all therapists and in the oversight and supervision of their practice. Reference to supervision reminds me that I understand that not all therapies *require* regular, monitored and recorded supervision of clinical practice.

2 The exercise of a duty of care.

The key *issue* here is that care for the client is paramount. Not the defensive insistence on the ultimate benefit of the therapy. Not the maintenance of the therapist's sense of self-worth and competence. Not the therapist's bank balance. In therapeutic intervention 'duty of care' creates an obligation and is not a voluntary option. I know that I'm emphasising the obvious. But the ramifications of a duty of care are considerable. I discovered that under Common Law all practitioners have a duty of care to their patients. I could argue that an aspect of 'duty of care' is to seek formal regulation.

A potential *peril* is that the therapist may be resistant to the notion that the therapeutic treatment is anything other than fulfilling a 'duty of care'. It may have similarities with the resistance which many people have to the idea that they could possibly be racist or sexist or that they act in ways which are oppressive to others. I suggest that therapists

should be challenged, perhaps in supervision, perhaps through the very procedures of either self or statutory regulation, to reflect critically on the assumption that 'duty of care' is the obvious and self-evident expression of their altruism.

A clear *prospect* and advantage is that a careful and critical approach to 'duty of care' will lead to a reflective culture which takes nothing for granted. Careful exploration of the complexities of 'duty of care' may, hopefully, create a culture in which clients feel confident – confident that they themselves can be critical if they deem this to be appropriate.

3 The building of public trust in therapies which are being offered for the public benefit.

The *issue* of trust is not only serious for politicians but is so basic that it is the glue of all good relationships – professional and personal. Its absence essentially undermines the necessary aspects of any therapy, particularly those which rely on the nature of the relationship for therapeutic effects.

A *peril* here is that therapists may simply assume that what they do is for the public benefit and that therefore they assume that they ought to be and will be trusted. 'Trust me I'm a . . . .' became a joke - but is not a joke. It is a residue of an archaic deferential social structure in which powerless people had no self confidence and no personal or social means of challenging those who had power over them. Perhaps the residue is still around in the sense that those who are ill and who are desperate for healing may put their trust in inappropriate people simply out of dire need.

The client's need for healing and well-being may collude with the therapist's need to be trusted. Collusion is not a good basis for trust.

The *prospect* that regulation will increase public trust is one of my own basic assumptions about the rigorous implementation of a supportive and challenging regulatory process. My concern is that CAM therapies continue to assume that they are essentially trustworthy without taking the risk of putting that assumption to test in public forums of accountability.

I suggest that regulation ought to address the public interest question: *What good reasons are there for me to trust you with my illness, my dis-ease, my despair, my distress other, that is, than your assertion that you are trustworthy ?*

4 The creation of forums in which research can be carried out and published, ongoing critique implemented and carefully evidenced developments put into place.

A central *issue* here is the establishment of a virtuous circle of evidence, critique and reflective practice. This also implies that practices for which there is no form of supportive evidence are discontinued.

A serious *peril* here is that in the absence of a research culture in a particular therapy the training and practice are based on the mere repetition of traditional and received practices which are stuck in the past. There will only be *ad hoc* developments and improvements. Ineffective practices may be perpetuated. If therapists do not expose themselves to the rigours of a sceptical research culture, then there is the danger that the therapists can adopt the fantasy that they are 'right' and that their theory is 'true'.

The *prospects,* for me are clear and positive but challenging - the knowledge base of the CAM therapies will increase, a critical culture will be assured, the trust of the public and of other health professionals will be more confident and there will be an enhancement of informed consent. It's worth pointing out that research should never be used in an attempt to support preconceived ideas or to protect therapies from criticism. As Pasteur said: 'Venerate the critical spirit, without it all else is nothing. It always has the last word'.

5 The establishment of formally validated training courses which include quality assurance and quality control procedures.

A central *issue* here is that training in CAM therapies should be subject to a form of external scrutiny at the stage of validation and external examination of trainees' performance to validate the standards and outcomes of the training. The level of the training in comparison with other forms of therapy should be demonstrably equivalent or validity different.

One way of addressing this *issue* would be for CAM therapy training to be allied to universities so that there can be formal and external quality assurance and quality control. This would enhance processes of accountability and transparency. Such an alliance might create dialogue between therapies and even with 'orthodox' health trainers and practitioners. Such an alliance between CAM therapies and orthodox approaches could contribute to a change of culture from one of conflict and competition, and perhaps isolation, to one of cooperation and coordination. Another benefit would be the possibility for the existing national bodies of CAM therapies to be jointly involved in the accreditation of individual therapy training courses.

There are real or imagined *perils* in adopting a university source of validation. It is conceivable that CAM practitioners would feel restricted, hampered and perhaps threatened by engaging with a university's validation procedure. Some CAM practitioners may feel, with some justification, that they are so 'alternative' that orthodox sources of validation and scrutiny are simply not appropriate. In such cases 'alternative' and 'orthodox' are seen as essentially incommensurate. A danger is that 'alternative' may be a synonym for 'secretive'.

I have experience of the ways in which universities are extending their notions of 'inclusion' into their world of validation. I think that there are ***prospects*** here rather than perils. Unless 'alternative' therapists are determined to see themselves as 'outsiders' then a process of regulation which includes university validation seems to me to open up

prospects. Another possibility would be to go down the NVQ professional qualifications route. These are designed to value and validate professional practice. These suggestions are not mutually exclusive. Quality assurance and quality control are integral to regulation and indeed to good practice.

6 The production and publication of standards of professional practice and competence along with codes of ethical practice and user-friendly complaints procedures.

The *issues* here are fairly self evident. I cannot see how any professional practitioner, therapeutic or otherwise, can possibly disagree with the preparation and publication of standards of professional practice, codes of ethical practice and user friendly complaints procedures. A crucial question for me is: How are these standards determined, examined and monitored - and by whom ?

Perils There is the possibility that grand-sounding published standards and codes of practice lack a proper organisational structure by which they can be implemented. The rhetoric is not the reality.

On the other hand I can see many *prospects* for the enhancement of informed consent and the development of confidence based on trust given knowingly from the client to the therapist. This information should include user friendly complaints procedures which should incorporate an independent judgement on complaints. These standards of professional competence, ethical practice and complaints procedures should, I propose, be available as part of the initial contract with users. I'm not sure whether training programmes include training on *the preparation of client contracts* and *the formalities of complaints procedures*. If not, it is my view that these should be included.

7 The creation of cultures which are committed to informed consent.

This final principle is, in some respects, a summary of the previous principles.

From my point of view a crucial *issue* derived from this principle involves the clear specification of the boundaries/limitations of presumed effectiveness of different therapies and the linked issue of referral procedures. In the BBC Radio 4 series on CAM therapies 200 therapies were mentioned. If it is the case that all these therapies are valid, then how are the boundaries of their effectiveness determined ? How is competence defined, learned, maintained, monitored and enhanced ? And crucially, how is the public informed and reassured on these matters ?

Some CAM websites provide information and make extensive claims as to therapeutic effectiveness. Are any attempts made by competent bodies to monitor the contents of CAM websites ?

Unless carefully delineated boundaries of evidenced effectiveness are stated, then there cannot be informed consent. Naïve trust is not informed consent. Some people's gullibility should not be a substitute for informed consent.

I therefore think that wide-ranging claims of therapeutic effectiveness actually create *perils* for both clients and practitioners. The perils are those of incredibility and incredulity. Un-evidenced and unqualified claims do not constitute helpful information. To make extensive and unsustainable claims is to undermine more restricted and valid claims. What forms of redress do clients have in the event that the claims of the therapy are manifestly not achievable ?

From my point of view there are *prospects* here because serious and sustained attempts to create cultures of informed consent are empowering. Lack of information and withholding contradictory information is disempowering as well as being dishonest. Secrecy and mystification are inimical to informed consent. Ignorance is not bliss – it is the necessary condition of confusion.

Conclusion

I shall end with questions on relationships between Orthodox and CAM therapies. (Saks 2003) Complicated though they are, I suggest that they need to be addressed in a persistent way as they are integral to a wide range of issues which surround illness, distress, dis-ease and the various forms of therapy intended to be curative or palliative. They are relevant to issues of regulation.

1 Should specific alternative therapies be applied in mainstream health contexts, in completely separate settings, or as part of a new integrated service based on holistic health centres ?

2 Should physicians be the gatekeepers for the alternative therapies or should orthodox and alternative practitioners operate as co-equals, working alongside each other?

* 3 Should alternative practitioners generally seek the legally enshrined professional regulatory frameworks possessed by orthodox health professionals ?

* 4 Should all fields of unorthodox practice be at least minimally based on the establishment of codes of ethics and lengthy education programmes, even if they do not gain formal exclusionary closure ?

5 Should shared learning with conventional practitioners be encouraged, in order to enhance future collaboration, and if so at what level ?

6 How, moreover, should the development of an evidence base be supported for alternative therapies – by the private sector, the state, or both, as is the case with orthodox medicine ?

7 And who should pay for the therapies concerned – the consumer at the point of access, the insurance plans, or the state ? (Saks 2003 pp 155-156).

I add a question of my own:

8 Should the mere fact that it is, by default, permissible to practise any form of unregulated therapy on the public be deemed to make such practice of any form of therapy acceptable ?

I conclude with the assertion that unregulated practice tends to be secretive and lacks transparency and accountability. It tends to prevent informed consent. It could be disempowering because there are serious risks of people being exploited without even recognising that exploitation is occurring. All this when they are at their most vulnerable and insecure.

Regulation may not be a panacea but it could have beneficial effects.

We are moving from a 'trust me' to a 'show me' culture. I approve of that shift.

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- A copy of the paper '*The validity of complementary and alternative therapies: A critical approach'* which I gave at the ACHRN conference in July 2004 and which complements this one on Regulation is available along with other relevant papers on www.bowlandpress.com click on 'Seminar papers'. I gave at the some of these papers at ACHRN meetings in Manchester.

- The important Section on 'Regulation' from the House of Lords: Science and Technology – Sixth report. Copies of this can be made by entering: *Regulation of Complementary and Alternative Therapies* into the search engine.

- A document which addresses issues, details and processes of a *Regulatory Framework and Organisational Audit*. I prepared this while I was CEO of a small, national counselling organisation. The long term aim was to achieve statutory regulation. www.bowlandpress.com

References

Gillett's (2004) article addresses some facets of these questions as do the edited books by Jütte *et al* (2001) and Dinges (2002). The May/June (2004) issue of 'Alternative Therapies in Health and Medicine' has contributions which are relevant.

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Other seminar papers which I have prepared and given to the Alternative and Complementary Health Research Network can be accessed on: www.bowlandpress.com Click on 'Seminar papers'.

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