Legal pitfalls of psychiatric research

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Background The increasing complexity of psychiatric research, including recent attempts to evaluate mental health legislation, suggests legal advice may be valuable in a wide range of research contexts.

Aims We aim to illustrate both the legal pitfalls of research in psychiatry and the potential for solutions if the methods are carefully chosen.

Method Two examples of research are subject to legal analysis, one involving advance directives, the other the random discharge of compulsory out-patients.

Results This analysis illustrates that participation in research may expose clinicians to additional forms of liability, but the legal risks can be minimised through changes in the methods or additional safeguards.

Conclusions Collaboration between academic law and psychiatry can enrich research agendas and avoid serious legal pitfalls. We argue that sound legal advice should be sought at the planning stage of research in psychiatry, but the fear of liability should not lead to overly defensive research practices. The aim should be to strike the right balance between avoiding unacceptable exposure to liability and stifling innovative research.

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Psychiatric research is often conducted oblivious to the legal consequences. Legal advice is occasionally sought in relation to the competence (or capacity) of people with mental illnesses to consent to participate, or where medication is to be administered without consent. However, the increasing complexity of psychiatric research, including recent attempts to evaluate mental health legislation, suggests legal advice may be valuable in a wider range of research contexts.

REASONS FOR SEEKING LEGAL ADVICE

A legal analysis of a proposal at an early stage may be useful for several reasons. The methods may be unlawful in some respect. They may involve a breach of mental health legislation or the provision of unlawful treatment. Those who follow the research protocol (or their employers) might then be exposed to additional risks of liability in the courts or in disciplinary proceedings. If patients who pose a risk to others are discharged earlier than usual, an injured victim might sue the researchers for negligent discharge of that patient. Similar concerns would arise in the early discharge of patients with a high risk of suicide. If the analysis indicates the research would be unlawful, or would generate unacceptable risks of liability, then the methods should be modified or the research should not proceed. If it does proceed, advice may still be necessary concerning the scope of any insurance cover or contracts of indemnity required.

Legal advice may also assist with ethical clearance. Research that is unlawful might be considered unethical for that reason. Controversial legal issues should, therefore, be considered before submission to an ethics committee. However, it cannot be assumed that ethics committees will have access to experienced legal advice, or that they will adequately screen research proposals on this basis.

Another reason for addressing the law is that researchers usually wish to publish their results. This may be problematic if they discover later on that their methods have been unlawful in some respect. At the very least, publication may expose the researchers to criticism or journal editors may refuse to publish their work. For fear of exacerbating their liability, researchers may be forced to abandon their plans for publication.

Lawyers, however, often err on the side of caution to protect their clients. Acting on overly conservative legal advice could produce defensive research practices, thus inhibiting innovative and incisive studies. The right balance must be sought between ensuring researchers receive proper legal advice for their own protection and avoiding the erection of unnecessary barriers to important work.

We shall illustrate these themes with two recent examples of psychiatric research in which legal advice was clearly required. One concerns the use of advance directives in psychiatry, the other a controlled trial of compulsory out-patient care.

USE OF ADVANCE DIRECTIVES IN MENTAL HEALTH CARE

At the present, we are undertaking a study to assess the consequences of asking patients with chronic mental illnesses who have been compulsorily admitted to hospital to record their advanced directives (or future preferences) for care. In this parallel group, randomised controlled trial (RCT) patients participating in the experimental arm are asked to complete a 'preference for care' booklet ('the booklet'), just prior to discharge from hospital. Patients in the control group receive usual psychiatric care. Main outcomes at 12 months are: admissions to hospital; further use of the Mental Health Act; level of medication prescribed; and patients' and professionals' satisfaction with care. The legal issues considered in planning this research were:

(a) the criteria and process for assessing the competence of patients to complete the booklet;

(b) whether completion of the booklet by a competent patient might later preclude provision of treatment a clinician believed was indicated;

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(c) whether clinicians might be exposed to any additional forms of liability if treatment did proceed contrary to patients' stated preferences.

(d) whether completion of the booklet might mean that clinicians invoked the authority of the Mental Health Act even more frequently in order to override patients' preferences.

These questions could only be addressed by a clear understanding of English law concerning advance directives in the context of mental health care.

Law concerning advance directives

For an advance directive to be effective or valid, English law (Kennedy & Grubb, 1998) requires that it shall:

(a) have been completed by a patient who was competent at the time;

(b) have been completed voluntarily and without coercion;

(c) not have been competently revoked by the patient at a later time;

(d) be clearly applicable to the circumstances which arise.

We concluded that many patients' statements in the preference for care booklets in our research would meet these requirements and might therefore bind clinicians in certain respects concerning later treatment options. There were even aspects of our methods that enhanced the validity of the booklet as an advance directive. Patients' competence was to be assessed specifically at the time they made their statements of preferences; those statements would often relate to particular treatments (even named medications) of which they had considerable experience; the patients' preferences would be clearly evidenced in writing; and the booklet's completion would be supervised by a health professional (A.P.) who could verify the circumstances. These features of the research context would buttress the case that the patient's statements in the booklet would meet the law's criteria for an effective advance directive that should ordinarily be honoured.

One particularly significant question asked patients to specify treatments they would not want to receive. Typical responses ('no haloperidol', 'no injections') could be viewed as specific prohibitions of treatments that would intrude upon the patient's person. For a clinician then to provide that treatment, despite that prohibition, might constitute a battery of the patient, unless this was authorised by mental health legislation or justified under common law principles of necessity (R. *v.* Bournewood Community and Mental Health NHS Trust, 1998; Dawson, 1999).

Limitations of advance directives

There are, nevertheless, distinct limits to advance directives concerning mental health care. They cannot require treatment to be provided that is unlawful or unethical, that is not clinically indicated or for which the resources are not available. There is no duty created to provide inappropriate or additional care. Furthermore, the patient's stated preferences can still be overridden if the clinician can rely on some form of legal authority or justification for providing treatment without consent. In the case of treatments for mental disorder, sectioning the patient under the Mental Health Act will usually provide that authority. Ignoring the patient's instructions would also be justified to prevent suicide or other serious physical harm, provided that the patient is sectioned as soon as practical if compulsion continues (Black *v.* Forsey, 1988; R *v.* Bournewood Community and Mental Health NHS Trust, 1998).

Increased use of the Mental Health Act 1983

The rule that the authority to treat provided by the Mental Health Act may override an advance directive raised in our study the prospect that patients who completed the booklet might be more exposed than the control group to compulsory treatment under the Act. Faced with clear evidence in the booklet of the patient's negative preferences for care (e.g. no injections), clinicians who felt the need to override such preferences might invoke the compulsory treatment process more often than otherwise.

We concluded that even if this were the case, our research would not be unlawful for the following reasons. It is not unlawful to listen carefully to patients' preferences or to record them. Nor would it be unlawful to section patients subsequently to obtain the authority to override their preferences. When the Mental Health Act's criteria are met, sectioning patients is lawful and it is often in patients' interests because it ensures they receive the benefits (of the procedures, documentation and review entitlements) that the Act deliberately provides for those treated under compulsion. Completion of the booklet simply provides one additional means through which patients' preferences are known.

Disclaimer at the end of the booklet

We decided to add a disclaimer to the booklet to reduce the chance that patients might think they had been misled or misinformed as to the binding character of their statement of preferences. The disclaimer informed patients that they might still competently alter their preferences at a later time and made it clear that in some situations their preferences might be lawfully overridden. The wording of this disclaimer was crucial. We did not wish to indicate the booklet was meaningless (its contents would still provide good evidence of the patient's views) but nor did we wish patients to overestimate its legal effects. Having conducted this legal analysis and altered our methods, we decided we could safely proceed with the trial. Its outcome will provide further evidence of the complexities of the use of advance directives in this field.

RANDOMISED TRIALS OF MENTAL HEALTH LEGISLATION

Another form of research that requires legal input is the evaluation of mental health legislation. For instance, a trial might be planned in which patients are randomly allocated to Section 3 or Section 2 of the Mental Health Act: that is, to a 6-month or 28-day compulsory admission. Here, the effect of the length of the compulsory admission would be examined. More controversially, groups of sectioned patients might be randomly discharged from all legal control. Use of the different sections of the legislation might even be considered close to random in any case, given the marked variance in practice that often exists between regions, hospitals and clinicians in this regard. The effects of such choices, however, can only be determined definitively by random allocation to different forms of legal control and measurement of outcomes such as subsequent rates of hospital admission, adherence to medication or relapse.

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NORTH CAROLINA OUT-PATIENT COMMITMENT TRIAL

The RCT has been recommended by a leading team in the USA as their preferred approach to the evaluation of compulsory out-patient care (Swartz *et al*, 1995). They have recently completed a major trial of out-patient commitment in North Carolina (Swartz *et al*, 1999; Swanson *et al*, 2000), the ethical difficulties of which were raised in a separate paper (Swartz *et al*, 1997). Several hundred adults with serious mental illness took part in the study. Participants had been compulsorily admitted to state mental health facilities and had been ordered by a judge to undergo out-patient treatment on discharge from hospital. When the responsible clinicians considered they were ready to leave hospital, patients were randomly assigned to discharge from all legal control or to compulsory out-patient management. All patients were offered assertive community treatment and were assessed on several outcomes, including subsequent acts of violence. This experimental evaluation of mental health legislation raises important ethical and legal concerns (Federal Judicial Center, 1981).

Ethical issues

The principal ethical difficulties of this kind of study are:

(a) the capacity of patients to consent to participate, when it has recently been established that they have met the criteria for compulsory treatment;

(b) the fact that patients randomly discharged from out-patient commitment may withdraw from treatment, with adverse consequences for their mental health; this difficulty occurs in all withdrawal or relapse studies (Shamoo & Keay, 1996);

(c) the potential for increased rates of suicide or violence among randomly discharged patients;

(d) the position of responsible clinicians who, having recently certified that a patient needs compulsory out-patient treatment, are now prepared to discharge that patient on a random basis following the research protocol;

(e) the position of carers or families who have recently applied for a patient's control by legislation, but who now find that patient randomly discharged back into their care.

Legal objections

If such an experiment were to be conducted under English law, a number of legal difficulties might arise in addition to these ethical concerns. It might be claimed that random discharge of compulsory patients is an abuse of the statutory discharge discretion in the hands of the responsible clinicians; or the researchers may be found liable in damages for causing any subsequent harms that befall randomly discharged patients or others around them.

Random discharge of compulsory patients might be described as waiver of the statutory discharge criteria in favour of the research protocol, or as an unauthorised suspension of the legislation, that could not be approved even by an ethics committee. Researchers cannot easily waive the provisions of a statute even to conduct a legitimate experiment. It could be said that random discharge is not based on the criteria that are stated or implied in the Act. It does not follow an individualised assessment of the patient against those criteria, conducted by the responsible medical officer (RMO). In terms of particular legal errors, it could be described as fettering a statutory discretion through the application of a pre-determined policy, delegation of the RMO's discretion to the researchers, taking into account irrelevant considerations, exercising a power for an improper purpose, or as failure to apply the correct legal test. Proof of any of those errors may lead a court to quash the discharge decision (and hence the research itself) upon an application for judicial review. In a similar vein, Smith has recently argued that placebos should not be used in drug trials involving compulsory patients who have been shown to need the treatment that placebos cannot provide (Smith, 1999).

The tort law implications of random discharge of compulsory patients might also be serious. The problem here is not one of imposing additional restrictions on patients' liberty, which might lead to proceedings for false imprisonment. Rather, it is early discharge that is being proposed, with the prospect of immediate harm occurring to the patient or others.

Failure to conduct an individualised assessment of the patient's suitability for discharge, or failure to consider carefully the safety of the patient's family, may leave the RMO exposed to civil liability for negligent discharge causing foreseeable personal harm (Hoggett, 1996; Jackson, 1997; Mason & McCall Smith, 1999). In some cases violence to family members (Holgate *v.* Lancashire Mental Hospital Board, 1937; Home Office *v.* Dorset Yacht Co., 1970) or suicide of the patient (Hay *v.* Grampian Health Board, 1995; Reeves *v.* Commissioner of Police, 1999) may be reasonably foreseen. For this reason, patients with a recent history of violence were excluded from the trial in North Carolina (Swartz *et al*, 1997), although this inevitably reduced the power and external validity of the study.

Random discharge need not always be considered unlawful in the case of patients assessed to present no immediate risk. A court might be convinced that there was genuine uncertainty among psychiatrists as to the efficacy of the statutory regime and that the proposed research would significantly advance knowledge. Evidence might be given of varying patterns of discharge in different parts of the country. In this situation, random discharge of sectioned patients in accordance with the research protocol might be considered a legitimate exercise of discretion on the part of the RMO. This positive view is especially likely if there is:

(a) full debate of these issues before the ethics committee;

(b) an independent monitoring committee established to audit the research;

(c) prior consultation with professional associations, organisations such as Mind (National Association for Mental Health), the Mental Health Act Commission, and lawyers representing the state.

In cases of particular controversy, a declaratory judgment might be sought from an appropriate court that it would be lawful for a clinician to follow the research protocol. Clinicians would still be wise, before participating, to require a signed guarantee of indemnity from the researchers which would protect them against any legal expenses and any damages awarded if they are sued. The researchers should also be well insured.

Statutory authority for experimentation

The ideal solution would be for RCTs of mental health legislation to be expressly authorised by specific legislation or under a more general statute that permits experimentation in the law, if certain safeguards are met. Regrettably, to procure the

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passage of such legislation is not very practical or likely. Nevertheless, this step was recently taken in New York. There, state legislation was enacted to establish an out-patient commitment regime on a provisional basis, pending its evaluation through an RCT at Bellevue in Manhattan (New York Mental Hygiene Law, 1994). Unlike the North Carolina trial, that study found no significant differences between the experimental and control groups on subsequent measures of rehospitalisation, arrest, quality of life, symptoms or adherence to treatment (Policy Research Associates, 1998). Providing enhanced community services improved patient outcomes but the evaluation found "no indication that, overall, the court order for out-patient commitment produces better outcomes for the client or the community than enhanced services alone". Many service providers believed the coercive elements of out-patient commitment would improve patient compliance, but no evidence was found to support that view. The study again excluded patients considered to be at high risk of violence in the community. Despite those negative findings the New York legislature extended the out-patient commitment regime throughout the state in 1999 (Kanapaux, 1999).

CLINICAL IMPLICATIONS

- A balance should be struck between the fear of liability and the need for innovation in research.
- Randomised controlled trials of mental health legislation deserve special scrutiny.
- If concerned, insist on indemnity and insurance.

LIMITATIONS

- Only two major examples of research are discussed.
- It is hard to state the law with certainty in this novel field.
- The ideal solution, special legislation, is not practical.

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