Section

10

Consent, abuse and liability

SECTION CONTENTS

23

Consent

INTRODUCTION

Over the past two decades there has been a shift within health care from an expectation that patients with medical problems should entrust themselves passively to the care of physicians to an expectation that they should cooperate in their own care, and even have some responsibility for the outcome of medical procedures they undergo. These changes are reflected in the terms we use: for instance, the word patient, which means someone who endures, is increasingly replaced by terms such as client or consumer, which suggest a more active and discriminating participant in the medical process.

Informed consent was not an issue in medical practice before the 1970s.[1] Today, it forms a central issue through a series of ethical codes applied to medicine, from the Nuremberg to the Helsinki Codes. It may seem immediately clear what informed consent is, but a moment's reflection should dispel this illusion. For example, in a study volunteers were given varying amounts of information about the drug's properties and expected side effects. The more

information the volunteers were given, the less likely they were to take the drug, despite being offered money.[2] When they found out that the drug being investigated was aspirin, most subjects said that what they now knew would not change their attitude to aspirin when they went home if faced with a headache or fever.

Despite its name, therefore, there seems to be a sense in which informed consent cannot be about being fully informed. Too much information can prejudice valid consent just as readily as too little. Rather than meaning fully informed consent, it would seem that informed consent must mean something more like valid or voluntary consent. There are two key issues. One is whether the consent is voluntary. Another is the issue of adequate or appropriate information, which, in practice, cannot be separated from the question of comprehension on the part of the person being informed. Finally, there is an issue of legal competence.

VOLUNTARY CONSENT

When an individual attends for a consultation, there is an implicit assumption that they are seeking help and will take the advice offered by the doctor, psychologist, community nurse or social worker. In this regard, a prescription often seems to function in two ways: on the one hand as a treatment for a particular condition, but on the other as a symbol of the advice being offered. Taking a little piece of paper away with them from the surgery may give the person the feeling that they are not alone in trying to sort the problem out.

Arguably, however, the question of informed consent has come to prominence in recent years precisely because we no longer accept this as a proper and fitting way of going about things. We do not voluntarily consent to current practice. There is a problem in that a surgery or outpatient setting is not one that is conducive to any of us being able to articulate our concerns. We may be worried by the condition that has led us to seek help. We may be anxious when faced

with the doctor, nurse, psychologist, or whoever. We may be aware of the queue of others after us, who need to be seen. Once the allotted appointment time of 10–15 minutes is up, it is often very clear that the doctor is wondering whether they are likely to get to lunch or to get home if all consultations during this session are going to take as long.

For these and other reasons, we often take the prescription. However, available evidence suggests that most people being treated with antidepressants, for instance, do not take them for longer than 4 weeks, despite recommendations that they be taken for 3–4 months. One reason for this may be that the pill prescribed does not suit them, but another reason that seems likely is that many people being treated do not voluntarily consent to the treatment and, once away from the pressures generated in clinical settings, they withdraw consent.

The lack of consent involved here probably does not reflect an opposition to drug treatment so much as an opposition to a style of treatment delivery, in which an authoritarian doctor decides what is best for a patient and issues instructions. Implicit in this authoritarian approach is the idea that medical science has developed to such an extent that there is something approaching certainty regarding the proper management of most conditions, and the doctor is an authority – or at least knows better than the patient – what they should be doing.

In contrast, a cogent case has been argued by a number of commentators in recent years that medical care should involve a greater acknowledgement of ignorance or uncertainty on the part of the practitioner and an invitation to collaboration.[3–5] According to this approach, treatment would be a matter of negotiation rather than one of instruction: a negotiation that would recognise that an illness is one event within the drama of someone's life and that, for a variety of reasons, rigid adherence to a treatment regimen, with all the side effects that may be entailed, may not be that person's top priority.

From this perspective, the issue of voluntary consent becomes a matter of good clinical practice. This is not something that can be properly defined at law. Even signed consent forms, in certain circumstances, may not be interpreted by a court as indicating valid consent, while on the other hand the lack of a signed consent will not necessarily be taken to indicate a lack of consent should someone apply for legal redress for a claimed injury.

The law is only a blunt instrument. Ideally a profession should give some indications about what it thinks on certain key issues. In this case, what would seem to be required are a set of statements about what psychotropic drugs do and what their role is in the management of nervous disorders. The problem in mental-health work lies in getting the different professionals comprising a mental health team to come to some agreed form of words regarding the treatments they deliver. On a national scale it would be even more difficult to get all psychiatrists, for example, to agree among themselves on a common form of words for what the antipsychotics do. In the absence of such agreements, patients exposed to different mental- health professionals are all too likely to be given quite different, even contradictory, views on the nature or purpose of their treatment. The possession of a book such as this can perhaps in some way redress this problem, by offering a clear set of statements with which their therapist may agree or disagree, and in the process reveal something of their approach to therapy.

A clinical style that is more likely to result in valid consent to taking the risks involved in any act of health care hinges, in my opinion, on an ability of health-care professionals to live with explicit ignorance about the likely outcome of their interventions in the circumstances of their patient's life. The acknowledgement of ignorance and the sharing of knowledge and power that such an approach advocates is not one that all health-care professionals agree is appropriate or one that all can live with easily, even in limited circumstances. Indeed it is not the approach

that all patients want –sometimes we just want someone who knows what they are doing to take over responsibility for us.

INFORMATION AND COMPREHENSION

How much information do people need about the risks and benefits of treatments? Most commentators come down in favour of informing the taker of a drug of the significant risks associated with treatment rather than making them aware of every possible risk. There are a number of issues here.

One is the question of being able to make an informed judgement of whether to consent to treatment or not. A bald list of side effects or complications is unlikely to help any of us to make up our minds. In contrast, meeting someone who is taking the drug or who has undergone the treatment in question is more likely to offer a tangible example of the issues involved.

The issue of a real-life flesh and blood example rather than abstract lists also brings home the fact that, in making decisions, there is often a question of isolation involved. It is not an easy matter for anyone to be faced with ‘facts’ in clinical settings; these facts often bring with them implicit requests to make our minds up soon, without the benefit of prior knowledge of the issues involved. Where psychotropic drug taking is concerned, this isolation and the disempowerment that it brings about could be managed by encouraging prospective drug takers to visit local user groups or MIND branches, or by having advocates on wards. This is a model that might also be applied to electroconvulsive therapy for instance.

Groups such as MIND have sometimes been seen as hostile to medical practice in the past. If patient groups are actually hostile, a pattern of more frequent referral might encourage a more collaborative approach. This would seem increasingly necessary as the role of the community at large in accepting medical practices is becoming ever more clear. This is a

message pharmaceutical companies understand all too well as they get ever more active in setting up patient special interest groups. While, medicine was much more authoritarian 50 years ago, there was some understanding that doctors were on their patients' sides. The relentless progress of technical developments since and pharmaceuticalization of medicine has led to a disintegration of this community of understanding. This became very clear with the benzodiazepine crisis, in which doctors and pharmaceutical companies rather than the addicted patient became regarded as the problem by the larger non-drug-taking community.

A further important point is whether the information that is given comes with implicit or explicit permission to return with further concerns and queries at a later date, or even the permission to consult a third party. In this case, the privileges of the wealthy, who think nothing of seeking further advice elsewhere if they are not happy with what they have paid for, contain a pointer to the state of affairs that would be desirable for all.

Finally, on the question of information, there is the issue of comprehension. Clinical settings are often very stressful and there is a good deal of research to suggest that only half of the information imparted in a consultation is retained afterwards. One way to overcome this would be to copy letters sent to the patient's general practitioner, detailing what has happened at the consultation, to the patient also. This would give people an opportunity to remind themselves of the recommendations that were made and a chance to review these recommendations in a less stressful setting.[6,7]

The language in which recommendations are made may pose its own problems. The practice of medicine, as with the practice of anything else, involves the comprehension of a jargon. This jargon becomes so commonplace to practitioners that they often forget that the terms they use may be meaningless to the person they are seeing. The term schizophrenia, for

example, is famously likely to suggest something akin to a split or multiple personality disorder to most lay people – a condition that would not, on the face of it, appear to be appropriately treated with drug therapy.

In clinical trials, for example, I have regularly found that, despite what may have seemed to me to be clear instructions, a patient may simply not grasp that of the two pills they are taking only one is active, while the other is a placebo. Again and again it becomes clear that many patients do not appreciate that the anticholinergic drugs they are taking (see Ch. 2) are actually reversing side effects brought about by the antipsychotic drug they are also taking.

USER ISSUES

LEGAL COMPETENCE

Where mental health matters are concerned, the question of legal competence revolves around the issue of whether the person has been detained compulsorily in a hospital and for treatment against their wishes. Detention assumes that the patient is not, at the time of detention, capable of validly consenting to what appears to be the best available treatment for their condition. All too often, the interpretation put on the status of a detained patient is that he or she can be forced to take treatment. This is not the case. The forcible administration of medication, whether the individual is a voluntary or detained patient, may provide the basis for a legitimate claim of assault. Conversely, in circumstances where it is clear that there is an emergency – someone has been violent or is clearly threatening injury to themselves or others – this assault may be justifiable, whether or not the individual has been compulsory detained.

The grey area is where mental-health staff suspect that problems may be brewing and that a patient may soon become violent. A concern about potential trouble is more likely to lead to an earlier intervention with medication in circumstances in which there are staff shortages or where

staff training is such that there is little confidence in non-pharmacological methods of managing difficult behaviour. The forcible administration of medication in these latter circumstances may well amount to an assault.

Far from permitting such assaults, the spirit of detention under most legislation is that patients thereby detained should be treated as though their relatives were constantly present. The treatment should be such that a relative would be likely to approve were they present to witness what was happening. These Acts were, at least in name, enacted to protect patients, rather than to legalise assault. Staff very quickly forget that in most parts of the world through to the end of the 20th century prisoners have had more rights that detained patients.

Having said this, it should be recognised that what actually happens often depends on the persuasive skills of staff members. Many individuals have considerable skill at persuading others to go along with a sensible course of action. There are probably a number of components to such skills, ranging from sheer physical presence and/or force of personality to a number of other tricks of the trade. Such skills appear to me to be in danger of being lost, and the current over-reliance on pharmacological methods of treatment tends to militate against the development of such skills. The more prescriptive Codes of Practice, treatment algorithms or care pathways are, the greater the effect they are likely to have on the confidence of staff to act in the best interests of patients, as these subtler patient management skills cannot be as readily codified.

At present mental capacity legislation or procedures are being brought into healthcare. It is not yet clear what effect if any this will have on practice within mental health settings.

COMPLIANCE

There is a very considerable overlap between the areas of consent and compliance. Those who do not consent to treatment are unlikely to comply with it afterwards. Many people, when they

consent, do so only provisionally. For instance, a consent to antidepressant treatment will often involve an agreement to take the medication only until some improvement appears; it will not in the first instance have meant to the patient an agreement to go on taking medication for months or years.

Playing on concerns about poor compliance with antidepressants, pharmaceutical companies provided many SSRIs in one pill a day form. This, however, was largely a marketing driven exercise and should not be thought of as the answer to problems with compliance. The issues involved in non-compliance hinge on relationships and education, rather than whether the pills come in a once-a-day formulation. Current research suggests that the greatest single determinant of compliance is the quality of the relationship between the patient and their keyworker or prescriber.[8] This is caught best by William Osler's famous quip that the distinguishing feature of human beings is their propensity to industrially self-medicate: in other words, patients often have much more faith in their pills than in their therapists. It may speak volumes for their relationship with their therapist if, against this background, they choose to give up treatment.

Another important element in the equation is an individual's personal situation. Becoming a patient is just one more episode in personal dramas that involve getting or holding down jobs, sexual relations, driving safely, and so much more.[4] Nursing staff and other mental-health keyworkers may be much more aware of this than their medical colleagues, and could probably do a great deal to minimise confrontations by emphasising difficulties with side effects and how treatment is getting in the way of a person getting on with their life. This is much more likely to happen in other areas of healthcare, such as the management of diabetes than it is to happen within mental health settings [9].

One of the weapons a patient or their keyworker can use in the face of medical power is the weapon of data. Filling up rating scales such as the LUNSERS (Liverpool University Side Effect Rating Scale)[10] is a way to face a physician with data; if the physician is being as scientific as they claim, this tests how they will respond to data.

A more specific version of the same would be to create rating scales specially designed for each problem being faced by the patient – this is easily done (see Fig. 23.1). Using scales such as this, the individual (perhaps helped by a keyworker) would rate how much difficulty they were having from voices, for instance, and how much from a side effect such as weight gain, stiffness or sexual dysfunction. The progress of problems stemming from both the illness and the treatment could be charted over the course of several weeks in this fashion and then presented to the prescriber (Figs 23.2–23.4).

If a prescriber refuses to respond to these data, or if their behaviour is not manipulable by feedback of this sort, it may be time to change prescriber.

PRESCRIBING

The role of prescribing in issues of compliance and consent also needs to be considered. A prescription, initially, was an order to a pharmacist to dispense a particular medication, but until quite recently it was not the only way a patient could obtain medication. Most drugs, including thalidomide for example, were sold over the counter (OTC). Alternatively, based on an earlier prescription, a patient could go back to the pharmacist for virtually endless repeats.

This situation changed in 1951 when the US regulators made new drugs available on prescription-only.[11] Between 1951 and 1962, there had been resistance to this development. The prescription-only category had been introduced in 1914 to control the availability of drugs such as cocaine and the opiates. When in 1951 it was extended to restrict the availability of the first

really effective agents, the new antibiotics, this seemed odd to many. Why should a system designed for addicts be applied to free citizens? The thalidomide disaster of 1962 copper-fastened the new system in place, and since then all of us have effectively been forced to hand over control of our health care to professionals in a way that we did not have to do before.

In recent years, some of the new 'wonder' drugs have become available OTC – the histamine H2 blockers such as cimetidine and ranitidine, for instance. Is there any reason why the selective serotonin reuptake inhibitors (SSRIs) or antipsychotics could not also be available OTC? With respect to safety and possible interactions with other drugs, the SSRIs are at least as safe as the H2 blockers. If chlorpromazine had been available OTC, it seems a safe bet that it would never have been self-prescribed by users in the megadoses that were administered by clinicians during the 1960s, 1970s and 1980s. It is more likely that users would have opted for regimens pretty close to what medical opinion 40 years later seems to be coming around to recommending as optimal.

Sold OTC, the major tricyclic antidepressants would probably have been marketed as tonics rather than antidepressants: they improve sleep, appetite, energy, etc. Seen in this light, they might be far more acceptable to many people. Part of the appeal behind alternative medicine and the use of health foods is that this kind of management leaves control of health in one's own hands and there are not the same disease implications. If you are stressed or burnt out – something we all are from time to time – you can take St John's Wort. To get Prozac, you have to be given a mental illness first of all.

The prescription-only question is thus bound up intimately with the question of disease. In 1962, the FDA attempted to minimise the risks of treatment by restricting the use of drugs to those who were genuinely ill, so that any risks brought about by a drug could be weighed in the

balance of clear benefits also produced. In the case of depression, it would seem that many people simply do not accept a disease model of depression: they do not consent to treatment on these premises and, as a consequence, they very often do not comply. In addition what the regulators in 1962 failed to anticipate was the ability of pharmaceutical companies to sell diseases. Restricted to marketing pharmaceuticals for serious diseases, they have responded by making us all diseased (see Section 11).

Figure 23.1 Rating scales used to determine a person's experience while taking psychotropic medication.

Figure 23.2 Occurrence and distress caused by paranoid feelings, as rated by self-assessment questionnaire (SAQ).

Figure 23.3 Occurrence and distress caused by voices, as rated by self- assessment questionnaire (SAQ).

Figure 23.4 Dry mouth and agitation as rated by self-assessment questionnaire (SAQ).