Platform

Consent to randomized treatment: a reply to Brewin

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Dr. Thurstan B. Brewin[1] has launched a vigorous assault on the doctrine of informed consent. He believes that his views are widely shared within the British medical community; however, he fears that many lawyers and laymen may unwittingly accept this doctrine. Since inappropriate insistence on informed consent is likely to have a harmful effect on patients, Brewin invites the medical profession to engage in a "rearguard action" against the pressures of changing social attitudes. Although one might expect to find less hostility towards the doctrine of informed consent among North American physicians, Brewin's attitudes are by no means uncommon among them, and his arguments may strike a responsive chord with many. It seems important, therefore, that Brewin's attitudes and arguments be carefully scrutinized.

In this article I shall attempt to defend the doctrine of informed consent and to show why attempts to discredit it, especially in the context of randomized clinical trials, ought to be resisted. Brewin's attack on the doctrine commits the "straw-man" fallacy, which ascribes to one's opponent a distorted and palpably weak version of his or her position. One then proceeds to criticize this oversimplified and easily vulnerable target. Having demolished the straw man, one invites the audience to conclude that the real man has been successfully refuted.

Brewin's position and its antecedents

The doctrine of informed consent has frequently been attacked by physicians who are less than fully sympathetic. A classic of the genre was provided by Lester Coleman,[2] who insisted that the doctrine requires that "no details can be omitted". Not only must physicians provide patients with an exhaustive and exhausting course in anatomy and physiology, but also they must outline every conceivable risk, however remote. Thus, according to Coleman, physicians would have to warn sick and already anxious patients who are awaiting surgery that "cases have been reported of patients who, in their semi-somnolent preoperative condition, have fallen off the table and fractured their skulls or their limbs."[2] Coleman's insistence that the doctrine of informed consent requires that physicians provide their patients with information about such exceedingly remote but alarming contingencies nicely illustrates Brewin's contention that "too much information may be as bad as too little". Starting from the moral principle that a patient's welfare takes priority over "abstract principles or slogans" (such as "informed consent" or "patient autonomy"), Brewin follows in the path of the esteemed Franz J. Ingelfinger.[3] Ingelfinger's doubts about the validity of informed consent rested on the highly technical nature of most medical procedures: "How can he [the layman] appreciate the sensation of living for days with a multilumen intestinal tube passing through his mouth and pharynx? How can he interpret the information that an intravascular catheter and radiopaque dye injection have an 0.01 per cent probability of leading to a dangerous thrombosis or cardiac arrhythmia?" These rhetorical questions lead us to conclude that without a medical education or a proper scientific background, patients or research subjects cannot realistically be expected to assimilate such technical information. They are simply incapable of understanding the hazards to which they will be exposed, and of weighing and balancing such risks against the possible benefits.

Considerations of this sort led Ingelfinger and a host of others, now joined by Brewin, to conclude that the process of obtaining informed consent is no more than an elaborate ritual, a device that, when the subject is uncomprehending, confers merely the semblance of propriety on the enterprise. If informed consent is a sham and "often leads to increasing confusion — for example, as to which hazard goes with which treatment" — then patients will be alarmed and made anxious for no good reason.[1]

If we accept these arguments the doctrine of informed consent would appear both impossible to implement and undesirable. In Brewin's view, to withhold information from patients or research subjects is "not merely ethically permissible, but ethically preferable" because it is required by the principle of patient welfare.

Brewin concedes that "some patients thrive on a diet rich in de-

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tailed information about their illness; some like the 'status' of giving special consent; others feel reassured by it, even when it is little more than a formality." But he believes that for the rest (the majority?) of the patients it is the physician's duty to withhold information, paternalistically, in order to protect the patient's "peace of mind", to minimize "anxiety, doubts, or lack of confidence", to sustain "morale" and to preclude "serious and lasting misunderstandings".

This is the gravamen of Brewin's case, but he buttresses it with several subsidiary arguments and then applies it, inappropriately (as I shall argue), to randomized clinical trials. One of Brewin's subsidiary arguments appeals to considerations of efficiency in the allocation of scarce medical resources. In this context the resource is the physician's time: "Time spent on obtaining informed consent, when there is no logical ethical need for it, is time that could have been spent on more important aspects of patient care." He also suggests that there is a danger that "once in possession of written consent some doctors might become a little less concerned than they should be about their ethical responsibilities". Thus, compulsory written consent could diminish the care with which physicians communicate with their patients.

Arguments against Brewin's position

Brewin's rejection of the doctrine of informed consent rests on the dubious assumption that informed consent requires that detailed and complete technical information be communicated to and comprehended by the patient or research subject. This is the "straw man" mentioned earlier. However, this doctrine requires no such absurdity, and none of its advocates has ever, to my knowledge, demanded anything so unrealistic. The doctrine is designed to make meaningful the patient's or research subject's right to autonomy. Without knowing the "relevant" facts, a person is in no position to control a fundamental aspect of his or her life. To be swamped and confused by a mass of technical detail equally undermines the patient's or subject's right to autonomy. Indeed, since empirical studies have shown that a patient's comprehension varies inversely with the elaborateness of the material presented,[4] no good result is likely to come from providing a patient with all the details of the proposed therapy or experimental procedure and its conceivable sequelae.

Fortunately, this "all-or-nothing" dichotomy can be avoided, thereby saving us from falling into the trap of physician paternalism offered by Brewin. Judgement and discretion must be used in dispensing information to patients and subjects with a view not to protecting them from a harsh reality but to providing them with information they can effectively assimilate rather than with raw technical data that merely confuse and overwhelm.

The legal position is less clear than one might wish, but it seems to be agreed by the courts that something less than total information is satisfactory. In the American case of *Canterbury v. Spence*[5] the United States Court of Appeals held that "the test for determining whether a particular peril must be divulged is its materiality to the patient's decision; all risks potentially affecting the decision must be unmasked. A risk is thus material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy."

The doctrine of informed consent requires that a physician disclose only the material facts. A physician who fails to disclose an exceedingly remote risk of minor harm is not culpable legally or morally. There is no magic formula available to guide physicians in distinguishing material from immaterial risks and significant from insignificant facts. Reason, judgement and discretion must be exercised by physicians seeking to chart a defensible course between the extremes of total disclosure and total concealment. Both risk and stake are germane, as are the particular attitudes and values of each patient or research subject. All the relevant information must be presented to patients and subjects in a form that can be used by them in their decision-making. Since some will misapprehend the information and others will be reluctant to admit difficulties of comprehension, it is the physician's responsibility not to proceed with treatment or research until he or she is sure that the patient or subject understands the information.

Further, the material significance of a risk depends upon the significance a *reasonable* patient or research subject would attach to the risk. However, if the physician knows that a particular patient or subject would attach significance, whether reasonably or unreasonably, to some risk, then the physician is obliged to disclose such a risk to the person. The importance of this qualification emerged in the report of the board of regents of the University of the State of New York[6] in the notorious case involving patients at the Jewish Chronic Disease Hospital in Brooklyn. The regents found that "a patient has the right to know he is being asked to volunteer and to refuse to participate in an experiment for any reason, intelligent or otherwise, well-informed or prejudiced. A physician has no right to withhold from a prospective volunteer any fact which he knows may influence the decision." The subjects in that case were not told that the cells with which they were to be injected were live cancer cells. The physicians regarded the experiment as harmless, and in defence of their actions pleaded "therapeutic privilege" as justification for nondisclosure. They did not wish to upset potential subjects unduly by the use of the emotive word "cancer". However, the board of regents found that the decision belonged to the volunteers and ought not to have been usurped by the physicians.

It seems clear that physicians cannot seek refuge behind the doctrine of therapeutic privilege in a situation in which the research is nontherapeutic (that is, not intended to benefit the subjects). In cases of straightforward therapeutic treatment (the exclusive purpose of which is to benefit the patient) and therapeutic research (which is intended to promote the twin goals of therapy and research) there will be some controversy about the weight that should be assigned to the some-

times competing values of therapeutic privilege and patient autonomy.

One potentially useful proposal, designed to reduce the problem of explaining scientific facts to patients or subjects who are not scientists, is to discuss the therapy or experiment with them in the presence of a third party, the "patient's or subject's friend".[7] This person should be scientifically qualified and skilled in communicating with laypersons but independent of the doctor or experimenter, and should be able to put him- or herself entirely on the side of the patient or subject. His or her role is to ensure, by asking questions, that an adequate explanation has been given and understood. The employment of social workers, nurses or trained paraprofessionals to facilitate truly informed consent can save a lot of time. This is not to say that physicians do not have an important informational role; rather, the task of ensuring properly informed consent need not — and indeed, should not — rest exclusively with physicians.

As for Brewin's suggestion that formal procedures for obtaining written informed consent will likely result in a diminution of the physician's sense of moral responsibility, one simply does not know whether this putative effect will even arise in practice. *A priori* speculation tells us little. The effect produced by conscientious adherence to an intelligent policy of informed consent could just as easily be the opposite of that feared by Brewin; such procedures may enhance rather than diminish the sensitivity and the sense of moral responsibility already felt by most physicians.

A response to Brewin's concern for the patient's psychological well-being and to his desire to spare patients unnecessary doubt, fear and anxiety is a little more complex. His desire to promote a patient's peace of mind is clearly a legitimate goal. High morale can have important therapeutic effects, whereas low morale can promote the opposite. And yet it is difficult to suppress one's unease when Brewin exhorts physicians to be "flexible, considerate and discrete, never imposing unnecessary 'informed consent' ". True, Brewin adds the phrase "yet always ready to discuss anything with patients who wish it", but from his discussion it seems clear that he places a strong onus on the patient to request information, and that he reserves for the physician the discretionary power to dispense or withhold information for the patient's benefit. This explains why he opposes legal or medical rules that would restrict the physician's ability to withhold, distort or delay giving information. Unfortunately, he almost entirely neglects the costs and dangers of encouraging the sort of physician paternalism he favours.

Brewin is concerned about the investment of the physician's time that is required by the doctrine of informed consent. But if physicians are to assess each patient's needs in a careful and conscientious manner so as to be able to dispense the therapeutically correct amount of information in the right dose at the right time, then they will have to invest a great deal of time with every patient to ensure that they have a proper appreciation of that patient's attitudes, values, needs and comprehension. Such an individualized approach might benefit some patients when the physician is conscientious and gifted with psychological acuity and skill. Even so, the physician may misperceive or miscalculate the patient's need for information. The possibility of mistake and abuse becomes dangerously high when the physician is not fully conscientious or psychologically perceptive in interpreting the patient's needs and wishes.

By withholding information from a patient, physicians are usurping, to some extent, the patient's right to participate in decision-making concerning his or her own health, including the decision as to whether particular therapy should be undertaken. The patient's attitudes and values may differ significantly from the physician's. An informed patient may therefore make a decision at variance with that of the physician. The right of patients to autonomous decision-making is vitiated when relevant information is withheld from them. For many patients the right to control what happens to their bodies is more important than their peace of mind.

Moreover, empirical evidence suggests that most people want to be fully informed about diagnosis, prognosis, treatment alternatives and risks, and that they cope better psychologically when they are properly informed than when they are deprived of information.[8-11] In withholding information from patients, physicians may simply be projecting their own fears onto their patients rather than respecting the wishes or needs of their patients.[12]

There is also an inherent danger that if we accept Brewin's policy of paternalism such a policy would produce among physicians an attitude of superiority towards patients that borders on contempt. Of course, patients often suspect they are being duped when a physician withholds information from them. When, as a result of ignorance or misinformation, patients are prevented from participating in decision-making concerning their health (including whether to continue to be patients), they may come to feel an intensified sense of vulnerability, distance and uncertainty, which may affect their morale. It can also be morally corrupting and psychologically burdensome for physicians whose enhanced knowledge and power are accompanied by special and often onerous responsibilities. Such a situation can sap the vital reservoir of trust between doctor and patient that is the basis of effective therapy.

Where it has become common for physicians to suppress, withhold, distort or delay giving information, the patient's family and friends come to recognize that this is the prevailing practice, and their trust in the honesty of the medical profession is, to some extent, undermined. When they themselves later become patients, this erosion of confidence may seriously prejudice their trust in the information they receive from their physicians. This is a significant long-term disadvantage of the policy favoured by Brewin.

These negative effects of physician paternalism are likely to be aggravated by certain realities of the medical system within which most seriously ill patients are now treated. Such treatment is very likely hospital-based, and the doctor is probably part of a health care team that includes other physicians, nurses, and sundry other professionals and paraprofessionals. Any policy of in-