SYMPOSIUM ON CONSENT AND CONFIDENTIALITY

Some limits of informed consent

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Many accounts of informed consent in medical ethics claim that it is valuable because it supports individual autonomy. Unfortunately there are many distinct conceptions of individual autonomy, and their ethical importance varies. A better reason for taking informed consent seriously is that it provides assurance that patients and others are neither deceived nor coerced. Present debates about the relative importance of *generic* and *specific* consent (particularly in the use of human tissues for research and in secondary studies) do not address this issue squarely. Consent is a propositional attitude, so intransitive: complete, wholly specific consent is an illusion. Since the point of consent procedures is to limit deception and coercion, they should be designed to give patients and others control over the amount of information they receive and opportunity to rescind consent already given.

Across the last 25 years informed consent has been central to discussions of ethically acceptable medical practice. It is seen as necessary (and by some as sufficient) ethical justification for action that affects others, including medical treatment, research on human subjects, and uses of human tissues. Some commonly cited reasons for thinking that informed consent is of great importance are quite unconvincing: informed consent has been supported by poor arguments and lumbered with exaggerated claims. My intention is not to deny its importance, or to argue for any return to medical paternalism, but to take it sufficiently seriously to identify some of its limitations as well as its strengths.

Informed consent is nothing strange. It is a familiar and ethically important aspect of everyday transactions. Shopping and borrowing a book from the library, taking one's clothes to the cleaners and buying a train ticket are ethically acceptable if, but only if, all parties to the transaction take part willingly in awareness of ways in which others' proposed action will bear on them. It may seem pompous to speak of giving informed consent to these everyday transactions. Traditionally we emphasise informed consent only in more formal contexts, typically involving documents, signatures, and legal requirements and other rituals of consent, such as those used in signing a contract or getting married. But in everyday as in more formal contexts we accept that transactions are ethically and legally questionable, or even void, unless all parties are aware of the essential features of the transaction and take part willingly.

There is broad agreement that informed consent has become more important in medicine in the last 25 years because medical practice too has become more formalised.[1] The largely tacit understandings and trust which (we at least imagine) used to be found in everyday, one to one, face to face relations between doctors and patients have given way (as the title of one book rather ominously puts it) to relations between patients and *Strangers at the Bedside*.[2] Of course, medicine is not the only part of life in which formality, bureaucracy, and explicit ways of seeking, giving, recording, and respecting informed consent have multiplied. They are also more prominent in education, financial services, consumer protection, and other fields in which social relations have become less personal, more bureaucratic, and more complex, displacing traditional relations of trust. The change has been accelerated because institutions and professionals increasingly see obtaining informed consent as protection against accusation, litigation, and compensation claims. As one sociologist of medicine aptly writes, informed consent has become "the modern clinical ritual of trust".[3] As often with rituals, there is disagreement both about its real meaning and about its proper performance.

Before turning to these disagreements I note several reasons why rituals of informed consent cause more difficulty in medicine than in almost any other area of life. The first reason is very familiar: we can give informed consent only if we are competent to do so. Informed consent has its place in relationships "between consenting adults"; it is possible only when we are, as John Stuart Mill puts it, "in the maturity of our faculties".[4] But medical practice constantly has to deal with exceptional numbers of people who are (temporarily or permanently) not in the maturity of their faculties. Innumerable discussions of informed consent in medicine and medical ethics focus on these hard cases; there are lots of them.

We cannot give informed consent when we are very young or very ill, mentally impaired, demented or unconscious, or merely frail or confused. Often people cannot give informed consent to emergency treatment. Even in the maturity of our faculties we may find it quite taxing to give informed consent to complex medical treatment when feeling lousy.

These hard cases provide a staple diet for medical ethics. Some writers look for ways to make consent easier for those who find it hard. Others seek alternative criteria for permissible treatment of patients who cannot consent, and concede that many patients have to be treated with a degree of paternalism.

A second limitation of informed consent procedures in medicine is that they are useless for selecting public health policies. Public policies, including public health policies, have to be uniform for populations. We cannot adjust water purity levels or food safety requirements to individual choice, or seek informed consent for health and safety legislation or quarantine restrictions.

Vaccination polices are an interesting and possibly hybrid case: in so far as we think of them as a matter of public health policy they cannot be based on individual choice, or on informed consent. In the United Kingdom, however, we have treated vaccination only partly as a public health matter. We allow parents to refuse to have their children vaccinated without medical reason. Some have done so at little or no cost or risk to their children by sheltering behind protection provided by others' vaccinated children. The proportion of children vaccinated with measles, mumps, and rubella (MMR) has fallen, and free riders now face a problem. They still do not want to expose their children to the risk of measles, but can no longer do so by refusing vaccination. Their current ambition—well

stoked by parts of the media[5]—is to use an alternative vaccine which they claim (evidence is not provided) would be safer for their children, but which will not provide the same level of protection for the population—including for infants below the age of vaccination. Public health policies can be undermined if their implementation depends on individual informed consent.

A third limitation of informed consent is that medical treatment of individuals uses personal information, about third parties that is disclosed without their consent. For example, family history information, genetic information and information about exposure to infections are often disclosed to medical practitioners without the consent of all to whom the information pertains. We do not expect patients to obtain prior consent to disclosure of such information from their relatives and contacts, and this would often be impractical or impossible. This humble but pervasive fact about the way medical information is sought and used cannot be reconciled with the claim that informed consent is necessary for all ethically acceptable medical practice.

A fourth limitation of informed consent emerges when people with adequate competence to consent are under duress or constraint, so less able to refuse others' demands. Prisoners and soldiers, the vulnerable, and dependent often have ordinary capacities to consent but cannot refuse, so undermining any "consent" they offer. These cases have traditionally been seen as problematic in recruiting subjects for experiments; they are no less problematic in obtaining informed consent to medical treatment.

BEHIND THE RITUAL OF INFORMED CONSENT

Evidently informed consent cannot be relevant to all medical decisions, because it cannot be provided by patients who are incompetent to consent, cannot be used in choosing public health policies, cannot be secured for all disclosure of third party information, and cannot be obtained from those who are vulnerable or dependent. Informed consent might nevertheless be important for the ethically acceptable treatment of individual patients who are competent and free to consent in cases where no information about third parties is needed. Indeed, it is a commonplace of medical ethics that informed consent is indispensable in these cases. The reasons offered for this view are varied and perplexing.

Informed consent in medical ethics is commonly viewed as the key to respecting patient *autonomy*. This claim is endlessly repeated but deeply obscure. There are many distinct conceptions of *individual autonomy* in circulation, and even more views of the value and importance of these various conceptions. In a survey of views of autonomy, Gerald Dworkin noted that it has been equated with:

> Liberty (positive or negative) … dignity, integrity, individuality, independence, responsibility and self knowledge … self assertion … critical reflection … freedom from obligation … absence of external causation … and knowledge of one's own interests.[6]

Other writers have equated autonomy with "privacy, voluntariness, self mastery, choosing freely, choosing one's own moral position and accepting responsibility for one's choices".[7] The list could be extended in many ways, and the feasibility and the value of all conceptions of individual autonomy are hotly contested. It seems to me, however, that if informed consent is ethically important, this *cannot* be because it secures some form of individual autonomy, however conceived. Informed consent procedures protect choices that are timid, conventional, and lacking in individual autonomy (variously conceived) just as much as they protect choices that are self assertive, self knowing, critically reflective, and bursting with individual autonomy (variously conceived). Contemporary accounts of autonomy have lost touch with their Kantian origins, in which the links between autonomy and respect for persons are well argued; most reduce autonomy to some form of individual independence, and show little about its ethical importance.[8]

The ethical importance of informed consent in and beyond medical practice is, I think, more elementary. It provides reasonable assurance that a patient (research subject, tissue donor) has not been deceived or coerced. I shall not rehearse the deeper theoretical reasons for thinking that we have obligations not to deceive or to coerce. I believe there are convincing reasons for thinking that we have such obligations, which provide good reasons not to impose treatment or action on patients—or on others—without their informed consent.

In saying this I do not mean to suggest that informed consent is the *only* ethically important consideration, in medicine or elsewhere. The libertarian tendency in medical ethics sees informed consent as *necessary* and *sufficient* justification for action. For libertarians everything is morally permissible "between consenting adults". Most other ethical positions do not view consent as *sufficient* justification. Even if there is informed consent, we may judge surgery without medical purpose, medical practice by the unqualified, or unnecessarily risky treatment unacceptable and may think it wrong to use human tissues as commodities, as inputs to industrial processes, or as items for display.[9] Informed consent is one tip of the ethical iceberg: those who think otherwise overlook the rest of the iceberg.

PERFORMING THE RITUAL: CONSENT PROCEDURES

How can consent show that there is neither deception nor coercion? What makes a ritual of informed consent effective? Events at Alder Hey Hospital and the Bristol Royal Infirmary have made these questions urgent and controversial in the UK. Is the task to ensure that patients, research subjects, and tissue donors sign up to specific propositions set out in explicit consent forms? Or can a single signature—or a gesture of assent—imply consent to a range of distinct propositions? Proponents of *specific* and *generic* consent are at work up and down the land drafting regulations, codes of practice, and guidelines, consent forms, and information leaflets. How are these disputes to be settled? Should they be settled in the same way for treating patients, for recruiting research subjects and for removing tissues (including postmortem removal)? What should be done given that it is seldom feasible to get specific consent to future uses of donated tissue? Is it necessary to seek further consent whenever new research purposes are envisaged? If so, what is to be done if donors cannot be found or are dead?[10] Can agreement on these issues be achieved in time to shape reform of the Human Tissues Act 1961, which the government promised in their response (or reaction?) to the Redfern Report on events at Alder Hey?[11]

A reasonable starting point is to note that consent is a *propositional attitude*, given in the first instance not to another's action, but to a proposition describing the action to be performed (other propositional attitudes include *knowing*, *desiring*, *hoping*, *expecting*, *believing*). Propositions may be more or less specific, and some limit has to be drawn to the amount of detail included. The inclusion of excessive or technical detail, for example, will eventually overtax even the most energetic, and undermine the possibility of informed consent. On the other hand, consent that is too vague and general may also fail to legitimate action.

It is commonly assumed that in consenting to a description of what is to be done patients also consent to other descriptions of the treatment or procedure that are—for example, *entailed by* or *logically equivalent to* the description to which consent is given. It is also commonly assumed that in consenting to a description of what is to be done the patient consents to the *likely consequences* of its being done. Both

assumptions are evident in the thinking that assumes that implied consent will reach the parts that generic consent does not reach; but proponents of specific consent procedures also assume that consent travels beyond the propositions to which it is explicitly and literally given in signing a consent form.

Yet strictly speaking, consent (like other propositional attitudes) is not transitive. I may consent to A, and A may entail B, but if I am blind to the entailment I need not consent to B. Consent is said to be *opaque* because it does not shadow logical equivalence or other logical implications: when I consent to a proposition its logical implications need not be transparent to me. Transitivity fails for propositional attitudes. Consent and other propositional attitudes also do not shadow most causal connections. I may consent to C, and it may be well known that C causes D, but if I am ignorant of the causal link I need not consent to D. Again, transitivity fails for propositional attitudes. When I consent to a proposition describing an intended transaction, neither its logical implications nor the causal links between transactions falling under it and subsequent events need be transparent to me*: a fortiori* I may not consent to them.

Events at Alder Hey illustrate the *opacity of consent*. Some parents consented to removal of tissue, but objected that they had not consented to the removal of organs—although, of course, organs are composed of tissues. They did not agree that their consent to removal of tissue implied their consent to the removal of organs. As a point of logic the parents were right.

These simple facts create a dilemma. The real limits of patient and donor comprehension suggest that it is unreasonable to seek *consent* for every detail of a proposed treatment, or of a proposed research protocol, or of a proposed use of tissues. Yet the logic of propositional attitudes suggests that we cannot simply assume that implied consent will spread from one proposition to another, or from one proposition to the expected consequences of that which it covers, making any further consent unnecessary. There are many ways of skinning this cat. I conclude by sketching one approach that I think plausible.

Our aim in seeking others' consent should be not to deceive or coerce those on the other end of a transaction or relationship: these are underlying reasons for taking informed consent seriously. It follows that consent is not always improved by trying to ensure that is given to more, or more specific, propositions: more specific consent is not invariably better consent. Complex forms that request consent to numerous, highly specific propositions may be reassuring for administrators (they protect against litigation), and may have their place in recruiting research subjects: yet they will backfire if patients or practitioners come to see requesting and giving consent as a matter of ticking boxes. Our aim should, I suggest, be to achieve *genuine* consent, and this may not always be best done by seeking specific consent to a great many propositons.

Patients, research subjects, and tissue donors give genuine consent only if they are neither coerced nor deceived, and can judge that they are not coerced or deceived; yet they must not be overwhelmed with information. This balance can perhaps be achieved by giving them a limited amount of accurate and relevant information and providing user friendly ways for them to extend this amount (thereby checking that they are not deceived) as well as easy ways of rescinding consent once given (thereby checking that they are not coerced). Genuine consent is apparent where patients can *control* the amount of information they receive, and what they allow to be done.

Genuine consent is not a matter of overwhelming patients with information, arrays of boxes to tick or propositions for signature. The quest for perfect specificity is doomed to fail since descriptions can be expanded endlessly, and there is no limit to a process of seeking more specific consent. It is not, however, difficult to give patients control over the amount of information they choose to receive, by offering easy access to more specific information that lies behind an initial, or second, or third layer of information provided. Accurate information of varying degrees of specificity can be provided by offering fact sheets, explanatory leaflets, discussion, and (with care) by counselling—and time to absorb further information. If additional accurate information is reliably available as demanded, patients will not be deceived: even a patient who decides on the basis of limited information has judged that the information was enough to reach a decision, and is not deceived.

Nor is it difficult to give patients greater control over what happens by making sure that their consent is rescindable, and that they know it is rescindable. Of course, consent to treatment is not always rescindable: I cannot have my appendix put back in once removed. But I can decide that I want no further chemotherapy, or refuse recommended medication. And consent to participate in clinical trials or in research, or to give tissues (for purposes other than transplantation) can be rescinded. Patients and others who know they can at any time change their mind about continuing a treatment, about participating in research, or about use of tissues they have given are not coerced and know that they are not coerced.

Patients who know they have access to *extendable information* and that they have given *rescindable consent* have in effect a *veto* over what is done. It is true that exercising the veto may come at a price for patients: if I do not consent to surgery I do not get it. But for research subjects the cost of refusal is only exclusion from a study, and for tissue donors only the loss of an opportunity to be generous. This way of looking at informed consent seems to me not only to reduce possibilities of deception and coercion, but to make it plain to patients, research subjects, and tissue donors that they may determine how far they will be informed, and that (when it is technically possible) they remain free to rescind their initial choice. Where these standards are met, there are reasonable assurances that nobody is coerced or deceived.

DISCUSSION

Professor Dame Margaret Turner-Warwick made the suggestion that, for treatments such as surgery where damage could potentially result, the term "informed request" should be used rather than "informed consent". The patient is, in effect, requesting treatment and this way of putting it might put the relationship between doctor and patient on a more trusting basis. Baroness O'Neill said this raised the issue of whether different rituals or procedures of consent should be used according to the context—that is, according to the level of risk. The risks involved, and therefore information required by the patient, are very different when taking a blood sample, when compared with having surgery, taking part in a clinical trial or having your data used in medical research. Her opinion was that it was not a good idea to impose uniform procedures on how to inform the patient—such as a mandatory form that needed to be filled in to prove consent was given only after the patient had been given all the relevant facts.

It also raised the question of how much information a patient required to be considered "informed". In her opinion, the amount and level of information given should be dictated by the patient, donor, or research subject, not by the physician. And it would be ethically wrong to require patients to handle a form as complicated as a mortgage application at a difficult time in their lives. Not all patients want to be burdened with all the detail, while other require an in depth understanding. She emphasised that there are two parts to the issue of informed consent: the information given and the consent of the patient. The information available at a particular time influences a patient's decision. In an ideal world, if patients can make a choice, then they should be able to rescind that decision. Clearly this is sometimes problematic, indeed impossible. But sometimes it is possible, for example, for decisions to take part in medical trials to be rescinded.

Professor Mark Walport, registrar of the academy, accepted that the importance of consent related to the potential level of harm that could result from either the procedure or the sharing of data. With this in mind, surely, the use of anonymised data could not result in any harm to the individual, and, consent therefore need not be given? Baroness O'Neill agreed with the conclusion, but said that the best way forward was to make clear from the outset the purposes or actions for which the patient was giving informed consent, including the secondary use of data. But it seemed absurd to insist on specific informed consent for the use of anonymised data. Firstly, it would be unfeasible as many data are old and secondly, because so many people can benefit from the use of such data. With proper safeguards, generic consent should cover the anonymous use of data in subsequent studies.

Professor Julian Peto from the Institute of Cancer Research pointed out that anonymisation of the data does not mean no one knows to which patient the data refers. Indeed, when using old data—for example, for comparing rates of breast cancer and abortion, named data have to be used. Baroness O'Neill pointed out that anonymisation did not mean nobody knew the identity of patients, just that they were not published. She advised that, at some stage well before publication, data should be coded.

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ECHO

Informed choice and screening organisation

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Patients are more likely to make an informed choice to accept a screening test if it is arranged as part of a routine hospital visit rather than if it requires a separate visit. As the rate of informed choice is influenced both by the information provided and the manner in which testing is organised, it is essential to discover the method of organisation that leads to the highest rate of informed choice. Two general hospitals were compared, each applying a different method of organisation for maternal serum screening for Down's Syndrome. One hospital offered the test as an extension of the routine blood taking visit whilst the other arranged for a separate visit to take place especially for the test.

A questionnaire that measured knowledge of the test and attitudes towards it was returned on time by 84% of the 2313 eligible women. The results were measured against eventual uptake and showed that the proportion of women making an informed choice to accept the test was higher at the routine visit hospital than the separate visit hospital (41% v 21%). A similar proportion at both hospitals (23%) made an informed choice to decline the test.

Whether choice is informed or not is more important in some screening programmes than the level of uptake - particularly in prenatal programmes where the potential outcome can lead to invasive tests or termination. The authors therefore recommend that a randomised trial is undertaken to determine whether or not the causal findings from this descriptive study stand up to critical appraisal.

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