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.

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”. 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 permissibility of 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 policies 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—i.e. to use an alternative vaccine which they claim (evidence is not provided) would be safer for their children. Consent is ethically important, this cannot be because it secures some form of individual independence, and show little about its ethical importance.4

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.5 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?6 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?7

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 consequences. 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 to 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 it 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 many, but 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.

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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.

REFERENCES
5 Jenkins S. A sad case of media meddling not reason. The Times 2000 Feb 8.
7 See reference 1: 8.

Informed choice and screening organisation

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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