MEDICAL ETHICS

BEYOND CONSENT?

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In the first term of their first year, Edinburgh University medical students are introduced to medical ethics. The first subject on which they have lectures and tutorials, and on which they are examined, formally in the first year and in clinical examinations later in the curriculum, is consent. None are left in any doubt about its importance; and Cardozo's dictum is duly deferred to.

> Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without the patient's consent commits an assault.[1]

The competent patient's consent to medical treatment or research is essential. But this was explicitly acknowledged only relatively recently and its full implications for medicine are still being worked out. What precisely is required by the concept of *informed* consent for example, and when or even whether that concept requires to be applied, remains debateable. Official guidance on the practicalities of what precisely is required for consent to be valid, moreover, is not always unambiguous.

Small wonder then, that some busy doctors seize all too literally on the legal commentator's notion of consent as 'the "magic" . . . that . . . transforms the status of an act from illegitimate to legitimate'.[2] Magic has always appealed to harassed human beings, especially when the alternative is lengthy labour or patient negotiation. The demand, still occasionally encountered in busy hospitals, that someone – if not the patient, then a relative or even another doctor – sign the consent form, is as magical a practice as anything in *Harry Potter*. But in life rather than literature, of course, magic does not necessarily work. It is not just that a signed consent form, on its own, may have no legal standing. Nor is it just that consent, in itself, is insufficient to transform the status of an act (a harmful sado-masochistic act, for example) from illegitimate to legitimate. It is also that the legal 'magic' of consent to medical treatment could not even begin to work, if society had no confidence in the skill and, crucially, the good intentions of doctors.

Consent is necessary but not sufficient. 'Beyond Consent?' is not intended to suggest that consent can be dispensed with, but that there is more to it, more beyond it, than the bureaucratic magic of 'consenting a patient'. To explore this theme, I will first set current views of consent in a historical perspective, then discuss some proposed remedies for problems raised by consent, and finally suggest a way of understanding consent which takes account of the particular and unique context of medicine.

HISTORY

The requirement for individual, let alone informed, consent to treatment is relatively recent. Consent originally was a political concept, often but not always implying a voluntary act, and sometimes referring to the submission, and consequent obligations, of the vanquished to the victor.[3] In the modern medical context, where until recently it was more common to speak of patient 'compliance' than of 'concordance', something of this submissive-dominant relationship still clings to the concept of consent. In ancient Greek medicine, by contrast, the notion of a patient's right to give or withhold consent appears to have played no part in their relationship with doctors. In Hippocratic times, physicians knew that if their treatment was to succeed, they needed the cooperation of patients and their families; and especially if their patients were affluent, they often were genuine doctors of medicine, teaching and sharing information with their patients. In that world, it certainly was recognised that an act by a physician might be either legitimate or illegitimate: for the Hippocratic Oath to have been seen as necessary, there must have been doctors who used their pharmacological knowledge to assist poisoners, or the intimacy allowed them to seduce or gossip about patients.[4] But part of the point of their Oath, for Hippocratic physicians, was that it should promote standards of competence and conduct which gave their medical practice the good reputation on which their livelihood depended, and thereby offered potential patients a way of distinguishing between trustworthy and untrustworthy physicians. The moral distinction that mattered most in this cradle of European civilisation and scientific medicine, in other words, was not between the rightness and wrongness of medical acts (or the wrongness that could be made right by consent), but between the goodness and badness of medical practitioners.

Even as late as the eighteenth and nineteenth centuries, consent played little part in the relationship between doctors and patients. Wealthy patients, who might think of their doctor as 'the highest form of body servant', attending and often nursing them individually at home, were in many respects like their ancient Greek predecessors. From a scientific point of view however,

they provided poor material for the newly developing fields of medical research. It was the poor, charitable inmates of the new hospitals whose condition could be monitored in large numbers, who could contribute most to the advance of medical knowledge. But in their case, consent, or at least explicit consent, was not seen as important. Their enjoyment of the potential benefits of hospital treatment, far better than they could otherwise have expected, was regarded as providing tacit or implied consent to their medical treatment and, by the same token, to their participation in medical research.[5]

But all that, as people say, is 'ancient history'. Today, the medical profession is officially included among those potential invaders of bodily integrity against whom common law affords everyone a right to be protected. How did this view of doctors, as potentially guilty until proved innocent by patient consent, gain such prominence? No doubt the number of delinquent doctors who got into trouble with the law was sufficient for Cardozo's early twentieth century dictum about surgeons to sound credible in court. But an element of healthy scepticism notwithstanding, this has never been the majority view of the medical profession. What made it possible for this way of thinking about doctors in general to seem credible, at least to those who thought about such things, probably was the evidence emerging later in the twentieth century of the many non-consenting subjects of harmful medical research in Nazi Germany and then, as Beecher[6] and Pappworth[7] revealed in the 1960s, in the US and the UK.

A clearly perceived need to protect the safety and self-determination of human subjects of medical research, seems to be what has set the pace and standards for consent principles and procedures not just in research but also in medical practice. Few perhaps, except the most over-enthusiastic and insensitive researchers, would dispute the appropriateness of insisting on individual and explicitly informed consent in the orderly and time-affording context of recruiting mature human subjects for non-therapeutic and potentially harmful clinical experimentation. But not all medical research is non-therapeutic and potentially harmful. Much epidemiological and health services research is innocuous to individual patients, and potentially important for patients generally and for the public health. But such research can be difficult or impossible to undertake if informed consent is required from each and every individual whose medical record, often anonymised, requires to be consulted, or whose primary care medical practice is selected as the subject or control for a new health service procedure. Some therapeutic clinical experimentation and much medical treatment moreover, is undertaken with patients who while technically competent, are ill, and either unable or unwilling to read, mark, learn and inwardly digest the kind of information that should be presented to a healthy volunteer for a clinical trial. If the pace and standards for current consent principles and procedures generally, are in fact being set and driven by what is required in the case of clinically invasive research, how ethically appropriate is that?

CURRENT PROBLEMS AND REMEDIES

Among the leading problems arising in this context is that of what and how much information doctors are required to provide for the patient's consent to treatment to be valid. Neither the law nor the General Medical Council (GMC) offer a definitive answer to this, suggesting that it should vary according to the patient's condition, comprehension and circumstances, and commending the kind of explanation in broad terms and comprehensible language that one might expect from a reasonably skilful doctor. But some academic contributions on this subject have attempted to be more helpful. Four of these will be mentioned, beginning with the subject of what constitutes a medical procedure, discussed in a recent paper by AR Maclean of Glasgow.[8]

How much is enough?

It is sometimes claimed that *truly* informed consent is an impossible ideal, since strictly speaking this would require the patient to know as much as the doctor about each and every step in the medical or surgical procedures proposed, a full understanding of which would require the doctor to provide the patient with the equivalent of an undergraduate and postgraduate medical education. Charging the doctor with failure to provide that, clearly would be the *reductio ad absurdum* of informed consent. On the other hand, if the doctor fails to provide the patient with an explanation of certain attributes and possible suffering and complications of the proposed procedures, consequences may ensue such that, had the patient known of their possibility, he or she would not have consented to the procedures. An example of this, cited in AR Maclean's paper, was the failure for which an anaesthetist was found guilty of serious professional misconduct by the GMC, when he omitted to inform a fully clothed patient in a dental chair that the procedures for which he sought her consent included the insertion of a rectal suppository to provide postoperative analgesia. His normal practice apparently was to inform patients of this after they recovered consciousness.

Of course, many people might say that this anaesthetist lacked common sense. But today, as debates on everything from fox hunting to interpretation of the data protection law illustrate, common sense is not so common. Proceeding from a precedent of this kind, what is to prevent more and more detailed information about each and every step in medical or surgical procedures being claimed as necessary for valid consent? The answer Maclean proposes to this is complex, but essentially it involves drawing a

conceptually defensible line. He does this by distinguishing between, on the one hand, integral parts of a medical procedure, and on the other, major sub-procedures not necessarily entailed by the main procedure. In seeking consent for the main procedure, information should be provided about the 'aim and purpose of the procedure; the area and extent of any breach of bodily integrity; and the effects and the risks of the procedure'. This need not involve information being given about each and every integral part of the procedure, or any minor variation thereto. But in the case of a major sub-procedure, not necessarily entailed by the main procedure, such as the rectally introduced analgesia in the GMC case, the purpose, area, effects or risks of the main procedure are significantly affected, and thus not covered by consent to the main procedure. So while information about, and consent to, every part of a medical procedure may not be required, information about and consent to major sub-procedures is.

Perhaps this proposal might be subject to conflicting clinical interpretations of where exactly the line is to be drawn between parts of a procedure and sub-procedures, and when a sub-procedure becomes sufficiently major to affect significantly the information given about the main procedure. But Maclean's distinction at least has the merit of introducing some conceptual clarity, and offering possible footholds on a notoriously slippery slope. It might even, by extension, assist difficult debates in research ethics committees about, for example, the legitimacy of research studies in emergency medicine which involve minor variations in surgical procedures on randomised patients unable to give consent. Following Maclean's line of argument, a key question to ask would be whether the purpose, area, effects or risks of the emergency surgery were or were not significantly affected by the proposed experimental variation.

Balancing consent – risks, urgency and time

The second contribution is less recent and more wide-ranging. In a paper published in 1998, Mats Hansson of Uppsala offers a model for 'balancing the quality of consent' against variables in the medical treatment and research contexts.[9] In both contexts, he argues, these variables include the primary values at stake for the patient or subject, namely their integrity, health and well-being, which are more at risk in some kinds of treatment or research than in others. The variables also include the time available for the communication process, which is short or non-existent in emergencies, but longer, or much longer, in other treatment or research contexts. Hansson's model, at its simplest, balances the quality of consent required, against both the importance of and risk to the values at stake, and also the time available. The more vital the values at stake, and the more the time available, the more extensive are the information-imparting and consent procedures required. This seems to make good sense, at least provided the 'time available' is not interpreted too subjectively by busy doctors.

This simple model, on the other hand, takes little account of the values at stake for others which may be put at risk if consent is withheld by too many individual patients in the research context. Hansson argues that 'this is the price to be paid for giving self-determination priority' in morality. But in his view the priority of self-determination is based on recognition of the individual as a moral agent and member of the moral community, which involves responsibilities as well as rights. Thus, if the medical researcher communicates well and treats the individual as a moral agent and potential collaborator, this may encourage the individual to be altruistic in his or her choice to give or withhold consent.

A possible objection to Hansson's model concerns epidemiological research. Although this may pose no threat to the physical health or welfare of subjects, their integrity may be affected by genetic or other potentially stigmatising information being associated with them, or with the ethnic or other group to which they belong. Because the time available is not constrained in these circumstances, extensive information and consent procedures may be required. But in practice such extensive procedures may lead to a low response rate, which is not in the interests of other patients or the public health. To meet this problem, Hansson varies his model, so that for research of this kind, the quality of consent required has to be balanced, again against the importance of, and risk to, the values at stake, but in this case also against, not the time available, but the degree of confidentiality possible. The more vital the values at stake, and the less strict the confidentiality possible, the more extensive are the information and consent procedures required. In other words, the less the chance of individuals being identified as a result of epidemiological research, the less need there is for extensive information and consent procedures; and indeed where strict confidentiality is assured and there is no risk to the vital values of the individual's integrity, health or well-being, it may simply be sufficient for information to be made generally available that such research is being conducted.

According to a recent report, an approach not unlike this appears to have been adopted in New Zealand in the use for primary care research of anonymised information from patients' electronic medical records.[10] There

> patients are assumed to have given consent if they are registered with practices affiliated with the computer research network of the Royal New Zealand College of General Practitioners. These practices put up notices in their offices, stating that

> information from a patient's consultation, investigation, or referral may be used for research once it is stripped of identifying data.
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> *Reproduced with permission from Jepson RG, Robertson R. Difficulties in giving fully informed consent.* BMJ, *2003.*

A similar approach was recommended some years ago in the UK for the use in epidemiological research of the anonymised results of HIV testing of blood samples taken for routine purposes from pregnant women: individual consent was not to be requested, but information about the procedure was to be publicised in the relevant clinics, albeit in this case, because vital values were at stake, at least in principle, the same information advised women that if they requested that their blood sample should not be anonymously tested for HIV, their wish would be respected.[11]

Community obligation and consent

Hansson's view of self-determination as the characteristic of a moral agent and member of the moral community with responsibilities is supported in a third contribution, which I shall mention only very briefly. It is in a recent paper by J Cassell and A Young, 'Why we should not seek individual informed consent for participation in health services research'.[12] They point out that the very nature of health services research 'into organisational structures or care pathways that may influence outcomes at a population level' means that individual patients 'cannot opt out of the model of service provision during the research period' or 'out of the intervention . . . if it becomes the standard local model of care'. Ethics committees who demand individual informed consent in these circumstances are thus demanding the impossible. By obstructing health services research, moreover they are allowing 'managerial experimentation' and 'unevaluated organisational changes . . . which place patients at risk' to proceed unchecked. But there is, Cassell and Young claim, an ethical alternative to this misguided attempt to apply individual informed consent standards to health services research. It consists in recognising that, in relation to the National Health Service (NHS) and its privileged and popular place in the UK, UK citizens are not primarily consumers or even patients, but members, and that 'membership of the NHS . . . shares with citizenship the fact that it carries certain universal and equal rights,' which in turn entail the responsibility to ensure that other members of the NHS are not discriminated against by our failure to participate in research designed to establish the optimal means of promoting equitable care for all.

As long as the NHS maintains its privileged and popular place in the UK, this argument against the demand for individual informed consent in health services, and probably also in epidemiological research, seems very persuasive. But the final academic contribution I would like to cite is even more radical in its criticism of current views on consent, and especially of those based on the idea of individual autonomy or self-determination.

Ability to decide – coercion and deception

In her Gifford Lectures on 'Autonomy and Trust in Bioethics'[13] and related writings,[14] Onora O'Neill of Cambridge argues that the 'ritual of informed consent' in practice often amounts to little more than the patient's 'right to choose or refuse treatments on offer' from 'a smallish menu – often a menu of one item – that others have composed and described in simplified terms'.[15] What patients give or withhold their consent to, in other words, is not the proposed treatment or procedure itself, but a description of the treatment or procedure. But no description, however well communicated, can capture, convey and enable the patient to comprehend, all that the treatment or procedure actually will involve for the patient. Simply adding more and more detailed technical information about each and every step in the treatment or procedure is no answer to this, not only because objectively its limits are those of the medical curriculum, but also because an objective account, for example of the standard consequences of a treatment, is not the same thing as an individual patient's subjective experience of those consequences.

This is rather like – if I may put the boot on the other foot, as it were – what junior doctors often say about their undergraduate education on breaking bad news 'it's not that it wasn't helpful, but nothing can really prepare you for actually having to do it'. Keeping the boot on the medical foot is also a reminder that knowing too much may actually be unhelpful. Alfred Tauber, the distinguished American physician and author, describes how, unable to pass an agonising kidney stone, and after extensive investigations and advice from colleagues and friends over several weeks, he remained immobilised by indecision over whether the pain was bad enough for him to submit to surgery.

> Finally during the sixth pain episode, my urologist made the decision. I was whisked into the operating room. "Well, Fred, it's time. You've had enough." I nodded numbly. In the operating room, before falling asleep, I remember him joking to the anaesthesiologist, "This guy is in for an orchidectomy" – in laypersons' terms, a castration. They both laughed and smiled at me as I fell under their spell.[16]
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> *Reproduced with permission from Tauber AJ.* Confessions of a Medicine Man. *MIT Press, 2000.*

Tauber's agony of indecision was the consequence not only of knowing too much, but also of his physical agony. Individual autonomy or self-determination, respect for

which is often said to be the philosophical basis of informed consent, O'Neill observes, may be difficult enough to exercise at the best of times. But when we are ill, even if we are technically competent to consent, we may be in no fit state to make complex decisions about our future. In this respect, incidentally, I wonder whether the insistence of informed consent, originating in the research context, maintained its momentum in its application to obstetrics and paediatrics, where the patients or parents are not themselves ill. Be that as it may, it is certainly the case that many patients, as O'Neill observes, find the choices they are now presented with burdensome, and that an increasing number suspect, as one said to me recently, that 'it's really because doctors are afraid of being sued'.

O'Neill's argument, on the other hand, is not that medicine should return to old-fashioned paternalism. It is rather that the notion of individual autonomy regularly cited as the philosophical basis of informed consent is philosophically shallow and a travesty of what Kant, who introduced the concept of autonomy to philosophy, meant by it. At the risk of greatly oversimplifying O'Neill's argument, the key point here is that autonomy is not independent, let alone consumer, choice, but what the word literally means – 'self-legislation'. Self-legislation does not mean 'being a law unto oneself', in other words making oneself an exception to laws that apply to others. Self-legislation, rather, means being supremely reasonable, by thinking and acting on laws or principles which all others could accept and act on. Two such principles, O'Neill points out, are 'do not coerce' and 'do not deceive', since the contrary to these ('you may coerce or deceive') cannot be accepted and acted on by everyone as their basic principles without reason and society alike falling apart.

These two principles, O'Neill argues, provide the real philosophical basis for informed consent. 'Our aim in seeking others' consent,' she writes, 'should be not to deceive or coerce those on the other end of a transaction or relationship'. In the medical context, this aim, of genuine consent, is not always achieved and may be obstructed 'by seeking consent to a great many propositions,' which can degenerate into box-ticking. In practice, the best approach, O'Neill suggests, may be by giving patients

> 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.[17]

THE CONTEXT OF MEDICINE – CONTRACTS AND COVENANTS

O'Neill's approach to consent in one respect is minimalist, but is also very practical. Whether a legal doctrine of informed consent based on the twin principles of non-coercion and non-deception can be formulated in ways that encourage genuine rather than medically defensive consent, is a question I am not qualified to answer. One can only hope that Cardozo, whom I quoted at the outset, was justified when he observed that in the evolution of the law 'if a rule continues to work injustice, it will eventually be reformulated'.[18] But perhaps I might be allowed one final reflection on the question of consent in medicine.

So far the emphasis has been mostly on *what* (procedure, treatment) patients consent to. But consent is also about *who* one consents to. It is also, that is, about relationships, which can be of many kinds. Two of these, at some distance from one another on the continuum of human relationships, are the marriage relationship and the garage relationship. In the latter, when I take my car in for a service, I am not particularly interested in who does the work, or indeed with the details of what work actually is performed. Perhaps I should be, because my life and that of others may depend on it; and perhaps I would be, if it was a smaller garage or I was a motor enthusiast. But the garage is part of a large chain, which has supplied and maintained my cars over several years without any problems and, satisfied that it has a business reputation to maintain, I readily consent to the minimally understood *what* specified on my bill. The *who* plays only a very minor role in all this: I smile back to the smiling receptionist, and learn something about house prices in the area nearby from the courtesy car driver. But beyond that, my garage relationship is essentially a contractual one.

The marriage relationship, by contrast, is essentially founded not on a contract but on a covenant. A covenant (some legal usage apart) differs from a contract in at least two ways: it is made with a unique rather than a legal person, and it is not conditional on the performance of specified duties. In the covenant of marriage, in other words, consent is informed largely, if not entirely, by the *who* rather than the *what*. Some forms of marriage, it is true, have been more specific about duties such as 'obey *him*' and 'forsaking all others,' breach of which in turn has been seen as grounds for divorce. But the grounds today are more likely to be the partners' own admission that the relationship has broken down irretrievably; and the essentially covenantal rather than contractual character of marriage is made clear in the open-ended commitment expressed by the traditional words 'for better, for worse'. Traditionally

too, in a Scottish marriage, all that is essentially required is that the couple tell one another, before witnesses or a minister, that they consent to being husband and wife. Their mutual consent, again, is informed by the *who* rather than the *what*. The primacy of the *who* over the *what* moreover extends in different degrees to other close relationships less formal than marriage, which in turn are founded on and sustained by an awareness of the other as 'you' rather than 'him' or 'her'.

To say all this of course is not to deny that there may be contractual elements of a minor and implied kind in the marriage relationship, about who does what in the division of family labour for example, and in that sense the marriage relationship and the garage relationship are on a continuum. And somewhere along this continuum, I suggest, we find the medical relationship, which itself is a continuum. Towards the end of the medical relationship closer to the garage relationship – holiday inoculations, minor illness and most epidemiological and health services research, neither the *who* nor the *what* of consent is of major interest or importance to most patients: the small print is there for those who wish or have the time to read it; and if things do get complicated, usually there is, eventually, a doctor available who can sort things out. But towards the end closer to the marriage relationship, more vital values are at stake; and both *what* and *who* a patient consents to, assumes increasing importance. As far as the *what* is concerned, of course, more information might be gained from the Internet. But the Internet cannot or will not deliver an individual's diagnosis or prognosis – and even if it offered this, it probably would be by one of those programmed decision-trees for diagnosing computer faults, which constantly prompt you to ask another question and end up by advising you to telephone a technical adviser (whose line turns out to be permanently engaged). At the serious end of the medical spectrum, in other words, even as far as the *what* is concerned, the *who* of an expensively trained doctor with other patients to attend to is probably the best thing on offer. At the serious end moreover, doctors and other health professionals are important not just as technical advisers, but also as wise and friendly counsellors who will stand by the patient and stay the course with him or her. There is, and always has been, in medicine an element of the covenant. Not in all doctors all the time, and not as sustained as in marriage and other close personal relationships. But having listened over the years to a great variety of doctors discussing what bothers them, and what they care about, I am not at all surprised that however much public criticism there is of doctors, most people exclude their own doctor from that.

My own GP retired at the end of last year. I have never needed to consult her on anything more than the very minor, but I dropped a note to thank her and wish her a happy retirement. A letter from her came back a few days later, signed personally, but no doubt the same as to other patients who had written. It included the words: 'I will miss all my patients. You have been very loyal.' Well in my case, loyalty had cost very little. But her use of that old-fashioned word 'loyal' indicated the kind of relationship that good doctors have with their patients, in its essence not contractual but covenantal. The doctor as potentially guilty until proved innocent by patient consent, just does not make sense in that context. Perhaps it is time for the law to think again.

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