Informed consent: moral necessity or illusion?

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Abstract

There is a professional and legal consensus about the clinical duty to obtain informed consent from patients before treating them. This duty is a reflection of wider cultural values about the moral importance of respect for individual autonomy. Recent research has raised practical problems about obtaining informed consent. Some patients have cognitive and emotional problems with understanding clinical information and do not apparently wish to participate in making decisions about their treatment. This paper argues that such research does not undermine their potential to provide informed consent. Rather, sufficient resources are required to create better communication skills among clinicians and more effective educational materials for patients. Finally, cognitive and emotional inequality among patients is maintained to be a reflection of wider social and economic inequalities. Researchers who take the right to informed consent seriously should also address these.

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Key messages

- There is a professional, legal, and moral consensus about the clinical duty to obtain informed consent.
- Patients have cognitive and emotional limitations in understanding clinical information.
- Such problems pose practical problems for successfully obtaining informed consent.
- Better communication skills among clinicians and more effective educational resources are required to solve these problems.
- Social and economic inequalities are important variables in understanding the practical difficulties in obtaining informed consent.

The recent literature on informed and shared decision making within clinical care has revealed a pronounced tension between three competing factors:

- Paternalistic conservatism about disclosure of information to patients has been eroded by moral arguments now largely accepted by the medical profession.
- While many patients may wish to be given information about available treatment options, many also appear to be cognitively and emotionally ill equipped to understand and retain it.
- Even when patients do understand information about potential treatment options, they do no necessarily wish to make such choices themselves, preferring to leave final decisions in the hands of their clinicians.

The second and third factors are ostensibly at odds with the first. Given the difficulties they pose, should we not recognise the utopian nature of the goal of properly informed consent and return to the more honest and realistic paternalism of the past?

This paper argues the contrary. After documenting the professional consensus surrounding the goal of informed consent in clinical practice, the practical obstacles to its achievement will be explored. It will then be shown that these constraints are not convincing as either moral or empirical justifications for questioning the pursuit of informed consent in clinical care. Instead, it will be argued that what does follow from practical problems in obtaining informed consent is the need for specialised clinical training and other resources that will support both clinicians and their patients in becoming partners in care.

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Importance of informed consent: a professional and legal consensus

There can be no doubt that respect for the right of patients to make informed choices is now widely accepted as one of the key duties of any good health professional. Whatever practical problems may exist in fulfilling this clinical duty, the institutions that shape the practice of medicine all confirm that patients should accept or reject treatment proposals on the basis of information about what they are for, what they practically involve, and what their risks are. These institutions include professional bodies and the judiciary, as well as the advisory bodies that also influence professional opinion. This paper will focus on regulations within the UK.

The most important medical regulatory body in the UK is the General Medical Council which makes the following statement about the importance of the principle of informed consent:

"*Successful relationships between doctors and patients depend on trust. To establish that trust you must respect patients' autonomy—their right to decide whether or not to undergo any medical intervention . . .*"*(They) . . . must be given sufficient information, in a way that they can understand, in order to enable them to make informed decisions about their care.*"[1]

The GMC has the power to de-register any clinician found to be in breach of this principle.

Legally, if patients believe that clinicians have abused their right to make informed choices about their care, they can pursue a remedy in the civil courts for having been deliberately touched without their consent (battery) or for having received insufficient information about risks (negligence). To avoid the accusation of battery, clinicians need to make clear what they are proposing to do and why "in broad terms". With respect to negligence, the amount of information about risks required is that deemed by the court to be "reasonable" in light of the choices that patients confront.[2 3]

Legal standards of disclosure concerning informed consent differ in different jurisdictions.[4] For example, the legal standard in the UK is comparatively weak compared, for example, with many parts of North America. Indeed, it is sometimes argued that there is no legal right to informed consent in the UK at all! Despite such claims, the law does give patients the right to basic information about their proposed care and this has been reinforced by the 1998 Human Rights Act.[5] Moreover, the law is constantly evolving and there is little doubt about the increasing seriousness with which the judiciary in the UK is underlining the right of patients to adequate information about their proposed care.[6]

This same respect for the right of patients to informed consent is evidenced in a variety of advisory documents from other bodies concerned about the conduct of good clinical practice.[7–9] On the face of it, therefore, there is a professional and legal consensus in the UK about the clinical duty to obtained informed consent for treatment and research, one which is repeated in other parts of the world.[10–12]

Informed consent: a professional and legal illusion?

The consensus about the importance of informed consent for acceptable clinical practice does not sit well with a wealth of recent research findings about the problems of communicating relevant information to patients. Indeed, the problems revealed in these studies suggest that professional and legal demands to obtain informed consent could become vacuous and dangerous moral abstractions. The vacuity relates to the prescription of goals for good communication that seem impossible to deliver in clinical practice. The danger lies in creating unrealistic expectations in patients about clinical communication, thus imperiling the very clinical relationship that informed consent and partnership in care are supposed to foster.

The most potentially damaging research suggests that patients are unable to understand or remember the details of the information required for educated choice. Some studies appear to show that patients do not fully comprehend basic information about conditions, prognoses, and treatments.[13–15] There are even more profound difficulties concerning the understanding of risks, a crucial category of information that patients require in order to make appropriate future plans and to act in what they believe to be their best interests.[16 17] Even when patients do understand information about the nature, purpose, risks, and alternatives of proposed treatments, it is often quickly forgotten—so much so that it is unclear how it could have ever constituted the foundation for coherent deliberation about treatment choices.[16 18]

The reasons for the cognitive and emotional limitations that lie behind such lack of comprehension and memory are complex. They relate both to specific characteristics of individual patients themselves (maturity, education) and also to the ways in which these have been influenced by their socioeconomic background and environment.[19] Yet clinicians have to deal with individuals as they find them. Given the barriers to effective communication created by the varying potential of many patients to understand and remember what they are told, would not medical care be dramatically improved if clinicians stopped pretending that they could facilitate patient choice that is really educated? Surely, it should be accepted that real informed consent is an illusion and that clinicians should get on with the job of using their expertise to determine and to act upon what is in the best interest of patients.[20]

This proposal gains credibility from further research which suggests that, even when patients do understand treatment options and associated risks, they do not want the partnership in care embraced by regulatory and advisory bodies. Rather, a significant proportion of patients indicate that they wish their clinicians to make final decisions about the treatment they will receive and the risks they will take in the process.[21] To the degree that this is true, it adds further weight to the view that, in the overall process of providing good medical care, the moral importance of the communication of information can be overemphasised. On the face of it the primary reason for this communication is to enable patients to choose for themselves. If they want little part in such choice, then what is the fuss all about?

Why is informed consent so morally important?

One thing is clear. An enormous amount morally hinges on how seriously we take these empirical findings that question the feasibility and relevance of the clinical duty to obtain informed consent. On the one hand, "ought implies can". Morally speaking, it is absurd to impute a duty that cannot be practically fulfilled. On the other hand, great caution must be exercised in any conclusion from the research in question that the duty to obtain informed consent should be foresworn or watered down. To do this would be to give up one of the most cherished moral prizes won over the past two centuries—namely, the right of individuals to exercise control over aspects of their lives that they deem critical for whatever reason.[22 23] Thus, if we are to question the right to informed consent on the grounds of practicality, we had better be sure of our ground. On further inspection the grounds for scepticism are not as strong as they might at first appear.

Although the research findings in question are somewhat indeterminate, suppose for the sake of argument that they do show that there is little relationship between attempts to obtain informed consent and effective clinical outcomes.[24] If so, why should so much importance be attached to attempting to provide patients with information that most of them will probably not understand? The difficulty with such an argument can be illustrated by imagining a colony of slaves who are of such great instrumental value to their owners that they are provided with the best clinical care available.[25] However, the slaves are told nothing about the care they will receive and are certainly not asked to consent to it. Such communication and consent would entail extra work for the hard pressed doctors in the slave colony and would detract from the achievement of optimal clinical outcomes. Would there be anything morally objectionable about such an approach?

Of course there would. Slavery is morally wrong precisely because it entails the denial of the right to refuse to allow one's body to be used in specific ways. The immorality of the scenario envisaged has nothing to do with the scientific/technical quality of the medicine practised or its outcomes and everything to do with the moral circumstances in which it is delivered. From one perspective, medical care may well be beneficial and its practical benefit may have little to do with whether or not patients choose it. Yet once the potential for such choice is removed, the care still remains harmful. The harm in question is not physical but moral.

Whatever the perceptions and preferences of the slaves themselves—let us assume that they have been brainwashed into passive acceptance of whatever care is provided—the fact remains that, in not providing them with information about their proposed care and not obtaining their consent to it, one of the defining characteristics of their humanity will have been ignored. This is because humans have the ability to conceptualise the future and to make choices about it in ways that animals do not.[26] To the degree that medical care ignores rather than nourishes this ability, then it harms through failing to acknowledge the potential that patients have as humans for exercising control over their lives. Thus, if patients are denied the information that they require to consent validly to treatment, they are effectively turned into slaves for medical purposes. The harm that endures may or may not be accompanied by psychological suffering. Its reality takes the form of the objective indignity to which the patients are subjected.[27]

The potential for informed choice

The prospect for such harm would not exist if there were there no potential for informed choice. However, nothing in the research on the difficulties some patients have in understanding clinical information suggests the absence of such potential. All that the evidence shows is that, in educating patients, clinicians sometimes face serious difficulties. For example, the communication of clinical risks to patients can indeed be fraught with difficulty. A high percentage of patients (and many clinicians) make fundamental errors in risk evaluation, even when presented with the simplest information.[16 17]

However, the fact that not all patients make such mistakes illustrates the possibility of achieving better results with those who do. Research suggests, for example, that the understanding of risk does improve when information is tailored to the personal characteristics and preferences of individual patients.[28] Evidence also indicates that even better results can be achieved by combining a variety of methods of framing and communicating risks rather than presuming that any one approach will suffice.[28 29] In short, patients can improve their understanding of risks and other aspects of clinical information. Given the moral unacceptability of doing otherwise, clinicians should do their best to encourage this potential through taking the duty to try to obtain informed consent seriously.

Further research demonstrates that many patients do desire information on their options and that, given the opportunity, they will make coherent clinical choices based on their knowledge.[30] For example, it has been shown that, over time, the individual patient will reason quite similarly when presented with similar clinical decisions.[31] The potential coherence of their decisions is important in light of the tendency of patients to forget clinical information about themselves.[16 18] Thus, failure to remember does not constitute a good reason to question the right to informed consent. We all show forgetfulness in our everyday lives. The fact that we may also not remember the exact information upon which we made specific choices in life no way detracts from the moral importance of our having been allowed to make them.

Despite these arguments, it might still be argued that serious efforts to educate patients are not cost effective. Even if many of the obstacles to good communication and understanding could potentially be overcome, to do so may demand an unreasonable slice of scarce healthcare resources. Such arguments would be weak on their own terms, as well as having unacceptable moral implications. Evidence has shown that the outcomes of clinical treatments can improve when patients have greater understanding of their purposes and risks. To the degree that this is so—and there is still much research to be done here—there will be a direct link between better communication with patients and improvements in both the efficacy and the cost effectiveness of care.[32]

Many patients have the potential for achieving greater clinical understanding and the positive desire to do so. They also have clear preferences which may sometimes threaten their well being and may be in conflict with their clinical advisors.[33] This fact underlines the moral importance of honouring the preferences of patients for informed participation in the decision making process, while accepting that this will not necessarily mean that they will always want to take final responsibility for the details of all clinical decisions.[34] For example,

patients might reasonably assume that clinicians will not proceed with treatments that they decide are dangerous for some reason unknown at the time that consent was given. In short, patients are not stupid. Why then do they so often exhibit such poor comprehension of related issues with such damaging consequences for them and for the perception that clinicians have of them?

Poor clinical communication: what should be done?

There is good evidence that many clinicians are themselves poor communicators.[35] Patients have consistently protested about the failure to communicate effectively and this is believed to be one of the key causes of increasing patient litigation and even more time consuming formal complaints. Poor communication about risks can lead to patients making potentially dangerous decisions about their medical treatment.[36] Equally, clinicians have themselves revealed how inadequate their communication is with patients, even in circumstances where it should be of a high standard—for example, obtaining informed consent for participation in research.[37] Indeed, the evidence of poor communication in medicine is so widespread that it is unclear what sense to make of the research that suggests that patients are themselves poor recipients of information. What is clear is that, if the potential of patients for better understanding is to be realised, clinicians need to receive better training in communication skills.

Ample evidence now exists to confirm the effectiveness of teaching communication skills to medical students and doctors.[37] Through such teaching, clinicians have improved their ability both to collect the information required from patients for effective diagnosis and treatment and also to educate them about their treatment choices. Most clinicians have not been properly trained in this regard, at least in the UK. It is vital that they become so.

Finally, even the best trained clinician will require more than good communication skills to improve the standard of patient comprehension of clinical information and thus the process of informed consent itself. Good communication requires time and resources. When average consultation times are so short and there is a paucity of well designed and produced literature and other informational aids for patients, even the best communicators will be hard pressed to educate patients to their full potential.[38 39] Time and educational materials cost money in circumstances where the resources of health services are or may be increasingly stretched. In determining the level of planning the funding of health care that is morally fit for autonomous citizens, it is crucial that the requirements of informed consent are allocated the moral importance that they deserve.

Conclusions

This paper has argued that it does not follow from research showing that patients have problems understanding and remembering information that clinicians should not do their best to obtain informed consent for treatment. On the one hand, much of this research reveals a self-fulfilling prophecy with patients. If clinicians treat patients like children who should basically do as they are told, the consequence may well be patients who are unable to mobilise the skills to deal with clinical information and who lack the confidence to participate in and to take responsibility for clinical choices about themselves.[40] On the other hand, the evidence that has been reviewed demonstrates the ways in which this pattern of paternalism can be broken. Effective training in communication skills can make a genuine difference to the success that clinicians have in educating their patients.

What has not been argued, however, is that good communication skills and improved educational material will completely resolve the cognitive and emotional problems that patients face. As is evidenced by the variability of rates of understanding in relation to socioeconomic background, much more profound social and political change will be required for significant reductions in such differences. This is hardly surprising. Since the poor and uneducated are disadvantaged in so many other walks of life, it would be extraordinary if health care were an exception. This is why the struggle for more social equality is a prerequisite for improving the moral quality of all aspects of health care provision, including the provision of information to patients and their ability to articulate their preferences and to participate in decision making about their care.

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