SELECTED SUMMARY

From informed consent to informed request: strengthening shared decision-making

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Obtaining valid consent is regarded as essential before there can be an ethically or legally appropriate medical intervention. The justification is, simply, that patient autonomy should be respected. The patient's body is hers, and she has a right to do with it what she chooses. In order for that choice to be real, it has to be a choice made by a patient who is competent to make it. That competence has two elements. First, the patient must have the cognitive hardware and software necessary to receive, retain and process the information, weighing the benefits and the burdens of the proposed treatment against each other. Second, the inputs must be the relevant ones: the information to be processed must be (i) accurate and (ii) sufficient.

Moulton et al describe and criticise the way the law of informed consent operates in England and the USA. They characterise the former as the application of the standard of the reasonable clinician, whereby the clinician will not be liable in the tort of negligence so long as she has provided the information that would be provided by a responsible body of clinicians in the relevant specialty. This characterisation is not entirely accurate. There has been a gradual evolution away from this position (1), with the House of Lords' decision in *Chester v Afshar* (2) marking the high watermark of judicial acknowledgement, in the context of civil litigation, of the importance of patients' autonomy rights. Professional guidelines, such as those produced by the UK General Medical Council (3) also emphasise that patients should be at the center of the consenting process, and the vindication of their autonomy rights is the object of the procedure. The courts, in considering what is demanded of a "responsible" doctor, have regard to those guidelines. The authors' characterisation is a reasonably accurate description of the general legal and ethical zeitgeist, if not an accurate summary of the state of the substantive law. In the USA, they point out, there is a dual standard of information provision – the "reasonable doctor" standard and a patient-based standard ("reasonable patient" standard).

The problem with the law in both jurisdictions is that it fails to honour the very principle (autonomy) which it purports to serve. Both the "reasonable doctor" and "reasonable patient" standards are bad at holding clinicians meaningfully to account, since they are amorphous: there is a wide variation in both physician practice and patient preference.

So what is to be done?

They make two broad and related proposals. First, we need to change our language. The notion of a "consenting" patient needs to be abandoned. The word "consenting," they powerfully observe, "implies passive acquiescence in the doctor's decision, not an active informed choice on the part of the patient." Second, we need to adopt the theory and practice of shared decision-making (SDM).

The first proposal might seem flippant. It is not. The language we use crucially conditions our attitudes. They suggest an alternative: "informed request". This, they say, "would be a better way to describe what is needed, ascribing an active role to the patient and acknowledging their decision-making role." The patient's declaration, which is now so often a meaningless acknowledgement that the clinician has mumbled his way through a list of incomprehensible complications, would be replaced with something along the lines of: "I have considered my options, reflected on my own values and preferences, and would now like you to proceed with surgery." It is a simple but critical shift from current practice.

But what is this SDM? It is where patients and clinicians work together to select investigations, treatments and support packages, based on clinical evidence and the patients' own preferences. The authors emphasize a balance between autonomy and beneficence, grounded in SDM, using decision aids. Various aids can help: sympathetic presentations (perhaps graphical rather than merely verbal) of the relevant outcome probabilities; web-based tools that allow patients to control the information they receive based on their individual preferences (they are often either swamped with or starved of information); questionnaires which check the extent of understanding and patient involvement.

There has been a shift from providing minimal information to providing too much information but it has not improved informed consent practices. Although the provision of information is important it is only valuable if it leads to understanding, otherwise it is pointless and can be harmfully

confusing. The four models of doctor–patient relationships defined by Emanuel and Emanuel (4) – informative model, interpretive model, deliberative model and the paternalistic model – provide a useful lens through which to view patient–doctor interactions in the context of information-provision. If the doctor–patient relationship is based on the "informative model," for instance, the doctor as a technical expert provides all the information and then implements the patient's chosen treatment option. This may result in the patient's autonomy being respected in a sense (although autonomy too requires that when patient autonomously authorises an option she should have understood what it is that she is authorising) but it may be that the chosen option is not in the best health interests of the patient. At the other end of the Emanuels' spectrum is the "paternalistic model," where the "beneficent" physician, basing her decision on medical facts, decides what option is best for the patient and the patient passively acquiesces. The patient's values and preferences are not taken into account. These two models reflect the polarity that Moulton et al argue against. A balance between autonomy and beneficence that Moulton et al propose can be achieved through patient-centred consultations, as seen in the "interpretive" or the "deliberative" models, in which, briefly, the physician engages with the patient and helps her to see the significance of the relevant medical facts in the light of the patient's own values. The consultation is a mutually respectful conversation, in which autonomy and beneficence negotiate a balance.

SDM works. Various states in the USA: Maine, Minnesota, Oregon, Vermont and Washington, have legislated to promote SDM. It is early days, but it seems to change, very positively, the way that patients perceive their own treatment. It may, apart from being ethically the right thing to do,, make economic sense: there is now evidence that more surgical procedures are performed than fully (SDM) informed patients would wish (5,6). It is not surprising. Patients, intimidated by the amount or complexity of information, often opt for procedures that they would not choose if they were fully involved in the decision, frequently going passively along with the clinician's suggestion. The number of procedures would probably drop with SDM.

It will, of course, be necessary to persuade clinicians and their lawyers that SDM does not pose a threat of litigation. That should not be difficult. The Washington legislation specifically provides that engagement in SDM is prima facie evidence of informed consent. That provision is no doubt helpful, but surely it is unnecessary. It would be hard for any claimant's lawyer to argue otherwise.

The authors' suggestions are pertinent in all jurisdictions. In many developing countries, (for instance Pakistan and India) the predominant form of doctor–patient relationship, (except, perhaps in a few urban centers populated by literate and wealthy patients), is paternalistic. Patients generally passively acquiesce in decisions made by the doctor or the family. There are many reasons for this, including low degrees of literacy and a rigidly hierarchical society. Yet SDM is possible and perhaps particularly important here. Moulton et al in their paper claim that well-designed information material and trained staff can engage patients in SDM, irrespective of the patient's social status. So all patients, anywhere, can and should become active participants rather than passive recipients of decisions made by others (7). We would expect that in developing countries visual images would prove to be more effective vehicles of the necessary information, rather than text, speech or abstraction.

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