Sweet spot in informed consent lies in idea of 'core disclosures'

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Recently, the Singapore Medical Council (SMC) imposed the maximum fine of $100,000 on a doctor for not disclosing the possible side effects of a steroid injection.

A significant segment of the medical community opposed the penalty, citing the fact that doctors do not always explain the side effects of that treatment and others that are similarly routine and of low risk to patients, and that the harsh penalty can lead to a proliferation of defensive medicine.

Doctors tell patients about risks and benefits of medications and other interventions so that patients can meaningfully decide whether or not to go ahead with the interventions. When patients decide to go ahead after weighing the pros and cons, we say that they have given "informed consent". How much information should doctors disclose regarding their proposed interventions, when they seek informed consent from patients?

Between the two extremes of saying nothing and swamping a patient by giving the full list of possible side effects, no matter how minor, there must be a sweet spot.

One approach is suggested by authors Ruth Faden and Tom Beauchamp in their seminal work, A History And Theory Of Informed Consent (1986), in their concept of "core disclosures".

Core disclosures are decided by two important criteria. First, what information do patients typically want to know to help them decide whether to accept or reject the proposed intervention or medication? Second, what information do doctors think is important to convey to patients about the proposed treatment?

The criteria that these questions express can determine that low-risk over-the-counter medications like paracetamol can be prescribed without mention of side effects for patients who are not allergic to them.

However, the adequacy of core disclosures is complicated by the fact that different people have different informational needs in consenting to an intervention. There is no one-size-fits-all approach to informed consent. To see this, we have to understand what makes informed consent ethical.

Here are two general ethical rules: We should not harm other people. People should be able to make decisions that they deem best for their lives, as long as their decisions do not harm other people.

Suppose a doctor performs surgery on a patient without his consent. She has harmed the patient by cutting open his body. The first rule is violated and the surgery is unethical. Now suppose the patient consents to the surgery after weighing the pros and cons communicated by the doctor. In virtue of meeting the second rule, the patient's consent transforms an unethical action into one that is no longer unethical. American law Professor Heidi Hurd calls this transformative ability the "moral magic of consent".

But different people have different informational needs for making a decision that they deem best for their lives. Many patients do not mind not knowing side effects of medication that are of short duration and mild discomfort, like the thinning and discoloration of skin on the wrist.

For some patients, however, the same side effects can have inordinate value in making the decision. An example of such a patient is if the person affected models wrist watches.

Can we then err on the side of caution and make disclosure standards high for informed consent, ensuring that the information provided in seeking consent is as relevantly comprehensive as possible?

Ms Faden and Mr Beauchamp point out that effective communication does not solely consist in the provision of information. It also depends on the uptake of the disclosed information.

If the relevantly comprehensive information is too detailed, voluminous or technical, the patient may not be able to absorb or understand it, compromising his decision-making.

Between the Scylla of insufficient information and the Charybdis of information overload that compromises uptake, lies a sweet spot where just enough information is conveyed simply enough for the patient to use in meaningful decision-making.

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Many bioethicists, including Mr Beauchamp and Ms Faden, recommend uncovering the informational needs of patients on a case-by-case basis, through conversation during the process of seeking consent.

The conversation starts with the doctor telling the patient the core disclosure – risks, benefits and alternatives to the proposed intervention that patients typically want to know about and that doctors think important to convey about the intervention.

The patient's non-verbal and verbal feedback on the core disclosure is paramount to customising the subsequent communication. Was the patient frowning? Distracted at certain points? Can the patient answer questions about the disclosure like: "From what I mentioned just now, what is a common side effect of this injection?" If a doctor detects hesitancy, he can elicit further informational needs by asking: "You seem concerned. Is there any part of my explanation that you would like to know more about?"

Such conversations can be protracted. A translator may be required. The doctor has to make a judgment call on how thoroughly to ensure a patient's understanding of a core disclosure. In general, the more risky a proposed treatment is or the more serious side effects it has, the more time and care should be taken in facilitating the patient's understanding of the core disclosure and in uncovering any further informational needs before eliciting the patient's consent.

Those who oppose the SMC's judgment worry that the practice of defensive medicine will proliferate. Indeed, such practices will result in higher costs to patients if doctors need to spend a lot more time with them. Health insurance premiums will increase as a result. Arguably, patients with less financial resources suffer most when costs rise. This affects a just distribution of health resources.

Rather than have doctors practise defensive medicine, a more palatable approach is to adopt Faden and Beauchamp's and focus on core disclosures underpinning a level of disclosure that suits the patient's circumstance.

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