Consent – a fundamental part of medical practice

Notwithstanding time pressures in general practice, it is vital that adequate consent is obtained prior to any investigation or procedure, writes Dee Duffy

CONSENT IS A FUNDAMENTAL COMPONENT of the doctor-patient relationship and it must be forthcoming before any examination, investigations or medical treatment are carried out.

Doctors have a duty to respect patients' bodily integrity and right to self-determination, and patients clearly have a right to refuse medical treatment or withdraw consent.

In March 2022, the HSE published the updated *National Consent Policy*,[1] setting out guidance for HSE staff on the issue of consent. The policy reiterates the fact that all adults have a fundamental ethical and legal right to decide what happens to their own bodies and confirms that the core principles of what constitutes valid informed consent and good practice remains unchanged.

The updated policy takes into account legislative and policy changes since the previous version was published in 2013, including the Assisted Decision-Making (Capacity) Act 2015, which is due to commence shortly.[2] All persons over 16 are presumed to have capacity for the purposes of consenting to medical treatment and addressing issues of capacity to consent are beyond the scope of this article.

Consenting process

As stated in the HSE policy, consent is a process of communication where the person has received sufficient information to enable them to understand the nature, potential risks and benefits of the proposed intervention. Therefore, it requires ongoing and effective dialogue between the clinician and patient, rather than a one-off, 'last-minute' signing of a form.

This concept is supported by paragraph 9.1 of the Medical Council's *Guide to Professional Conduct and Ethics*.[3] which states that doctors should help patients to make decisions that are informed and right for them. It goes on to say that doctors should not give patients the impression that their consent is simply a formality or a signature on a page.

Verbal or written consent?

In general practice, consent for examinations, investigations and treatments is mostly given verbally by patients. Patients in general practice sometimes imply their consent by complying with the proposed examination or treatment, eg. by rolling up their sleeve to have their blood pressure taken. For physical examinations, doctors should always explain clearly what is involved and ensure that the patient consents before proceeding. Doctors should always comply with their obligation to offer a chaperone for intimate examinations, which is provided for in the Medical Council ethics guide.

Patients should be asked to sign a consent form for more serious or invasive procedures with higher risks, following a discussion on the risks and benefits of the proposed treatment. However, it is very important to note that the signed consent form should accompany but not replace the explanations given to the patient.

Informed consent

When obtaining consent from a patient, doctors must have a full understanding of the procedure or treatment, how it is carried out and the risks associated with it. Only then will they be in a position to inform the patient sufficiently in order to obtain informed consent.

When speaking with patients about a proposed treatment or procedure, it is important to consider how best to facilitate

communication with the patient. Where possible, doctors should ensure that patients are given sufficient time and information to make an informed decision. Some patients may benefit from the attendance of a family member or support person. Doctors should consider the individual needs of each patient, their knowledge of their condition and their ability to understand the information given. Where there are language difficulties, the use of a translator and the provision of information sheets in the patient's own language may be necessary. Printed or educational material should be given in addition to, and not in substitution for, a verbal explanation.

The nature, complexity and urgency of the intervention should be discussed, including the likelihood of success or failure of an intervention to achieve the desired aim. The risks of taking no action or taking an alternative approach should be explained. Material risks, common side-effects and potential complications should be discussed, taking into account that patient-specific factors relating to occupation or lifestyle may influence their decision. Patients should be given adequate time to reflect on the risks and benefits with regard to their own circumstances.

What happens if consent is not obtained?

Clinicians who examine or treat patients without obtaining adequate consent could find themselves facing a complaint from a patient. Technically, touching another person without permission could constitute an assault.

In medical negligence proceedings, where patients may have suffered an injury following a procedure, it is often alleged that the consenting process was substandard, deficient or non-existent. Sometimes patients claim that had they been made aware of a particular complication, they would not have gone ahead with the procedure and their injury would not have occurred. Doctors should record carefully the consenting process and the risks and benefits discussed. This would be very important should a claim ensue.

Refusal/withdrawal of consent

Every adult with capacity is entitled to refuse medical treatment or withdraw consent and doctors must respect a patient's decision, even if they disagree with that decision. In these circumstances, a doctor should explain clearly to the patient the possible consequences of refusing treatment and, where possible, offer the patient a second medical opinion. It is important to take detailed notes of any such discussions with a patient.

Case study

Jane, an 18-year-old patient with full capacity has had multiple attendances over the past four years with complaints of an ingrown toenail and recurrent painful infections requiring antibiotic treatment. Jane usually attends with her mother. At the most recent consultation, the GP recommended that Jane attend the minor surgery clinic on a scheduled date for a wedge resection of the nail. He said that by removing part of the nail, it would help prevent further painful infections and the need for antibiotics. However, he did not have time to discuss in detail what the procedure would entail.

A few weeks later, Jane and her mother arrived for the appointment. The GP was assisted by his practice nurse and they both welcomed Jane and explained to her that she was having a partial removal of her big toe nail, following recurrent painful infections. The nurse gave her a consent form to sign, which Jane did immediately without reading.

Jane was asked to lie on the couch and the GP prepared the local anaesthetic. When he approached Jane to inject the needle, she became extremely distressed and began crying. The GP, practice nurse and Jane's mother tried to calm her to no avail. The GP asked Jane's mother to sit in the waiting room as he thought it would be easier to address the patient's concerns without her mother present. He then proceeded to try to inject the anaesthetic while the practice nurse held onto Jane's foot in order to keep it still. Jane continued to be distressed and started screaming loudly.

The GP then aborted the procedure as due to Jane's inability to stay still he couldn't safely inject the anaesthetic. Jane and her mother left the surgery, quite upset and angry after the experience and afterwards submitted a complaint to the GP practice. The GP and practice nurse were also shaken by what had happened.

In hindsight, the GP considered that it would have been preferable to have a meaningful discussion with Jane when the procedure was first recommended, explaining exactly what was going to happen step by step before, during and after the procedure. This would have given adequate time for Jane to prepare herself. There was also no discussion of what would happen on the morning of the procedure. The GP had mistakenly assumed that Jane had known the local anaesthetic would be injected into her foot.

During the stressful interaction on the day, the GP misjudged the situation and initially continued to attempt to inject the local anaesthetic in circumstances where Jane was refusing or withdrawing consent. When considering what happened for the purpose of responding to the complaint, he felt in retrospect that by asking the patient's mother to leave the room, this exacerbated the patient's already heightened distress and the correct course of action would have been to halt the procedure and arrange for a follow-up consultation to discuss whether Jane wanted to try again another day.

In summary

We understand that GPs are under time pressure but it is vital that adequate consent is obtained prior to any investigation or procedure. We recommend that the following is borne in mind:

- Has the nature and purpose of the procedure been fully explained in advance of the procedure?
- Has the patient been warned of the (material and relevant) risks involved?
- Have alternatives to the procedure (including taking no action) been discussed?
- Has the patient had an opportunity to ask questions or raise any concerns?
- Has any available written patient information been given?
- Do the notes reflect the discussions and the consenting process?

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References
1. HSE National Consent Policy. 2022. www.hse.ie
2. Assisted Decision-Making (Capacity) Act 2015. www.irishstatutebook.ie
3. Guide to Professional Conduct and Ethics for Registered Medical Practitioners-8th Edition The Medical Council 2019.www.medicalcouncil.ie