Comment

Increasing importance of truly informed consent: the role of written patient information

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Complaints to the General Medical Council (GMC) and litigation against doctors are currently rising at an alarming rate, with an increase of 23% from 7153 in 2010 to 8781 in 2011 [1]. This equates to a 1:64 chance of the GMC investigating any individual doctor. Of all the causes of dissatisfaction among patients, one of the most common is the feeling that they ‘were not told’ that a particular outcome might result from a given treatment. Sometimes even the fact that the individual has signed a consent form, which specifies the resultant effect, is inadequate defence; because the patient may justifiably claim that the explanation was rushed, or provided in such a way that they were unable to understand the full implications of the treatment. This is particularly true for the rarer but more life-threatening complications.

One way to turn the rising tide of complaints and litigation against the profession is to provide every individual patient with specific written information, provided in good time, about the treatment that they are about to undergo. Moreover, ideally one should ask them to confirm, with a signature, that they have read and understood the relevant document [2]. It should be remembered that consent itself is a process of information exchange rather than an individual event and is best obtained as a two-stage process. Patients should be made aware of the consequences of not intervening as well as all the alternatives to the treatment that is being proposed, the advantages and the risks and complications. Patients should have time for reflection before committing; therefore, consent is best not performed exclusively on the day of surgery.

It seems appropriate to consider here the sort of up-to-date information that needs to be provided, both in verbal and written form, to patients undergoing some of the more common procedures for urological conditions. The BAUS itself has procedure-specific consent forms for the most common operations, which are a good resource. For example, before TRUS-guided biopsy of the prostate the patient should be aware of the strong possibility of haematuria, rectal bleeding and haemospermia (which may be persistent), urinary retention, and the much less common, but alarming and even life-threatening, possibility of bacteraemia, sepsicaemia and gram-negative shock [3]. Since recent foreign travel, especially to Asia or Africa, and recent antibiotic use have been identified as risk factors for this complication, patients should be informed about this before the procedure [4]. Some may opt to delay the biopsy or choose a transperineal approach under general anaesthesia instead.

In spite of some recent rivalry from competing laser technologies, TURP is still the most common surgical procedure performed to relieve BOO. Most patients can expect a good outcome, but they do need to understand, and confirm that they have understood, that they may expect to suffer irreversible retrograde ejaculation (the most common source of patient complaint after TURP), and that, less commonly, they may be troubled by bleeding with clots in the short term and occasionally with a urethral stricture in the longer term.

Radical prostatectomy, whether performed by the open approach or laparoscopically, with or without robotic assistance, carries with it not only the prospect of cure of localised prostate cancer, but also a set of sequelae and complications about which the patient needs to be informed before the procedure is performed. In an ideal world, one could argue that the individual should actually tick the boxes and sign to confirm that he accepts that he may suffer some bleeding and bruising, stress urinary incontinence, erectile dysfunction, which may persist, permanent loss of ejaculation/fertility, as well as potential shortening of the penis. The possibility of bowel and vascular injury, deep vein thrombosis and pulmonary embolism as well as subsequent wound and groin hernias should also be listed. A signed consent form alone that mentions these possibilities and probabilities may not in itself stand up in a court of law to prove that the individual truly knew and understood what he was letting himself in for, if something were to go wrong.
External beam radiotherapy is another example of a treatment method that carries potential risks as well as significant benefits. In the acute setting, fatigue and temporary alterations in bowel and urinary symptoms (sometimes marked) can occur; however, it is the chronic side effects that are of more concern from a consent viewpoint. The common side effect of impotence, the less common rectal bleeding and infertility, and the rare side effects of secondary malignancy and urethral stricture are usually well documented and can be simply explained to the patient. However, the alteration in bowel habit that commonly occurs is often inadequately explained and documented. This can manifest as a spectrum of symptoms of varying severity, including chronic frequency, faecal urgency, loose motions, abdominal pain, bloating, mucous discharge, and even faecal incontinence in rare cases. These symptoms often have the largest impact on the patient’s daily functioning and quality of life, and care must be taken to fully inform the patient when making treatment decisions.

Radiotherapy for intermediate- to high-risk prostate cancer is usually combined with androgen deprivation therapy (ADT), for up to 3 years. This can result in hot flushes as well as sexual dysfunction including erectile dysfunction and loss of libido. Other risks associated with ADT include osteoporosis, loss of male secondary sexual characteristics and features of metabolic syndrome. Patient lifestyle alterations and early medical intervention are key to limiting the long-term effects of ADT; patient educational material, in conjunction with detailed consent, ensures that the importance of these measures has been emphasised appropriately.

Systemic therapies (chemotherapy, immunotherapy and targeted therapies) are also treatment methods where patients need to be informed in detail of the risks of treatment. Chemotherapy for testicular cancer is one of the great success stories of urological oncology; however, it is associated with significant short-, medium- and long-term risks. Patients and their oncologists may focus on short-term toxicity, such as alopecia, myelosuppression and nausea, but there are important long-term risks that need to be clearly explained and understood before consent. These include neuropathy, ototoxicity, lung fibrosis and infertility, but also an increased risk of secondary malignancies and cardiovascular disease [5]. Informed consent before treatment may be the first step in patient education about these important long-term risks.

In conclusion, while it may seem unnecessarily gloomy to document and ask patients to tick and sign off each and every possible outcome and complication of either investigation or treatment, in today’s increasingly litigious world it is probably best practice to do so [6]. It can also act as a prompt for discussion of issues about which patients are concerned or which they don’t fully understand, ultimately strengthening the doctor–patient relationship. Although we all, of course, subscribe to the Hippocratic ethic of ‘primum non nocere’ (first do no harm), in practice, things can and do go wrong. In that situation a ticked and signed information sheet, in addition to the usual consent form may be the best way to show that truly informed consent was obtained.

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Conflict of Interest
None declared.

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Abbreviations: GMC, General Medical Council; ADT, androgen deprivation therapy.