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Safety and efficacy of interventional procedures

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the integrated care of asthma in many areas. One way to address this is through greater involvement of patients in their own management. Asthma action plans have been shown to work when these plans are personalised and imaginatively linked to the individual patient's goals and problems. The guidelines provide an excellent resource and should act as a stimulus for patients and staff to work together to provide appropriate care in asthma.

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Scrutinising the evidence and issuing guidelines without stifling innovation

Throughout the world, systems are in place to ensure that any new drug is subjected to rigorous trials, appraisal, and approval before unrestricted use on patients. Medical devices are also subject to scrutiny and approval. By contrast no system exists for interventional procedures, many of which are done by surgeons but increasingly by other specialists as well. Recent press reports of surgical scandals and heightened public concern have led to political and consumer pressure for formal systems to assess new interventions.

In the United Kingdom, initial moves were made in 1996 by the setting up of the Safety and Efficacy Register for New Interventional Procedures (SERNIP). It was founded by the royal colleges, with limited funding from the NHS, and was entirely voluntary. The register gradually accumulated a list of new procedures and allocated each to a category signifying its perceived degree of safety and efficacy, but the profile and impact of this register were limited. Australia followed suit with the Australian Safety and Efficacy Register for New Interventional Procedures—Surgical (ASERNIP-S)—established by the Royal Australasian College of Surgeons and funded by the Commonwealth Department of Health and Ageing—and made more tangible progress.[1]

The Australian surgery register has published systematic reviews on a range of surgical procedures,[2] with recommendations about their use or the need for further evaluation. Funding has limited the register to reviewing a maximum of about 10 procedures each year, ranging from laparoscopic live-donor nephrectomy[3] to ultrasound assisted liposuction.[4] Hospitals in Australia have generally acted on advice from the register, promoting the use of procedures along recommended lines and restricting the use of others pending more evidence. Recommendations from the register have provided increased impetus for systematic audit of some procedures and have stimulated a randomised trial of laparoscopic colonic surgery.[5] It has also established a horizon scanning project with a database of procedures, either recently introduced or likely to find their way into surgical practice soon,[6] which can be systematically reviewed when sufficient evidence exists.

In the United Kingdom, one result of the Bristol affair was a mandate for the National Institute for Clinical Excellence (NICE, www.nice.org.uk) to take over responsibility for safety and efficacy of interventional procedures, with a remit altogether more comprehensive and demanding than that of its predecessor or of the Australian surgery register.[7] Expectations include a database of all new procedures, cooperation of all surgeons and other doctors undertaking new procedures, and recommendations that will be observed throughout the health service—all in a process that is public and transparent. Success, therefore, requires a balance between the primary aim of protecting patients and the need to encourage and foster innovation. Doctors will need to be engaged by clear assurances that their own protection from clinical and medicolegal risk is a central theme.

The intention is to review the evidence about new procedures, and to collect data on all cases for procedures under special scrutiny—rather than attempting to restrict their use. This will be a complex exercise but has the potential to gather information about safety and efficacy quickly. The Australian surgery register has experienced the difficulties of data collection by using a range of data submission techniques ranging from paper through to fax and web based systems. NICE is committed to electronic data capture, with much smaller datasets, including only key items about safety and efficacy. The coordinated system of clinical governance now established in the United Kingdom is likely to facilitate this.[8] Protecting private patients is more difficult, but involving the private sector seems important because this is where many new procedureare first undertaken.

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Collection and validation of data on a large scale are expensive, and the cost of systematic reviews is considerable—an average of £30 000-£50 000 ($48 800-$81 350; €45 500-€75 800) for the Australian register. Funding is unlikely ever to be sufficient for collection of data on all procedures, and NICE will rely heavily on help from a network of specialist advisers and on its multidisciplinary advisory committee.

No other countries yet have systems in place for monitoring of new interventions. The American College of Surgeons is considering an approach but has yet to act. The Australian example and the more regulated United Kingdom plan may give other countries food for thought, but many uncertainties remain. What precisely is a new procedure? If an existing procedure is modified, how much modification makes it new? If new technology is used for an established procedure, is that new? (NICE will be explicit about its focus on procedures rather than devices.) Should doctors be restricted in undertaking new procedures? How can compliance with submission of data and guidance best be achieved? What data should be publicly available and what should be done if outcomes vary between doctors? Without clear assurances about confidentiality neither doctors nor patients will be eager to cooperate.

Finally, safety and efficacy also require a long term perspective. NICE intends to ensure that new procedures receive specific codes in the national coding system at an early stage, so that their dissemination can be monitored and any reporting of adverse events is in the context of some kind of denominator. Procedures with obvious potential for long term adverse events will need special consideration, and this will form part of the complex evolution of monitoring of safety and efficacy.

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Not to be taken as directed

Putting concordance for taking medicines into practice

When the medicines that doctors prescribe fail to produce the benefit they expect, they often respond by varying the dose or selecting an alternative medicine. Thus doctors seem to behave as though non-compliance is a problem for other doctors. Although we know that about half of the medicines prescribed for patients with long term conditions are not taken as prescribed,[1] the concerns of health professionals have focused almost exclusively on improving the quality of their own prescribing choices. Similarly, attention and resources devoted by pharmaceutical companies to discovering, developing, and promoting new drugs utterly dwarf their efforts to see that medicines are taken by patients. Yet non-compliance continues to represent a serious therapeutic deficit at the core of medical practice, with consequent massive personal, societal, and economic cost.

Patients do not comply with medication for several reasons.[2] Non-compliance may be intentional or involuntary. It may relate to the quality of information given, the impact of the regimen on daily life, the physical or ental incapacity of patients, or their social isolation. Many interventions to overcome these impediments have been tried, but evidence of sustained success is scant.[1]

The difficulty for health professionals lies in acknowledging that it is the patients' agendas and not their own that determine whether patients take medicines. Patients have their own beliefs about their medicines and medicines in general. They have their own priorities and their own rational discourse in relation to health and care, risk and benefit.[3] These may differ from and sometimes contradict those of the doctors. They are, however, no less cogent, coherent, or important.[4]

By drawing on these findings and insights a new relationship between prescriber and patient was described.[5] The term concordance was introduced. While compliance describes the degree to which the patient follows the prescribed regimen of medicines, concordance describes an agreement between a patient and a healthcare professional about whether, when, and how medicines are to be taken. Concordance therefore refers to the creation of an agreement that respects the beliefs and wishes of the patient, and not to compliance—the following of instructions.

Doctors and patients may not always agree. The implication of concordance is that when this happens

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