NICE/NPSA patient safety pilot

Bruce Campbell and Sarah Garner

In recent times, there has been a burgeoning 'patient safety agenda' to which some surgeons find difficulty in relating.^{1,2} Do surgeons not strive for the best balance between risks and benefits in planning treatment? Is not their professional life centred around avoidance of complications and giving their patients the safest treatment they can? Surely, the auditing of problems with their peers keeps their levels of self-criticism and learning honed?

It is understandable that clinicians, working with the greatest zeal in their own milieu, often have a somewhat narrow view of the many issues that affect the safety of their patients – many of them connected with documentation, administration, communication and matters which are easy to lose sight of from the operating theatre and the end of the bed. Some of the issues may relate to areas from which surgeons feel distanced by the increasing complexity of hospital management and the reduced capacity of consultants to control what happens to their patients. However, a broad view is important, as is some involvement in the wide range factors that can result in harm to patients, either by omission or by commission. That broad view should include special awareness of the particular issues of concern to the public and the media – currently, hospital-acquired infections.

The NHS's National Patient Safety Agency (NPSA) was established in 2001 with a mandate to identify patient safety issues and find appropriate solutions. The NPSA has produced Patient Safety Alerts on a great variety of matters, from wristbands to epidurals.³ In early 2007, following the publication of *Safety First*, NICE and the NPSA were asked by Sir Liam Donaldson, Chief Medical Officer, to collaborate on a pilot project to develop 'technical patient safety solutions'.¹ A technical patient safety solution is an intervention that has a demonstrated ability to prevent, or reduce, harm to patients. The concept was to use the rigorous processes developed by NICE to produce guidance in areas that the NPSA had highlighted as patient safety issues.

The fundamental principles of the NICE guidance development processes are: (i) underpinning of guidance by a sound evidence base; (ii) obtaining advice from external clinical and patient experts; (iii) involving a wide range of stakeholders; and (iv) transparency throughout the process, including public consultation on the draft guidance.

The two topics chosen for the pilot were purposely very different. One was ventilator-associated pneumonia (VAP) – a problem which has caused considerable concern in the US⁴ and internationally, but which has received little prominence in the UK. The second topic was 'medicines reconciliation' on admission to hospital: this means being sure that, on admission, there is a correct list of medicines that the

patient was taking before admission. Discrepancies are frequent and sometimes dangerous, and they are frequently reported to the NPSA.

From the outset, the aim was not to produce a full guideline but to produce focused recommendations on specific interventions that had been examined. The recommendations ('technical patient safety solutions') had to be based on adequate published evidence and supported by specialist opinion. They would be mandatory (like NPSA Safety Alerts), so they would need to be practical and to encounter no major implementation obstacles relating to, for example, practicality, professional opposition or cost. A workshop was held, to which a wide range of specialists and other stakeholders were invited, to ensure that the scope of the pilot and the ways in which the two topics were to be reviewed was considered reasonable.

The pilot was carried out against a very tight time scale, which made production of two systematic reviews and economic models a considerable challenge. Requests were sent to all the relevant professional organisations to nominate Specialist Advisors. Their speed of response was quite variable and later there was criticism of NICE from a few specialists that they had not been involved at an early stage. In fact, the NICE had gone to great lengths to involve specialists from the start. It is important that those leading professional organisations recognise the importance of creating organisational structures to enable a swift reaction to requests from NICE for nominees. In order to issue guidance in the shortest time possible, it is vital that organisations respond within the consultation periods (NICE is bound by time lines stipulated for production of each piece of guidance). The windows of opportunity for advice and comment are published at the start of each project and preplanning is required so that Specialist Advisors are not asked by their professional bodies to respond at very short notice.

For medicines reconciliation, there was little published evidence on potential strategies. Most of the available evidence focused on the involvement of pharmacists in the process, as soon as practical after admission, and showed consistent benefit. Pharmacist involvement resulted in fewer errors than the conventional system of clerking by junior doctors and often the repeated (and variable) recording of medications.

In their discussions, the Committee recognised the need for junior doctors to take good histories and to prescribe competently. However, the evidence was sufficient to recommend that pharmacists should be involved as early as possible after admission (ideally within 24 hours) to promote and check on correct medicines reconciliation. The recommendations

acknowledged that the way in which pharmacists would be involved might differ between clinical areas (for example, between elective admissions to cardiac surgical unit and emergency admissions to a psychiatric unit). They stipulated that the immediate need was for all units to put policies in place (implicitly acknowledging the fact that sufficient pharmacists and pharmacy technicians may not be immediately available). The comments received at Public Consultation resulted in some changes to the draft guidance but were broadly supportive of the recommendations. The guidance was published in December 2007.

For ventilator-associated pneumonia (VAP), the process has been delayed and guidance is unlikely to be published before late summer of 2008. That is because NICE was successfully taken to 'Resolution' (similar to the Appeals process for NICE Technology Appraisals) by consultees who were unhappy that NICE had not fully explored the role of antibiotics. The Resolution Panel determines whether NICE has either made a factual error, or failed to follow its own processes properly.

A large number of comments were received on the 2007 draft VAP guidance – many of them multiple or repeated criticisms from a small number of people. Changes were made in the light of these; nevertheless, the Resolution Panel determined that processes had not been properly followed, insofar as the Committee had not seen all the available evidence on Selective Decontamination of the Digestive tract (SDD). SDD consists of giving non-absorbable antimicrobials as oropharyngeal paste or gel, and via nasogastric tube: in some regimens, an antibiotic is also given intravenously.

A systematic review on the evidence for SDD was undertaken and the Patient Safety Advisory Committee reconvened in March 2008. At the time of writing, the draft guidance is out for public consultation. Following complex discussions about the published evidence and the opinions of Specialist Advisors, the draft guidance recommends that:

1. Mechanically ventilated patients who are intubated should be positioned with their upper body elevated (in a semi-recumbent or seated position) for as much of the time as possible. For some patients this will not be appropriate (for example, those with spinal injuries).

2. Oral antiseptics (for example, chlorhexidine) should be included as part of the oral hygiene regimen for all patients who are intubated and receiving mechanical ventilation.

With respect to SDD, the Patient Safety Advisory Committee examined evidence which suggested that selective decontamination of the digestive tract (SDD) using topical antibiotics may reduce the incidence of VAP and that SDD regimens that include systemic antibiotics may also reduce mortality. However, it did not recommend SDD as an intervention to reduce VAP on the basis of comments from the Specialist Advisers who stated that UK intensive care specialists had particular concerns about the risk of infection with *Clostridium difficile* and the induction and/or selection of resistant, including multiresistant, micro-organisms as a result of SDD. The evidence reviewed by the Committee was from non-UK patient populations with potentially important differences to current UK patients. The Committee concluded that further research into SDD is urgently required in a UK setting.

A lack of robust evidence meant the Committee was unable to make recommendations for action on the use of kinetic beds. Although the evidence supported the use of elements of care bundles, there was insufficient evidence to recommend a care bundle of any specific design.

Quite apart from describing the NICE/NPSA Patient Safety Pilot, this account gives some flavour of the lengths to which NICE goes to obtain and take account of the opinion of specialists and others in all the guidance it produces. The enduring aim is to get all those involved to embrace the process at an early stage, rather than to receive criticism 'after the event'. NICE is always open to suggestions of new ways in which specialists feel able to be involved in giving advice.

References

1. <http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_062848>.
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