Guidelines on skin antisepsis before central neuraxial blockade

This issue of Anaesthesia sees the publication of the latest guidelines from the Association of Anaesthetists of Great Britain and Ireland (AAGBI), in partnership with the Obstetric Anaesthetists’ Association (OAA), the Association of Paediatric Anaesthetists of Great Britain and Ireland (APAGBI) and Regional Anaesthesia-UK (RA-UK), on skin antisepsis before central neuraxial blockade [1]. Tellingly, the document is titled: ‘Safety Guidelines’, raising the questions: just what is safe (or unsafe), and what is the evidence? However, before thinking about the impact of this new guideline, I want to comment on the current status of guidelines in general.

Guidelines – too much of a good thing?

The explosion in guidelines highlighted by Kearns and colleagues in this journal in 2013 [2] is a problem for the National Health Service (NHS) itself and for all NHS staff. They found more than 400 pages of guidance that applied to a fictitious patient with a hip fracture and three pre-existing co-morbidities. The total number of guidelines that apply to all patients receiving care in the UK is surely too many to count. How should we manage the current situation, and how should we plan for the future? If guidelines are to be of any use and if they are to retain their credibility, should their use be rationalised? On the other hand, does the fact that so many are produced and that, when published, they are often highly cited, imply that clinicians, readers, carers and perhaps even patients want them?

To be useful, guidelines need to be accessible, applicable and practical. (These criteria are my own. Others have developed more formal assessment tools for rating guidelines, for example the AGREE II initiative (see www.agreetrust.org) funded by the Canadian Institutes of Health Research). Accessing documents produced on such a grand scale is a real issue. Accessibility requires archiving and collating, providing a search mechanism, and making the results of such a search available at the point of care. Just the first part of this process – archiving – is problematic in itself, as there is no single resource or library where all guidelines applicable to UK patients are kept. The likelihood of such a library’s creation is low – major IT projects in the NHS have a very poor track record [3]. Just collecting all guidelines in one place would be difficult enough, but they would need to be ordered using a suitable taxonomy, kept up-to-date and be written and presented in a uniform fashion.

Modern search engines can provide a solution to both archiving and collating. They continually index source documents – searching both the title and author data and the text of the document itself for key words. Users of the most up-to-date desktop operating systems such as Apple OS X Mavericks (Apple Inc., Cupertino, CA, USA) and Windows 8 (Microsoft Corp., Redmond, WA, USA) will be used to system searches (Apple Spotlight or Windows Search, retrospectively) where results are displayed almost instantaneously, ordered according to the type of result (documents, figures, PDFs, spreadsheets etc), and can be refined. An internet-based search, such as Google (www.google.co.uk), enables the user both to make a thorough search (by including all possible resources, sites, virtual libraries, etc.) and to refine the results by use of inclusion and exclusion criteria to yield only those documents of interest. For example, most readers will recognise that a simple Google search is too broad. (Entering the term ‘clinical guidelines’ into Google brings up ~145 000 000 results). Refining search criteria risks excluding important results and experience is necessary to ensure that all applicable source documents are found. (The current generation of young researchers and clinicians will not have struggled...
with the early searches of Medline using slow, dial-up or university network connections, when practicability and cost limited each user to one attempt at getting their search right).

Where would a clinician undertake such a search – on a desktop computer, a computer terminal (in the operating theatre or other clinical area), a tablet computer or a smartphone? All of these solutions must be catered for and a good website (and search engine) should be optimised for all platforms. Rather than searching as needed, perhaps frequently used guidelines could be pre-loaded onto a portable device? Three years ago, United Airlines announced that all of its pilots would carry their flight manuals (the paper versions can weigh up to 17 kg) on an iPad (Apple Inc), saving 16 million sheets of paper per year and 1.2 million litres of fuel [4]!

The applicability of guidelines is a perennial problem. Simply the huge number of guidelines and their overlap, as demonstrated by Kearns et al. [2], ensures that not only is finding the right guideline difficult, but gauging the primacy of similar or overlapping (or even worse, contradictory) guidelines is even more problematic. Could national bodies take responsibility for rationalising guidelines in their area? If so, who would judge guidelines? Who would take responsibility to withdraw a guideline felt to be too old, too poorly researched or trumped by better advice? Perhaps the greatest problem is the risk of guidelines’ simply expiring. Too many resources are filled with old documents that remain accessible and risk offering outdated advice. Nothing inspires less confidence in a web-based document than finding old material or links that do not work – though from a medicolegal perspective, an important aspect of guidelines is the ability to access older or superseded versions if it becomes necessary to consider the contemporaneous standard of care in cases that occurred some years ago.

The production of practical advice is the ultimate aim. Yet guidelines may be written that fail to match the real-world situation – on ‘the shop floor’. Clinicians who wish to be seen to adhere to guidelines then struggle to match expectation with reality. By being so accessible, guidelines are found by lawyers (and, of course, why not – we should not be hiding these documents) and their lack of practical applicability may mean little to litigants. A further, unintended consequence of a guideline is ‘guideline paralysis’ whereby a real-world decision is delayed or avoided for fear of doing the wrong thing, compounded by guidance that fails to work in an acute situation. Phrases such as ‘could’, ‘might be best served’, ‘in ideal circumstances’, ‘discuss with others/seniors/experts/national centres...’ rarely help. Perhaps one reason for the failure of a guideline to offer practical advice is that it was not piloted first. (The Association of Anaesthetists has previously trialled guidelines before their publication to ensure their practicality [5]). Furthermore, it is difficult to predict all the circumstances in which a guideline may be consulted. All authors and sponsors of guidelines need to be aware of this risk and ensure that they do not make matters worse by publishing a document that cannot be used.

The skin antisepsis guideline
The new AAGBI guideline on skin antisepsis before central neuraxial blockade was written jointly with the OAA, APAGBI and RA-UK, although some might question why other interested parties, such as the British Society of Orthopaedic Anaesthetists, were not involved. A clear stimulus to their production were the recent cases of arachnoiditis that have reached the Courts and been the subject of previous commentaries and case reports [6, 7]. It is worth reviewing the evidence for harm, and how the Courts have interpreted this. (Detailed advice on the medicolegal aspects of guidelines is available elsewhere, for example the Scottish Intercollegiate Guidelines Network (SIGN) website: see http://www.sign.ac.uk/guidelines/fulltext/50/section1.html). Chronic adhesive arachnoiditis is a rare condition, and may occur as a complication after spinal [6, 7] and epidural analgesia [8]. It leads to a debilitating, progressive and sometimes devastating damage of the lower cord roots, often associated with hydrocephalus. There are many potential causes; in some cases it is obvious, in others much less so. The leading case associating this condition with skin antisepsis preparations has been described in this journal [6] and in Anaesthesia News [9] by Bogod. In short,
Angeline Sutcliffe developed chronic adhesive arachnoiditis after an apparently straightforward spinal anaesthetic and the Court found that on the balance of probabilities, there must have been a negligent contamination of the spinal injectate with antiseptic agent, as no other cause was offered [10]. This might have been a case where the legal maxim ‘res ipsa loquitur’ (‘the thing speaks for itself’) could have been used. It can be paraphrased thus: because an injury occurred, there must have been a cause, and in the absence of any other non-negligent cause, a negligent act must be to blame. This editorial is not the right place to debate the use of this argument, and the trial judge rejected its use (although it was one of the issues considered when the Sutcliffe case went to appeal [11]); the crucial point is that while there was clinical evidence of an injury, the exact mechanism of injury was unclear, and the act that led to the injury was inferred rather than proven. There is evidence that both chlorhexidine and alcohol are neurotoxic, and contamination of either the injectate or the apparatus used to perform the block may have led to the arachnoiditis in some or all of the cases reported after spinal or epidural anaesthesia. Thus, the issues are: is there a link between chronic adhesive arachnoiditis and skin antisepsis preparations; what component of the available antiseptics might be the cause of the injury (or pathological process); if the cause is chlorhexidine, can a different risk be attributed to the two available concentrations; and, is the use of different concentrations of antiseptic agents associated with a different risk of central neuraxial infection? All of these points are debatable and some may be controversial. (These particular guidelines attracted more comments when put out to consultation than any previous ones, though the Working Party was unable to find evidence to support most of them (F. Plaat, personal communication). Importantly, the scientific evidence is limited and some of the guideline group’s recommendations are extrapolations from small studies or based on case series. For example, despite its recommendation to support the use of 0.5% chlorhexidine in alcohol, the guideline states: “...the Working Party acknowledges that there is a lack of data to support the use of one concentration of chlorhexidine over another for [central neuraxial block]” [1]. Furthermore, there are commercial concerns to bear in mind. One of the currently available products uses 2% chlorhexidine in alcohol and is popular with clinicians for central venous cannulation. Importantly, there is no convincing evidence to suggest that this concentration (and therefore this product) should be withdrawn.

It is right that the evidence is reviewed, a consensus reached and guidance published. Existing practice is ingrained in our psyche and experienced practitioners may have performed many thousands of central neuraxial blocks with few complications, and certainly nothing as devastating as arachnoiditis. However, even performing several thousand procedures without a complication does not exclude the existence of a risk. So, as the guideline states, practising clinicians are faced with balancing the risk of arachnoiditis – which is very rare, but circumstantial evidence suggests it may be linked with the use of skin antisepsis preparations – with the risk of central neuraxial infection, which can be equally devastating and for which we do have an estimate of the likely incidence. (For example, the 3rd National Audit Project study determined the 95% confidence intervals for the incidence of bacterial meningitis after peri-operative spinal anaesthesia as 0–2.7 per 100 000 [12]).

How does this new guideline score when judged for accessibility, applicability and practicality? To maximise accessibility, the document has been published as a free, full-text article under the Creative Commons Attribution license, allowing widespread distribution (as for other AAGBI guidelines published in Anaesthesia). The guideline is free to read, download and copy for local use, even by non-members and non-subscribers; all that the licence requires is that the provenance of the guideline is included in all reproductions. The applicability of the guideline seems clear. Many thousands of central neuraxial blocks are performed each week [12] and, as the authors describe, the need was to produce clear, up-to-date advice in the light of the recent developments about skin sepsis in terms of both case reports (and case law) and the scientific evidence. Thus, the guideline was written to offer practical advice to clinicians, and achieves that with one exception – 0.5% chlorhexidine in alcohol (the recommended anti-
septic) is currently not available as a 'swabstick' (a popular method of application). The other recommendations are relatively straightforward and common-sense.

The guideline will, in my opinion, help clinicians. It provides advice based on some evidence, some extrapolation of data and the consensus views of an informed group. Although the underlying cause and effect remains unclear, we do now have practical advice to guide us in our daily clinical practice.

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Competing interests
I am a member of the AAGBI Board where these guidelines have been discussed; however, these views are my own and do not represent those of the AAGBI nor of my employer.

I have provided expert witness (medicolegal) reports for the Court in cases of suspected arachnoiditis.

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