EDITORIAL – TECHNICAL SECTION

Home-made, adapted and modified devices in surgical practice

The reviewer of the Technical Note 'Retraction of oedematous eyelids with paper-clips' provided the stimulus for this article (see *first Technical Note in this issue*). He rather liked the ingenuity of this practical tip, but questioned whether it might expose users and their hospitals to the risk of litigation if a patient were damaged by a 'home-made device'. His comments expose a difficult dilemma between innovation and regulation.

The most recent regulatory advice about 'home-made devices' is contained in an Alert published in 2004 by the Medical Devices Agency (MDA), now part of the Medicines and Healthcare products Regulatory Agency (MHRA).¹ It deals with:

1. Adaptation of non-medical products (for example, paperclips to hold eyelids open [see Technical Notes] or infant feeding bottle teats in management of infected gastrostomy sites²).
2. Modification of medical devices (for example, remodelled syringe barrels for applying orthopaedic cement^{3,4} or cutting the ends of urethral catheters⁵).
3. Use of medical devices for purposes not intended by the manufacturer – 'off-label' use (for example, the cuff of a flatus tube placed over a gastroscope to remove ingested foreign bodies,⁶ sucker tubing as a sheath over orthopaedic drill bits⁷ or using a bladder hydrodistension catheter for creating space during retroperitoneoscopy⁸).

The Alert draws attention to the potential dangers of using any of these kinds of devices. All the examples above have been published in the Technical Section of the *Annals* in recent years.

There is a real tension between the understandable approach of the regulators to protect patients from unintended damage, and the innate tendency of surgeons to modify, develop and innovate to facilitate the procedures they do. Certainly, the goal of both clinicians and regulators should be 'first, do no harm', but slavish adherence to any blanket ban on adaptation or off-label use would be a significant disincentive to innovation and technical flexibility in the eyes of most surgeons. They see minor modifications of technique and of devices as a traditional and proper element of progress in surgery. A particular difficulty for surgeons is blurring of the distinction between minor technical modification of what they do (beyond the normal scope of regulation) and of what they use (technically always within the scope of regulation). How might the gap between the regulators and the innovators best be bridged?

There is a clear process for any clinician wanting to develop a device to be marketed: the debate is not about those. It is about apparently minor adaptations, like the examples above, which would be most unlikely ever to spur their originators to go through the regulatory process of having their 'devices' formally approved as fit for purpose. Pursuing assessment of minor adaptations in formal research would also be unattractive, both because of the difficulty in planning robust evaluation and because of the mountain of bureaucracy, which now militates against research into simple little ideas.

The MDA Alert provides some specific guidance. It advises that when there is judged to be no alternative to off-label use or modification of a device, clinicians should 'carry out and document a full risk assessment and ... consider the ethical and legal implications'. This 'risk assessment' ought to be part of the normal thought process of any surgeon in considering use of a modified device. Discussion with colleagues is a sensible part of risk assessment and could perhaps be regarded as a variant of the Bolam test (*i.e.* a responsible body of colleagues would support use the modified device). What are the potential risks of harm? How are they balanced by the potential advantages and the seriousness of the condition being treated? Documenting all this is a less familiar step, which might sound daunting, but it could be achieved on a single piece of paper for many minor adaptations, modifications or off-label uses. Hospital Trusts frequently approve sensible departures from manufacturers' stipulations (but it might be a problem if managers, including clinicians, lack flexibility or vision).

Very properly, the MDA Alert emphasises consent, stating that 'the patient must be fully informed ... and a note made in their records' when an off-label device is to be used. In principle, there can be little argument with this. In practice, there may well be reasonable exceptions, particularly in the emergency setting, where adaptation is often not anticipated and is done in life-threatening circumstances (for example, the use of a urinary catheter balloon to control aortic bleeding, drawing pins or epiphyseal staples to control bleeding from paravertebral vessels during emergency aortic aneurysm repair⁹ or skin staples to repair penetrating cardiac injuries¹⁰). Even for elective procedures, explaining the use of a modified piece of equipment for one small part of a technically complex operation would rate low in the priorities of most surgeons, in the context of ensuring that patients understand the main risks, benefits and purpose of a procedure.

Another stipulation of the MDA alert is ‘unless there is no suitable CE marked device’. Such a device may exist but be unavailable for the occasional emergency, or it may not be available for elective work with the increasingly restrictive systems of central purchasing of equipment (another stimulus for surgeons to modify and adapt what they have to hand).

Clinicians have a duty of care with regard to patients’ safety, which underpins the demands of regulation on their use of devices. However, that duty of care extends to providing the best treatment they think they can offer with the lowest acceptable risk and, in some circumstances, that may involve sensible modification or adaptation of devices. When contemplating any off-label use, surgeons need to be mindful of the increasingly regulated environment in which they work and the potential medicolegal risks. Documenting a ‘risk assessment’ (benefits and risks) both concentrates the mind and provides a measure of protection if problems occur. There will never be one simple way of reconciling the demands of the regulators and the constant invention of surgeons in developing their everyday practices. Both surgeons and those involved in clinical governance need to be aware of these issues and to adopt a considered and flexible approach to sensible innovation.

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