The surgeon and medical devices: adverse incident reporting and off-label use

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Recent events have highlighted the problems that can arise from the use of medical devices. The Poly Implant Prothèse breast implant affair and controversies surrounding metal-on-metal hips have focused the attention of the public and clinicians on medical device regulation and the safety of implants. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for the regulation of the devices but the agency's ability to do this depends on manufacturers, surgeons and other users to report any events that might point toward underlying safety issues. This article aims to clarify the roles and responsibilities of clinicians when using medical devices. It describes the range of incidents that they should report and how to report them. It also explores the implications of off-label use.

Adverse incident reporting

An adverse incident refers to any event that has caused or could have caused an unexpected or unwanted event, either for the patient or for the user of the device. Clearly, any incident that causes significant injury or death should be reported to the MHRA. However, there are more subtle incidents, which, if reported, might help define a device's safety profile. In particular, reports by users of possible implant related complications occurring both in the short and long term allow the MHRA to track the performance of these devices. Commonly, incidents will be recognised and reported by clinicians but a wide range of other users of devices may make reports, including clinical scientists and patients.

'Incidents' that ought to be reported include events that have necessitated further medical or surgical intervention and any event, possibly related to a device, that causes a permanent deterioration in a patient's health. Persistent faults with a device that are not rectified by repeated service or maintenance should also be reported. A full list of incidents that should be reported to the MHRA can be found in the device bulletin DB 2011(01) on its website (<http://www.mhra.gov.uk/>).

Incidents that appear to result from human error are also worth reporting because they may lead to modifications of the device or changes in the instructions for its use. Furthermore, it is important to realise that reporting *potential* problems can be valuable: a number of such reports can lead to advice from the MHRA, designed to prevent the occurrence of harm.

In February 2013 the General Medical Council published *Good practice in prescribing and managing medicines and devices*,¹ which stipulates that doctors should report incidents and near misses to the MHRA. They are not required to do so by law, and that contrasts with the situation for manufacturers, who are under a legal obligation to report such incidents to the MHRA. The MHRA provides a simple online reporting system at www.mhra.gov.uk and will also inform the manufacturer of any incidents reported to them via this route.

Off-label use

Off-label use of a medical device occurs when a clinician uses a device for an indication that has not been included in the instructions supplied with it (the instructions for use or 'IFU'). This type of use is becoming increasingly frequent and has some important implications for liability if things go wrong.

Like off-label use of medicines, off-label use of devices has led to important advances in medical care. For example, the first metal stents were only approved for use in the biliary tree to relieve jaundice but they found a far more widespread use treating arterial stenosis (in conjunction with balloon angioplasty). However, the implications of off-label use are serious in terms of personal responsibility when a complication does occur. Prior to marketing a device, a manufacturer should undertake a thorough risk analysis as well as conducting sufficient preclinical and clinical testing to establish that a device is safe and suitable to be used for the purpose for which it was intended. The aim is to elimi-

nate or minimise risk as much as is practically possible and to confirm that the benefits outweigh the risks.

If a device is then used for a purpose for which it has not been tested, the risk to the patient and user cannot be quantified, and the liability for the safety and the performance of the device could then be transferred to the user. This is also true when a device is modified or adapted by a clinician prior to use. In such situations of off-label use or device modification, the user may become the *de facto* manufacturer of the device and, consequently, the legal obligation to report any adverse events that occur will fall to the clinician.

It is important for clinicians to have a thorough knowledge of the content of the instructions that accompany any device, in particular the indications for its use. They may discover that what they considered to be accepted practice is in fact contrary to the indications for use of the device. A good example of this is in the use of endovascular stents for repair of abdominal aortic aneurysms. Many of these devices have their indications for use restricted by the degree of angulation of the aortic neck but vascular specialists continue to place such stents in angulated aortic necks in excess of these limits in order to treat patients who would be at high risk for open surgery.

It is not necessary to report off-label use to the MHRA but it is good medical practice to inform the medical director of the hospital about it. It is also important to ensure that the patient has been informed adequately and that this is documented clearly. Hospitals have local procedures for dealing with off-label use. Clinicians should make themselves aware of these because failure to comply with the procedures may render them personally liable if harm is caused. Discussion of off-label use of devices at multidisciplinary team meetings, with clear documentation of the points raised and of agreement by consensus among the team, helps to provide support for such use.

Clinicians can reasonably put pressure on manufacturers to extend their recognised indications for use of devices and can assist them by publishing reports of cases in which the devices have been used off-label successfully. Reports published in peer reviewed journals can be used as evidence to support the use of devices for novel indications. They may not only persuade an existing manufacturer to extend their current indications but may also alert other manufacturers to a potential gap in the market, leading to the development of specific devices for the newly identified indication.

Conclusions

Surgeons should have a low threshold for reporting adverse incidents to the MHRA. These include incidents that have obviously been caused by devices, those related to human error using devices and instances of potential harm ('near misses'). All these reports serve the greater good because they may contribute to a pattern of reports that together lead to identification of risks that may be serious.

With regard to off-label use of devices, it is important for surgeons to check the indications for which the devices they use are licensed. They may be personally liable if harm occurs using a device for other indications or if they have modified the device. Off-label use may be beneficial for patients and may advance practice but it should be done with proper consent, good documentation and within prescribed processes.

Reference

1. GMC. *Good practice in prescribing and managing medicines and devices*. London: General Medical Council; 2013.