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ANALYSIS

Medical device recalls and transparency in the UK

Matthew Thompson and colleagues' attempts to obtain data on recalled medical devices raise questions about the UK regulatory system

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Medical device regulation is currently being questioned in both Europe and the United States.[1] Although both systems are under review, that's where the similarity ends. Both the approval process and policies on access to data are very different. And our research, published this week in *BMJ Open* and part of a wider series of investigations in which the *BMJ* has been involved, shows how difficult it makes it to find out about recalled devices in the UK.[2]

US and European systems

In the US, there are essentially two ways devices are reviewed before approval. A more rigorous process, known as premarket approval (PMA) involves reviewing evidence of clinical tests of a new device. A less stringent approach, known as the 510(k) process, is intended for the approval of devices that are similar to others already on the market. Once a device has been either approved or cleared by the Food and Drug Administration under one of these routes, it can be marketed. However, there has been growing concern that the 510(k) route involves a far lower degree of scrutiny than PMA and is being used inappropriately for some devices, and that both processes involve far less regulatory oversight than approval of new drugs.[3 4] Even PMA scrutiny is not very high—typically only one or two studies are submitted, of which the majority are non-randomised, single arm studies with fewer than 100 participants.[5 6]

When devices fail or have faults they may be recalled. The FDA publishes a list of recalled devices and the regulatory processes they had passed through. Zuckerman and colleagues analysed 113 medical devices recalled by the FDA from 2005 to 2009 because of risks of serious health effects or even death. They found that less than a fifth, 19% (21/113) had gone through the more stringent PMA process.[3] One reason the FDA relies heavily on the 510(k) process is that it allows the FDA's Center for Devices and Radiological Health, which is fairly small, to review a large number of devices each year.[3]

In Europe, the approval process is not done by a central government agency like the FDA but by for-profit organisations called notified bodies. There are roughly 74 notified bodies across Europe responsible for evaluating medical devices. These bodies ensure a device conforms to appropriate regulations, which then enables a manufacturer to display a Conformité Européenne (CE) mark for that device.[7 8] Each member state specifies a national regulator to implement the European directives, and oversee approval of new devices: in the UK this is the Medicines and Healthcare Products Regulatory Agency (MHRA). There are three categories of medical devices: class I (devices which pose the lowest risk, such as wheelchairs or surgical tables), class II (medium risk devices such as endoscopes or ultrasound devices), and class III (high risk devices such as artificial joints and implantable defibrillators). The classification of a device determines the type of data a manufacturer needs to supply to the notified body.

Hurdles in trying to obtain information about device failures in the UK

We aimed to replicate Zuckerman et al's US study in the UK.[3] As reported in our paper,[2] we set out to quantify the number and types of medical device failures in the UK, the health consequences from these failures, and the data that had been supplied for premarket approval. We thought that these were straightforward questions—ones that someone else would have already asked—but unfortunately our research threw up numerous hurdles.

Our search for data to answer our research started with the MHRA. The MHRA publishes two types of information (or warnings) about medical devices on its website: field safety notices, which manufacturers issue when a device needs to be recalled for technical or clinical reasons; and medical device alerts, which provide information about recalls and recommend what action should be taken by NHS trusts, primary care, and care homes.

We assembled a database of all medical devices mentioned in field safety notices (2124 devices) and medical device alerts

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(447 devices) during 2006 to 2010. At this point we encountered the first of several barriers to obtaining the information we needed. The MHRA does not indicate the class of device mentioned in safety notices or alerts. We therefore had to classify each of the devices ourselves, based on its description. In doing this we found the basis for device classification seemed somewhat confusing. For instance, we classified contact lenses as class I devices (low risk), whereas contact lens cleaners were class II (medium risk).

The second problem was that information about the number of recalled devices, the risk of harms to patients, and the premarket approval process was not available from the MHRA. These data are held by the manufacturer and the notified body. Since both the notified bodies and the manufacturers are exempt from freedom of information legislation, we decided to contact them directly by email. We started with the manufacturers of 192 recalled devices, each of which lists a contact responsible for the recall. Only 53% (101/192) replied and only four (2%) provided any clinical data; 11 (5.7%) declined to formally participate, 27 (14%) acknowledged the email but provided no response, 21 (11%) provided partial answers, and 38 (20%) emails bounced back because of an incorrect email address or out of office reply. The notified bodies told us that information was confidential and not available for scrutiny.

What did we find?

We therefore had to base our analyses on the publicly available MHRA field safety notices and medical device alerts. We found an increase in the number of field safety notices over the study period, from 62 in 2006 to 757 in 2010 (1220% increase). But field safety notices provide mainly corrective action and few clinical data for us to assess harms.

In contrast, the 447 medical device alerts contained a summary of the problems encountered. This enabled us to use our clinical judgment to categorise potential harms. We categorised harms associated with recalled devices using the FDA's classification system. In class 1 recalls there is a reasonable probability that the device will cause serious adverse health consequences or death; class 2 recalls are defined as causing temporary or reversible adverse health consequences; and class 3 recalls are where the device is not likely to lead to adverse health consequences. We found that 88% (53/60) of recalls of class III (high risk) devices were consistent with FDA class 1—that is, a reasonable probability of serious adverse effects or death. Even for the lowest risk devices, this figure was 34% (45/133).

To quantify the effects of recalled medical device on patients, ideally we would want accurate figures for both the numerator (that is, how severe the risk is, number of episodes of harm or death) and denominator (number of devices used).[9] However, we could not access satisfactory data for either of these. The MHRA does operate an adverse event reporting site that manufacturers, health and social care workers, and patients can use to report adverse incidents. Each year, it publishes the number of adverse events received. In 2009 the MHRA received 9099 reports of adverse incidents involving medical devices, an effective increase of 5% from the previous year.[10] Of these reports, 1885 (20.7%) involved serious injury (including revision of implants or pacemakers) and 202 (2.2%) involved death.[9] However, the MHRA acknowledges "significant concerns" that not all locally recorded incident reports are being submitted to the MHRA.[10]

Our attempts to get numbers of adverse events for specific devices were unsuccessful. The Freedom of Information Act is over-ridden by medical device legislation. Article 20 of the EU medical devices directive states: "Member States shall ensure that all the parties involved in the application of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks."[7]

And, in terms of the denominator, there does not seem to be accurate figures for the number of devices used, or even which devices are in current use, nor how many have been replaced or discarded. Obviously this information is most critical for high risk class III devices. But unfortunately the MHRA does not hold a list of these devices.

Should the system be changed?

Medical devices are essential for modern health and social care, and regulatory oversight of devices must tread a fine line. A balance is needed between providing a regulatory environment that encourages the design and manufacture of medical devices and providing safeguards so that people who use devices can be confident they have been properly examined. Moreover, approval of medical devices involves cooperation and affects trade not just within Europe but worldwide.

We found a serious lack of transparency in the data available for independent scrutiny. We were able to use some of the publically available information from the MHRA website, but this was often insufficient to address our main research aims. Unlike the US, where some information can be obtained from the FDA under freedom of information laws if necessary, in the UK this proved impossible. As a result we were not able to quantify the number and types of device failures, their effects on morbidity and mortality, or the quantity and quality of premarket data submitted for approval. So, although we know there were 2124 field safety notices and 447 medical device alerts between 2006 and 2010, we do not know what proportion of the total number of devices in use these represent. We were wholly unsuccessful in obtaining details from manufacturers of premarket data used in the approval of devices that were later recalled .

Concerns about lack of premarket data have previously been expressed by Susanne Ludgate of the MHRA, who stated in 2010 that she was "appalled at how many devices are brought to market with a lack of appropriate clinical data." [11] She directed particular criticism at the shortcomings of the notified bodies—for example, in failing to assess clinical data adequately and their unwillingness to challenge companies. The MHRA says it is planning substantial changes to its strategy for handling adverse incident reports, which will include an "expanded and developed system for identifying, analysing and acting upon emerging incident signals, patterns and trends."[12]

A unified system of approval in Europe has the potential not only to reduce duplication in terms of device approval, but also to maintain commercial viability for the medical technology industry. Currently there are proposals being considered at a European level to rationalise the existing regulations for several areas, including premarket assessment. These propose the need to "Strengthen the notified body assessment in terms of demonstration of competence, impartiality and transparency, providing for timely and uniform action in the areas of vigilance and reinforced market surveillance."[13]

Given the ubiquity and variety of medical devices in modern healthcare, it is inevitable that a proportion will fail to perform as expected, or even cause harm. What seems unacceptable is a system of regulatory approval for devices (most of which are paid for in the UK by the NHS) that lacks even a basic level of transparency for independent evaluation. Patients and clinicians

need to know the evidence for effectiveness of any medical device, as well as its potential harms.

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