

EDITORIAL

Imperfect regulation of implants

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Towards the end of last year, a prominent UK newspaper carried a leading article 'Revealed: faulty medical implants harm patients around the world'.¹ This was followed shortly after by a BBC News article on the same subject.² The Implant Files Project, an international group coordinated by the International Consortium of Investigative Journalists, published some impressive statistics about implant problems. The main targets were meshes for pelvic floor and hernia reconstruction, breast implants, cardiac pacemakers and a contraceptive, but orthopaedics did not escape unscathed. Problems with total hip, knee and intervertebral disc replacements also featured prominently. Even allowing for journalistic dramatisation and over-simplification, the figures quoted are worrying. Between 2015 and 2018, 62 000 adverse events with implants were reported in the UK alone, a third of them causing serious complications, including 1 004 deaths. In the USA the FDA recorded 5.4 million events over the past decade, with 500 000 implants requiring removal, and 83 000 deaths.

Prof Derek Alderson, the president of the Royal College of Surgeons, was quoted as saying there had been enough incidents involving flawed devices to 'underline the need for drastic regulatory changes', including the introduction of mandatory national registries for all implantable devices.

'In contrast to drugs, many surgical innovations are introduced without clinical trial data or centrally held evidence,' he said. 'This is a risk to patient safety and public confidence.'

Three years ago, I wrote in an editorial for this journal, 'New techniques need to be validated independently before, not after, they are released on the market. And as commercially naïve, enthusiastic and adventurous surgeons we must learn not to confuse novelty with progress'. I still feel the same, and think we need improved enforcement of the present imperfect regulation of implants.

The criticisms of the present system can be reduced to the following:

- absence of independent clinical trials of implants in humans (as opposed to pigs!) before their release on the market
- failure of manufacturers to respond constructively to complaints about their products
- failure of manufacturers to reveal previous rejections by regulatory bodies when making application to a new body
- considerations of commercial confidentiality obstructing enquiries
- acceptance by a regulatory body of an implant on the grounds of approval by another regulator, or similarity to another implant, without performing an independent evaluation

Medical implants in the USA are licensed by a single body, the reputable FDA, although the process is slow. But in the EU there is no overall regulator; and a 'CE mark' of approval can be issued by any one of 58 'Notified bodies'. These are non-governmental companies, and if one declines approval of a product, application may be made at another one with no need to disclose the rejection elsewhere. Regulation in the EU is due to be upgraded in 2020, but apparently there is doubt as to how effective this will be. The Medicines Control Council of South Africa is the official regulator in this country but it is dysfunctional.

So should we simply rely on European or USA licencing for protection even though their processes are open to criticism? I think this would be a mistake for two main reasons and believe that that we need to evaluate any implant under South African conditions, while remaining alert for problems encountered in other countries. My first reason is that different countries have different profiles of patients and implant use, and different surgical traditions or preferences, often regional. This may skew results in different locations, such as our country, and local registers are needed to identify poor performers. There is a second important aspect. Implant problems can be divided into design errors, which would apply to every implant used, and manufacturing problems where a certain batch of implants may be flawed for some reason. Design errors in devices from reputable manufacturers will become obvious in time, especially in countries where large numbers of the implant are used and registers are kept. This would allow recognition of a problem implant irrespective of where it is used. Manufacturing problems and implants from little known manufacturers may be different, however. In a small market like South Africa, it would be quite possible for an occasional sub-standard batch of implants from a recognised company to form a substantial proportion of an importer's order. This would cause a localised problem with an implant that is not noticeable against the background of its success elsewhere, and would only be picked up by a register in the area where they are concentrated. Another problem is the use of cheap implants from unknown sources often in the Far East. They usually have no history of performance and are imported by opportunistic entrepreneurs, often to supply a Provincial tender. Again, any low-cost devices that are below standard would only be recognised if their use is recorded and tracked. So South African implant registers may be very important for the identification of such problem batches or imports, and the patients who are at risk following their use.

I agree with Prof Alderson that mandatory registers for all implants have become necessary. South African implant registers

would certainly make a contribution to the global experience, but they are probably more valuable for their ability to recognise inappropriate implant use and manufacturing defects in this region. The government cannot be expected to organise this without our help, and it would be ridiculous to expect the fiercely competitive orthopaedic industry to police itself. I believe the onus is on each surgeon to record his implant use in a register owned and administered by the respective professional body – in our case the SAOA and its sub-groups. We are all aware of past problems in South Africa with arthroplasty registers, and this would probably need some form of legislation to motivate our less compliant colleagues. As a back-up, the hospital groups should also be made responsible for recording implant use, including details of the patient and surgeon. Costs could be recovered from a small levy added to the price of each implant. The medical aids could be expected to support such registers as they would benefit financially from identifying and eliminating substandard hardware and their attendant complications. Medical aid and hospital administration systems could certainly be programmed to record and forward data to central registers at minimal cost and inconvenience to all concerned.

I have written this editorial as one with no experience of implant registers or the practical problems around them. I realise this is a controversial subject but I hope that a dispassionate, objective examination of the matter will result in increased understanding and support for the SAOA and the leaders in our speciality in their efforts to achieve this ideal. I believe we have a professional obligation to do so.

References

1. *The Guardian*. 5 November 2018
 2. *BBC Health News* 25 November 2018
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