In response to the Editor's Choice: **The trouble with medical devices**

- Fiona Godlee

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1. The Regulation of Medical Devices

- **Alan G. Wade**, **Director**

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Your feature edition (Published 18 May 2011) has certainly highlighted the problems of the regulation of medical devices, particularly in Europe. Attempts to draw parallels between drug regulation and that of medical devices however can only be taken so far.

In general implants such as prostheses and stents are designed for long-term use with modifications and innovations often implemented to extend the life rather than the short-term functioning of the device. In order to show the benefit of innovation any traditional trials would require to run for many years. This potentially is extremely expensive and certainly if required prior to marketing approval would curb innovation and delay the introduction of devices with potential loss of benefit to patients. Device manufacturers and regulatory authorities are also meant to have in place an organised system for collecting any safety concerns/ reports after licensing and report on these regularly. There is little evidence that this is occurring and raises a bigger question as to how we can assess the risk/benefit once a device is on the market.

The solution may well lie with the patients themselves. We have developed a unique web-based system supported by nurse led telephone responses to collect patient reported outcomes (PROs) from patients who voluntarily register to supply data (thus producing a prospective patient registry). Having successfully undertaken several projects with drugs and vaccines we have shown that patients can satisfactorily identify both benefits and adverse events. We are currently extending the system to medical devices and are attempting to interest regulators, producers, clinicians and of course patients themselves.

At the very least regulators and device manufacturers should transparently report risk/ benefit on patients after licensing and make this knowledge available to patients/prescribers/ users of devices.

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