Health and Social care Committee

Access to medical technologies in Wales

MT ToR 4 – Declan O' Doherty

I am responding to your letter of 23 august 2012 in my capacity as Chair of the Orthopaedic NSAG.

The aim of Trauma and Orthopaedic Surgery is to restore painfree mobility and function and a major challenge is to get it right first time. For our speciality delivering this safely and effectively depends upon the appropriate use of technology. While we are aware that there are barriers to the adoption and implementation of healthcare technologies, we have also recently seen the recall of a widely used hip implant because of device related adverse events and a number of other implants have subsequently been withdrawn from the market. We need, therefore, to put in place systems that restore public and professional confidence in the way new medical devices and technologies are brought to the market.

Our specialist society (the British Orthopaedic Association) on whose council I am currently the Welsh representative has been working with the MRHA (Medicines and Healthcare products Regulation Agency) and other relevant bodies on a project called 'Beyond Compliance' recognising that the safest, best and most successsful systems are those that always go beyond merely complying to the bare minimum that regulations require. The emphasis has been on orthopaedic implants but there are lessons that apply to all medical technologies.

We recognise the need to improve the rigour of processes around CE marking.

We need to recognise which implants/technologies are simply uncontroversial modifcations of what is currently available and could potentially be introduced into practice immediately . But devices/technologies which contain entirely new design features or are previously untested on humans should have a phased clinical introduction. This implies that there is a specific 'Assessment Committee' and it also implies the need for a specific assessment procedure to assess performance and safety before full introduction.

We recognise the need for rigorous post-market surveillance. In orthopaedic surgery this involves the use of NJR (National Joint Registry) and PROMS (Patient related outcomes measurement).

The first priority therefore is to prove that new technologies are safe and effective.

However, the available evidence (as noted by NHSadopttech at Manchester University) suggests that proven patient safety and clinical effectiveness are not of themselves sufficent to ensure the adoption and implementation of new technology. Rather, there are organisational and policy barriers and the many stakeholders, from commissioners to finance directors to doctors to project managers, can have a disproportionate effect on implementation ie it only takes one 'no' to kill a project. The NHS Technology centre has a roadmap for 'creating sustainable change' which

highlights the hurdles to overcome. It would be useful for Wales to identify its key stakeholders and its roadmap, work out where the hurdles are and how they can be overcome.

In addition, in the current financial climate, it may be necessary to have a process that assesses the relative merits (in terms of effectiveness and 'bang for buck') of two technologies competing for the same resource eg insulin pumps versus a new hip implant.

I hope that this is helpful to you. The Orthopaedic NSAG would be delighted to be involved in your inquiry.
--
Kind regards

Declan O'Doherty