Response to a request by the National Assembly for Wales's Health and Social Care Committee for comments on the SCOPE of an inquiry examining the appraisal of, and access to, medical technologies.

Comments from

Pete Phillips (Director, Surgical Materials Testing Laboratory),

June Scott (NWSSP Procurement) and

Alun Tomkinson (Consultant ENT Surgeon, UHW).

Introduction

The above named authors have a wide experience in the testing, assessing and procurement of medical devices for the NHS in Wales. Our views in this document are mainly focussed on medical devices, but much of this also relates to medical technologies and techniques.

Background

Of particular interest in this matter is our experience when SEAC mandated a move to novel single-use tonsillectomy instruments, which resulted in a doubling of return to theatre rates due to post-operative bleeding. Subsequent work by PP, JS and AT on behalf of the Welsh Assembly Government resulted in the ability to continue to comply with the SEAC requirements and an avoidance of further patient harm through a well controlled and safe procurement exercise and continued surveillance where appropriate. Our experiences have been widely published and publicised.[1]

The surveillance programme has recently demonstrated differences in complication rates with the technique used for tonsillectomy (for example, coblation, a novel type of surgical procedure, where the post-operative bleed rate is significantly greater compared to traditional methods[2]). This information is highly valuable to surgeons and their patients.

SMTL, funded by the Welsh Government, regularly test devices which do not meet International standards, or where the performance is unacceptable, even though the devices themselves can be marketed legally as they bear the CE mark. For example, recent testing by SMTL of the novel non-Luer syringes, to comply with the NPSA requirements, has demonstrated that one CE marked device was unsafe for the storage of chemotherapy agents or other medicines, with leakage rates greater than 40%. The same devices demonstrated concerning deficiencies when assessed using mannequin simulations.

Other authors have noted problems with medical devices, proposing similar assessment schemes to those used by ourselves – a combination of laboratory testing, audits, and non-clinical assessments by clinicians – to ensure that unsafe/unsatisfactory devices are eliminated before they are introduced into the clinical environment. For example the

1 Clin Otolaryngol. 2005 Apr;30(2):135-42.

2 Laryngoscope. 2011 Feb;121(2):279-88

ADEPT paper published in Anaesthesia in 2011 reflected our concerns about the introduction of novel technologies and devices[3]. Cook[4], in an editorial for Anaesthesia in 2003, noted that the performance of newly introduced disposable laryngoscopes was less good than standard equipment, and yet the market was flooded with these CE marked devices with negligible evidence of their safety.

Implications for medical device procurement

At present, the assessment of new medical devices can be *ad-hoc*. However, our experience over nearly 30 years of assessment and procurement demonstrates that there is value in controlled, scientific assessments of these devices before they are used in patients. We believe that the value is threefold:

1. The assessments can help prevent patient harm, by eliminating poorly designed devices before they are used on patients;
2. Devices which are shown to be acceptable *in-vitro* are more likely to be accepted and adopted by clinicians;
3. The assessment intelligence can be used to drive evidence-based procurement for the NHS in Wales;

It is clear that these assessments do not only provide value with new and novel devices. As the NHS in Wales attempts to obtain better value for money in procurement, a plethora of cheaper devices is becoming available, in particular from the Far East. Some of these competitively priced devices are safe and acceptable, whilst others are not.

Within the welsh NHS, Procurement, SMTL and various clinicians (mainly through the Procurement structures) attempt to assess new devices as well as newly-sourced devices (i.e., devices which have been around for a while in standard configurations, but which are now available much cheaper from China in particular). Outside of this grouping there is a lack of joined-up thinking.

However, the grouping of Procurement, SMTL, clinicians and the various committees within the Welsh NHS is, in our view, a significant step above the systems in use elsewhere in the NHS.

The Welsh Office in the 1980s implemented a unique and far-sighted approach to dressings and medical devices through the funding of a testing laboratory which was intimately linked with procurement. There is a now a clear opportunity to implement a system similar to the AWMSG[5] for medical devices, allowing Wales to combine their experience of controlled procurement of devices with the strategic lessons learnt from the AWMSG.

As procurement is an essential aspect in acquiring medical devices and technology, we believe that there are opportunities to re-assess how the Welsh NHS funds, plans, coordinates and manages the procurement of medical technologies. This re-assessment should cover potential duplication and collaboration opportunities.

---

3 Anaesthesia. 2011 Aug;66(8):726-37.

4 Anaesthesia. 2003 Feb;58(2):107-10

5 All Wales Medicines Strategy Group

Scope

We think that the Scope of the inquiry should encompass:

1. Whether a committee similar to the AWMSG should be constituted, which would deliver 'joined up thinking' in the medical device/technology arena for NHS Wales;
2. Whether this committee or another grouping can or should be responsible for horizon scanning for new devices and technologies, as well as examining the trailing edge of medical technology, where many feel clinicians are most exposed, due to the cost-based introduction of me-too devices;
3. How to increase clinician involvement in non-clinical (for example, laboratory and mannequin testing) and clinical assessments (in patients) of medical devices through clinical engagement;
4. The potential for setting up an NHS-based non-patient evaluation centre (covering for example, mannequin assessments, simulators, and human factors issues);
5. The role of surveillance, which can provide a safety-net to monitor the introduction of new devices and ensure they are not causing an increase in patient harm;
6. The role of health economics and commercial analyses in the procurement process, to ensure that the NHS in Wales is spending its money wisely, and to aid in decision-making with regards to novel technologies;
7. Funding mechanisms specifically for high-cost technologies (for example, CT/MRI);
8.

In summary, we believe that there is the opportunity for the Committee to investigate and make recommendations on a robust infrastructure which is designed to assess medical device and technology evidence independently, to help inform clinicians and the procurement process as to whether they should be introduced, and to drive evidence-based procurement of medical devices and technologies in the Welsh NHS.

The authors would be interested in providing further information to the committee if it wishes, and in participating in the subsequent inquiry if established.

FOR FURTHER INFORMATION PLEASE CONTACT :

Peter Phillips Director SMTL Princess of Wales Hospital Coity Road Bridgend, CF31 1RQ Tel: 01656-752820 pete@smtl.co.uk	June Scott Head of Contracting NWSSP – Procurement Services Bevan House 25-30 Lambourne Crescent Llanishen Cardiff, CF14 5GT Tel: 029 2031 5500 June.Scott@wales.nhs.uk	Alun Tomkinson Consultant ENT Surgeon University Hospital of Wales Heath Park Cardiff, CF14 4XW Tel: 029 2074 7747 Alun.Tomkinson@wales.nhs.uk