Health and Social care Committee

Access to medical technologies in Wales

MT ToR 33 British Pain Society

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British Pain Society Response

1. The uptake of medical technology in Wales, and the possible barriers to effective new (non-drug) treatments being more accessible to patients;

'Medical technology' needs to be defined in order to be clear about barriers and what is actually made available to patients. It has been a little problematic in responding to this request as there are many different technologies available from self-management Apps through to implantable devices. Given cost issues and ensuring that the majority benefit from technology the response provided her focuses on Apps and web technologies. Interestingly more than 500,000 medical technology products are available today. Medical technology apparently represents only 6.3% of total healthcare expenditure in Europe (http://en.wikipedia.org/wiki/Health_technology#Definition_of_medical_tech).

Apps

From the perspective of pain management, there are a number of patient Apps available in the UK looking at assessment, goal setting and pacing, etc. However, we are not aware of any developed Apps specifically designed and applicable to the patient population in Wales. Therefore, we suggest a guarded conclusion being that uptake of medical technology in Wales has been slow. Cardiff University is developing an App for opioid conversions to aid clinical decision making and safety. A small number of Apps have been developed for pain issues by clinicians working within the NHS in the UK, however, the majority of pain Apps have been developed in the USA and are limited in transferability. In Wales we have no central repository of these so it is unclear what is available and currently, other than MHRA, there appears to be no 'kite' mark for quality and evidence base for existing Apps. We are not aware of any audit of patients in pain to establish whether they are using Apps to support their pain management and self-management and this may need to be raised with Public Health Wales as a potential for investigating. It is important to ensure that patient are directed to appropriate Apps. Barriers tend to be generic and include, but not limited to, resources available, lack of funding, time and adoption, poor knowledge base and guidance and poor engagement by users.

Websites/e-learning

A similar conclusion to the above comments re Apps can be reached for e-learning and websites in Wales. We do have Health Working Wales and Welsh Backs which are very important sources of information for patients but we are not aware of any other bespoke Welsh e-learning patient information sites for pain. It would be extremely useful to have http://www.paintoolkit.org/ available for the Welsh pain population; they have produced evidence of improvements that are cost effective and very competitive when compared to the poor outcomes of some of the other treatments available that are costly to the Welsh pain population. Barriers are similar again to the above and also include lack of promotion and engagement with the sites, lack of motivation from the patient

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population and user ability, network connectivity and access to computers and other hardware (also an issue for Apps).

2. Current appraisal processes for new medical technologies
Within the evolving area of Healthcare mobile applications, there is currently little regulation, however there is the formation of emerging best practice.

It is worth noting the guidance provided by the Medicines and Healthcare products Regulatory Agency (MHRA), in relation the development of mobile applications and the Medical Device Directives.

If Decision Support software "*performs a calculation or the software interprets or interpolates data and the healthcare professional does not review the raw data, then this software may be considered a medical device*."
http://www.mhra.gov.uk/Howweregulate/NewTechnologiesForums/DevicesNewTechnologyForum/Forums/CON084987

The explicit addition of the word "software" could capture most, if not all, health apps.

It is understood that the Mersey Burns app is the first publicly available app to be registered with the MHRA as a Class I medical device and therefore the first publically available UK app to carry the CE mark. (see http://www.d4.org.uk/research/regulation-of-health-apps-a-practical-guide-January-2012.pdf)

This is a significant case study and demonstrates that if an application is developed which presents "*complex calculations, which replaces the clinician's own calculation and which will therefore be relied upon, then it will certainly be considered a Medical Device*", according to the guidance from the MHRA.

If the software has applications which consist of both medical device and non-medical device modules, the modules which are subject to the Medical Device Directives must comply with the requirements of the Medical Device Directives regulated by the MHRA and must carry the CE marking. The non-medical device modules are not subject to the requirements for medical devices. In terms of website content and eLearning modules, which are associated with institutions, organisations and public bodies, these will adhered to the internal validation/approval process set in place by the creators institute. This process may vary from organisation to organisation.

3. The decision-making process in NHS Wales on funding new medical technologies/treatments.
In terms of chronic pain management, there are a set of directives which are mandatory and stress the importance of e-learning. However, this was written in 2008 and Apps had not really made an impact. Whether funding through the Chronic Conditions section at the Welsh Government is possible is unclear. The Orthopaedic Innovation Board has funding from the Welsh Government to reduce orthopaedic surgery and improve community resources. The last funding round will be in March 2013 and a bid submitted to work on some App or e-learning resource may be possible but this would need clear evidence of outcomes and costings. Heath Boards are struggling with addressing finances at present and so it would be unlikely that they would fund such developments and centralised funding for Health Boards has now ceased. Charitable, pain-related organisations also may be interested in developing self-management Apps and e-learning. Cardiff University is working with Public Health Wales to address early back, hip and knee pain management and developing a self-management App and e-learning has already been discussed.

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