National Assembly for Wales

Health and Social Care Committee

Access to medical technologies in Wales

Evidence from Welsh Health Specialised Services Committee (WHSSC) – MT 36

GIG CYMRU NHS WALES

Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru (PGIAC)

Welsh Health Specialised Services Committee (WHSSC)

Inquiry into Access to Medical Technologies In Wales

Written response from the Welsh Health Specialised Services Committee (WHSSC)

1. On the 01 November 2013, the National Assembly for Wales Health and Social Care Committee invited a response from the Director of Tertiary and Specialised Services, Welsh Health Specialised Services Committee into the access of medical technologies in Wales. The following document represents a response to the terms of reference and scope of this inquiry. WHSSC would be prepared to provide oral evidence through the office of the WHSSC Medical Director if invited to do so by the inquiry.

2. To examine how the NHS assesses the potential benefits of new or alternative medical technologies. In the experience of WHSSC the following assessment processes that are applied in NHS Wales are listed in order of robustness of method and techniques applied in the assessment.

2.1. **National Institute of HealthCare Excellence (NICE) technology appraisals**. These exist in the form of two main products currently – Technology Appraisal Guidance (TAG) and Interventional Procedural Guidance (IPG – see 2.3). Both these products differ in their status in relation to Wales. TAG are currently mandated for implementation in Wales under the existing arrangements between WAG and NICE. Although normally associated with the evaluation of pharmacotherapeutics, TAGs on medical technologies have also been produced covering medical technologies (e.g. TA95 ***Implantable cardioverter defibrillators (ICDs) for the treatment of arrhythmias***). This assessment process is extremely robust, taking into account structured evidence on both clinical and cost effectiveness and clinical expert and public stakeholder perspectives. With the development

and expansion of the NICE MedTech programme, it is envisaged that this method will be applied to an increasing number of Medical Technologies.

2.2. **Health Technology Assessment** is one of a suite of five open access journals published by the NIHR Journals Library, providing an important and permanent archive of research funded by the National Institute for Health Research (NIHR). The journal publishes research funded by the Health Technology Assessment (HTA) programme, which is the largest of the NIHR programmes. Set up in 1993, the HTA programme funds independent research about the effectiveness, costs and broader impact of healthcare treatments and tests for those who plan, provide or receive care in the NHS. This appraisal is very robust and frequently acts as a precourser to NICE TAG. HTA does not carry any mandatory status to fund, but its appraisal methods are rigorous and internationally recognised.

2.3. **NICE Interventional Procedure Guidance (IPG).** This previously was the most frequent route for the assessment of new or relatively new medical technologies by NICE. IPGs do not carry a mandatory status in NHS Wales, assess evidence on clinical effectiveness based on lower quality of evidence relative to TAG and do not take into account any data on cost effectiveness. IPGs are primarily concerned with safety data for the intervention in question, secondary to effectiveness data.

2.4. **Welsh Health Specialised Services Committee, Evidence Evaluation and Prioritisation Framework.** In April 2011, WHSSC agreed to the development of an evidence evaluation and prioritisation framework for the assessment of new and existing medical technologies, interventions and packages of care.

2.4.1 An appraisal framework was developed to apply high standards of scientific rigour and appraisals science, including the assessment of evidence for clinical and cost effectiveness, epidemiology and impact assessment based on budget, organisational, patient and public and equality assessments.

2.4.2 In 2013/14 this process assessed 85 different intervention and packages of care in relation to cardiothoracic, cancer, rare diseases, renal, mental health neurosciences programmes directly linked to a governance framework centred on clinically informed resource allocation.

2.4.3 This multi-criteria decision analysis is to be continued this year for a further 40 assessments. The products of this work are directly related to the decision making architecture of WHSSC to inform the Annual Plan and commissioning of specialised services in Wales.

2.5. **Welsh Professional Guidelines**. These are guidelines and recommendations developed by Welsh professional groups. The methods

of evidence appraisal are unpublished, vary in quality significantly between the different groups and are frequently prone to local professional bias. They are usually based on local interpretation of evidence, rarely if ever include data on cost effectiveness and/or quality of life and are usually based on clinical opinion;

2.6. **Local Drugs and Therapeutics Committees.** These local Committees make hospital-based decisions on access to a range of medical devices, frequently without recourse to a robust health technology assessment. The case for access is promoted by interested clinicians, with resource decisions often being made at hospital directorate level. Frequently, the wider implications of these decisions across the organisation or for other organisations may not be considered have poor corporate oversight, which may lead to 'incremental creep' rather than a systematic approach to patient access;

2.7. **The Individual Patient Funding Request (IPFR) process in Wales**. This constitutes the lowest grade and quality of appraisal process currently in Wales. Each Health Board is required to run an IPFR Panel which considered individual cases on the basis of 'exceptionality'. The quality of appraisal varies considerably between Health Board and most Panels operate without robust methods of evidence appraisal. WHSSC would agree with the conclusions of the *Review of the appraisal of orphan and ultra-orphan medicines in Wales* which has indicated that the IPFR process needs to be linked to much strong appraisals process such as the AWMSG process for drugs or any MedTech appraisals process that may be established in Wales in the future. The *Review of the appraisal of orphan and ultra-orphan medicines in Wales* was recently submitted to the Minister for Health and Social Services on Oct 2013.

3. To examine the need for, and feasibility of, a more joined up approach to commissioning in this area.

3.1 It is the opinion of WHSSC that a prospective and systematic approach to evidence-based commissioning and resource allocation is urgently required and this was the rationale for the establishment of the process of specialised services appraisal summarised in 2.4. This approach is being further developed in 2013/14 and includes the establishment and feasibility of this approach at Health Board level for the integration of specialised and non-specialised services through the developing concept of collaborative commissioning (e.g. work undertaken with Aneurin Bevan Health Board and WHSSC).

3.2 Furthermore, the concept of developing specific clinical access policies, service specifications and quality and outcome dashboards would increase the feasibility of a more joined up, technically correct and precise approach to both patient care and the introduction of new technologies in Wales. It is beyond the scope of this short response to explain the development of this approach in any further detail and

WAG may wish to question WHSSC and pathfinder Health Boards separately on this issue.

4. **To examine the ways in which NHS Wales engages with those involved in the development of new medical technologies**. There are three critical aspects to this from the WHSSC perspective.
   4.1. *Research and Development*: commenting on the interactions between the manufacturing industry and the R&D infra-structure in Wales in detail is outside the scope of this report. However, there is a clear need to increase efforts on MedTech R&D in Wales and to highlight to the MedTech Industry to accept the need for good quality research to be conducted before attempting market access in NHS Wales. MedTech companies are significantly behind the thinking and practice of their pharmaceutical counterparts although the acknowledgement of high quality research has been increasing accepted in recent years. Significantly more could be achieved in collaboration with the industry over this issue;
   4.2. *Involvement in appraisal and assessment of medical technologies*. This is more difficult due to the current lack of a formal appraisals process for MedTech in Wales. The current level of involvement with the MedTech industry is usually at the procurement rather than appraisal stage although, WHSSC did run a manufacturers stakeholder day as part of the Cardiac Review inviting the Association of British Healthcare Industries (ABHI) to present in 2007 on cardiac technologies. Other organisations, notably some Providers in Wales have had more success in interacting with MedTech as part of a formal programme of capital replacement scheme (e.g. Velindre NHS Trust, platform for stereotactic ablative radiotherapy) but the quality of this varies considerably;
   4.3. It is the opinion of WHSSC that appropriate levels of engagement with the ABHI are essential and would be mutually beneficial to patients and the population of Wales. However, this needs to be undertaken as part of a transparent process of stakeholder engagement linked to a clear and robust appraisals process for MedTech in Wales;
   4.4. *Procurement Level.* This is currently the most frequent level of interaction with the MedTech industry. As a result, the focus tends to be on cost and price point rather than quality or evidence of effectiveness and is one of the primary reasons why access to poorly evidenced technologies occurs.

5. **To examine the financial barriers that may prevent the timely adoption of effective new medical technologies and innovative mechanisms by which these might be overcome**.
   5.1. WHSSC would like to make the following distinction. There are financial barriers that are entirely appropriate as they provide a framework of due diligence, expected in the delivery of high quality and

cost effective, affordable and sustainable public services; there are financial barriers that are inappropriate related to a financial process associated with 'silo budgeting' and inter-organisational financial disputes.

5.2. *Appropriate financial 'barriers'*: In particular, the clinical and scientific community consistently conflate these two very different financial contexts. The robust assessment of what has been termed broadly 'cost effectiveness' is a cornerstone of public accountability and demonstration of 'reasonableness' in the allocation of public resources. This concept, often inappropriately shorthanded as 'value for money' has been embedded as part of technology assessment since the early 1990s and subsequently endorsed by the Office of Health Economics and HMR Treasury as 'best practice'.

5.3. The methods associated with these sciences are frequently highlighted as 'financial barriers' to implementation. The assessment of cost effectiveness is being ignored by some new processes being developed for early access to new Medtech in NHS England (e.g. *Commissioning Through Evaluation* for SIRT and Selective Dorsal Rhizotomy).

5.4. Therefore assessment of cost effectiveness is a vital component in assessing the effectiveness of any MedTech innovation. It is suggested by WHSSC that this should be *strengthened* in Wales and advice should be sought from Swansea School of Health Economics (Professor Ceri Phillips), Department of Health Economics, University of South Wales (Professor David Cohen), Centre for Economics in Health, University of Bangor and NICE for advice on this issue, relating to both appraisals sciences and budget impact assessment ;

5.5. *Inappropriate financial 'barriers':* Pursuant to there being a robust appraisals process for MedTech in Wales, the management of 'inappropriate' financial barriers could be achieved by having:

5.5.1. A clear transparent and robust process for the evaluation of medical technologies, linked to prioritisation;

5.5.2. Resource allocation decisions relating the principles of clinical and cost effectiveness, timeliness and clear decision making and accountability;

5.5.3. Linked to process for monitoring and re-evaluating the clinical and quality outcomes produced following implementation.

6. Conclusion – Wales requires a Medical Technologies Appraisals Group which must include representation and engagement with commissioners.