

Response of the All Wales Medicines Strategy Group to the National Assembly for Wales' Health and Social Care Committee enquiry into access to Medical Technologies

About The All Wales Medicines Strategy Group

Established in 2002, the All Wales Medicines Strategy Group (AWMSG) provides advice on both new and existing medicines, medicines management and prescribing to the Welsh Government's Minister for Health and Social Services in an effective, efficient, and transparent manner.

AWMSG brings together an expert panel of NHS clinicians, pharmacists, academics, health economists, industry representatives, patient advocates and lay representatives to reach a consensus on the use of new medicines and on policies that promote the best use of medicines for patients in Wales. All involved work together to ensure equity of access to the most clinically appropriate and cost-effective medicines. The Group's main priorities are:

- Appraisals: To develop timely, independent and authoritative advice on new medicines.
- Medicines management: To develop resources to support prescribers and thereby maximise health gain through the safe and cost-effective use of medicines.

AWMSG works closely (via a memorandum of understanding) with NICE to complement the NICE appraisal programme and thus ensure appraisal of new medicines not on the NICE work-programme.

The following response draws on the experience gained by AWMSG in Wales since 2002, and its possible application to the area of medical technologies.

Comments in relation to the terms of Reference of the Review.

1. To examine how the NHS assesses the potential benefits of new or alternative medical technologies.

In addition to its work on the appraisal of new medicines, NICE publishes health technology appraisals (HTA's) of selected new medical technologies (including devices and diagnostics) through its Medical Technologies Evaluation Programme (MTEP). Just as NICE technology appraisals of medicines are relevant and valuable to NHS Wales, we believe that the NICE technology guidance is produced to a high standard and is likely to be highly relevant to the needs of patients in Wales. The programme is supported by a Medical Technologies Advisory Committee (MTAC) with a member (the Vice-Chair) who works in NHS Wales. Since December 2010, NICE's MTAC has approved 15 pieces of guidance on medical technologies and a further 8-9 are in preparation. The Cedar Evaluation Centre based in Wales is an active External Assessment Centre for medical technologies for NICE and has a strong track record of delivery in this area.

The difficulty with the NICE guidance on medical technologies is that unlike corresponding guidance on new medicines, it is not mandatory and so it is up to commissioners in Health Boards in NHS Wales and related organisations to make decisions on the uptake of the guidance. This can result in variation of access to clinically-effective and cost-effective technologies across Wales, or in delays in decision-making, particularly when the initial outlay may be significant, and the cost benefit to be made occur sometime into the future. In

addition, only selected medical technologies (around 5 per year to date) are assessed by NICE. A proactive approach to HTA of new medical technologies in Wales will help to inform central strategic planning and support existing or future prioritisation frameworks

We note that detailed information about clinical effectiveness and cost effectiveness of medical technologies is also more difficult to obtain than for medicines, so there are significant differences in the processes for HTA of medical technologies. Nevertheless, it is important that appraisals of such technologies adhere to the same key principles that have been identified in relation to appraisals of medicines. The ideal appraisal process should be transparent, timely, relevant, in-depth and usable (*Garrido et al.* 2008) http://www.euro.who.int/_data/assets/pdf_file/0003/90426/E91922.pdf

Transparency of the HTA process is important to ensure that all stakeholders' involvement is clear to each other, and to ensure that process issues around technology appraisal do not cloud the vitally important scientific issues. Transparency also engenders greater trust among stakeholders, since it also involves full declaration of relevant interests by decision makers

Timeliness of the HTA process ensures that clinically-effective and cost-effective health (including medical) technologies can be made available as soon as possible.

Relevance is important in ensuring that the advice produced is appropriate and applicable to the needs of the user and therefore **usable** by the service. This requires close communication with all stakeholders (particularly clinicians) throughout the HTA process.

In-depth appraisals, using all the available evidence on clinical and cost effectiveness and the expertise of health technology assessors and health economists are vital to give stakeholders confidence in the guidance produced.

Efficiency of the appraisal process for all health technologies is essential if the NHS Wales is to obtain optimum value for money and an avoidance of duplication work.

Independence of the organisation conducting the HTA process from policy-makers and government is vital ensuring that the guidance produced can be trusted, and has sufficient credibility among those working in NHS Wales.

A process for appraisal of medicines not on the NICE work programme has been available in Wales for over 10 years via the All Wales Medicines Strategy Group. AWMSG has conducted over 183 appraisals of medicines since 2002. In October 2010 the high standard of the AWMSG appraisal process was acknowledged by the award of accreditation by NICE's Accreditation Programme, NHS Evidence. This allows AWMSG to carry the Accreditation Mark on any new clinical guidance produced under the accredited process, assuring health and social care professionals that they are accessing some of the best information available online to make informed decisions about patient care. This same rigour should be applied to any future processes developed in Wales for the appraisal of medical technologies.

Several new developments in the assessment of health technologies may also be relevant. NICE are developing a process for the appraisal of **Highly Specialised Technologies (HST's)** and AWMSG has proposed that their guidance on medicines should be adopted in Wales. If medical technologies other than medicines are added to the HST work

programme, the implications to NHS Wales of this guidance in relation to medical technologies will need to be considered.

It is also anticipated that two major amendments to the current NICE methodology appraisal of medicines will be made to address **Value Based Assessment (VBA)** of medicines from September 2014. Firstly, the wider societal benefits of health technologies will be expanded beyond those falling on the NHS, e.g. costs to carers and employers. Secondly, a measure of “Burden of illness” will be considered by NICE in order to reflect the severity of the illness. Burden of illness takes into account both the quality of life as well as the length of life. AWMSG has aligned its appraisal process closely with that of NICE’s Technology Appraisals and so AWMSG has proposed that it will adopt these measures of value in future appraisals when appropriate. The potential implications of this approach to possible future HTA of medical technologies other than medicines in NHS Wales will also need to be considered.

Finally, an important review of the processes in Wales for appraisal of Orphan and ultra-orphan medicines has been published very recently and the possible implications of its recommendations to the appraisal of medical technologies other than medicines will require careful consideration. <http://wales.gov.uk/topics/health/publications/health/reports/?lang=en>

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

Over the thirteen years of AWMSG’s development, it has become more common (as personalised medicine starts to fulfil its potential) for certain new medicines to be linked with “companion” technology products, including companion diagnostics. In addition, the mode of delivery of some medicines is becoming increasingly sophisticated, necessitating technological developments in association with the pharmaceutical product. NICE has demonstrated by its appraisal of medical technologies that “therapeutics” in the 21st century is about much more than just medicines and it has produced critical appraisals of evidence across the whole range of therapeutic modalities. Thus there are 7 items of NICE guidance on diagnostic technologies in preparation. For these reasons we believe that certain medicines and related medical technologies need to be considered alongside each other, indicating the need for a more joined approach to assessment, appraisal and commissioning in this area. It is therefore also vital that the processes that are developed are closely aligned with the Welsh Health Specialised Services Committee, which is tasked with ensuring that the population of Wales has fair and equitable access to the full range of specialised services.

The **horizon scanning** process for new medicines in Wales has developed rapidly over recent years, linked up with other UK centres and helping to inform AWMSG’s appraisal work plan. This affords NHS Wales more information to plan its future budgeting priorities in the prevailing tight economic climate. A similar coordinated approach should also be applied to new medical technologies, since some will have a major immediate impact on costs to the service.

Surveillance systems are vital in ensuring safety for patients. Wales is fortunate in that its relatively small size and well-developed communications networks can potentially ensure better rates of safety reporting. Thus in 2010, and thanks to the work of the Yellow Card Centre Wales (part of the AWMSG support network) the reporting of suspected adverse

reactions to medicines by health professionals and patients in Wales was 50% higher than in the UK overall (*Data from Yellow Card Centre Wales*). A more joined up approach to the central safety reporting of issues associated with medical technologies would provide stronger safety signal generation and thus help to inform NHS Wales of concerns at an early stage. Strong safety systems are also important in informing future commissioning priorities.

3. To examine the ways in which NHS Wales engages with those involved in the development/ manufacture of new medical technologies.

AWMSG has developed a responsive HTA process for medicines that ensures strong engagement with manufacturers before, during and after appraisal. Thus AWMSG was the first HTA body to welcome manufacturers to give evidence at the appraisal process, which takes place in public. NICE, having observed this approach, have since adopted it, and now meet in public with the manufacturers present and able to contribute.

It is recognised that some small manufacturers may have relatively limited health expertise (some health technology manufacturers fall into this category) so opportunity is given for advice from AWMSG network health economists. In addition the HTA process itself is scrutinised by a dedicated user-group which advises the AWMSG steering group about possible enhancements to the HTA process. This transparent approach, if applied to possible future medical technology HTA processes, would ensure that those developing and manufacturing medical technologies would be fully engaged and have a voice in future developments.

4. 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.

It has become clear over the last decade that a positive recommendation by NICE or AWMSG for a medicine does not automatically result in timely adoption of the medicine by NHS Wales. This can occur despite clear mechanisms for the uptake of advice on all recommended (including high-cost) medicines. Thus the barriers to implementation of guidance are not just financial. They are also sometimes related to the slow dissemination of evidence-based advice to local decision makers and prescribers on what treatments are most effective and cost-effective. It should be noted that the majority of medicines appraised by AWMSG are recommended as an 'option for use', and a decision is made by clinicians within the health board as to how best to treat the patient. A positive recommendation does not, by default, mean that it is 'better' than other medicines already available.

The Welsh Analytical Support Unit (WAPSU, part of the AWMSG Support Network) was established in 2010 to monitor implementation of NICE and AWMSG guidance. By monitoring uptake of new medicines, it supports Health Boards in ensuring patients can rapidly access effective and cost-effective treatments in an equitable manner. It also supports Welsh Government in its central strategic planning role and it advises the procurement process in Wales. Its work has also been associated with rationalisation of medicines use and saving of significant financial resources.

We believe it is essential that any new processes for the managed introduction of medical technologies into NHS Wales are supported by robust monitoring mechanisms to ensure timely and equitable adoption of guidance.

Conclusions

We have made specific proposals on how the NHS in Wales might assess the potential benefits of new or alternative medical technologies. We believe that the processes should be more joined up, and feel that this goal is feasible. Not all the barriers to adoption are financial and we have made some suggestions on how these might be addressed. We would be pleased to provide any further details in relation to this submission, and thank the Committee for the opportunity to contribute to the enquiry.

All Wales Medicines Strategy Group, November 2013