Health and Social Care Committee

Meeting Venue:
Committee Room 1 - Senedd

Meeting date:
5 February 2014

Meeting time:
09:05

Cynulliad Cenedlaethol Cymru
National Assembly for Wales

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Agenda

Informal pre-meeting (09:05 - 09:15)

1 Introductions, apologies and substitutions

2 Inquiry into access to medical technologies in Wales: Evidence session 3 (09:15-10:15) (Pages 1 - 28)

Cedar
Dr Grace Carolan-Rees

National Institute for Health and Care Excellence (NICE)
Sally Chisholm

Dr Peter Groves, clinician and vice-chair of NICE's Medical Technology Advisory Committee

3 Inquiry into access to medical technologies in Wales: Evidence session 4 (10:15-11:05) (Pages 29 - 34)

Dr Susan Peirce

Institute of Physics and Engineering in Medicine
Professor Stephen Keevil, President
Professor Colin Gibson, Consultant Clinical Engineer

4 Inquiry into access to medical technologies in Wales: Evidence session 5 (11:15-12:05) (Pages 35 - 38)

Professor Ceri Phillips, Professor of Health Economics, Swansea University

Professor David Cohen, Retired Professor of Health Economics at the University of South Wales

5 Papers to note (Pages 39 - 40)

Letter from Christine Chapman, Chair of the Communities, Equality and Local Government Committee, in relation to the First Minister's evidence session on matters relating to the Welsh language

Document is Restricted

National Assembly for Wales

Health and Social Care Committee

Access to medical technologies in Wales

Evidence from Cedar – MT 33

Cedar response

About Cedar

1. Cedar (www.cedar.wales.nhs.uk) is an NHS-academic evaluation centre which is part of Cardiff and Vale University Local Health Board (UHB) and Cardiff University. Cedar supports decision making in healthcare by providing information and recommendations on:
    - Emerging health technologies
    - Medical devices
    - Diagnostic tests
    - Healthcare interventions
    - NHS service configuration
2. Cedar has an established history of evaluating medical devices since 1977 for a succession of UK government funded NHS organisations. Today, the expertise of the Cedar team make Cedar a generalist NHS evaluation centre, able to tackle a wide variety of medical, surgical and general healthcare topics.
3. The Cedar team has expertise in:
    - Critical appraisal of clinical evidence
    - Health economics
    - Clinical device trials
    - Patient registries and data linkage
    - Observational studies
    - Patient reported outcome measures
    - Technical testing
    - Usability studies

How does the NHS assess the potential benefits of new or alternative medical technologies?

4. There is no consistent, scientific or systematic approach in the NHS Wales to assessing the benefits of new or alternative medical technologies.
5. The first step, identifying new or alternative medical technologies, happens by a number of methods such as clinicians attending conferences, talking with colleagues, reading published

papers or being approached by sales people. Cedar is unaware of any systematic horizon scanning within Wales to identify technologies that are clinically effective and may be cost saving. Cedar has a horizon scanning role as part of our work for NICE in its process for selection of technologies for evaluation.

6. Individual clinicians make up their own minds about the potential benefit of a new technology. There may be varying opinions between individual clinicians within the same department or between different organisations. There may be professional reluctance to adopt a potentially beneficial technology and this can be a significant barrier to adoption. There is some justification for differences of opinion or reluctance to adopt based upon usability and compatibility factors. Usability is not necessarily evaluated during CE marking or in published research studies and this remains a significant information gap.
7. Published research on medical devices is often limited in volume and is of poor quality compared with evidence for pharmaceuticals. There are important reasons why device trials may fail to match the standards of pharmaceuticals studies. The device regulatory process is completely different, as is the market. Well conducted research studies are very costly and device manufacturers may be small or medium sized enterprises with limited research budgets. For devices, the time period over which the manufacturer can expect to make a profit is very much shorter than for pharmaceuticals; manufacturers must constantly improve and innovate to produce new products.
8. There may be many devices that have the same function, but achieve this in a different mode of action. Therefore there is a question about whether the devices should be considered as a class (multiple technology) or as a single manufacturer's product (single technology). If a multiple technology evaluation is undertaken, can the evidence reasonably be lumped together? If a single technology, the evidence may be very limited and as the product evolves, a point may be reached when it become sufficiently changed that past studies are no longer valid when applied to the newer product.
9. Research studies on devices are difficult to conduct in the accepted high quality design of 'double blinded randomised controlled trial'. With a device the patient and operator can be aware of whether an active or 'dummy' device are in use, making blinding impossible. Devices may change the complete patient care pathway, which can be challenging for randomisation. It may be necessary to make a considerable investment in a new technology, with the standard procedure being discontinued, leaving only the opportunity of service evaluation rather than comparative research.
10. More vocal clinicians who are persistent in their demands are more likely to get the technologies they want. Unless the decision makers are fully informed and skilled to make judgements between different demands on limited resources, the decision will not always be the best for the organisation overall. Within NHS Wales there are different people making such decisions, depending largely on the purchase cost. Groups involved in purchasing decisions include clinicians (doctors, nurses, therapists, healthcare scientists), general managers, procurement specialists and estates staff. Budget holders and devolved budget holders have authority to spend up to a particular limit.

11. The prioritisation panel set up within Cardiff and Vale UHB was (briefly) an excellent example of a systematic approach to decision making concerning investment in new services or technologies and disinvestment in out-dated procedures. However it is no longer meeting, since there is no funding to progress any decisions even if there is a good case for adoption.

What are the ways in which NHS Wales engages with those involved in the development/manufacture of medical technologies?

12. Individual clinicians may develop working relationships with representatives of medical technology firms.
13. Commercial research allows the NHS to engage with manufacturers.
14. MediWales is a Welsh Life Sciences Forum and the networking and representative body for med-tech Industry, academics and the NHS. MediWales facilitates collaborative working between these groups.

What are the financial barriers that may prevent the timely adoption of effective new medical technologies, and what are the innovative mechanisms by which these might be overcome?

15. The end of the financial year when budgets are particularly squeezed, or in a good year when there may be a potential surplus; this presents a real barrier to effective decision making. Windfall surpluses, when large amounts of money have to be spent quickly, present opportunities and challenges for decision making. Some individuals have pre-prepared business cases that they can submit rapidly, but there may be better ways to spend the money.
16. Barriers also exist between different parts of the organisation e.g. between directorates, and this is a barrier to adoption. There is no incentive to make overall savings in the organisation if your own part of the organisation would incur additional costs. The Clinical Engineering Department in Cardiff & Vale UHB has had many ideas that would make overall savings, but past experience is that they take on additional work to save costs for the organisation, but without the additional resources required. A more holistic approach throughout the organisation may encourage innovation without the current disadvantages.
17. Lack of funding: Cardiff and Vale UHB has no capital equipment budget this year. It has a huge backlog of obsolescent equipment that presents a risk to patients and the organisation but no resources to replace this.
18. The financial divisions between capital and revenue funding, staff and non-staff reduce the flexibility of the system.
19. The re-introduction of the prioritisation panel would help to overcome some of these issues.

What is the need for, and feasibility of, a more joined up approach to commissioning in this area?

20. A more evidence-based, and consistent approach would benefit patients, and the NHS. An important factor in deciding to adopt new technologies is to identify the position in the care pathway where the technology would be introduced. The care pathway is very important because healthcare technologies can be very disruptive, for example moving care between secondary and primary care. It is important to identify the full impact of the technology, otherwise there may be unintended consequences. Introducing such technologies needs careful planning and full engagement of all parties. Care pathways are not always well defined in NHS Wales. Better planning for the introduction of new technologies would present a good opportunity to ensure that care pathways are defined as part of the adoption process.
21. It is important to identify clearly the patient population who might benefit from the technology. Some technologies might have many potential applications, but perhaps clinical and cost effectiveness evidence for one condition. If the technology were applied more widely, then it may not be effective or it may not present good value for the NHS. This requires joined-up thinking potentially across different specialities.
22. The new intervention must be compared with current standard care in Wales, but it may be prudent to consider other alternative technologies that address the same clinical problem. The new technology needs to be placed within the wider context.
23. Usability factors are important as well as clinical efficacy, safety and value for money. Usability needs to be included in evaluation for a fully joined-up approach to commissioning.
24. NHS England is just introducing 'Commissioning Through Evaluation' which allows limited introduction of new technologies and interventions at a small number of centres, with a requirement to gather evidence, for example though a patient registry, and a plan for evaluating the outcome of the pilot.
25. NICE has the Health Technologies Adoption Programme (HTAP), an implementation team that selects pilot sites (for example a large teaching hospital, and a District General Hospital) to implement guidance. The implementation team at HTAP are able to monitor the implementation and identify the barriers and say how these were overcome. HTAP produce a 'site demonstrator' implementation pack to facilitate widespread introduction of new technologies.

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National Assembly for Wales

Health and Social Care Committee

Access to medical technologies in Wales

Evidence from NICE – MT 11

Inquiry into Access to Medical Technologies in Wales a submission from NICE

1. NICE is an executive non-departmental public body operating within the wider health, public health and social care system. NICE provides guidance to support practitioners and managers in making sure that the care commissioned and provided is of the best possible quality and offers the best value for money. Regulations require NHS bodies to comply with technology appraisal recommendations within three months of publication. The Health and Social Care Act (2012) also places a requirement on the Secretary of State for Health to "have regard to the quality standards prepared by NICE", in discharging their duty to improve the quality of services.

2. NICE looks forward to continuing to work with stakeholders in Wales to develop and promote guidance and other products on medical and diagnostic technologies, using its existing published processes.

3. In response to the well documented barriers that prevent timely adoption of effective medical technologies NICE has developed a Heath Technologies Adoption Programme (HTAP). The focus of which is to work with NHS and Social Care providers, commissioners, patients and manufacturers to identify and resolve adoption barriers to implementation of NICE medical technology and diagnostics guidance. The National Assembly for Wales Health and Social Care Committee may be interested to hear more about this programme and NICE would be prepared to give oral evidence if invited.

National Assembly for Wales

Health and Social Care Committee

Access to medical technologies in Wales

Evidence from Dr Peter Groves, Consultant Cardiologist, Cardiff and Vale UHB – MT 5

The National Assembly for Wales's Health and Social Care Committee Inquiry into the Access to Medical Technologies in Wales
Response from Dr Peter Groves, Consultant Cardiologist, Cardiff and Vale UHB

1) Professional Background – I have been a Consultant Interventional Cardiologist at Cardiff and Vale UHB since 1996 and Lead Clinician for the Structural Heart Disease Interventional Programme since 2010. I have been involved in the NICE Medical Technologies Evaluation Programme since 2006. From 2006-2009 I was the UK Cardiology representative on the Interventional Procedures Advisory Committee and from 2009 to present have been Vice-Chairman of the Medical Technologies Advisory Committee at NICE. I am therefore involved at a UK national level in the evidence-based appraisal of new technologies and also lead a clinical team that is vigilant to the arrival of new technologies which will improve the safety and efficacy of patient care in the Cardiac Department at Cardiff and Vale UHB.
2) The Medical Technologies Evaluation Programme at NICE publishes guidance on new medical technologies. This follows the undertaking of a detailed review of the published evidence on safety, efficacy and, in some cases, cost implications. I would suggest that NICE guidance is as much applicable to clinical practice in Wales as it is in other parts of the UK and that NICE guidance should therefore serve as a reference point for the commissioning and implementation of new medical technologies in NHS Wales. I would propose the strengthening of formal interaction between NHS Wales and NICE that provides mutual benefit to both organizations.
3) The current approach to the introduction of new technologies into clinical practice in NHS Wales is, in my experience, clinician driven. This requires

considerable determination and persistence on the part of clinicians and clinical teams to convince organizations and commissioners alike that a case can be made for implementation. In my opinion, a more pro-active stance should be adopted in Wales to ensure that opportunities are not lost to improve patient care and to ensure that we keep up with developments in other parts of the UK and Europe.

4) In my opinion, processes should be established that specifically facilitate the implementation of new technologies in NHS Wales. The adoption of a collaborative and 'open door' approach to the interaction between clinicians, senior managers and commissioners should be encouraged.
5) Cost implications are fundamental to any new commissioning strategy. I would propose, however, that these be considered in the perspective of the whole NHS. For example, the Medical Technologies Advisory Committee at NICE will only promote the implementation of new technologies in NHS England that are beneficial to patients and are, overall, either cost neutral or cost saving to the NHS. This requires an understanding and consideration of cost expenditure balanced against cost savings with the acceptance that these may be divorced both in temporal and budgetary terms. The outcomes require detailed and independent expert cost modelling but subsequently provide data that have cost implications to the NHS both in the short and long term. New technologies that may be beneficial to patients but are likely to be cost expending overall should, in my opinion, not be discounted by NHS Wales. Under these circumstances, a process is needed to guide organizations, commissioners and clinicians as to how such technologies may be considered and adopted.
6) While I think it would be wasteful of valuable resources to duplicate the work of NICE in Wales, once supportive national guidance has been published it is important, in my opinion, that an all-Wales approach to commissioning is defined and agreed that will prioritise implementation in NHS Wales in the context of acknowledged budgetary constraints.

Dr Peter Groves, MD, FRCP
Consultant Cardiologist,
Cardiff and Vale UHB,

Vice-Chairman,

Medical Technologies Advisory Committee,

NICE 15th October 2013

National Assembly for Wales

Health and Social Care Committee

Access to medical technologies in Wales

Evidence from Dr S Peirce – MT 32

Submission to the National Assembly for the Wales, Health and Social Care Committee

Inquiry into access to medical technologies in Wales

Sir/Madam,

Personal background: I am a Clinical Scientist experienced in the evaluation and use of medical technologies. I have contributed to other discussions and evidence submissions for this inquiry as part of the Welsh Scientific Advisory Committee symposium (2nd October 2013) and also as part of the PATH project (S. Ulucanlar *et al*.). However, I have some additional personal views derived from many years of studying and working in and around medical physics/clinical engineering departments in NHS hospitals (in England and Wales), recent research projects and my time working as a device evaluator in Cedar, both for the Centre for Evidence-based Purchasing (CEP, 2005-2007) and for NICE (2012-present day).

1. In my role as a researcher and evaluator my job is generally to conduct a rigorous and objective review of the available evidence for a particular technology. To carry this out successfully requires a range of specialist skills: information scientist, critical analysis of the published evidence, scientific/technical knowledge of the technology in question, clinical understanding of the patient condition and also the healthcare context in which it might be used. It also demands a substantial time contribution. However, when a new technology is under consideration in the NHS these tasks primarily end up as the responsibility of the clinician. They become aware of new technologies relevant to their practice at conferences/meetings, via colleagues or industry representatives. However these professionals have other priorities and little time to devote to a thorough evaluation of whether the claimed benefits (clinical, resource and/or financial) are realisable in the local context.

2. Is it also debateable whether most clinical staff have the information skills to locate and critically appraise the (likely low volume and low quality) evidence available or the technical/scientific understanding to effectively interrogate the technology. Healthcare staff with the latter skills should be found in the medical physics/clinical engineering departments of hospitals. They are likely to have a whole-system view of the hospital (rather than the silo/departmental view of the clinical or low/mid-level managerial staff) and as such may be ideally placed to identify otherwise unperceived consequences of adoption in other departments. They will certainly have

a well-developed understanding of whole-life costs and requirements of the technology, which again may not be anticipated by a clinician with more immediate and restricted priorities. However, in Cardiff and Vale UHB senior clinical engineers who have previously filled this role have retired over the last few years and not been replaced. I suspect that financial pressures on staffing levels would have resulted in a similar disinvestment and loss of expertise in other hospitals around Wales.

3. NHS staff involved in attempting to adopt healthcare technologies that require relatively formal procedures, approval from multiple levels of managerial hierarchy and input from several departments often complain about the protracted nature of such processes. Absence of key personnel, intermittent committee meetings and other priorities often mean that such decisions can be dragged out over many months or even years. In such an environment it is likely to be the persistent and the powerful who get what they want, rather than those with the best case for adoption. Meanwhile the financial climate, commissioning bodies and governments can change around them rendering such decisions pointless and a waste of expended time and effort.

4. It is a truism by now that 'the NHS has more pilots than British Airways'. Local clinicians and managers are keen to gain personal experience of the technology in question rather than rely on even high-quality peer-reviewed evidence produced in someone else's clinical environment. Reinterpreting evidence in a local context is appropriate given that benefits from device-based technologies are critically dependent on how they are used (in contrast to pharmaceutical technologies). However, such local evaluations can be informal, poorly designed, poorly evaluated and rarely published. Rigorous, transparent, centralised evaluations (such as those produced by NICE/CEP/Device Evaluation Service or Health Technology Assessments) may be used as supporting evidence to convince others, but their rigid methodologies often preclude their perceived relevance to local practice.

5. In practice the lack of immediately identifiable capital finance is rarely the absolute barrier to adoption it is assumed to be. Healthcare professionals can be very creative in their determination to locate funds for their technology of choice. Persistence is a useful quality in those pursuing technology adoption, however is it appropriate for senior clinicians to spend significant amounts of their time acting as fund-raisers? Alternatively, technology has frequently been procured opportunistically simply because money is left over at the end of the financial year or a specific grant is made available with little time in which to make a well reasoned and robustly prioritised purchasing decision. Medical equipment management departments still provide examples of expensive medical devices bought in haste and rarely (if ever) used.

6. Notwithstanding that recent cuts in capital expenditure has left hospitals without the means to replace aging equipment I suggest that simply making specific capital funds available for Welsh Health Boards to acquire innovative shiny new kit is inefficient and ineffective. It will not improve the processes involved or result in more appropriate decision-making regarding the adoption of novel devices. It is a short-term measure that can provide attractive headlines, but will anyone assess whether these devices actually improve services or patient outcomes? How will the success of the Health Technology Fund be evaluated? The money would be better invested in improving future decision-making about healthcare technologies. I believe that the aim should be to save money and time that would be wasted by adopting inappropriate

technologies and develop more effective ways to identify those that can provide realisable benefits. We should not create a centralised 'Welsh NICE' nor necessarily provide each Welsh hospital with it's own 'technology adoption' department. I would like to suggest instead the provision of a regional service that is locally-responsive but with the rigour and transparency to produce evaluations and advice that are relevant to other Welsh (and possibly English) health and social care organisations. Such a service could (for example):

- locate technology solutions to locally-identified problems,
- identify and review the available evidence for a technology of interest,
- advise, design and evaluate local trials and disseminate the results where evidence is insufficient,
- assist with the production of business cases alongside finance, procurement and clinical personnel,
- provide objective leadership for decision-making pathways,
- provide a liaison between industry and the NHS (industry often find access to the NHS difficult and struggle to identify appropriate personnel to contact).

7. Such a service would require a mix of skills and personnel: information scientists, clinical engineers/medical physicists/evaluation researchers, other clinical scientists, healthcare economists, statisticians. It would require close working with the clinical services and management to whom it provides these functions. It should be able to provide a timely, independent and objective response for technology adoption enquiries and should have no vested interest in its recommendations. Local decision-making does not require a full systematic review or randomised clinical trial but this service might also be able to identify and direct questions for which these are appropriate methodologies to suitable organisations or facilities. A wider search strategy for suitable healthcare technologies would also enable smaller, newer manufacturers to have more equitable access to the NHS rather than just large companies with significant promotional budgets. This service could also increase the access to such expertise for smaller healthcare organisations without substantial academic or technological links, thus potentially enabling more equitable access to appropriate technologies at different levels of healthcare provision and supporting national programmes of technology adoption.

I am prepared to give oral evidence if required.

Dr Susan C Peirce
BSc, MSc, MSc, PhD, MIPEM, CSci

National Assembly for Wales

Health and Social Care Committee

Access to medical technologies in Wales

Evidence from Institute of Physics and Engineering in Medicine – MT 19

IPEM submission to the Welsh Government Health and Social Care Committee inquiry into 'Access to medical technologies in Wales'
October 2013

1. Background

Physicists, engineers and technologists play vital roles in delivering our healthcare. The Institute of Physics and Engineering in Medicine (IPEM) is the professional organisation that represents this workforce. We are a charity with over 4,000 members from healthcare, academia and industry.

Our members help to ensure that patients are correctly diagnosed and safely treated for illnesses such as cancer and stroke. They also maintain and manage medical equipment such as MRI and ultrasound scanners, X-ray machines, drug delivery systems and patient monitors.

Their research and innovation leads to new technologies and methods that improve on existing medical treatments. They provide new solutions that enable older people and patients with injuries or long-term conditions to complete everyday tasks.

IPEM's objectives are to:

- Ensure and improve the quality, safety and effectiveness of science and technology in healthcare.
- Maintain high standards of professional development for healthcare scientists, engineers and technicians.
- Ensure that the right medical physics and biomedical engineering workforce is in place and provide our members with the support that they need.
- Encourage research and development and increase the uptake of new knowledge and innovations by the medical physics and biomedical engineering sectors.
- Raise the profile of medical physics and biomedical engineering.
- Build two-way engagement with patients and public.
- Ensure and improve the quality, safety and effectiveness of science and technology in healthcare.

2. IPEM response to the Committee's request for views on the scope of the inquiry

In October 2012, IPEM suggested that the Committee may wish to consider including within the scope of its enquiry the extent to which existing and emerging medical technologies can contribute to more holistic and to more personalised health and social care. For example, by supporting 'self-care' that may include 'care closer to

home' (as an alternative to having to stay in hospital) thus enabling individuals to share in decision making that relates to their own care planning.

IPEM further suggested that, in relation to medical technologies appraisals and evaluations which consider both clinical and economic evidence, the Committee may wish to consider whether or not this evidence base is sufficiently broad to inform the decision-making process on funding those medical technologies that may contribute to more holistic and to more personalised health and social care.

3. IPEM's contribution to the inquiry

As the professional organisation representing those applying physics and engineering to medicine, IPEM should very much welcome the opportunity to contribute to the inquiry drawing upon the expertise of our members many of whom are embedded within existing clinical services and pathways. In particular, we should wish to input in relation to two of the four terms of reference, namely:

- To examine how the NHS assesses the potential benefits of new or alternative medical technologies;

- 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.

3.1 Assessing potential benefits and overcoming barriers to timely adoption

Even when there is good evidence available nationally to suggest that the adoption of new or alternative medical technologies may prove beneficial, local circumstances may frustrate or even prevent take up within specific organisations, services or pathways. The reasons for this are often unclear and may only become apparent as a result of detailed examination of those local circumstances which, in turn, may prove to be highly complex.

Healthcare science professionals have a fundamental role to play in ensuring that the right medical technology is used with the right patient, in the right way, at the right time in order to get the right outcome. Many engineers, physicists and technologists undertake this role in relation to specific patients as part of day to day service delivery but equally have the expertise and hands on experience to design and deliver systematic change fine tuned to local circumstances. Often service pressures are such that time spent on the latter is insufficient to effect widespread change although healthcare science led adoption of new and alternative medical technologies undoubtedly occurs.

In order to address this issue and bring about a 'virtuous cycle' of service improvement and cost reduction fuelled by innovative change, IPEM has been working with the medical royal colleges to develop Higher Specialist Scientific Training (HSST) as part of the Modernising Scientific Careers initiative. Both the Medical Physics (MP) and the Clinical Biomedical Engineering (CBE) HSST very specifically include driving technological change in relation to medical technologies. For example, the CBE HSST envisages clinical scientists whose essential focus will be to ensure that patient pathways are optimised via the optimal use of technologies.

The curriculum vision statement goes on to say that this will be achieved by (those who have completed the training) supporting clinical service provision, in particular, working closely with and within multi-disciplinary teams who provide clinical services. Additionally, they will be capable of analysing and transforming healthcare service delivery through health economic appraisal and a systems approach; undertaking health technology assessments, analysing and optimising health system delivery. Such a methodology will include an identification of the problem, developing an appreciation of stakeholder's views, leading to the creation of system models, finally resulting in practical solutions.

As the vision statement also identifies, it will become increasingly important for objective decisions to be made on what techniques and technologies should be adopted as well as those that should not. Those who have completed the training will be well placed to advise and assist in such decisions; supporting the introduction of new techniques and technologies, including those which span across healthcare disciplines and organisations. They will build bridges between patients and clinical communities, ensuring the effective use of healthcare technologies, for optimal patient outcomes.

It is proposed to begin the delivery of HSST in 2014. As it is a five year programme of training, it will be towards the end of the decade before the first cohort will have completed their training. However, integral to the training is a doctoral level award that will require the trainees to demonstrably deliver innovative changes. As a result, health organisations hosting HSST trainees are likely to find them powerful drivers for the adoption of new and alternative medical technologies because, in order to successfully complete their training, they will have had to identify specific local benefits and overcome specific local barriers.

3.2 Oral evidence

The detailed contents of the HSST curricula together with the documented reasoning underpinning their development are substantial. IPEM would be willing to provide oral evidence in this regard if called upon to do so.

Professor Colin Gibson
Vice President Professional
Chair, IPEM UK Liaison Group

Written comments prior to attendance at National Assembly for Wales' Health and Social Care Committee inquiry into access to medical technologies in Wales.

There are a number of parallels with this inquiry and the review of the appraisal of orphan and ultra-orphan medicines for the Minister that was produced in October 2013. A series of principles informed that review that would also be relevant for this inquiry. They were:

- Scientific rigour
- Inclusiveness
- Transparency
- Independence
- Challenge and review
- Support for implementation
- Timeliness
- Consistency
- Connectivity
- Equity

NICE undertakes health technology appraisals (HTA's) of selected new medical technologies (including devices and diagnostics) through its Medical Technologies Evaluation Programme (MTEP), using approaches that are regarded as being thorough and fit for the purpose of assessing the relative effectiveness and cost-effectiveness of these technologies. These approaches are employed by AWMSG in their appraisals of medicines for use in NHS Wales, and with slight modifications in other countries.

In many senses, the problem does not lie in the appraisal of these technologies but rather in the implementation of the recommendations emerging from such appraisals. In relation to medicines there is an 'obligation' to implement NICE/AWMSG recommendations within a finite time period, but this does not apply to technologies. In the review of orphan and ultra-orphan medicines the lack of connectivity in the processes surrounding therapeutic appraisal was clearly evident and it was recommended that, for example, the role of WHSCC should be amended to enable closer involvement and integration with the appraisal process.

The engagement of manufacturers with the appraisal process is likely to be key, as the commissioning of technologies is not currently related to any official appraisal process and is based on individual business cases, where degrees of rigour and detail would not adhere to the processes of AWMSG and NICE in their therapeutic appraisals. If manufacturers are to fully engage with an official appraisal process, then frustrations among manufacturers and clinicians evident in the review of orphan and ultra-orphan therapies due to implementation delays, cannot be allowed to be replicated.

There are an expanding number of manufacturers of such technologies within the life sciences sector in Wales, and conversations with some of them indicate their awareness of the need to increase the evidence relating to the effectiveness and cost-effectiveness of their products. Further,

there is a recognised NICE appraisal centre – CEDAR – based at University Hospital of Wales, that has a developing expertise in undertaking such appraisals and which would integrate well within the AWMSG framework.

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ACCESS TO MEDICAL TECHNOLOGIES IN WALES

Please note that I have recently retired and am no longer an employee of the University of South Wales. I remain, however, the health economist member of the All Wales Medicines Strategy Group and support the comments already submitted by AWMSG to the Health and Social Care Committee on Access to Medical Technologies in Wales.

1. I believe the investigation would benefit from a clear definition what it means by the expression 'medical technology'.

The related term 'health technology' is normally interpreted to have a wider meaning than just devices. The International Network of Agencies for Health Technology Assessment defines a health technology as "Any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. This includes the pharmaceuticals, devices, procedures and organizational systems used in health care." Although the Committee's consultation document specifies that it not wish to consider access to medicines it is does not specify what it means by technologies. I mention this because some of the submissions already made appear to equate the term to 'medical devices'. This is not a problem if that is what the Committee is concerned with, but this could be made more explicit.

2. The first term of reference of the inquiry is to examine how the NHS assesses the potential benefits of new or alternative medical technologies. As an economist I would argue that evidence based decisions should never be made solely on an assessment of potential benefits. Given that NHS resources will always be scarce, evidence of cost effectiveness is also required. This principle is accepted by all organisations involved with the evaluation of medical technologies including NICE.

3. I support the proposal by Public Health Wales in their submission to this enquiry to create a Welsh Health Technology Assessment Board.

The current structure and working practices of the All Wales Toxicology and Therapeutics Centre and AWMSG provide an excellent model of how the new organisation could be structured with a new Board equivalent to AWTTC and a new Assessment Group equivalent to AWMSG.

In my view, however, the new organisation would need to account for (at least) four important differences between the process for assessing medicines and that for assessing medical technologies.

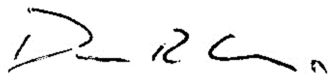
- Approvals of medicines by AWMSG and subsequently ratified by the Minister are mandatory and apply equally across Wales. The organisational effects of introducing new technologies, however, will often be significantly greater than when introducing new medicines and variations in effects between Health Boards will be also greater. Thought therefore will need to be given as to whether technology approvals should necessarily have the same all-Wales status as do medicines approved by AWMSG.

- The factors which complicate the evaluation of medical technologies – as specified in the NICE Medical Technologies Evaluation Programme Methods Guide. – mean that the quality of evidence required to conclude that "the case for clinical effectiveness, safety and cost effectiveness has been made" will have to be lower than that applied by AWMSG for medicines.

- The dynamic nature of technologies suggests that re-appraisal after a period of time will be required. While this is currently the case for AWMSG, differences in the nature of technologies suggest that imposing a common length of approval in all cases would not be sensible. The new Assessment Group should will be need to identify an appropriate approval time for each technology – or set of related technologies – that are approved.

- AWMSG currently focuses on benefits in terms of health gain, measured in Quality Adjusted Life Years (QALY). This will be broadened to include a wider assessment of societal benefits and costs when Value Based Assessment is introduced later this year. Given the broader nature of medical technologies, their assessment should also go beyond the narrow cost per QALY approach and should include non-financial effects of the organisation.

I hope these comments are helpful.



David Cohen
Professor of Health Economics

Y Pwyllgor Cymunedau, Cydraddoldeb a Llywodraeth Leol

Communities, Equality and Local Government Committee

Cynulliad Cenedlaethol Cymru
National Assembly for Wales

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CF99 1NA

David Rees AM
Chair
Health and Social Care Committee

28 January 2014

Dear David

As you will be aware, matters relating to the Welsh language fall within the remit of the Communities, Equality and Local Government Committee. We have recently taken evidence from the First Minister, as Minister with responsibility for overseeing and co-ordinating Welsh language policy. The Committee has subsequently written to the First Minister highlighting specific areas of Welsh language policy that we intend to keep under review. A copy of the letter is enclosed, for information.

The session covered a number of issues, including some that fall within the remit of other scrutiny committees. As such, it served to reinforce the cross cutting nature of the Welsh language and highlighted the importance of a more co-ordinated our approach to its scrutiny across committees.

In this context, the Committee agreed that I should write to all committees asking them to consider their existing approach to scrutiny of the Welsh language as it relates to their remit and to seek views on how best the Welsh language can be mainstreamed into all aspects of our scrutiny work. In addition, the Committee would welcome your views on how best Welsh language considerations could be taken forward in the budget scrutiny process.

It would be helpful if you could provide your views on the above as soon as practicable and, if possible, by the end of February.

Croesewir gohebiaeth yn y Gymraeg a'r Saesneg / We welcome correspondence in both English and Welsh
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I look forward to hearing from you.

Yours sincerely

Christine Chapman AC / AM
Cadeirydd / Chair