Pecyn dogfennau cyhoeddus

Y Pwyllgor Iechyd a Gofal Cymdeithasol

Lleoliad:
Ystafell Bwyllgora 1 - Y Senedd

Dyddiad:
Dydd Mercher, 19 Chwefror 2014

Amser:
09:05

Cynulliad Cenedlaethol Cymru
National Assembly for Wales

I gael rhagor o wybodaeth, cysylltwch â:
Llinos Madeley
Clerc y Pwyllgor
029 2089 8403
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Agenda

Rhag-gyfarfod anffurfiol (09.05 - 09.15)

1 Cyflwyniad, ymddiheuriadau a dirprwyon

2 Ymchwiliad i'r mynediad at dechnolegau meddygol yng Nghymru: Sesiwn dystiolaeth 6 (09:15 - 10:15) (Tudalennau 1 - 38)

Byrddau Iechyd Lleol
Fiona Jenkins, Cyfarwyddwr Gweithredol Therapïau a Gwyddorau Iechyd, Bwrdd Iechyd Prifysgol Caerdydd a'r Fro

Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru
Dr Geoffrey Carroll, Cyfarwyddwr Meddygol
Dr Phil Webb, Cyfarwyddwr Cynorthwyol

3 Ymchwiliad i'r mynediad at dechnolegau meddygol yng Nghymru: Sesiwn dystiolaeth 7 (10:15 - 11:05) (Tudalennau 39 - 45)

Partneriaeth Cydwasanaethau GIG Cymru
Mark Roscrow, Cyfarwyddwr, Gwasanaethau Caffael

Labordy Profi Deunyddiau Llawfeddygol
Pete Phillips, Cyfarwyddwr

Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Alun Tomkinson, Llawfeddyg Clust, Trwyn a Gwddf

4 Papurau i'w nodi (Tudalennau 46 - 49)

Cofnod y cyfarfod ar 5 Chwefror 2014

Llythyr gan y Pwyllgor Busnes ynghylch effeithiolrwydd Pwyllgorau wrth wneud gwaith craffu ar y Gyllideb

5 Cynnig o dan Reol Sefydlog 17.42 i benderfynu gwahardd y cyhoedd o'r cyfarfod ar gyfer y canlynol: Eitemau 6 a 7 (11:05)

Egwyl (11.05 - 11.15)

6 Trafodaeth breifat ar adroddiad drafft y Pwyllgor ar Waith Arolygiaeth Gofal Iechyd Cymru (11:15 - 12:15) (Tudalennau 50 - 88)

7 Ystyried dull gweithio'r Pwyllgor ar gyfer ei waith dilynol ar y cyfraniad a wneir gan fferyllfeydd cymunedol i wasanaethau iechyd yng Nghymru (12:15 - 12:30) (Tudalennau 89 - 91)

Mae cyfyngiadau ar y ddogfen hon

Mae cyfyngiadau ar y ddogfen hon

THE WELSH NHS CONFEDERATION
CONFFEDERASIWN GIG CYMRU

National Assembly for Wales Health & Social Care Committee
Inquiry into access to medical technologies in Wales
Submission from the Welsh NHS Confederation
November 2013

Introduction

- The Welsh NHS Confederation, on behalf of its members, welcomes the opportunity to respond to the National Assembly for Wales' Health & Social Care Committee's inquiry into access to medical technologies in Wales.
- By representing the seven Health Boards and three NHS Trusts in Wales, the Welsh NHS Confederation brings together the full range of organisations that make up the modern NHS in Wales. Our aim is to reflect the different perspectives as well as the common views of the organisations we represent.
- The Welsh NHS Confederation acts as an independent voice in the drive for better health and healthcare through our policy and influencing work and by supporting members with events, information and training. Member involvement underpins all of our various activities.
- The Welsh NHS Confederation and its members are committed to working with Wales' elected representatives, the Welsh Government, our partners and the public to ensure there is a strong NHS delivering high quality services to the people of Wales.

Response

The terms of reference of the inquiry are:

- To examine how the NHS assesses the potential benefits of new or alternative medical technologies;
- To examine the need for, and feasibility of, a more joined up approach to commissioning in this area;
- To examine the ways in which NHS Wales engages with those involved in the development/ manufacture of new 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.

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

There are a number of routes by which NHS organisations can address the above. It is important to note that this question can be investigated from different perspectives:

- The NHS can be utilised as a beta testing site for new technologies, particularly smaller equipment. This gives the NHS the opportunity to review critically any new / alternative technologies before they come on the market and to be involved in finalising the design before release, marketing etc.
- The NHS can be utilised to "confirm" and "validate" formally the proposed application of the device in clinical practice.
- The NHS can be utilised to validate "alternative" uses of the device which have hitherto not been associated with the device post its release.
- The NHS is the gateway to patient access and opinion and there is more scope to develop this re: new / alternative medical technologies.
- Current procurement rules can limit how the NHS assesses the potential benefits of new or alternative medical technologies.

Assessing the potential benefits of new or alternative medical technologies must be carried out in the right environment to assure patients will not come to harm. This will require full engagement with research governance, NHS ethics, and other relevant regulatory guidance.

How can these be achieved:

- NHS organisations can agree to be potential sites for the evaluation of all new devices. NICE through its Medical Technologies Evaluation Programme have developed a process whereby they put equipment / device evaluations out to tender, for interested parties to bid. One organisation in Wales that looks to submit responses to the NICE evaluation calls is Cedar Healthcare Technology Research Centre. Engagement with Cedar can identify NHS sites with an interest and expertise in new technologies and who can help them undertake the "clinical" evaluation of these new technologies.
- The NHS can undertake research (in partnership with academia) to provide the evidence base for the use or alternative use of a device in clinical practice. In Wales, the Welsh School of Primary Care Research and the three NISCHR (National Institute for Social Care and Health Research) funded Trials Units (South East, West and North Wales) have a strong history of supporting such research. This can be accessed by the NHS as a research partner.
- Forming links with Industry through research is an important mechanism to help address the above bullet point. For example there is the:
    - Knowledge Economic Skills Scholarship (KESS) scheme. This scheme funds the undertaking of research by academia and often in association with an NHS organisation. As part of the funding scheme an Industry partner has to agree to provide financial input (approx. £3,000 - £5,000).
    - Knowledge Transfer Partnership (KTP). The NHS can participate in Industry or Academic led projects. Matched funding is required.
    - Research studies at PhD and MSc level can be developed to evaluate the utility of medical devices developed by industry partners.
- Direct links at specialty (Departmental) level with Industry, enable identification of the opportunities for clinical disciplines to assess / evaluate new technologies
    - as part of the procurement process or
    - as part of a research opportunity where
        - a new technology has its intended functionality assessed
        - or an alternative use is identified which requires an evidence base for its use in clinical practice.
- Recognition of and full engagement with the appropriate NHS professionals, across all specialties to review, investigate, evaluate and document all potential benefits of new technologies.

To examine the need for, and feasibility of, a more joined upapproach to commissioning in this area

With the development of shared services, notably procurement, this may be possible. However, for Medical Technologies, this may prove problematic as increasing the number of stakeholders, where their requirements are due to clinical service provision, may be different and this could prove difficult.

- One company may not be able to provide technologies where "one size will fit all". This can result in the purchasing of equipment that meets no one's needs fully, as a compromise. There is an increasing evidence base that recent large procurements of clinical services and equipment across the UK have failed or have over-run considerably, due to the complexity and the resources required to implement and manage on a large scale, often negating the perceived benefits of large commissioning projects.
- Large commissioning projects could lead to the monopolisation of the provision of a device and its associated consumables. This may have financial benefits but increases the clinical risk considerably as the scale of any failure in the continuation of service provision would be much larger and more difficult to rectify quickly. This does occur and In the last five years there have been a number of failures in service provision due to issues with medical

technologies companies products. Using fewer companies could also lead to a decrease in competition with some firms dominating as a consequence and umbrella pricing in the longer term. In addition only commissioning large projects may exclude 'start ups'.

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

There are several ways in which this can be / is being achieved:

- The recent development and launch of Health Research Wales (HRW) in May 2013 will facilitate the engagement of the NHS, Higher Education Institutions (HEI) and Industry partners. HRW provides a central portal (and brand) through which Industry can gain access to appropriate NHS sites with an interest and expertise in various technological fields. It is anticipated that the use of a sign-posting portal will help the development of partnerships and input into technology development at an earlier stage.
- Development of strong partnerships between the NHS and Academia facilitates the engagement between suitable partners and scientific / clinical specialties. This has been enhanced through the development of University Health Board status and the development of South East Wales Academic Health Science Partnership (SEWAHSP) and its Industry working group. SEWAHSP also has Industry membership through organisations such as MediWales. In North Wales, the Betsi Cadwaladr University Health Board hosts the National Institute for Social Care & Health Research [NISCHR] Academic Health Science Collaboration North Wales Regional Hub made of partners from health, Powys teaching Local Health Board, Welsh Ambulance Services Trust, Bangor and Glyndwr Universities. Further partnership with the Universities is evidenced in the Collaborative Strategic Board, the joint Intellectual Property Group with Bangor and Glyndwr Universities and active links with the Centre for Health Economics and Medicine Evaluation, Bangor University.
- Developing direct partnerships with each of the NHS organisations and Industry partners such as MediWales and diagnostic companies, will help facilitate the development and manufacturing of new technologies driven by the NHS.
- One area that could be developed is "patient led" device development . Developing devices that the patients consider would be helpful to them, their condition and quality of life, at the "idea" stage, rather than having NHS professionals and Academics assuming the position on making the decisions and developing devices on their behalf.
- There are a number of schemes that encourage and support (financial and legal) the direct development of new/alternative technologies, such as:
    - the Health Technologies Challenge. This scheme is being directed and co-ordinated through the South East Wales Academic Health Science Partnership
    - NISCHR Funding schemes such as 'INVENT'.

  To facilitate commercialisation of new/alternative technologies, individuals and clinical teams need appropriate support and sign posting to expertise and advice. This could be provided on an All Wales basis
- The Welsh Government has the Department for Business, Enterprise, Technology and Science (BETS), which also helps facilitate and develop opportunities for partnership building between the NHS, Academia and Industry, providing an economic viewpoint on the development and manufacturing of new 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

The financial barriers can be divided into two areas:

- Funding resources required to support the validation / evaluation of new technologies, the safe and effective delivery / implementation and future monitoring of new technologies.

What would help?

- Greater flexibility between "budgets" where a reduced spend in one specialty as result of a given development can be used to support the new development managed by another specialty.

Recognition that investment (even pump priming) in staff resources can result in the following:

- Taking a more scientific / evidenced based approach where choosing / implementation of all such technologies is managed by the appropriate professionals to avoid "waste" and prevent the use of technologies that are not fit for purpose.
- Allows time for greater engagement / co-ordination between all the stakeholders with clear lines of accountability, to ensure informed decisions are taken between those managing and using any devices.
- Development of clear documentation to ensure that devices are used appropriately to reduce any clinical risk and to optimise the financial and clinical benefits.
- Purchasing the medical technologies is often a barrier, even when the case for the clinical and financial benefits are clearly made. This is particularly the case when "Capital" is required and replacing equipment takes priority over "new technologies".

What would help?

- Development of an Invest to Save fund for capital purchases for innovative new technologies may be a possible way to overcome barriers.
- Allowing the carryover of ring-fenced funding (badged as development funding) between financial year(s), to reduce the risk of impulse / rushed (and perhaps inappropriate, untested) purchases. Choosing the appropriate Technology and purchasing can be complex, requiring sufficient time to ensure an informed decision is taken. Having time limited budgets can lead to poor purchasing decisions to beat the financial year deadline. (see 4, b, I, above reference Invest to Save)
- Removing the "Capital" limit of £5,000 will allow more flexibility in the use of non-capital funding. This level of Capital is now outdated due to the costs of devices / equipment.
- Ensure, where appropriate, there is standardisation of manufacturer, equipment (hardware/IT) and consumables across an NHS organisation. This provides inherent resilience and allows for economies of scale in terms of purchasing power with the manufacturers. Putting all eggs in one basket can be a risk, but at a single NHS organisational level this may be managed contractually via risk transfer.

National Assembly for Wales

Health and Social Care Committee

Access to medical technologies in Wales

Evidence from Cwm Taf University Health Board – MT 1

Cwm Taf Local Health Board
Ynysmeurig House
Navigation Park
Abercynon
Rhondda Cynon Taf
CF45 4SN

Dear David,

Cwm Taf Health Board has considered your enquiry regarding access to medical technologies in Wales. Our response is detailed below which follows the terms of reference identified in your letter of 23rd July 2013.

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

There are a number of routes in which NHS organisations can address the above. It is important to note that this question can be investigated from different perspectives:

1) The NHS can be utilised as a beta testing site for new technologies, particularly the smaller equipment. This gives the NHS the opportunity to critically review any new / alternative technologies before they come on the market and help in finalising the design before release, marketing etc.

2) The NHS can be utilised to formally "confirm" and "validate" the proposed application of the device in clinical practice.

3) The NHS can be utilised to validate "alternative" uses of the device which have hitherto, not been associated with the device post its release.

4) The NHS is the gateway to patient access and opinion and there is more scope to develop this re: new / alternative medical technologies.

5) Current Procurement rules can limit how the NHS assesses the potential benefits of new or alternative medical technologies.

How can these be achieved:

a) NHS organisations can agree to be potential sites for the evaluation of all new devices. NICE through its Medical Technologies Evaluation Programme have developed a process whereby they put equipment / device evaluations out to tender, for interested parties to bid for. One organisation in Wales that looks to submit responses to the NICE evaluation calls is CEDAR. Engagement with CEDAR can identify NHS sites with an interest and expertise in new technologies and who can help them undertake the "clinical" evaluation of these new technologies.

b) The NHS can undertake research (in partnership with academia) to provide the evidence base for the use or alternative use of a device in clinical practice. In Wales, the Welsh School of Primary Care Research and the South East Wales Trials Unit (SEWTU) have a strong history of supporting such research. This can be accessed by the NHS as a research partner.

c) Forming links with Industry through research is an important mechanism to help address the above bullet point. For example there is the Knowledge Economic Skills Scholarship (KESS) scheme. This scheme funds the undertaking of research by academia and often in association with an NHS organisation. As part of the funding scheme an Industry partner has to agree to provide financial input (approx. £3,000 - £5,000) where there must be financial input by Industry. Research studies at PhD and MSc level can be developed to evaluate the utility of medical devices developed by industry partners.

d) Direct links at specialty (Departmental) level with Industry, being cognisant of the opportunities for clinical disciplines to assess / evaluate new technologies as part of the procurement process or as part of a research opportunity where a new technology has its intended functionality assessed or an alternative use identified which requires an evidence base for its use in clinical practice.

e) Recognition of and full engagement with the appropriate NHS professionals to review, investigate, evaluate and document all potential benefits of new technologies, to include Pathology, Clinical Engineering, Occupational Therapy and Radiology, etc.

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

With the development of shared services, notably procurement, this may be possible. However, for Medical technologies, this may prove problematic as increasing the number of stakeholders, where their requirements due to clinical service provision, may be different and this could prove difficult.

a) One company may not be able to provide technologies where "one size will fits all". This can result in the purchasing of equipment that meets no ones needs fully, as a compromise. There is an increasing evidence base that recent large procurements of clinical services and equipment across the UK have failed or have over-run considerably, due to the complexity and time resources required to manage on a large scale, often negating the perceived benefits of large commissioning projects.

b) Large commissioning projects could lead to the monopolisation of the provision of a device and its associated consumables. This may have financial benefits but increases the clinical risk considerably as the scale of any failure in the continuation of service provision would be much larger and more difficult to rectify quickly. This does occur and In the last 5 years there have been a number of failures in service provision due to issues with medical technologies companies products.

c) A joined up approach to commissioning may be possible if a multi-company approach is taken where the manufacturers work together themselves in responding to a call, and provide the appropriate equipment, meeting the requirements of all stakeholders included in the commissioning. The benefit of this approach is that the manufacturers decide amongst themselves who can provide what for each stakeholder to meet the requirements / specification. This approach may not be attractive commercially to the companies as they would all wish to have the "lions share" of a contract.

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

There are several ways in which this can be / is being achieved:

a) The recent development and launch of Health Research Wales in May 2013 will facilitate the engagement of the NHS, HEI and Industry partners. HRW provides a central portal (and brand) through which Industry can gain access to appropriate NHS sites with an interest and expertise in various technological fields. It is anticipated that the use of a sign-posting portal will help the development of partnerships and input into technology development at an earlier stage.

b) Development of strong partnerships between the NHS and Academia facilitates the engagement between suitable partners and scientific / clinical specialties. This has been enhanced through the development of University Health Board status and the development of South East Wales Academic Health Science Partnership (of which Cwm Taf HB is a member organisation) and its Industry working group. SEWAHSP also has Industry membership through organisations such as MediWales.

c) Developing direct partnerships with each of the NHS organisations and Industry partners such as MediWales and diagnostic companies, will help facilitates the development and manufacturing of new technologies driven by the NHS.

d) One area that I think should be developed is "patient led" device development. Developing devices that the **Patients** consider would be helpful to them, their condition and quality of life, at the "idea" stage, rather than having NHS professionals and Academics assuming the position on making the decisions and developing devices on their behalf.

e) There are a number of schemes that encourage and support (financial and legal) the direct development of new/alternative technologies. One such scheme is the Health Technologies Challenge. This scheme is being directed and co-ordinated through the South East Wales Academic Health Science Partnership (of which Cwm Taf HB is a member organisation) and SARTRE (Prof Lars Sundstrom). The scheme takes a direct approach by asking Clinicians for clinical problems / ideas which they post on a website accessed by other clinicians and academics. The ideas are then voted upon by the web fraternity and the "best" idea(s) for potential development are pursued in terms of developing a project team and providing pump priming financial support.

f) The Welsh Government has the Department for Business, Enterprise, Technology and Science (BETS), which also helps facilitate and develop opportunities for partnership building between the NHS, Academia and Industry, providing an economic viewpoint

on the development and manufacturing of new medical technologies.

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.

a) **The financial barriers can be divided into two areas**:

i) *Funding resources required to support the validation / evaluation of new technologies, the safe and effective delivery / implementation and future monitoring of new technologies.*

What would help:

1) Greater flexibility between "budgets" where a reduced spend in one specialty as a result of a given development can be used to support the new development managed by another specialty.

Recognition that investment (even pump priming) in staff resources can result in the following:

a) Taking a more scientific / evidenced based approach where choosing / implementation of all such technologies is managed by the appropriate professionals to avoid "waste" and prevent the use of technologies that are not fit for purpose.

b) Allows time for greater engagement / co-ordination between all the stakeholders with clear lines of accountability, to ensure informed decisions are taken between those managing and using any devices.

c) Development of clear documentation to ensure that devices are used appropriately to optimise the financial and clinical benefits and reduce any clinical risk.

ii) Purchasing the medical technologies is often a barrier, even when the case for the clinical and financial benefits are clearly made. This is particularly the case when "Capital" is required and replacing equipment takes priority over "new technologies".

What would help:

1) Each NHS Organisation could have an annual budget set aside and separate from the Capital replacement budget, specific for purchasing new technologies.

2) Allow carryover of ring-fenced funding (badged as development funding) between financial year(s), to reduce the risk of impulse / rushed (and perhaps inappropriate, untested) purchases. Choosing the appropriate Technology and purchasing can be complex, requiring sufficient time to ensure an informed decision is taken. Having time limited budgets currently hamstrings the NHS and can lead to poor purchasing decisions to beat the financial year deadline.

3) Removing the "Capital" limit of £5,000 will allow more flexibility in the use of non-capital funding. This level of Capital is now outdated due to the costs of devices / equipment.

4) Ensure standardisation of manufacturer, equipment (hardware/IT) and consumables across an NHS Organisation. This provides inherent resilience and allows for economies of scale in terms of purchasing power with the manufacturers. Putting all eggs in one basket can be a risk, but at a single NHS organisational level this may be managed contractually via risk transfer.

Many thanks,

Mr Chris Hopkins,

Cwm Taf Local Health Board

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.**

National Assembly for Wales

Health and Social Care Committee

Access to medical technologies in Wales

Evidence from NWSSP Procurement, SMTL, Mr Alun Tomkinson et al – MT 20

Inquiry into access to medical technologies in Wales

On behalf of NWSSP Procurement, SMTL, Mr Alun Tomkinson and others.

October 2013

"A joined up approach to commissioning."

Introduction

1. The Procurement of medical devices for the NHS in Wales is managed by the Procurement division of the Shared Services Partnership. This provides a collaborative approach across the ten Health organisations in Wales, which has a history going back over 30 years of working in this way. In the spirit of working in partnership, this response is supported by a number of leading individuals from within the NHS who are listed in Appendix 1.

2. The medical device regulatory process does not always ensure devices are fit for purpose and safe in clinical use, and evidence of efficacy is frequently poor. Clinicians wishing to assess devices clinically may expose patients to risk, especially as errors caused by inadequate usability have become increasingly common. In 2012, the BMJ[1] noted that safety of medical devices "i*s dealt with in an unsatisfactory way, and efficacy not at all",* and that *"a new system that improved scientific evidence of safety, required evidence of efficacy, ... would be well worth considering.*"

An MHRA (Medicines and Healthcare products Regulatory Agency) report by Campbell[2] also stated:

> *"The evidence on safety and efficacy of new devices and new procedures at the time they are introduced into UK practice is very variable. Some have been evaluated in well designed studies but more commonly the evidence base is modest or poor."*

3. These are not theoretical concerns. Wales has its own experience of poor quality devices causing clinical harm - when the move to SEAC (Spongiform Encephalopathy Advisory Committee) mandated single-use tonsillectomy instruments took place, Welsh NHS return-to-theatre rates from post-operative bleeding increased from 1.5% to 4.4%[3]. A collaboration of procurement, clinician engagement and laboratory testing at SMTL (Surgical Materials Testing Laboratory) brought the situation back under control.

4. The problem is recognised internationally - from 2005 through 2009, the FDA (Food and Drugs Administration) received approximately 56,000 reports of adverse events[4] associated with the use of infusion pumps, including numerous injuries and deaths. 14 of these reports were Class I – situations in which there is a reasonable probability that use of the recalled device would cause serious adverse health consequences or death.

1

2 ˇ http://www.mhra.gov.uk/Howweregulate/Devices/Devicesregulatorynews/CON082083

3

4

BMJ.

Clin

5. The problem is also recognised outside the UK. The Liaison Officer to the European Standards technical committee CEN/TC 205/WG 3 (which deals with medical gloves) reported recently that:

> *Currently, no regulatory bodies in EU confirm the conformity assessment process of manufacturers of examination gloves, nor do they validate that all the claims made for a product can be substantiated.*

6. Within the Welsh NHS, there is already a well coordinated and respected approach to medicines through the AWMSG (All Wales Medicines Strategy Group). We believe that a similar approach for devices and medical technology would build on our experience in this area, delivering significant benefits, increasing clinician engagement, and enhancing patient safety.

Background

7. In considering our response to the request for comments it was felt that it would be important to provide a framework against which the response should be seen. The following were felt to be key areas in this:-

I. Any new or different product should be judged against a demonstrable improvement in the clinical outcome for the patient and or a change in the clinical pathway.

II. Risk Pool costs are escalating , with claims of £60m last year, forecast £71m 2013/14 , with in excess of £500m open liabilities being reviewed. Discussions with Welsh Risk Pool have identified cases where poor quality and/or poorly designed medical devices have caused patient injury leading to significant settlements. For example, inappropriate choice of holders (stirrups etc) for a Lithotomy procedure has lead to a settlement of £50,000 damages and £12,000 costs.

III. CE marking has mixed confidence among clinicians;

IV. Financial pressures and a growing elderly population are dictating increased efficiency in interventions, reduced costs of ownership and purchase, shorter in-patient stays, and better clinical outcomes. Better or improved Value for Money for NHS Wales is therefore vital.

V. It is recognised that a more flexible approach to budget setting and management across directorates and indeed organisations might well be required, including whole-of-life costings for expenditure and non-silo budgets – a case of “think globally, act locally”.

VI. Clinician engagement with device/technology procurement could and should be better; Wales has a very inclusive and collaborative approach to Procurement across all its categories. This is particularly important where for over 30 years we have had various mechanisms for working with professional clinical staff, and through this process managed to achieve far more standardisation of products than our English counterparts. This can, however be improved.

VII. The environment of “Comply or Explain” - if the Health Boards are not conforming to contracts, best practice, guidance and advice, we should explain why those decisions have been taken. To do that, we need better information and better structures;

VIII. Industry often complain about the lack of access to clinicians, especially their belief that the NHS is slow to adopt innovative products. They are often not clear about structures and certainly struggle with the differences between the English Health Care system and that which exists within Wales, and the “Celtic fringe”. Solutions and or products which can ultimately have a positive impact on the Welsh economy can form the basis for creating wealth employment opportunities and ultimately inward investment.

Horizon Scanning

8. There is presently no coordinated horizon scanning linked with the procurement of medical devices and new technology within the NHS. This is an area of opportunity, but again requires coordination.

9. A horizon scanning programme is in existence at the University of Birmingham, the *National Institute*

for Health Research (NIHR) *Horizon Scanning Centre*, which also hosts the *Secretariat for EuroScan* – the International information network on new and emerging health technologies

10. There are other data sources available which, if used appropriately, could help identify areas of focus:, including MHRA adverse incidents, the NRLS (National Reporting and Learning System), Welsh Risk Pool claims, SMTL defect reports, Procurement expenditure & adoption and NICE (National Institute for Health and Care Excellence) guidance and appraisals undertaken by CEDAR (Healthcare Technology Research Centre) in Cardiff & Vale Health Board

11. The Welsh NHS could and should make better use of the information provided by these centres and databases. However, at present, individual Health Boards and Trusts are left to make their own judgements, and in many cases have neither the expertise or the resource to link up this data. A coordinating body which draws together the research from these sources whilst also understanding and identifying Welsh unmet needs, could identify technologies which should be assessed for the Welsh NHS.

Assessing the potential benefits of new or alternative technologies

12. Once the areas of focus have been identified, the task of assessing which technology may deliver the required benefits can be addressed.

13. There are a number of groupings who should be involved in this process, including NHS clinicians, procurement, academia, trade bodies, and other interested organisations such as MediWales. The aim of this exercise would be to:

- benefit patient safety, by filtering and sieving out devices and technologies which are inappropriate to prevent patient exposure to risks. This may involve a multi-step screening process;
- assess the potential risks of medical devices. This will tie together concrete financial and clinical risks (for example, linking up Welsh Risk Pool data with NRLS, SMTL and MHRA incident data), and evaluating and introducing device adoption strategies such as those used in the “Beyond Compliance” programme.

14. We believe that adoption and adaption of the “Beyond Compliance” strategy could be useful. The “Beyond Compliance” programme uses a risk-based strategy, rating the risk of the device (orthopaedic implants) from 1 (low risk) to 4 (high risk), and recommending introduction rates (unrestricted through to limited), alongside a monitoring process (which may include Notified Body involvement for the highest risks).

15. This would then link into coordination of the selection and pre-procurement process, involving credible individuals and processes to reduce risk and gain clinician engagement. It should include:

    - Laboratory testing
    - Clinical engagement and assessment, including Human Factors and usability studies.

16. Assessment of devices in patients may expose patients to risk. Errors caused by inadequate usability have become an increasing cause for concern. Usability testing by clinicians, in a non-clinical environment similar to that used by the aircraft industry, enables safety and effectiveness criteria to be assessed.

17. High reliability industries such as the airline, oil, military and nuclear industries are *“safety aware and simulation savvy”*. In the medical device arena, simulation testing gives the opportunity to amplify real patient experience, and to introduce artificially contrived situations, which replicate the rare but difficult clinical situations when devices are most likely to fail or cause problems, uncovering potential issues which may not be discovered during the 'average' clinical assessment. It also has the great advantage of uncovering design flaws and other issues in a safe environment, reducing the risk of patient exposure.

18. However, the use of human factors assessments is not routine in the medical device field, and we are unaware of any routine use in the procurement of safety assured devices within the UK or elsewhere.

Swansea University have expertise in human factors assessment of medical devices such as infusion pumps, and this could be leveraged to provide evidence to Welsh NHS procurement, enabling the purchase of safety assured devices and technology.

19. The Surgical Materials Testing Laboratory (SMTL) in Princess of Wales Hospital, Bridgend, is funded by WHSSC (Welsh Health Specialised Services Committee) to test and provide technical information on medical devices. At present they deal with a range of commodity devices such as gloves, gowns, masks, dressings and surgical instruments, but there is an opportunity to expand their role regarding the technical aspects of medical device assessment.

20. There should also be a monitoring or measurement programme associated with these decisions to check whether clinical benefits are being delivered, risk is being mitigated; and to undertake further interventions if necessary;

21. As with most of our proposals, we envisage these assessments would feed into a structured Procurement process, to drive and manage the change once the intervention is assessed and approved.

Health Economics

22. The assessment of value for money is a key component within any commissioning framework. The use of cost-effectiveness techniques to evaluate the relative costs and benefits of medical technologies is a burgeoning area and one that NICE is increasingly getting involved with. **It is essential to ensure that resources committed to the procurement of medical technologies provide a level of return that is at least commensurate with the use of those resources in alternative or even competing areas within the health care environment.**

23. There is a danger in adopting novel technologies which can be mitigated by appropriate cost-effectiveness analysis, which relates the additional costs incurred in utilising the new technology to the additional benefits gained from its use. The metric(s) used to measure and value benefit can be based on health care effects, utility (quality of life) or monetary gains. The resultant ratio can be benchmarked to determine whether the technology represents value for money. Sensitivity analyses are incorporated to assess the degree to which parameter variation influences the findings of the cost-effectiveness analysis – and to provide an indication of the probability that the technology is likely to represent value for money.

24. We believe there is an opportunity to ensure closer liaison between health Economics and Procurement, to ensure the Welsh NHS is getting the best value for money.

Engagement with those involved in the development and manufacture of new medical technologies

25. We also believe there is a clear role for industry and innovators to be engaged in this process, especially with regards to understanding how the Welsh NHS makes decisions and procures medical technology.

26. There are a number of areas which would benefit from this including clarifying the appropriate point of entry into the Welsh NHS for suppliers depending on their development status (developing the technology, or requiring clinical data for regulatory approval). If we can provide an opportunity to at least address the "route" alongside the need for innovation then this would be a major step forward.

27. Welsh industry also has a clear appetite for participating in the strategic direction of the Welsh NHS, as well as a requirement to understand the direction of travel so that they can focus their own resources appropriately.

28. There are a number of groupings who should be involved in this process, including NHS clinicians, procurement, academia, trade bodies, and other interested organisations such as MediWales.

The Need for joined up approach to commissioning

29. One of the problems with stimulation a dialogue related to new technology adoption is how to persuade Clinicians , Health Boards and Trusts **not** to leap on every new technology and to have confidence in the

system. A successful strategy as outlined in this paper will open up the opportunity for interested clinicians to engage in the process for the wider benefit of the Welsh NHS, as opposed to operating in a silo. This should enable us to get past the 'I need to make my own decisions' issue, by demonstrating that the assessment and selection process is balanced, fair, credible, and most importantly, clinically driven.

30. At a time when the overall NHS budget is under huge pressure it is also important to take a more flexible approach to budgets. We need to better consider the whole life costs and total clinical pathways and recognise that whilst the cost of a particular device may be more expensive, if you look at the total costs then this may have an overall benefit. We cannot have a system which prevents this approach because of “silo budget mentality”.

31. Of course, there must be acknowledgement that many technologies and devices will be rejected when subjected to this level of scrutiny, and we should recognise that not every claim made by companies on potential clinical or financial advantage will stand up to detailed scrutiny. Nevertheless, even in these circumstances, this will provide invaluable feedback to industry, allowing them to redesign and develop a more successful device. Within the Welsh NHS we have a number of areas where this is already successful, delivering better and in many cases, more cost effective devices to Welsh clinicians and patients - Fluid warming, Compression hosiery, Tonsillectomy and Wound dressings.

32. By assessing evidence, laboratory studies, usability studies, health economics, and a number of other factors, a balanced view can be formed.

Process management

33. To achieve the ambitious aims outlined above, we believe that a group with strategical oversight is necessary, such as an All Wales Medical Device (or Technology) Management Group. This could provide a vehicle for a range of technical and clinical assessments in a similar way to that currently working within the drugs field. It should also coordinate and facilitate conversations between stakeholders, as no single person/organisation has the complete answer.

34. The system will also need an operational arm, and for that we believe Shared Services Partnership (Procurement) has a key role to play in this process and could provide a very useful “bridge” between industry and the needs of NHS Wales. Another area of critical importance is the potential impact of Procurement on the Welsh economy, and whether procurement could help grow and develop Welsh industry as part of this initiative, Welsh Government has already committed money to the Life Science section and Ministers are considering innovative approaches to products and the way this should or could work.

35. There also needs to be a body external to the NHS - who has the role of ensuring successful Welsh Health innovation can be developed worldwide, and can support companies in developing devices which have significant international potential.

36. An appropriate model for the strategic body is already in place - the AWMSG - which has been shown to be effective in the medicines arena. Perhaps more importantly, it also has authority and credibility, both of which are necessary to ensure engagement and compliance.

37. We strongly believe that medical devices are no less important than medicines in the modern Welsh NHS. At present, we are doing a dis-service to staff and patients through insufficient focus on the devices arena.

Joined up Working Works!

38. We have a number of Welsh examples where a joined up approach to Procurement that involves the correct level of clinical engagement can really work. The Tonsillectomy example referred to earlier is an excellent example where a process which coordinated a credible group of people involved who delivered a safe efficient outcome which wasn’t subject to multiple hospitals running their own trials. Wales followed the SEAC guidance, took Ministerial advice on the direction of travel, and delivered an effective solution with measurable benefits for patient safety.

39. Other examples exist, some of which have required far more effort to gain acceptance. If offered the opportunity to provide verbal evidence then we can expand on these,

Summary

40. There are a number of strands which could be coordinated at a National level:

    I. Horizon scanning for new devices/technologies which may be of benefit (clinical advantage, clinical safety, or financial);

    II. Identification of areas of focus: based on clinical risk, clinical benefits and potential savings (whole of life costings – including direct costs or indirect costs, such as litigation settlements);

    III. Deciding which pre-procurement route is appropriate – laboratory, simulation (for example, human factors) or clinical assessments;

    IV. Deciding which post-procurement monitoring system is necessary – product sampling (lab testing), formal surveillance (as per single-use tonsillectomy & neuraxial non-luer devices), use of incidence data (NRLS, SMTL, MHRA);

    V. Publicising the work programme to give industry (especially Welsh industry where liaison should be easy to facilitate) the opportunity to propose and submit technologies, and participate in procurement exercises. We should open up and clarify the 'rules of engagement' for industry and medical devices.

    VI. This is not just about novel technology – it is also about procuring appropriate technology and devices which are fit for purpose, evidence based, and which are cost effective.

    VII. A 'joined up' approach to commissioning. The Best Practice and Innovation Board have noted Procurement's potential to drive technology adoption on a national scale, especially as it is the single point of entry to the Welsh NHS where Procurement can also act as the gatekeeper.

41. The benefits of the above include

    I. Better clinical outcomes;

    II. Better assessment of new technologies;

    III. Better clinical engagement and adoption – in particular addressing clinicians perception of medical device regulation and CE marking;

    IV. Better risk management - reduced cost pressure on Welsh Risk Pool/litigation, and mitigating the risks currently inherent in the medical device sector;

    V. Better value for money;

    VI. Better outcomes for the Welsh Economy - involvement and opportunities for the Welsh medical device sector;

We would be happy to provide oral evidence if invited.

Appendix I

This response has been developed and supported by the following:

- Mark Roscrow & Andy Smallwood - NWSSP Procurement
- Pete Phillips, Director, SMTL
- Prof. Ceri Phillips, Health Economist, Swansea University
- Rohit Kulkarni - Orthopedic Surgeon ABUHB, Chair Expert Working Group - Orthopaedics (DH)
- Alun Tomkinson - ENT surgeon, C&VHB

- Simon Poulter - Anaesthetist ABMU HB, Chair of Medical Commodity Advisory Group)
- Gordon Staple - Paediatric anaesthetist ABMU HB, ACD Anaesthetics ABHU HB)
- Mark Stacey - Obstetric anaesthetist, C&V HB
- Prof. Harold Thimbleby - Human Factors, Swansea University.

Y Pwyllgor Iechyd a Gofal Cymdeithasol

Lleoliad:	Ystafell Bwyllgora 1 - Y Senedd
Dyddiad:	Dydd Mercher, 5 Chwefror 2014
Amser:	09:05 - 12:12

Cynulliad Cenedlaethol Cymru
National Assembly for Wales

Gellir gwylio'r cyfarfod ar Senedd TV yn:
http://www.senedd.tv/archiveplayer.jsf?v=cy_200000_05_02_2014&t=0&l=cy

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Aelodau'r Cynulliad:	David Rees (Cadeirydd) Rebecca Evans William Graham Elin Jones Darren Millar Gwyn R Price Lindsay Whittle Kirsty Williams Jenny Rathbone
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Staff y Pwyllgor:	Llinos Madeley (Clerc) Chloe Davies (Dirprwy Glerc) Philippa Watkins (Ymchwilydd)

1 Cyflwyniad, ymddiheuriadau a dirprwyon

1.1. Cafwyd ymddiheuriadau gan Leighton Andrews AC a Lynne Neagle AC. Roedd Jenny Rathbone AC yn dirprwyo ar ran Lynne Neagle AC.

2 Ymchwiliad i'r mynediad at dechnolegau meddygol yng Nghymru: Sesiwn dystiolaeth 3

2.1. Bu'r tystion yn ateb cwestiynau gan aelodau'r Pwyllgor.

2.2. Cytunodd Sally Chisholm i ddarparu'r wybodaeth ychwanegol a ganlyn:

- Cyfeiriadau at dystiolaeth am y ffactorau sy'n dylanwadu ar bobl, o safbwynt aml-ddisgyblaethol, pan fyddant yn penderfynu a ydynt am integreiddio technolegau unigol yn eu harferion clinigol ai peidio;
- Rhagor o wybodaeth ynglŷn â pha gyrff iechyd yng Nghymru sy'n cyfrannu ar hyn o bryd at y gwaith o ddatblygu canllawiau a rhaglen waith gyffredinol gan NICE;
- Rhagor o fanylion am y cynllun cymell - taliadau Comisiynu Ansawdd ac Arloesedd (CQUIN) - sydd ar waith yn Lloegr i annog rhagor o bobl i ddefnyddio arloesedd o fewn y gwasanaeth iechyd.

3 Ymchwiliad i'r mynediad at dechnolegau meddygol yng Nghymru: Sesiwn dystiolaeth 4

3.1. Bu'r tystion yn ateb cwestiynau gan aelodau'r Pwyllgor.

4 Ymchwiliad i'r mynediad at dechnolegau meddygol yng Nghymru: Sesiwn dystiolaeth 5

4.1. Bu'r tystion yn ateb cwestiynau gan aelodau'r Pwyllgor.

4.2. Gohiriwyd y cyfarfod am gyfnod byr yn ystod eitem 4 o ganlyniad i drafferthion technegol.

5 Papurau i'w nodi

5.1. Nododd y Pwyllgor ei fwriad i wahodd Comisiynydd y Gymraeg i sesiwn yn y dyfodol. Diben y sesiwn fydd ymchwilio i'r materion sy'n codi fel rhan o'i hymchwiliad i

ofal sylfaenol yng Nghymru, ac ymchwilio i faterion eraill sy'n rhan o'i hawdurdodaeth sy'n dod o fewn cylch gwaith y Pwyllgor.

Y Fonesig Rosemary Butler AC
Dame Rosemary Butler AM

Llywydd
Presiding Officer

David Rees AC
Cadeirydd
Y Pwyllgor Iechyd a Gofal Cymdeithasol
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5 Chwefror 2014

Annwyl David

Yn ei gyfarfod ar 28 Ionawr, trafododd y Pwyllgor Busnes effeithiolrwydd pwyllgorau wrth wneud gwaith craffu ar y gyllideb.

Yn benodol, ystyriodd y Rheolwyr Busnes bryderon a fynegwyd yn ystod y broses gyllideb ddiweddaraf am y diffyg cydberthynas rhwng portffolios y Gweinidogion a phortffolios y pwyllgorau, a bod hynny'n golygu nad oes gwaith craffu'n digwydd ar rai meysydd polisi gan unrhyw bwyllgor.

Roedd un enghraifft yn ymwneud â'r Gymraeg. Y Pwyllgor Cymunedau, Cydraddoldeb a Llywodraeth Leol sy'n bennaf cyfrifol am faes polisi'r Gymraeg. Er mai'r Gweinidog Addysg a Sgiliau sydd â'r gyllideb ar gyfer y maes, y Gweinidog sy'n gyfrifol am y maes yw'r Prif Weinidog.

Roedd pryder arall fod yr amserlennu o ran y gyllideb yn golygu bod y llythyrau a anfonir gan bwyllgorau at y Gweinidog Cyllid neu'r Pwyllgor Cyllid yn dod i law'n rhy hwyr i lywio gwaith craffu'r Pwyllgor Cyllid ar y Gweinidog Cyllid.

Felly, penderfynodd y Pwyllgor Busnes edrych ar y broses er mwyn sicrhau bod y gwaith craffu mor effeithiol â phosibl yn y dyfodol. Rwy'n ysgrifennu atoch i geisio eich barn am unrhyw faterion sy'n deillio o broses y gyllideb eleni ac am unrhyw sylwadau sydd gan eich Aelodau am sut y byddai modd gwella'r broses yn y dyfodol. Byddwn yn ddiolchgar pe gallech ymateb erbyn dydd Gwener 21 Chwefror.

Rosemary

Y Fonesig Rosemary Butler AC, y Llywydd
Cadeirydd y Pwyllgor Busnes

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Mae cyfyngiadau ar y ddogfen hon

Mae cyfyngiadau ar y ddogfen hon