

Y Pwyllgor Iechyd a Gofal Cymdeithasol

Lleoliad:

Ystafell Bwyllgora 1 – Y Senedd

Dyddiad:

Dydd Iau, 6 Mawrth 2014

Amser:

09.10

Cynulliad
Cenedlaethol
Cymru

National
Assembly for
Wales



I gael rhagor o wybodaeth, cysylltwch â:

Llinos Madeley

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Agenda

Cyfarfod preifat cyn y prif gyfarfod (09.10 – 09.15)

- 1 Cyflwyniad, ymddiheuriadau a dirprwyon**
- 2 Ymchwiliad i fynediad at dechnolegau meddygol yng Nghymru:
Sesiwn dystiolaeth 8 (09:15 – 10:05) (Tudalennau 1 – 27)**

Ymchwil Canser y DU

Emma Greenwood, Pennaeth Datblygu Polisi, Ymchwil Canser y DU

Clare Bath, Swyddog Materion Cyhoeddus Cymru

Dr Tom Crosby, Cyfarwyddwr Clinigol Canolfan Ganser Felindre a Chyfarwyddwr
Meddygol Rhwydwaith Canser De Cymru.

Bernadette McCarthy, Rheolwr Radiotherapi, Canolfan Ganser Felindre

- 3 Ymchwiliad i fynediad at dechnolegau meddygol yng Nghymru:
Sesiwn dystiolaeth 9 (10:05 – 10:50) (Tudalennau 28 – 32)**

Cynghrair Geneteg y DU

Buddug Cope, Cyfarwyddwr Datblygu Cynghrair Geneteg y DU
Emma Hughes, Swyddog Datblygu Cynghrair Geneteg y DU
Hayley Norris, Cynrychiolwyr cleifion

Toriad (10.50 – 11.00)

**4 Ymchwiliad i fynediad at dechnolegau meddygol yng Nghymru:
Sesiwn dystiolaeth 10 (11:00 – 12:00) (Tudalennau 33 – 42)**

MediWales

Gwyn Tudor, Rheolwr y Fforwm

Cinio (12.00 – 13.00)

**5 Ymchwiliad i fynediad at dechnolegau meddygol yng Nghymru:
Sesiwn dystiolaeth 11 (13.00 – 14.00) (Tudalennau 43 – 56)**

Yr Athro Carl Heneghan, Canolfan Meddygaeth Seiliedig ar Dystiolaeth, Prifysgol Rhydychen

Partneriaeth Gwyddoniaeth Iechyd Academaidd De-ddwyrain Cymru

Dr Corinne Squire, Rheolwr

Rhwydwaith Gwyddoniaeth Iechyd Academaidd Gorllewin Lloegr

Lars Sundstrom, Cyfarwyddwr Mentor a Chyfieithu
Deborah Evans, Rheolwr Gyfarwyddwr

6 Papurau i'w nodi (Tudalennau 57 – 62)

Llythyr gan y Prif Swyddog Nyrsio mewn perthynas â chymau gweithredu sy'n deillio o gyfarfod y Pwyllgor ar 30 Ionawr 2014 (Tudalennau 63 – 82)

7 Cynnig o dan Reol Sefydlog 17.42 i benderfynu gwahardd y cyhoedd o'r cyfarfod ar gyfer y canlynol:

Eitem 8.

8 Trafod ymateb y Gweinidog Iechyd a Gwasanaethau Cymdeithasol i lythyr y Pwyllgor ynghylch yr ymchwiliad dilynol i leihau'r risg o strôc (14.05 – 14.20) (Tudalennau 83 – 91)

Eitem 2

Mae cyfyngiadau ar y ddogfen hon

[National Assembly for Wales](#)

[Health and Social Care Committee](#)

[Access to medical technologies in Wales](#)

Evidence from Cancer Research UK – MT 31

Cancer Research UK submission to the National Assembly for Wales Health and Social Care Committee inquiry into access to medical technologies

October 2013

Cancer Research UK welcomes the opportunity to respond to the Health and Social Care Committee inquiry into access to medical technologies in Wales, our response is based on consultation with radiotherapy experts from Velindre Cancer Hospital.

Cancer Research UK is leading the sector in championing improvements to the radiotherapy service in the UK. In 2011, we ran the ‘Voice for Radiotherapy’ campaign which led to a commitment from the Prime Minister to improve access to advanced radiotherapy. In 2012, we supported the implementation of the Radiotherapy Innovation Fund (RIF), a £23 million investment by the UK Government designed to increase access to Intensity Modulated Radiotherapy (IMRT) across England.

Radiotherapy is a highly effective way of treating cancer. Four in ten people whose cancer is cured have received radiotherapy, and every year radiotherapy helps cure more people than cancer drugs. Cancer Research UK believes that all patients in the UK should have access to the most appropriate, high-quality treatment that their doctor recommends.

Access to radiotherapy in Wales is still lower than optimal – around 37%¹ of cancer patients in Wales receive radiotherapy as part of their treatment, which falls below the recommended level of 52%.² Although the UK invests far more in cancer research than any other country in Europe, it is often much slower to take up the fruits of this research. Innovations such as Intensity modulated radiotherapy (IMRT) were developed in the UK, but have been adopted more swiftly into practice elsewhere.

Key recommendations

¹ Cancer Research UK, *Achieving a world class radiotherapy service across the UK* (2009), 9.
http://www.cancerresearchuk.org/prod_consump/groups/cr_common/@nre/@pol/documents/generalcontent/crukmg_1000ast-3360.pdf

² Ibid

- We want to see improvements to the number of cancer patients accessing radiotherapy every year in Wales, and to see faster adoption of new techniques within the NHS in Wales. We welcome recent developments to improve the service such as the implementation of specialised commissioning and the Welsh Government Technology Fund. However, it is vital that there is a clear roadmap underpinning such activities to ensure that Wales can develop a world-class radiotherapy service in the future. Regarding new techniques, we would welcome the publication of a comprehensive plan in place setting out a plan for future service improvements.
- We would urge the Committee to undertake further work to understand the barriers to research being carried out within the Welsh NHS, and to ensure that commissioners use clear and transparent criteria to determine whether the evidence for use of a new technology is sufficient for routine use within the NHS.
- We support the principle of having a national specialised commissioning service for radiotherapy. However, this must work in practice to minimise the bureaucracy required to make improvements to the service and should use a transparent, consistent set of principles in commissioning new technologies.
- We would welcome greater clarity around the WHSSC approval process and, where possible, we want to see this process become more efficient.
- Locally, we also believe that structures for the approval of additional service delivery could be streamlined to help patients in Wales to gain quicker access to radiotherapy treatment.
- Closer alignment of capital and revenue funding is needed, and experts tell us that a more streamlined and transparent approach is needed for decisions on the revenue commissioning of radiotherapy, and that the process needs to be more facilitative so that cancer centres can make the best possible case for providing innovative treatments to patients.
- We would welcome the publication of a progress update on the report, *Radiotherapy Equipment Needs and Workforce Implications 2006 – 2016*, and more data on how radiotherapy is being delivered.
- Working with other nations to ensure that all patients the best possible treatment.

Faster adoption of new technologies and Developing the evidence base

We would like to see faster adoption of new radiotherapy techniques in Wales. An equivalent of the All Wales Medicines Strategy Group (AWMSG) for medical technologies could help develop this.

Research is vital to developing the evidence base supporting routine funding of new technologies within the NHS. However, radiotherapy research in the UK is underfunded and we are concerned that there are not enough incentives for research to be carried out within the NHS across the UK.

The commissioning of radiotherapy in Wales

We support the principle of having a national specialised commissioning service for radiotherapy, but the current system must be streamlined and its processes made more transparent.

Currently, Welsh Health Specialised Services Committee (WHSSC) is responsible for specialised commissioning. Whilst there are robust processes in place to assess the need for changes and introduction of new techniques to the radiotherapy service - through the WSAC Clinical Oncology Subcommittee, the Cancer Networks and the Cancer Centres - experts suggest that the specialised commissioning process is not joined up.

In addition, experts report long timescales between the point where detailed proposals for service developments are submitted by cancer centres and the point at which they are approved by the WHSSC. Also, that the decision making process that occurs between the various stages is not transparent and centres receive very little communication during this time. Therefore, greater clarity around the WHSSC approval process and where possible greater efficiency would be welcomed.

Streamlining of the bureaucratic process

At the moment, Local Health Boards (LHBs) are required to approve requests from cancer centres to deliver additional services before these are referred to the Welsh Health Specialised Services Committee (WHSSC). Experts tell us that it can take a long time for plans to be scrutinised at local level, and the cancer centres also have to manage the different processes undertaken by each LHB. Once requests are referred to the WHSSC, this adds further time to the bureaucratic process and therefore delays these services reaching patients.

Closer alignment of capital and revenue funding for radiotherapy

Experts suggest that a more streamlined and joined up approach is needed between the **capital** and the **revenue** funding of the radiotherapy service.

We welcome the Welsh Government Health Technology Fund which provided the **capital** investment for stereotactic body radiotherapy (SBRT) and stereotactic radiosurgery service (SRS) equipment at Velindre Cancer Hospital. However this service cannot be fully established without the **revenue** funding needed for delivering treatment to patients including staff time, the cost of implementing and operating machines, and training.

Revenue funding is commissioned through WHSSC. Experience across Cancer Centres in Wales suggests that the current system can be slow, with the business cases for intensity modulated radiotherapy (IMRT), image-guided brachytherapy and SBRT taking up to a year or more to process.

Assessing needs and planning for the future

In 2006, the Cancer Services Co-ordinating Group in Wales (now the Cancer NSAG) published

Radiotherapy Equipment Needs and Workforce Implications 2006 – 2016.³ It stated that:

- With current equipment and manpower resources, most patients in Wales are not receiving their radiotherapy according to the Welsh National Cancer Standards which endorse the Royal College of Radiologists (RCR) Standards.
- Currently Wales has 3.7 linear accelerators per million population, significantly less than the average provision in England or Scotland which stands at 4.7 and 4.98 linear accelerators per million respectively.
- In order to provide adequate provision of radiotherapy in Wales, it is recommended that Wales should aim to provide 58,000 fractions of radiotherapy per million population by 2016.

We would welcome an updated progress report on these issues, as more data is needed to analyse how radiotherapy is being delivered and whether improvements are being made.

Standards

We believe that a robust, transparent set of standards and principles need to be developed for the commissioning of new technologies in Wales which clearly delineates the responsibilities of all stakeholders. Currently, there is no cover-all service specification for the standard of the radiotherapy service in Wales - while we welcome efforts to introduce innovative techniques to the service, it is important that the governance structures covering the existing service are fit for purpose.

Working with the other nations

Experts suggest that it will also be important for Wales to work with groups in England including the Clinical Reference Group (CRG) for Radiotherapy, the Radiotherapy Board and the programme leads for Proton Beam Therapy. Work is also being undertaken in England to determine ambitions for the radiotherapy service over the next decade and we want to ensure that patients in Wales do not miss out on future innovations. We believe that all patients in the UK should have access to the most appropriate, high-quality treatment available and Wales should be prepared to align with other nations if this guarantees patients the best possible treatment.

Conclusion

We believe that a more joined-up, consistent approach to commissioning for radiotherapy is needed in Wales, and that work could be undertaken to promote faster adoption of new techniques across Centres.

We would be happy to provide further information or an expert to discuss these issues further, as required. Please contact Clare Bath (clare.bath@cancer.org.uk; 0292 089 2834).

³ Cancer Services Co-Ordinating Group, *Radiotherapy Equipment Needs and Workforce Implications 2006 – 2016* (2006), 6.

Glossary

- **Intensity modulated radiotherapy** uses hundreds of tiny devices called collimators to shape the radiotherapy area (delivering **3D conformal radiotherapy**), giving very precise doses to a cancer or to specific areas within the tumour or to avoid structures that would be damaged by the radiotherapy.
- **Image guided radiotherapy** uses scans during radiotherapy treatment to show changes in the size and position of the tumour.
- **Image-guided brachytherapy** is a form of radiotherapy that delivers radiation internally by placing a radioactive source within an applicator, which sits in or around the tumour. It uses CT or MRI imaging to pinpoint exactly where the cancer is before each treatment, which makes it possible to shape the radiation dose to match the shape of the tumour and avoid damaging vital organs.
- **Stereotactic body radiotherapy** and **stereotactic radiosurgery** are similar techniques which deliver radiotherapy in fewer sessions, using smaller and highly precise radiation fields as well higher doses than 3D conformal radiotherapy. Despite its name, stereotactic radiosurgery is not a surgical technique.
- **Proton beam therapy** uses a different type of radiation beam called a proton beam which gives a higher dose of radiation straight to the cancer, so there is less chance of damage to nearby healthy tissue.

About Cancer Research UK

Every year around 300,000 people are diagnosed with cancer in the UK. Every year more than 150,000 people die from cancer. Cancer Research UK is the world's leading cancer charity dedicated to saving lives through research. Together with our partners and supporters, Cancer Research UK's vision is to bring forward the day when all cancers are cured. We support research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses. In 2012/13 we spent £342 million on research. The charity's pioneering work has been at the heart of the progress that has already seen survival rates in the UK double in the last forty years. We receive no government funding for our research.

Eitem 3



Genetic Alliance UK
Supporting. Campaigning. Uniting.

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[Health and Social Care Committee](#)

[Access to medical technologies in Wales](#)

Evidence from Genetic Alliance UK – MT 21

Consultation response

Inquiry into access to medical technologies in Wales

Response from Genetic Alliance UK, 18th October 2013

Introduction

1. Genetic Alliance UK is the national charity supporting all those affected by genetic conditions. We aim to improve the lives of people affected by genetic conditions by ensuring that high quality services and information is available to all who need them. Our membership represents more than 160 voluntary organisations working for a wide range of conditions, many of which pose complex health and social care needs.
2. Genetic Alliance UK operates through project and policy work. One of our projects, Syndromes Without A Name (SWAN UK) supports families of children with undiagnosed genetic conditions. It is estimated that around half of all children who attend genetics clinics in Wales do not get a diagnosis for their condition – they may be affected by novel genetic mutations or chromosome rearrangements. Due to lack of a diagnosis, many families experience difficulties in accessing help and support from various services including health, education and social services.
3. In 2008 Genetic Alliance UK launched Rare Disease UK (RDUK), the national multi-stakeholder alliance for people with rare diseases and all who support them. RDUK is campaigning for a National Strategy for Rare Diseases in the UK, to ensure that patients and families living with rare conditions have equitable access to effective services.
4. We welcome the opportunity to respond to this inquiry.

The value of new or alternative medical technologies

5. There are many thousands of genetic conditions which affect patients and families in Wales, however, for those conditions, there are many fewer that have effective cures or treatments. Many of those that do exist are generally risky, expensive and/or bring significant adverse effects. The vast majority of patients with genetic conditions are left with palliation and mitigation, to limit the effect of the condition as much as possible to raise the quality and quantity of their lives as much as possible. There is an enormous burden of unmet need in the community of those affected by genetic conditions.

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Registered company number: 05772999

Tudalen 28

6. Early diagnosis of genetic conditions through utilising new, advancing medical technologies can provide significant benefits, both practically and psychologically for parents of children who have a genetic condition. A diagnosis offers the patients' clinician and family a greater understanding of health difficulties and a clear genetic diagnosis can enable more focussed treatment choices and therapeutic planning and better access to information about their prognosis and future needs.
7. A technology that has been revolutionary in providing many more children with an early diagnosis is microarray comparative genomic hybridization (array-CGH). This advanced technique for genetic testing detects copy number changes in a person's chromosomes. This means it looks for deletions or duplications in their DNA that would not be identified using conventional microscopy-based chromosome analysis (karyotyping).
8. The improvement in diagnostic power that is available using array-CGH over karyotyping is clear, and valuable to families. Many children with developmental delay who have had a 'normal' result from a microscopy-based chromosome analysis in the past have, after consultation with their parents, been retested using genomic micro array analysis. A number of these children have been found to have a microdeletion or microduplication.
9. The diagnoses that array-CGH can provide allows parents to better plan their child's life. The diagnosis can be given to the school system to enable the child to gain access to special services. It also provides an opportunity for parents to gain further insight and help from support groups where they can meet parents facing similar challenges. One parent commented: 'It gave closure and we are very grateful for the test. We, and anyone involved in her lifelong care, will be better equipped for the future'.
10. It is also significant that when a specific chromosome imbalance is diagnosed, the parents (and other family members) can be tested to find out whether they are carriers of changes in their DNA that put them at risk of having more children with a chromosome change. As a result, these new, advancing technologies are empowering parents to have more informed choice in planning for future pregnancies. Similar benefits should be considered as part of the assessment criteria for new and alternative medical technologies that help provide patients with a clear genetic diagnosis.

Assessment of potential benefits of new or alternative medical technologies

11. The patient perspective is vital in assessing the potential benefits of new or alternative medical technologies. The importance of including the patient perspective during the early stages of assessment is demonstrated in the example of array-CGH. The parent/family member will be best placed to value the real-life impact of early diagnosis and subsequent planning for services that can be realised as a result of the timely uptake of new medical technologies. Genetic Alliance UK supports the introduction of a mechanism that enables patients to participate in the early stages of NHS assessment of technologies.
12. It is vital that the NHS introduce a robust, transparent mechanism for assessing the potential benefits of new and alternative medical technologies which engages patients. Patients in Wales have been unable to gain access to advanced medical technologies that have been introduced in other nations of the UK for the purpose of genetic testing for some years. Array-CGH was introduced by genetics centres in England between 2009-2010; however, the service was only launched in Wales this year as a result of local service reconfiguration. Patients in Wales continue to be disadvantaged because of the lack of investment in clinical care which impedes service delivery, further research opportunities and weakens the impact of the Welsh Government's Science for Wales strategy.
13. As part of NHS assessment, Genetic Alliance UK supports the introduction of a process which aids the timely uptake and continued availability of new medical technologies for the benefit of patients in Wales by ensuring that appropriate funding is made available. Technologies such as Array-CGH and Next Generation Sequencing are revolutionising genetics services by allowing

testing to be undertaken concurrently, at a faster pace and with greater accuracy producing better results.

Capital Investment

14. Work undertaken by the SWAN UK project has highlighted the extent to which further investment in research and new technologies is vital to advance our knowledge of genetic conditions. Members of SWAN UK are involved in research studies which aim to associate the symptoms that children affected by a syndrome without a name present with changes in their genetic code. This work has the potential to discover many more genetic conditions and bring the benefits associated with a diagnosis to families affected by these conditions. This research utilises the new technologies being developed to read our genetic information faster and more cheaply.
15. These new technologies bring greater potential for a broader and more rapid search for patients with a rare disease; however, this service comes at a price. Infrastructure investment will be necessary to ensure the ability of NHS Wales to keep pace with these developments and to participate in this kind of ground-breaking research.
16. Investment in new technologies will in many cases lead to savings over the previous generation of technology. Better and quicker diagnosis will allow for quicker treatments and fewer events of wrong treatments being delivered to patients. Earlier intervention can prevent the need for more expensive 'end stage' interventions. As a result, health and social care budgets will benefit from this initial outlay on new technologies. Ultimately, capital investment will lead to cost savings and better health.

The need for sustainability in supporting the uptake of new technologies

17. The availability of funding to aid on-going development costs for new technologies such as next generation sequencing is essential to allow the NHS to keep pace with this constantly evolving field of development. A process to access funding which fills the gap in terms of on-going costs associated with reagents, staff time for developing protocols and validating clinical services locally is essential in allowing Wales to be part of a progressive health service that embraces new medical technologies which are fundamental to genetics research and providing diagnoses for patients.
18. Investment in expertise to analyse the genomic data that is generated as a result of using next generation sequencing technology is essential. There is currently a plethora of data which is being produced as a result of these highly advanced technologies which leads to a disparity between the amount of data being produced and the speed at which analysis can take place. This disparity has been attributed to the lack of sufficient expertise in bioinformatics and sequencing knowledge in Wales which results in inadequate support for conducting analyses of data. This additional support would bring real benefits to patients who currently experience a number of difficulties in accessing a diagnosis. Rare Disease UK's Experiences of Rare Disease: Patients and Families in Wales found that over 23% of patients surveyed had to wait more than 2 years for a diagnosis, with more than 13% waiting over 10 years. 33% of patients attended more than 10 GP appointments before receiving a diagnosis.
19. Genetic Alliance UK endorses the introduction of a process to support the training of specialist informaticians so that they are equipped to analyse the collection of genomic data that is produced as a result of next generation sequencing capabilities. This investment would result in quicker analysis of results leading to faster diagnosis time for patients and greater benefit for the health service in terms of focussed treatment choices and therapeutic planning at an earlier stage in the clinical pathway.

Embracing medical technologies

20. Genetic Alliance UK accepts that medicines are outside the scope of this inquiry; however, we believe that the NHS in Wales should be embracing diagnostic technologies that are associated with stratified medicine and are currently revolutionising the development process. Companion diagnostics are used to assess a unique trait of a patient's condition (biomarker), the outcome of a diagnostic test will determine whether that patient may respond to the associated treatment.
21. An example of how this technology works for patients can be seen in a treatment for breast cancer. A subset of patients will have lesions that express HER2 (growth-promoting protein). HER2 is also a biomarker for aggressive disease. Herceptin is a drug that has been designed to interfere with how this protein functions so a patient who tests positive for HER2 expression will be expected to benefit from this medicine. Conversely, a patient that does not have a presentation of this biomarker will probably not benefit from this treatment.
22. This method of targeted medicine ensures that patients are treated based on their response profile so that those patient populations who are known to respond to the treatment will receive the right treatment at the right time. This results in improved patient outcomes and a reduction in the number of patients receiving unnecessary treatments avoiding the risk of side-effects. Ultimately the health service will save on resources and costs as medicines will only be commissioned when they work for a specific patient population.

Joined up approach to commissioning

23. It is crucial that the NHS recognises that there needs to be a joined up approach to commissioning for clinical genetics services. At present the lack of process impacts negatively on patients who are already disadvantaged by the fact that they do not have a diagnosis for their condition and cannot access information or plan for the future as they have no prognosis of how their condition may develop. Genetic Alliance UK calls upon the Welsh Government to introduce and implement a commissioning process for genetics services in Wales.
24. Development of a commissioning process would require input from commissioners, clinicians, geneticists, researchers, Public Health experts and patient representatives who have experience of the service. This group would need to examine the way that genetics services are currently delivered in Wales. It would provide advice about opportunities to improve productivity and efficiency through a process that streamlines services to deliver care that is cost effective and has greater impact on improved outcomes and improved quality of care for patients. This process would include the development of a national procurement policy for medical technologies and the continued development of these services in Wales.
25. Array-CGH and next generation sequencing capabilities are advancing at a rapid speed. It is vital for patients that these technologies are made available so that it is possible to get early diagnoses so that parents/patients can make informed choices and plan for the future. Investment in the early stages of the process will incur further cost benefits later in the treatment pathway as treatments may be tailored to the particular condition. It will also provide benefits for the future planning of services in both the health and social care setting.

Genetic Alliance UK believes that the introduction of a process for commissioning genetics services is essential to enable NHS Wales to overcome the current barriers in accessing medical technologies. Ultimately, it is patients who will be disadvantaged by the lack of a robust, transparent process for assessing the potential benefits of new or alternative medical technologies and ensuring that they are made available in a timely way.

26. It is a transformational period for many patients with genetic conditions. Medical technology is advancing at a rapid pace and new developments have enabled genetic testing techniques to become more sophisticated, undertaken concurrently and at a faster rate, improving the rate and breadth of the search for a diagnosis. Early and accurate diagnosis will aid understanding which

will allow patients to better manage their condition and plan for the future. It is imperative that the right mechanisms and funding streams are developed to ensure that patients in Wales can take advantage of these latest medical technologies.



Alastair Kent OBE
Director



Association of British Healthcare Industries

Access to Medical Technology in Wales

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17 October 2013

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Evidence from Association of British Healthcare Industries (ABHI)

- MT 12

National Assembly for Wales: Health & Social Care Committee

Inquiry into access to medical technologies in Wales

Introduction

1. The Association of British Healthcare Industries (ABHI) welcomes the opportunity to contribute to this inquiry.
2. ABHI is the industry association for companies operating in the UK medical technology sector. We represent over 240 member companies, both large multi-national organisations and small British-based businesses. Our purpose is to promote the benefits, value and adoption of innovative, safe and effective medical technologies to ensure optimum and high-quality patient outcomes in the UK and key international markets.
3. Product development in Medical devices can be characterised by models, both running simultaneously. Firstly innovative and step change introduction of technology as described below and secondly rapid and incremental adaptation and improvement to existing products. It is important that processes are in place to enable both types of product developments to rapidly reach the market.
4. This response sees 'new or alternative medical technologies' as being either a) new or novel technologies that offer a beneficial step change in care delivery; or b) those that are in use at the moment, and form an integral element of existing best-in-class clinical practice, but are not consistently used across the NHS.
5. Every day, advances in medical technologies help improve and save the lives of patients in the NHS by enhancing treatments of many life-threatening diseases and long-term conditions. It is estimated that, across the UK, nearly 40 million people come into contact with a medical device every day.
6. Modern healthcare offers patients with ill health dramatically improved treatment outcomes and quality of life compared to the past. This is in part because continuous innovation in medical technologies changes the way health care is delivered, as it has done over most of the existence of the NHS, for example through developments of implants (the hip replacement), surgical techniques (laparoscopic surgery) or imaging (CT and MRI scanners).
7. Demand for healthcare is set to rise as an aging population, the growing prevalence of chronic diseases, and increasing public expectation continue to exert pressure on already stretched resources. The NHS faces unprecedented change to meet these challenges and must evolve to stay ahead of these societal shifts at a point when public expenditure is unlikely to grow significantly.
8. Against that background, the NHS needs innovation in medical techniques and equipment to make continuous improvement in delivering high quality patient care. For the medical technology industry – an important manufacturing sector for Wales as for the UK - developing innovations is a key driver for long term growth.
9. The challenge now is to change the relationship between the NHS and its suppliers of all kinds, to get better value from the technologies available, in order to enable the kind of service transformation that has been seen in other sectors of the economy.

Key needs

10. There needs to be a focus on monitoring and rewarding innovation uptake, specifically to streamline access to funding of innovations. A regime is needed in which there is measurement and monitoring of the uptake of innovation against national benchmarks of some sort, ensuring that variances in spread of "best clinical practice" in localities are scrutinised and addressed.
11. Procurement processes should be aligned to clinical needs, to become strategic enablers of innovation adoption. This includes basing purchasing decisions on specifications drawn up by clinicians that focus on

solutions that achieve required clinical outcomes rather than a simplistic version of “Most Economically Advantageous Tender” (MEAT).

12. There needs to be a link between evaluation systems and reimbursement processes (here we mean the system by which procedures/episodes of care are remunerated). This would allow for the seamless translation of a judgement about clinical effectiveness and economic utility of a technology into costing and payment systems. Further, there is the need for flexibility of reimbursement systems to embrace technological developments part way through funding cycles to avoid systematic delays in adoption.
13. Minimise the “pilot” culture Greater national coordination is required to trial innovations consistently such that local organisations do not continually pilot but rollout innovations based on experience and findings of early adopters or accepted national or international HTA processes.
14. Emphasis on achieving outcomes across the whole patient pathway. Quality standards and clinical indicators should be outcomes-based and define levels of care across whole patient pathways. Innovations that can aid the achievement of the outcomes being targeted should be explicitly referred to and clinicians encouraged to embed them in each step of a patient pathway.
15. Adopt a longer term view of investment return that also breaks down budget silos. The need hitherto to financially account much innovative equipment in a single year often inhibits the matching of benefits to cost over the medium/long-term. The positive impact of innovations must take into account the value brought across different budget cycles and silos. Breaking-down silos and bridging budgeting cycles requires greater collaboration across all parts of the NHS and across care settings. A whole system view of efficiency savings can be generated by a new approach to financing and investment decisions.
16. Strategic partnering with industry. The medical technology industry has potential solutions to assist the NHS meet the challenges it faces. To realise these solutions Board-level sponsored strategic relationships with industry must be the norm rather than the exception in the NHS.

Purchasing for outcomes

17. Medical technologies are a key element in the achievement of high quality clinical outcomes and modern healthcare is based partly upon the convergence of clinician skills with an extraordinarily diverse and specialised base across every aspect of engineering. The diversity of products and services that constitute medical technologies means that the mechanism by which they impact on outcomes varies. Some do so through their direct application, for instance cardiac implantable devices, and others indirectly, for example those technologies that reduce the amount of time taken to conduct a procedure or intervention. Taken together, changes in healthcare delivery have complemented and supported those in demography and public health, supporting people to continue to live active lives despite increased prevalence of long-term disease conditions.
18. Determining the outcomes being sought and how medical technologies can aid their achievement requires analysis across the care pathway to identify the extent by which care needs to improve, and an objective process to distinguish and purchase the technologies that may aid that improvement. For example in haemodialysis and peritoneal dialysis of adults with chronic renal failure, there is an understanding of high quality renal care across settings, age groups, and complexities to incentivise vascular access via a fistula or graft over other forms of access (as these have infective and thrombotic complications).

Purchasing for value

19. In public procurement, contracts are let by contracting authorities through a process of competitive tender. The aim is to achieve best value for money by opening-up public procurement to competition. What is sought is a balance between price and value – the Most Economically Advantageous Tender. A range of factors other than cost is taken into consideration, from reliability to training and support.

20. Total Cost of Ownership and Life-Cycle Costing are vital considerations and in the private sector are typically used to compile a return on investment (RoI) calculation or other cost-benefit analysis to inform a business case to support the investment strategy.
21. These concepts are known to NHS purchasers but they are not embedded in MEAT. The de facto application of MEAT is a system which places greater significance on unit cost of a product/service above quality and long-term benefits, though the MEAT principle was developed to level the price-value equation. This means that the benchmark for decision-making most often defaults to lowest acquisition price.
22. Purchasing for value will mean a better understanding and application of MEAT. In a publicly funded healthcare system the concept of “economically advantageous” must address whether public money is put to good use and primarily from the perspective of the taxpayer. In this context, both buyers and sellers, often stumble with cost-benefit equations, the quantification of benefits and the creation of ROI.
23. Suppliers develop economic models to convey value, taking into consideration elements such as opportunity cost and long-term benefits realisation, but are not able to convey their message to the correct decision maker. From the buyer’s perspective, the focus on current year savings leads to decisions that forsake the long-term.
24. To overcome these scenarios, an investment model needs to be jointly developed that:
 - underpins the procurement of medical technologies across the medium/long-term horizon, very likely over several years;
 - can withstand the scrutiny of a variety of stakeholders; and
 - is capable of informing value for money decisions.
25. This would be a significant development for the management of NHS resources. In the current climate, the historical approach in the NHS - “to improve quality more money has to be spent” - is redundant. The complex relationship between clinical improvement and finances has to be unpicked, to ensure that achieving quality and outcomes gains are routinely seen as returns on investment, gained from the use of scarce resources.

17 October 2013



[National Assembly for Wales](#)

[Health and Social Care Committee](#)

[Access to medical technologies in Wales](#)

Evidence from MediWales – MT 23

October 17, 2013

FAO: David Rees AM, Chair, Health and Social Care Committee, National Assembly for Wales, Cardiff Bay, Cardiff CF99 1NA,
HSCCommittee@wales.gov.uk

Ref: Inquiry into access to medical technologies in Wales

Dear Mr Rees,

1.0 Introduction

1.1 Thank you for the opportunity to make this submission to the inquiry into access to medical technologies in Wales. We welcome the fact that the Committee has identified this as an issue that requires consideration. We are pleased to note that, following the consultation on the scope of the enquiry, the benefits of new or alternative technologies; the need for a joined up approach to commissioning; and engagement with manufacturers of new technologies have all emerged as prominent themes.

1.2 MediWales is the innovation forum for the Life Science sector in Wales. Independently owned by its 140 members, which include industry, academic and clinical organizations. MediWales was originally established with support from the WDA and continues to run part funded by the Welsh Government Life Science Sector Team. MediWales' board of directors is drawn from senior figures in the sector and our Expert Advisory Group comprises over 30 of the most respected people in

academia, industry and healthcare.

1.3 This submission is intended to reflect the concerns raised by Welsh manufacturers regarding the introduction of new technologies into the Welsh NHS. Many of which have been adopted in other markets and so can demonstrate a proven track record in the delivery of improved patient care, disease management and/or reduce healthcare costs. However despite this demonstrable evidence companies are still experiencing systemic barriers to adoption in Wales.

1.4 Evidence was gathered during discussions with members of MediWales' Expert Advisory Group and at a dedicated meeting held in Cardiff on 11th October 2013. The issues raised can be supported by additional evidence if required. Included are two case studies to illustrate more widely identified concerns.

2.0 Concerns

2.1 The most pressing issues identified revolve around the importance of efficient identification, evaluation and adoption of the best available new technologies.

2.2 There is a gap between research into medical technologies in Wales and the adoption of new technology. Research is carried out within the NHS and coordinated by NISHCR, procurement is carried out by individual health boards and the procurement body Shared Services Partnership. However the former has no direct remit to drive adoption of new technologies and the latter is largely tasked with procuring known existing technologies. While this gap remains it is a barrier to adopting new technologies that may support improved patient care and reduce costs of care.

2.3 There are organisations within Welsh NHS and academia that are regarded as leaders in new technology assessment.

- SMTL (Surgical Materials Testing Laboratory) in Bridgend is often named as an example of best practice in device evaluation that the wider UK can learn from.
- Cedar at the Cardiff Medicentre is an external medical technology evaluation centre for NICE.

- The Wound Healing Research Unit at Cardiff University is recognised internationally for its work in trialing and evaluating devices.
- The Health Informatics Research Unit at Swansea University has a ground breaking, holistic approach towards evaluating new eHealth technologies.

2.4 Unfortunately while Wales boasts these exemplar centres of technology evaluation there is no systematic, all Wales, approach to the NHS identifying, evaluating and adopting new technologies, or an entry point for technology providers to submit new technologies for evaluation.

2.5 In 2010 MediWales presented a report to NISCHR titled '*Access to Clinical Expertise in Wales*'. The report summarises the outputs from a programme of events and working groups held with key stakeholders in the health technology sector in Wales. Findings were that medical technology development and adoption in Wales could be improved through access to clinical expertise at a number of stages. One of which was a formal process for the timely, cost effective evaluation of new technologies as they are brought to market. Many of the other recommendations made in this report were received well, developed and adopted by NISCHR, however technology evaluation remains a problem, apparently because there is no one organisation or department with the responsibility for taking a lead on the issue.

2.6 Barriers imposed by silo budgets within the NHS lead to narrow appraisal of cost advantages for adoption of new technologies: not a holistic approach, where a new technology may cost more per unit than an existing product but have enormous wider cost savings for the NHS/Social Services as a whole and certainly significant patient quality of life benefits.

2.7 A tendency to retender for products based on incumbent specifications or historical requirements can restrict the adoption of innovation.

3.0 Case Studies

3.1 The following case studies have been selected to illustrate a wider issue voiced by many of our members.

3.2 Invacare, Bridgend

This case study suggests that opportunity to improve the quality of life of COPD patients in Wales may be being missed by evaluation and procurement barriers to adoption of new technology. Invacare, a large, medical technology company based in Bridgend, have made little progress trying to enter the home oxygen market in Wales with a novel product that has been adopted by many other health providers. Home oxygen is supplied to over 100,000 patients in Wales, mostly for the management of COPD. Invacare's innovative product, Homefill, allows patients to fill small, easily carried, oxygen canisters rather than needing to rely on the regular delivery of much larger cylinders. This innovation can be demonstrated to provide some chronic patients with additional freedom and mobility. The company regularly competes for NHS contracts and so understands that they can win or lose competitive tenders, their concern is that there appears to be no way for the product to be objectively evaluated and fairly compared to traditional methods. Their experience suggests that contracting policies, a resistance to adopt disruptive innovation and incumbent interests have blocked the adoption of this innovation. They feel that there is a lack of system in place to present market and patient data for evaluation.

3.3 EKF Diagnostics Holdings plc, Penarth

EKF Diagnostics is an established company in the diagnostics market. EKF has sales in over 100 countries, over 300 staff and a turnover of around £30m. EKF have shared with us the experience of trying to introduce one particular range, a HbA1c point of care analyser, into the UK market. The product, Quo-Test, helps with the management of diabetes by allowing instant feedback to patients without the need to submit venous blood samples to a central laboratory. As with Invacare the company is experienced at competing for contracts and understand that tenders can be won or lost when assessed on a "level playing field". However they are finding it very difficult to even get this new product evaluated by the NHS in England or Wales. The company has independent studies and patient feedback that they are happy to share but cannot initiate an evaluation process. The company has submitted an application to NICE's Medical Technology Evaluation Programme (MTEP) but has been refused an evaluation for reasons that are difficult to understand. This refusal leaves the company with few alternative opportunities to present their proven Innovation to the Welsh and English NHS. They have therefore concentrated their effort on international markets where the product has been well received.

4.0 Conclusions

4.1 While evaluation remains an adoption gap, technology innovations required for the best possible patient care may not even be being considered. There is a lost opportunity for efficiency gains through use of alternative technologies. Expertise in treatments using 'state of the art' technology may also be lost. Considerable technological advances are being made at present that assist in treatment of patients at home through remote monitoring and eHealth applications and advancements that reduce the cost of medicines through improved diagnostics and targeted treatments. The current pace of developments in the field requires a concerted coordinated effort to be maintained in order keep abreast of these advances.

4.2 MediWales' primary stakeholder is Welsh Industry. In recent years the relationship between Welsh NHS and Industry has become increasingly collaborative. Access to clinical trials services, including permissions, contracts and timescales have either greatly improved or systems are in place that will deliver significant improvements. Welsh industry stakeholders have felt consulted and listened to throughout the developments that have resulted in the creation of Health Research Wales. This situation has resulted in numerous examples of clinicians and manufacturers collaborating on innovations that will deliver patient and cost benefits to the NHS. However, while working closely with industry and academia improves awareness of technological advancements, this spirit of collaboration is not an alternative for a systemic, impartial process of horizon scanning and evaluation.

4.3 Access to medical technology should always be driven by a collective effort to support the very best patient care. While economic benefits are a positive and the drive to reduce costs is a necessity, evaluation should be driven by wider reaching health economics models that include the long-term benefits to the population and fewer clinical interventions.

4.4 An agreed economic evaluation model used by the NHS and commercial companies would help them to pursue innovations more likely to be adopted, based on cost and value added.

5.0 Recommendations

- 1) We recommend an examination of current systems for identifying and adopting new technologies, including an examination of technology assessment across the UK and abroad and consideration of any gaps in the adoption processes in Wales.

- II) We recommend an examination of procurement practices and the role they can play in encouraging the adoption of the best technologies available.
- III) We recommend that the Committee consider the implementation of a national level system for the efficient identification, evaluation and adoption of new technologies that support best practice in improving patient care and reducing health care costs. We suggest that this system requires; proactive horizon scanning; a technology submissions process; transparent health economic assessment and technical evaluation.
- IV) We recommend the use of all existing available data, such as NICE evaluations, but we feel that that the adoption of NICE evaluations is by no means a complete solution.

6.0 Finally our members wish to stress that there should be a genuine sense of urgency about addressing the issues raised. Delay in introducing an appropriate system for access to medical technologies in Wales carries the risk of impacting on patient care now and for the foreseeable future. The MediWales team is happy to assist the Inquiry further through the submission of additional evidence or as a partner in the development of solutions.

Kind regards



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Oral Evidence for Health and Social Care Committee on behalf on South East Wales Academic Health Science Partnership (SEWAHSP)

The South East Wales Academic Health Science Partnership is a collaboration consisting of the 3 Universities; Cardiff, Cardiff Metropolitan and South Wales, the 3 University Health Boards; Cardiff and Vale, Aneurin Bevan and Cwm Taf and the 3 NHS Trusts; Velindre, Public Health Wales and The Welsh Ambulance Trust.

Our remit is to increase innovation and joint working between Universities, NHS and Industry. As such I am not in a position to address all the points of reference regarding NHS, commissioning and assessment procedures but can offer information on the ways in which academia engages with the NHS and industry; and how a partnership approach between the NHS, academic institutions and industry could be developed further and some examples of where this is happening in practice.

There are various groups within the Universities which engage very effectively with Industry and the NHS – sometimes these are individual Investigator led groups eg Prof Chris McGuigan’s group, sometimes larger initiatives such as the Arthritis Research UK Centre or the Wound Healing Research Unit and PDR (The National Centre for Product Design & Development Research). Another initiative was the Critical Care Alliance which was group of clinicians/scientists in the Sepsis field who formed a joint collaborative group which proved very attractive to Industry and directly led to gaining >£3M funding from TSB for 2 consortia including commercial groups.

The Health Technology Challenge Scheme

SEWAHSP have recently run a small scale pilot scheme aimed directly at forming new collaborations to address clinical problems through the Health Technology Challenge Scheme. This provided a *mechanism for interaction* between academic and clinical partners and an *incentive to participate* by making seedcorn funding available to support projects to solve the challenges (up to £25K). The scheme was two step process with the first being the establishment of an interactive website where participants could post their “challenges” and could view, comment and vote on all ideas posted. We then convened an expert panel to select a subset of challenges for which applications were invited, 7 challenges were selected and the call for applications issued. 4 projects have now been funded. The scheme cost under £100K in total and in terms of stimulating new project ideas and forming new connections and collaborations will go far beyond these four funded projects. Over 200 participants joined the website from across our partner organisations and beyond (we have some industrial members as well as university and NHS participants further afield), 21 challenges were received over 100 comments and votes submitted.

We are now actively in the process of further developing some of the ideas and challenges and forming project teams to apply for other sources of funding. We are also seeking funding for the next round and preferably to continue the scheme on a more regular basis and make

it Wales wide as this could easily be achieved with the current mechanism. The majority of the funding for the pilot was from the Intellectual Property Office Fast Forward Scheme, but as this is aimed at new initiatives would not be ideal for recurrent funding. The idea of an all-Wales scheme is proving to be a popular idea. Tenovus have expressed positive interest in taking an active role in the next round, on an all-Wales basis and the South West Hub of AHSC have offered their support with co-ordination. However, funding will be needed.

The Wound Healing Research Unit

This group led by Prof Keith Harding works very much at the interface of academia, clinical practice and industry with a pro-active focus on innovation to improve the treatments available for chronic wounds which are significant clinical problem and huge factor influencing the quality of life for patients suffering with an intractable wound. They work closely with industry running many clinical trials with new products for example:

WHRU has conducted 9 studies over the past 10 years for Convatec (part of Bristol Myers Squibbs). Including a randomised controlled trial of 131 patients, comparing AQUACEL[®] Dressing versus an alginate dressing, the following was observed:

- The mean wear time was significantly greater in the AQUACEL[®] Dressing group versus the alginate dressing group (P<0.001)
- Of the patients who healed, those in the AQUACEL[®] Dressing group healed 14 days faster than those in the alginate group (P=0.053)
- Ease of removal was rated by the investigator as excellent in 51% of the AQUACEL[®] Dressing group versus 24% in the alginate group (P=0.006)
- Ability to contain exudate was rated by the investigator excellent in 44% of the AQUACEL[®] Dressing group compared to 20% in the alginate group (P=0.002)

This dressing is now in regular use within the NHS.

Work with Photopharmica Ltd reported positive results from a WHRU Phase 2b study of Antimicrobial Photodynamic Therapy in the treatment of chronic leg ulcers.

In 2012, the WHRU undertook a clinical study commissioned by the National Institute for Health and Care Excellence (NICE) to determine the effectiveness of MIST ultrasound therapy compared to UK standard care for the treatment of non-healing venous leg ulcers. In this instance, the WHRU acted as the clinical experts in leading this clinical trial, which was independent from NICE, and the MIST manufacturer. This study is now awaiting a final report.

The potential of WHRU has been recognised with the formation of the Welsh Wound Initiative which should provide the ability to maximise the opportunities for innovation within this group.

Cardiff University

Cardiff University is presently addressing a significant innovation agenda through the development of its "Innovation System". The Cardiff University Innovation System will comprise the infrastructure and estate required to partner applied research of world-leading excellence that drives innovation with industry, government and other agencies. We will be

organising workshops in the new academic year to engage staff and industry to shape this work further.

A key part of this agenda is "Clinical Innovation" and a key focus is to further increase the University's engagement with clinical colleagues in order to identify clinical priorities which can be addressed by innovation for the benefit of patients and the health economy. This of course requires input from the private sector which opens up business opportunities and thus stimulates wealth creation particularly through alignment with the Welsh Government Life Science Initiative. Cardiff University and its Medical School in particular will drive the Clinical Innovation agenda by creating an environment to bring together clinicians, academics and industrialists. The Medical School has a strong tradition of innovation and will work with its existing innovators within this environment to convey ideas and best practice in order to encourage and provide leadership to others with potential to contribute to the success of the University's agenda. This environment will provide a key contact hub for organisations such as NISCHR and SEWAHSP.

Within this document I have tried to provide a few key examples rather than a comprehensive overview of interactions between industry, academia and the NHS. I will be happy to elaborate or expand further or provide more examples if this would be helpful and will be available to answer any questions at the committee meeting on the 6th March.

14th February 2014

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

The innovation process:

The process of development, validation and adoption of new technologies is recognised as being a lengthy process, and one that does not always meet the intended expectations.

This experience is contributing to the increasing focus on fast tracking the innovation process in healthcare across many healthcare systems.

Innovation in healthcare results from a collaboration between clinicians, scientists, entrepreneurs and commercial organisations - as well as managers and policymakers in healthcare. Defining present standards of care and utilising new technology to redefine products and services will allow new best practices to be implemented and audited across healthcare systems.

In terms of UK adoption of technologies there is currently no method similar to adoption of pharmaceuticals. Whereby, once clinical and cost effectiveness has been demonstrated, there is requirement for commissioners to adopt a technology across the wider NHS. Developing and delivering an effective evidence base, should be seen as a marker of quality for adoption not in the UK, but globally.

This is presenting unique problems whereby expediency in the innovation process, subverting the usual evidence requirements for effectiveness is leading to considerable harms and not realizing the full benefits of new technologies.

This reports highlights the important evidence components, which are an essential requirement to develop safe and effective technologies, these are:

1. **Role of regulation**
2. **Clinical Trials**
3. **Hierarchies of evidence**
4. **Health Technology Assessments**
5. **Health Technology Programme**
6. **NICE**
7. **Current UK Initiatives to improve innovation**

1. Role of regulation in assessing new and innovative devices

Whilst new drugs require at least randomized controlled trials to gain regulatory approval, for medical devices even under the more stringent US system (PMA approval process) only one controlled trial (not necessarily randomized trial) is required. However, an even more worrying issue with device regulation in both the EU and US is the use of 'substantially equivalent' in evidence submissions for regulatory purposes.

In 1976, in the US many devices were already on the market, so a less burdensome alternative to PMA known as 510(k) provision was approved. The 510(k) pathway did not require clinical trials; the manufacturer was only required to demonstrate a device was "substantially equivalent" to another device already on the market. The problem now is that the definition of equivalence is interpreted so loosely that the FDA admits they need to "clarify the meaning of 'substantial equivalence.'"

The predicate of equivalence is also used within the European Union (EU) regulatory system for device regulation. There are three European Directives related to device regulation. These directives, which lead to CE marking and access to the European market, state the extent and nature of clinical data required for approval.

Problems occur because even for implantable devices, the scrutiny of evidence at the outset is left to private organizations known as Notified Bodies; and second, clinical data required for the equivalent route can involve as little as "a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device". The use of equivalence is therefore left to the manufacturer and the Notified Bodies to determine, without any outside scrutiny of the decision making process centrally or within each EU country.

The level of clinical data required for a new device can be minimal. For example, a directive would

include as evidence for approval "a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device". This is a very low level of evidence and could be obtained in a few days, contrasting markedly with the type and extent of clinical trial data required for new drugs.

The specific council directives allow studies of other similar devices to be sufficient in a literature review for regulatory approval

► **B COUNCIL DIRECTIVE 93/42/EEC and 90/385/EEC**
• *_(k) 'clinical data' means the safety and/or performance information that is generated from the use of a device.*

Clinical data are sourced from:

- *_ — clinical investigation(s) of the device concerned, or*
- *_ — clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated, or — published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated.*

Even for the more stringent PMA process, there are profound differences in evidence requirements between the US and EU.

Rejected Devices by the US FDA that were approved in the EU:

Covidien PleuraSeal lung sealant system

This device went on the EU market in November 2007 and is used during elective pulmonary resection as an adjunct to standard closure techniques for visceral pleural air leaks. However, the Investigational Device Exemption (IDE) study (a clinical study for FDA regulatory purposes) produced unexpected interim results. In October 2010 Covidien announced a worldwide recall of all PleuraSeal lung sealant systems

Medtronic Chronicle

The Chronicle is an implanted system designed to measure and record haemodynamic variables continuously. In March 2007, an FDA panel refused to approve the device, citing statistically insignificant results as "lack of clinical effectiveness." It was nonetheless approved in Europe.

PIP breast implants

In 1991, breast implants manufactured by Poly Implant Prothese (PIP) received a CE mark for its silicone breast

implants. But in 2001 they changed the gel, so that it was different from the one described in the CE marking file. This modification led to rupture rates higher than silicone implants made by other manufacturers. On 30 March 2010, the French regulator—AFSSAPS— issued a recall of all pre-filled silicone breast implants manufactured by PIP, affecting an estimated 35 000–45 000 women worldwide.

Trilucent breast implants

First marketed in the UK in 1995 by LipMatrix, Trilucent implants were recalled and withdrawn from the market in 1999. The filler of the implants, which was derived from soybean oil, broke down in the body and leaked through the shell, causing ruptures. The breakdown of the filler was significantly different from that predicted during preclinical testing, and many patients had to have implants removed.

Conor CoStar drug eluting stent

CoStar is a cobalt, chromium, paclitaxel eluting coronary stent and received EU approval in 2006. In May 2007, Johnson and Johnson announced that a pivotal clinical study of the device had failed to find a significant difference on the primary end point, possibly because patients got a suboptimal therapeutic dose of paclitaxel. The trial did not identify safety issues. As a result of this trial, Conor terminated ongoing clinical trials and chose not to conclude the submission of its US premarketing approval. Conor discontinued the sale of the stent in Europe, Asia, and Latin America.

Reproduced from Cohen D. Out of joint: the story of the ASR. *BMJ*. 2011 May 13;342:d2905. doi: 10.1136/bmj.d2905.

Perhaps what is even more concerning than the device recalls and high profile cases (such as the MoM hips and PIP implants) is that many medical device problems go unnoticed.

However, it seems as though the tide is turning in terms of regulatory requirements. The US system is coming under increased scrutiny with calls for the removal of the 510(k) process. The influential Institute of Medicine has recommended the FDA do away with the 510(k) approval process and replace it "with an integrated premarket and post-market regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device life cycle." It is possible that all implantable devices in particular will require PMA approval and thus clinical trial data in the future. However, more stringent regulations are unlikely to be passed into law in the US without a substantial battle with the medical device industry.

Analysis of manufacturers' submission challenges, to the NICE medical technology program, reveals there are significant issues in relation to basic and

general research skills that need to be addressed amongst manufacturers.

In addition, interviews with manufacturers highlight the current status quo: 'pharmaceutical and medical technologies were also considered very different by manufacturers.' As such, the wide spread belief is, that devices do not require the same level of evidence as drugs to gain access to a market and be used in clinical practice.

Failures of medical devices cause harm and cost money. More stringent requirements to provide evidence from clinical trials for the efficacy and safety medical devices before they are approved should therefore be welcomed by patients, clinicians and the medical device industry.

Evidence for new devices must also be open to scrutiny by patients in individual countries, as well as health care providers and researchers. The potential risk of a new device should match the type of evidence required prior to approval for use in clinical settings. Without these changes to current systems, it is likely we will continue to see substantial complications arising from faulty devices.

2. Clinical trials

Clinical trials and drug studies are big business, valued at \$30 billion across 105 countries, and in less developed countries the number of trials is growing rapidly. Yet, in direct contrast, the number of drug trials in the UK has fallen substantially, from 728 in 2008 to 470 in 2010.

This suggests a potentially worrying global trend whereby expediency in the conduct of trials, for example by minimising regulation in different countries around the world assumes a greater value than mechanisms to ensure that trials are conducted with integrity and quality.

The proposal for a regulation of the European Parliament and of the council on clinical trials on medicinal products for human use and, and repealing Directive 2011/20/EC highlights the problems that have occurred. The substantial increases in administrative burdens required in the EU at the outset of a clinical trial, lead to an increased delay for launching a clinical trial by 90%, which now takes on average 152 days.

This length of delay is untenable and directly contributing to relocation of many trials outside the EU and the UK, to no doubt less burdensome environments. In addition, the near 100% increase in administrative costs have not demonstrated parallel increases in safety and highlight all that is wrong with the current system. Too burdensome, too slow, and beset with unnecessary administrative problems without clear upsides.

3. Hierarchies of Evidence

There are many different 'hierarchies' or 'levels of evidence' for studies. An understanding of the difference evidence requirements for improving healthcare is essential.

Early evidence hierarchies were introduced primarily to appraise the quality of evidence for therapeutic effects, while more recent attempts to assign levels to evidence have been designed to help systematic reviewers, or guideline developers and those involved in implementation.

More recent evidence-ranking schemes such as GRADE avoid common objection by allowing observational studies with dramatic effects to be 'upgraded', and trials may be 'downgraded' for quality and other reasons. Another advantage of the GRADE approach is that it takes other important factors such as directness, precision, and consistency when appraising quality of evidence.

However, what GRADE has gained in accuracy, it may have lost in simplicity and efficiency. The GRADE system takes time to master and moreover is intended for appraising systematic reviews used in the production of guidelines.

The 'bar' for how much and what kind of evidence is considered sufficient for fast track adoption are perceived by many in industry as being very unclear. There is no universal checklist or agreed set of evidence criteria, and decision makers across Europe adopt different approaches. In addition, the overall level of understanding by industry, regulators, clinicians about evidence and study designs - beyond initial validation studies - is often quite unclear.

This lack of clarity clashes with the global strategies of companies, who set up studies that are not

necessarily specific to the UK market. In fact, compared to larger markets such as the US, the UK market is often not seen as a priority, and studies are primarily designed to meet the requirements of the bigger markets.

One of the most important developments over the last 25 years has been the establishment of the Cochrane Library, which produces high quality systematic reviews, which are at the top of the evidence hierarchy. Currently half of the Cochrane groups are located in the UK and funded by the NIHR.

It is therefore essential to have an understanding and support the development of high quality evidence.

4. Health Technology Assessments

The development of NICE's Technology Appraisal Guidance involves independent assessment of the evidence. Individual teams, in academic centres, hosted in seven universities, across the UK, undertake these assessments.

The TAR centres prepare Technology Assessment Reports (TARs) for NICE's Multiple Technology Appraisal process, and Evidence Review Group (ERG) reports for its Single Technology Appraisal process, for consideration by the NICE Appraisal Committees. These assessments combine evidence for clinical effectiveness with cost effectiveness data, forming the basis for NICE decision making

5. Health Technology Programme

The HTA Programme is the largest of the NIHR programmes, funding 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.

Studies are funded via a number of routes including commissioned and researcher-led workstreams.

The research serves a variety of key stakeholders including: decision-makers in local government, policy-makers (including NICE), researchers, NHS health professionals, other NIHR stakeholders, and the general public.

6. Role of NICE

A key element of the regulatory system has been the National Institute for Health and Clinical Excellence (NICE), and a key aspect of NICE's decisions has been not just value, but also value for money. This has not been without controversy.

NICE also uses many strategies to support implementation of NICE guidance, including support products such as commissioning guides, costing spread sheets, generic business cases for capital purchases, pod-casts and a range of bespoke tools tailored on a case-by-case basis. Implementation support activities at NICE have recently been augmented by the transfer of the former National Technology Adoption Centre to NICE. Now known as the Health Technology Adoption Programme, activities include detailed adoption and site demonstrator projects which detail the "real life" impact on care pathways and cash flows as well as identifying and mitigating the key barriers to adoption.

Another key initiative to support adoption of NICE recommended technologies is the NICE Implementation Collaborative, established in response to a recommendation in the NHS Innovation Health and Wealth report. This is a partnership between the NHS, the life sciences industry, healthcare professional bodies, key health organisations and the public, who have committed to work with each other and other organisations to understand and analyse the barriers that exist to the implementation of NICE recommendations.

7. Current Initiatives to improve innovation in the UK

NIHR Diagnostics Evidence Cooperatives four Diagnostic Evidence Cooperatives that aim to stimulate collaborations between different stakeholders in diagnostic testing. For example, the aim of the Oxford NIHR DEC is to improve the implementation of IVDs in primary care settings.

Academic Health Science Networks (AHSN): which aim to improve health care through faster identification, adoption and spread of proven innovations, including through collaboration with industry.

Technology Strategy Board (TSB): is the UK's innovation agency with a goal is to accelerate

economic growth by stimulating and supporting business-led innovation.

NIHR Biomedical Research Centres (BRCs): drive progress on innovation and translational research in biomedicine into NHS practice.

NIHR CLAHRC:

NIHR CLAHRCs are an alliance of academic and healthcare organisations working to develop and promote a more efficient, accelerated and sustainable uptake of clinically innovative and cost-effective research interventions into patient care

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- [www.ce-marking.com In Vitro Diagnostic Medical Device Directive, IVDMD (98/79/EC). <http://www.ce-marking.com/medical-devices-in-vitro-diagnostic.html> (accessed 2nd April 2012).
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West of England AHSN Limited
6th Floor, South Plaza, Marlborough Street
Bristol BS1 3NX

Date: 10th February 2014
Ref: LS/NK

Dear Chloe,

Please find the West of England Academic Health Science Network's evidence to the Inquiry into Access to Medical Technologies in Wales that is being conducted by the National Assembly for Wales Health and Social Care Committee.

Background

The West of England Academic Health Sciences Network (WE-AHSN) is one of 15 Academic Health Science Networks (AHSNs) which have been set up in response to a recent consultation under Sir David Nicholson, the results of which were published in the report '*Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS*'¹ published by Department Of Health. It was recommended that regionally distinct AHSNs be set up and that responsibility for ensuring the NHS accelerates the adoption and spread of innovation, and harnessing the potential of the NHS to act as an economic driver, be devolved to these organisations. The West of England AHSNS (WE-AHSN) was licensed in Sept 2013 and is now a company limited by guarantee, wholly owned by its members and licensed to operate for 5 years by NHS England. It represents all the major stakeholders in health in the West of England. <http://www.weahsn.net>. Our member organisations are attached at appendix 1.

1

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_134597.pdf

Chair Professor Steven West

Managing Director Deborah Evans

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Working in Partnership to put innovations at the heart of health and care to improve patient outcomes and contribute to wealth creation

Tudalen 51

The West of England Academic Health Science Network has come together with the clear purpose of unlocking innovation and wealth in our health economies. Its stated missions are:

- To deliver measurable gains in health and wellbeing across the West of England focusing on the needs of our patients and local population.
- To make a meaningful contribution to the West of England and UK economy.
- To build a learning and delivery network to accelerate the adoption and spread of innovation and improvement of clinical outcomes and patient experience.
- To build a culture of partnership and collaboration.

In Response to the request for evidence we are pleased to offer the following comments ***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.***

One of our key priorities concerns working to streamline and harmonise procurement and adoption across WE-AHSN, thus making it easier, particularly for SMEs, to gain access to the NHS market. We have had excellent support in this endeavour from procurement colleagues in the Task & Finish group and are initially focussing on:

- Harmonising pre-qualifying criteria and approaches to procurement ie describing procurement opportunities in terms of outcomes & standards rather than a technical specification.
- Setting up clinical challenges with our members, working with companies to respond to these challenges and thus helping them to generate the evidence they need to respond to future procurement opportunities.
- Helping our procurement colleagues to engage with SMEs through joint outreach events and master classes and describe the processes already in place to facilitate procurement from a wide range of suppliers.

On a national level, we are contributing to the Procurement Rapid Design Group to support the 3ML (Three Million Lives) telehealth programme run by NHS England.

To understand the ways in which academia engages with the NHS and industry;

We have recently completed a scoping exercise studying over 20 leading international centres to determine elements of good practice in terms of how industry interacts with the academic and health sectors². In terms of interacting with industry we found that the models were often dictated by the industry sector with which the institutions were collaborating with.

For example the pharmaceutical sector is clearly keen to collaborate with the academic sector (basic and clinical) particularly in the in the translational research space and it

² Hecht and Sundstrom 20131

sees this as a mechanism to leverage public research to reduce its own R&D spend in the future.

We found that pharmaceutical companies are attracted mostly by 3 things:

- Access to key academic opinion leaders (particularly clinical opinion leaders)
- Places with enough critical mass to justify the overheads of putting in place a strategic relationship and an ability to grow the relationship for both partners benefit
- Infrastructures that have the ability to move quickly from concept to collaborative projects with minimal administrative burden

Partnerships between the pharmaceutical industry, the academic sector and the NHS are usually thematic in areas of strategic importance to the company for example infection/immunity or cancer. The prime attractant seemed to be access to a critical mass of high quality science or clinical expertise in the strategic area and mostly these involved one or a few institutions. In the research phases pharmaceutical companies generally like to work in closed consortia, they are happy to subscribe to these financially, and do not seem to mind working with several potential competitors to share the risk of setting these up. So at least in the earlier research phases, collaboration among pharmaceutical companies was not a barrier in the cases we looked at. Mobility of researchers between companies and academic/clinical settings is important and the companies frequently supply resources from their side to encourage the collaboration. When projects transition into clinical trials the relationship with clinical opinion leaders becomes more important and consortia are less likely. In these cases the companies prefer to deal individually with clinical research centres.

With larger companies in the medical technology sector consortia between companies is less frequent and there is generally an exclusive relation between one company and one institution. In contrast to the pharmaceutical industry the work carried out in these collaborations is often considered commercially sensitive. The prime output of these larger collaborations is knowledge transfer, graduate and postgraduate training. They are often seen as places for companies to try things out that they could not do in a more rigid corporate R&D environment. In the medical technology/device sector, the local clinical environment is absolutely critical: access to research active clinicians is the driving force, understanding how devices will be used in a local clinical setting is the key factor and this feedback is considered essential to drive innovation. Access to patients, a support structure to get studies off the ground quickly and leveraged public sector funding is often present in successful centres.

In several cases public private partnerships (PPPs) have evolved where the public sector and or charities (e.g. CRUK or Wellcome Trust) participate in these PPPs. Two models that have been evolved that typify this type of working with the Health sector (NHS) are Translational Research Partnerships³ which support pharmaceutical companies in the experimental medicine space and early clinical development phases (supported by

³ <http://www.nocri.nihr.ac.uk/research-expertise/translational-research-partnerships/>

Chair Professor Steven West

Managing Director Deborah Evans

NIHR) and Health Technology Cooperatives (HTCs⁴) more focused on medical technology development and supported by NIHR and EPSRC⁵. Drivers are somewhat different working with the SME sector than working with larger companies.

SMEs are more heavily dependent on accessing resources to be able to enter into partnerships with academia or the NHS. The classical push model involving technology transfer from the academic sector to SMEs or creation of spin outs continues to operate but is currently limited by the availability of risk capital. Some of this slack has been taken up by the public sector (e.g. Technology Strategy Board) or Research Councils (e.g. Biomedical Catalysts funds) and some major charities (e.g. Wellcome Trust translational programmes).

We have been involved in an alternative model in which challenge led innovation is encouraged through procurement of product development. The Small Business Research Initiative provides a 2-3 stage funding model for SMEs to develop solutions for unmet clinical needs. A first feasibility stage (£100K) explores the suitability of a product to fill a need identified by health practitioner and a second stage (up to £1M) delivers a solution which can be evaluated for adoption. We believe this model based on 'Clinical Pull' will be very effective as it has been already in several sector in the US. In this model the AHSNs collectively work to define the call topics and provide clinical challenges and assessors for review panels⁶.

To understand how a partnership approach between the NHS, academic institutions and industry could be developed further.

Encouraging and supporting the formation of partnerships between local NHS and HEI organisations to create local clusters of expertise and take advantage of local microenvironments seems to us to be critical. The WE-AHSN is an example of such a structure and this allows to collectively prioritise areas for development as well as deliver consistency of care across our area. 2 other good example in our area of similar partnerships are 1) Bristol Health Partners⁷ which use integrates groups focusing on health research into coordinated delivery teams (Health Integration Teams) and 2) the nascent Clahrc-West which will develop programmes to deliver evidence based research programmes in our area⁸.

Such local partnerships provide a framework to generate critical mass and allows the stakeholders to develop common agendas which bring scale and pace to adoption and spread of innovation. One way this can be achieved is by putting in place agreements allowing the free movement of resources across the partnership to minimise time from idea to implementation. This is also attractive to industry as it creates in effect a single

⁴ <http://www.nihr.ac.uk/infrastructure/Pages/HTCs.aspx>

⁵ <http://www.epsrc.ac.uk/SiteCollectionDocuments/Calls/2013/EPSRC-NIHR%20HTC%20Partnership%20Award%20Call%20workshop%20presentation.pdf>

⁶ <http://www.sbrihealthcare.co.uk/>

⁷ <http://www.bristolhealthpartners.org.uk/>

⁸ <http://www.bristol.ac.uk/news/2013/9662.html>

Chair Professor Steven West

Managing Director Deborah Evans

point of contact and reduces the administrative burden from them in maintaining multiple relations.

Using local unmet clinical need as the main driver for initiating projects to drive collaboration with the SME sector through challenge led innovation exemplified by the SBRI scheme, seems to us to be a good mechanism to use the pulling power of the NHS to drive local economic growth. A corollary of this is the availability of rapidly deployable proof of concept funding as the main driver for stimulating collaboration between the HEI, NHS and SME sectors.

Building consortia between academia Industry and larger companies around themes of common interest and strength seems like an excellent way to develop relations with larger companies where appropriate critical mass exists in a region. Using access to key opinion leaders to drive the formation of these consortia seems to us critical. A good example of this in Wales seems to be the nascent Welsh Wound Healing Innovation Centre.

Yours sincerely



Lars Sundstrom
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West of England Academic Health Science Network
Lars.sundstrom@weahsn.net
0117 900 2652

Chair Professor Steven West

Managing Director Deborah Evans

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Working in Partnership to put innovations at the heart of health and care to improve patient outcomes and contribute to wealth creation

Appendix 1

PROVIDERS OF NHS SERVICES
Avon and Wiltshire Mental Health Partnership NHS Trust
Gloucestershire Care Services NHS Trust
Gloucestershire Hospitals NHS Foundation Trust
Great Western Hospitals NHS Foundation Trust
North Bristol NHS Trust
Royal United Hospital Bath NHS Foundation Trust
South West Ambulance Service NHS Foundation Trust
University Hospitals NHS Foundation Trust
Weston Area Health NHS Trust
2Gether Partnership NHS Foundation Trust
Representative of the CIC 'club'
UNIVERSITIES
University of Bath
University of Bristol
University of the West of England
CLINICAL COMMISSIONING GROUPS
Bath and North East Somerset CCG
Bristol CCG
Gloucestershire CCG
North Somerset CCG
South Gloucestershire CCG
Swindon CCG
Wiltshire CCG

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Tudalen 50

Y Pwyllgor Iechyd a Gofal Cymdeithasol

Lleoliad:	Lleoliad Allanol
Dyddiad:	Dydd Iau, 13 Chwefror 2014
Amser:	09:30 – 12:20

Cynulliad
Cenedlaethol
Cymru

National
Assembly for
Wales



Gellir gwyllo'r cyfarfod ar Senedd TV yn:

http://www.senedd.tv/archiveplayer.jsf?v=cy_800002_13_02_2014&t=0&l=cy

Cofnodion Cryno:

Adeilad Margam, Prifysgol Abertawe

Aelodau'r Cynulliad:

David Rees (Cadeirydd)
Rebecca Evans
Elin Jones
Gwyn R Price
Lindsay Whittle
Kirsty Williams

Tystion:

Dr Nadim Haboubi, National Obesity Forum for Wales
Dr Dev Datta, Welsh Association of Gastroenterology and Endoscopy
Colin Ferguson, Royal College of Surgeons
Jonathan Barry, British Obesity and Metabolic Surgery Society
Jan Smith, Aneurin Bevan University Health Board
Alison Shakeshaft, Bwrdd Iechyd Aneurin Bevan
Scott Caplin, Bwrdd Iechyd Prifysgol Abertawe Bro Morgannwg
Dr Klesh Sidhu, Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru
Dr Suzanne Wood, Iechyd Cyhoeddus Cymru

TRAWSGRIFIAD

Gweld [trawsgrifiad o'r cyfarfod](#).

1 Cyflwyniad, ymddiheuriadau a dirprwyon

1.1 Cafwyd ymddiheuriadau gan Leighton Andrews AC, Lynne Neagle AC, William Graham AC a Darren Millar AC.

2 Ymchwiliad i argaeledd gwasanaethau bariatrig: Sesiwn dystiolaeth 1

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

2.2 Cytunodd Dr Haboubi i roi rhagor o fanylion am nifer y cleifion y mae wedi'u hatgyfeirio at lawdriniaeth fariatrig, a nifer y cleifion sydd wedi cael llawdriniaeth o ganlyniad i'r atgyfeiriadau hynny.

3 Ymchwiliad i argaeledd gwasanaethau bariatrig: Sesiwn dystiolaeth 2

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

3.2 Cytunodd Mr Barry i ddarparu rhagor o wybodaeth am yr 11 o restrau llawn o lawdriniaethau y nododd iddynt fynd ar goll yn y flwyddyn ariannol ddiwethaf, gan gynnwys rhagor o wybodaeth am beth y mae "11 o restrau llawn o lawdriniaethau" yn ei olygu o ran nifer y cleifion ac fel cyfran o faich gwaith cyffredinol Sefydliad Llawfeddygaeth Gordewdra a Metabolaidd Cymru.

4 Ymchwiliad i argaeledd gwasanaethau bariatrig: Sesiwn dystiolaeth 3

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

4.2 Cytunodd Dr Jane Layzell i egluro a oes gwerthusiad annibynnol o'r rhaglen "Ysgolion Iach" wedi'i gynnal.

5 Ymchwiliad i argaeledd gwasanaethau bariatrig: Sesiwn dystiolaeth 4

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

5.2 Cytunodd Dr Sidhu i roi eglurhad o'r ffigurau NICE a nododd yn ystod y sesiwn mewn perthynas â:

- nifer yr unigolion yng Nghymru sy'n gymwys i gael eu hatgyfeirio at wasanaethau bariatrig;
- nifer yr unigolion sy'n gymwys i gael llawdriniaeth fariatrig;
- nifer yr unigolion sy'n debygol o dderbyn llawdriniaeth.

6 Papurau i'w nodi

6.1. Nododd y Pwyllgor gofnodion ei gyfarfod blaenorol.

Y Pwyllgor Iechyd a Gofal Cymdeithasol

Lleoliad: **Ystafell Bwyllgora 1 – Y Senedd**

Dyddiad: **Dydd Mercher, 19 Chwefror 2014**

Amser: **09:22 – 11:58**

Cynulliad
Cenedlaethol
Cymru

National
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Wales



Gellir gwyllo'r cyfarfod ar Senedd TV yn:

http://www.senedd.tv/archiveplayer.jsf?v=cy_200000_19_02_2014&t=0&l=cy

Cofnodion Cryno:

Aelodau'r Cynulliad:

David Rees (Cadeirydd)
Leighton Andrews
Rebecca Evans
Janet Finch-Saunders
Elin Jones
Darren Millar
Lynne Neagle
Gwyn R Price
Lindsay Whittle
Kirsty Williams

Tystion:

Fiona Jenkins, Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Pushpinder Mangat, Bwrdd Iechyd Prifysgol Abertawe Bro Morgannwg
Dr Geoffrey Carroll, Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru
Dr Philip Webb, Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru
Pete Phillips, Labordy Profi Deunyddiau Llawfeddygol
Mark Roscrow, NHS Shared Services Partnership
Alun Tomkinson, Bwrdd Iechyd Prifysgol Caerdydd a'r Fro

TRAWSGRIFIAD

Gweld [trawsgrifiad o'r cyfarfod](#).

1 Cyflwyniad, ymddiheuriadau a dirprwyon

1.1 Ni chafwyd unrhyw ymddiheuriadau.

1.2 Croesawodd y Cadeirydd Janet Finch-Saunders i'r Pwyllgor ac estynnodd ddiolch i William Graham am ei gyfraniad at waith y Pwyllgor.

2 Ymchwiliad i'r mynediad at dechnolegau meddygol yng Nghymru: Sesiwn dystiolaeth 6

2.1 Atebodd Fiona Jenkins o Fwrdd Iechyd Prifysgol Caerdydd a'r Fro, Pushpinder Mangat o Fwrdd Iechyd Prifysgol Abertawe Bro Morgannwg, a Dr Geoffrey Carroll a Dr Philip Webb o Bwyllgor Gwasanaethau Iechyd Arbenigol Cymru gwestiynau gan aelodau'r pwyllgor.

2.2 Ar ddiwedd y sesiwn, cytunodd Dr Webb i ddarparu nodyn i'r Pwyllgor yn amlinellu un argymhelliad allweddol y byddai Pwyllgor Gwasanaethau Iechyd Arbenigol Cymru yn ei wneud i'r Pwyllgor mewn perthynas â gwella'r mynediad at dechnolegau meddygol yng Nghymru a sut y gellid cyflawni hyn.

3 Ymchwiliad i'r mynediad at dechnolegau meddygol yng Nghymru: Sesiwn dystiolaeth 7

3.1 Atebodd Mark Roscrow o Bartneriaeth Cydwasanaethau'r GIG, Pete Phillips o'r Labordy Profi Deunyddiau Llawfeddygol, ac Alun Tomkinson o Fwrdd Iechyd Prifysgol Caerdydd a'r Fro gwestiynau gan aelodau'r pwyllgor.

4 Papurau i'w nodi

4.1 Nododd y Pwyllgor gofnodion y cyfarfod a gynhaliwyd ar 5 Chwefror 2014.

4.2 Nododd y Pwyllgor y llythyr gan y Pwyllgor Busnes ynghylch gwaith craffu effeithiol y Pwyllgor ar y Gyllideb a chytunodd y dylai'r Cadeirydd ateb y Pwyllgor Busnes a chadarnhau bod y Pwyllgor yn cefnogi adolygiad o broses 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

5.1 Derbyniwyd y cynnig.

6 Trafodaeth breifat ar adroddiad drafft y Pwyllgor ar Waith Arolygiaeth Gofal Iechyd Cymru

6.1 Bu'r Pwyllgor yn trafod ei adroddiad drafft ar waith Arolygiaeth Gofal Iechyd Cymru.

7 Ystyried dull gweithio'r Pwyllgor ar gyfer ei waith dilynol ar y cyfraniad a wneir gan fferyllfeydd cymunedol i wasanaethau iechyd yng Nghymru

7.1 Bu'r Pwyllgor yn trafod a chytunodd ar ei ddull gweithio ar gyfer ei waith dilynol ar y cyfraniad a wneir gan fferyllfeydd cymunedol i wasanaethau iechyd yng Nghymru.

Yr Adran Iechyd, Gwasanaethau Cymdeithasol a Phlant
Department for Health, Social Services and Children
Prif Swyddog Nyrsio - Cyfarwyddwr Nyrs GIG Cymru
Chief Nursing Officer - Nurse Director NHS Wales



Llywodraeth Cymru
Welsh Government

Mr David Rees AM
Chair
Health and Social Care Committee
National Assembly for Wales
Cardiff Bay
Cardiff
CF99 1NA

Our ref: JW/AP
21 February 2014

Dear David

Health and Social Care Committee General Scrutiny Session – 30 January 2014

The committee requested some further information subsequent to my attendance at the above meeting. I am pleased to respond.

1. The direct impact of Healthcare Inspectorate Wales (HIW) reports on the work of the Nursing Directorate.

The reports prepared by HIW are considered by the Quality and Safety Committee internal to Welsh Government, which nursing officials attend and are raised in the joint HIW/DG-HSS health professionals meeting held on a monthly basis. On occasion evidence presented will lead to direct action by nursing officials. Below I have set out three examples from the last 2 years:

- a. Following the Essential Care investigation at Iorwerth and Ceredig Wards Bronglais General Hospital in spring 2012 the Nurse Director agreed with me a specific set of actions on the hospital site to drive improvements in nursing care, which included her being based there for the summer months. I gave clinical supervision to the Nurse Director on a weekly basis to monitor progress and I visited the hospital to meet senior and front line staff. The quality of care on this site has been kept under review since completion of the focussed work. These actions have led to significant improvements in fundamentals of care on the site.
- b. Following the Dignity and Essential Care investigation at Prince Charles Hospital Emergency Care Centre, in October 2012, an action plan was established by Cwm Taf Board, supported by RCN (Wales). The Nursing Officer for Patient Experience worked alongside HIW staff to monitor progress of the

implementation of the plan and took part in a series of visits to the Emergency Dept in 2013.

- c. The Wales Audit Office/HIW follow-up review of safety issues in CAMHS (December 2013) has highlighted that more work is required in reducing the numbers of children placed on adult wards. To take this forward in the first instance, we are convening a multi clinician group (adult and CAMHS mental health services) to review a mix of LHB inappropriate admission reports to Welsh Government with a view to discussing processes and procedures, and sharing information about risks and actions needed to ensure safety of the patient. The outcome of this will be to produce further guidance as agreed between CAMHS and Adult in patient services which will then be shared amongst LHBs.

2. The role of the Welsh Government's workforce, education and development services in the workforce planning process, including information about the indicators it uses when determining workforce plans

In 2013/14 the Workforce Development Unit which was part of the National Leadership and Innovation Agency for Healthcare (NLIAH) transferred to the NHS Shared Services Partnership (NWSSP). Welsh Government had a Service Level Agreement with NLIAH for it to undertake a number of functions on its behalf and to provide advice to the WG, this included workforce planning and education commissioning amongst other things. As part of the transfer to NWSSP the workforce function now predominantly provides support to the NHS rather than to the Welsh Government.

In 2013 the Welsh Government developed a new integrated planning framework which incorporates the six step planning model used previously in the separate workforce planning guidance. The 2013 integrated Planning Framework requires organisations to develop an integrated service, finance and workforce plan. As such there is no separate Welsh Government guidance provided on workforce planning. The new NWSSP Workforce function, now called the Workforce, Education and Development Service (WEDS) has provided best practice guidance to the NHS on workforce planning as part of its support to the NHS through the Working Differently Working Together programme.

WEDS uses workforce plans from NHS organisations to determine future education commissioning numbers for the health professional workforce. Other indicators for education commissioning levels include;

- Individual cost of training students.
- Student attrition.
- Service reconfiguration plans.
- Welsh Government policy.
- NHS financial position.
- Changes in working patterns.
- Education capacity.

3. The number of district and community nurses in Wales

	2009	2010	2011	2012	2013-Nov
Modern Matron	1.8	1	1	29.7	38.3
Health visitor	763.8	744.6	738.9	781.1	862.2
*District nurse	728.1	794.9	811.4	763.9	576.2
*District nurse (Enrolled nurse level)	16.4	11.3	11.8	16.5	9.3
Community nurses	1153.6	1203	1231.9	1270.3	1516.4
*Community Psychiatric Nurses	162.5	121.1	93.5	108.7	102.3
*Community Psychiatric Nurses (Enrolled nurse level)	1
Community psychiatry	1167.6	1129.8	1232.3	1312	1356.2
*Community Learning Disability Nurses	.	6.8	6.4	5.4	5.4
Community learning disabilities	294.9	308.2	290.2	290.1	279.5

The above table indicates the range of NHS employed registered nurses working in community and primary care. Those with a * indicate that they have a recordable qualification with the Nursing and Midwifery Council. The figures for 2013 are management data figures taken from the ESR data warehouse and as yet have not been recorded on Stats Wales. I have not included healthcare support workers who also work to support the community nursing teams.

4. The code of hygiene being developed by Public Health Wales on behalf of the Chief Nursing Officer, and confirmation of when this work will be completed

The Welsh Government is committed to zero tolerance of preventable healthcare associated infection (HCAI). NHS organisations in Wales have made significant improvements in reducing HCAI in recent years, including Meticillin resistant Staphylococcus aureus (MRSA) bloodstream infections and infections caused by Clostridium difficile; however more can and must be done to protect service users and achieve world class standards of service user safety. Effective infection prevention and control needs to be everybody's business and must be integral to everyday healthcare practice and based on the best available evidence.

Building on the 2011 'Commitment to Purpose – Eliminating Preventable Healthcare Associated Infections'; this Code of Practice sets out the minimum necessary infection prevention and control arrangements for NHS healthcare providers in Wales. The elements of the Code represent standards that organisations will be expected to meet in full across the range of healthcare services that they provide. Compliance with these standards should be evident to service users, visitors, staff and to the Welsh Government including Healthcare Inspectorate Wales.

Non-NHS providers of healthcare in Wales may refer to the requirements of this Code to inform the appropriate standards for infection prevention and control in their organisations and the services they provide. In addition NHS Wales organisations must ensure that when they contract or commission services that the requirements of this Code are reflected clearly within contracts and commissioning arrangements.

It should be emphasised that the requirements of this Code will reinforce and codify existing expectations of NHS Wales organisations, rather than introduce new expectations.

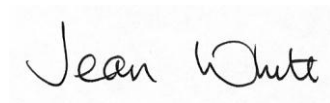
For the purpose of this Code of Practice, HCAI refers to any infection by any infectious agent acquired as a consequence of a person's treatment by the NHS in Wales, in any care setting including the person's own home, or which is acquired by a healthcare worker in the course of their NHS Wales duties.

This Code of Practice does not replace the requirement to comply with legislation that applies to healthcare services, for example The Health and Safety at Work etc. Act 1974, the Control of Substances Hazardous to Health (CoSHH) Regulations 2002 and relevant food safety legislation.

Public Health Wales has produced a draft Code in consultation with Health Boards for consideration by Welsh Government. It is anticipated that the final version will be issued at the end of March 2014.

Please also find attached (at Doc 1) the Annual Report Strengthening the Commitment for 2012/2013 as requested.

Yours sincerely

A handwritten signature in black ink that reads "Jean White". The signature is written in a cursive style and is positioned above the typed name and title.

Professor Jean White
Chief Nursing Officer
Nurse Director NHS Wales

Strengthening the Commitment (Scottish Government *et al*, 2012) is the report arising from the Modernising Learning Disabilities Nursing Review that was undertaken 2011 – 12. This review was initiated by Ros Moore, Chief Nursing Officer for Scotland on behalf of all the UK CNOs and involved people with learning disabilities, their families, learning disability nurses and other practitioners from across the UK. The report was formally launched in April 2012.

Recent decades have seen many reports published about learning disability nursing as might be expected in a profession where patterns and location of service provision have changed dramatically since the 1970s and in view increasing life expectancy and complexity of health need amongst people with learning disabilities. However, this most recent review of the profession was initiated in response to concerns that numbers of learning disability nurses were reducing whilst client need was increasing and that there had been a loss of focus and direction within this field of nursing practice.

What sets this report apart from previous reports is that not only does it make a series of recommendations but that structures to ensure implementation have been established at UK, national and local levels. Accordingly progress towards these recommendations is being monitored and this current document sets out progress within Wales to date (2012 –13). Each recommendation will be presented along with evidence of progress and also activities identified as the next steps. First, however, it is important to clarify how the implementation structure has been established within Wales.

Implementation within Wales

Strengthening the Commitment (Scottish Government *et al*, 2012) was launched in Wrexham in June 2012 at an event attended by the then Health Minister Lesley Griffiths AM. At this event a meeting was held to establish the All Wales Implementation Group that then had its first full meeting in December 2012. This group is chaired by Professor Ruth Northway and has membership from each of the Health Boards, three HEIs and the independent sector. To date the group have met on three occasions and are due to meet again in September 2013. The way of working established by the group is to have key goals identified for each meeting (relating to the recommendations) with information being collated between meetings in preparation for this discussion.

This group has representation at the UK implementation level through Jen French and Ruth Northway. Each Health Board has also established a mechanism for implementation at a local level (format dependent upon existing structures) and people with learning disabilities are involved in these processes both within the Health Boards and the HEIs.

Since the initial launch event in June 2012 two stakeholder events have been held in Llandrindrod Wells – one in November 2012 and the second in March 2013. These events have primarily been attended by nurses but some family members also came to the first one.

The following section of the report sets out the recommendations arising from Strengthening the Commitment (Scottish Government *et al*, 2012) and under each recommendation an indication of activity to date within Wales is provided along with the next steps to be taken.

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| 1. The four UK health departments and the independent/voluntary sector should establish a national collaborative to enable better understanding of, and planning for, a high-quality |
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and sustainable registered learning disabilities nursing workforce across all sectors.

Progress to date:

- Work is being undertaken by the Learning/ Intellectual Disability Nursing Academic Network to determine the number of places being commissioned for LD nursing across the UK and to note any trends.
- Within Wales the placements commission for LD student nurse places has increased in both the University of South Wales and Bangor University.
- Within Aneurin Bevan Health Board an issue in relation to workforce numbers over the coming 5 – 10 years has been identified and a succession planning programme has been instigated.
- Within BCUHB requirements are currently being reviewed within the context of a wider, Service review involving key stakeholders
- An independent sector network has been developed at a UK level and Welsh representation within this network has now been agreed.

Next steps:

- To improve data collection regarding learning disability nurses within the independent, voluntary and charitable sectors.

2. Systems to collect workforce data are required in each country, with links across the UK, for workforce planning for future provision of learning disabilities nursing. These should be able to capture information on service provision, educational and research requirements and should cover the independent/voluntary sector.



Progress to date:

- Within Wales a survey has been circulated to determine the number of RN(LD)s, their location and nature of employment, qualifications and age profile. This is a repeat of a previous survey conducted within Wales and will therefore allow for comparisons. For the first time, however, efforts have been made to engage the independent sector in this process. A specific process of trying to identify and target RNLD's working outside of the Health Service is currently underway in order to obtain the most complete mapping possible. To date 271 responses have been received of which 19 are from RN(LDs) working outside the NHS in the independent sector, HEIs and charities.
- Hywel Dda Health Board has an integrated workforce plan which informs educational commissioning numbers annually. This includes a risk assessment of the age/gender profile. The priority of the LD service modernisation process is to focus on the Mental Health (Wales) Measure whilst considering the workforce profile against the clinical services strategy.
- BCUHB Mental Health & Learning Disabilities Clinical Programme Group have developed a workforce plan that links to identified strategic priorities

Next steps:

- To adopt a range of strategies (including contacting housing providers) to try and identify as many RNLDs as possible living in Wales and encourage them to complete the survey. A cut of date for receipt of responses has been set as the beginning of December 2013
- To gather data regarding first employment destination of newly qualified RNLDs.

- To make workforce planning a specific agenda item for discussion by the All Wales group once data from the survey has been collated.
- To monitor the impact of the integration agenda on RNLDs

3. The development of new, specialist and advanced role opportunities should be considered in light of workforce planning, service development and education provision. In particular, this should focus on the roles of non-medical prescribing, psychological therapies and telehealth and in specific settings such as the criminal justice system, mental health services (particularly dementia) and autism services.



Progress to date:

- An initial mapping of specialist roles across Health Boards has been undertaken with a distinction being made between those who meet the Welsh Government requirements in relation to nurse specialist posts and those for whom an area of specialism is identified within their job title.
- The numbers meeting the requirements of nurse specialists is limited within Wales. In terms of areas of specialism being identified these include epilepsy, health liaison, dysphagia and behavioural support.
- BCUHB have been looking to develop specialist roles within identified areas (e.g. the development of Acute Liaison Nurse posts within the 3 DGHs, Mental Health Liaison Nurse and a recently developed Approved Mental Health Practitioner (AMHP))
- Following All Wales collaboration to develop the application for funding a Macmillan Specialist Nurse has been appointed to improve links between learning disability and cancer care services. Whilst based within Hywel Dda the post has an all Wales remit.
- An MSc Professional Practice is currently offered by the University of South Wales and within this it is possible to follow either a Learning Disability or Vulnerable Person Pathway. A module focussing on autism is available within this programme.

Next steps:

- The Macmillan Specialist Nurse post will commence in September and working with a steering group, the initial goal is to identify services and service deficiencies and then to prioritise areas for development. The project aims to fully involve people with learning disabilities and their families/carers when planning developments to ensure person centred approaches to cancer care are delivered. This three year project will be formally evaluated by the University of South Wales and an initial report will be included in the 2013-14 Strengthening the Commitment Annual Report.
- To support increased numbers of LD nurses to undertake study at MSc level in order to facilitate achievement of the educational requirements specified by the Welsh Government for specialist roles.
- To identify the extent of need for diploma and first degree level courses to meet the needs of nurses who require qualifications at these levels

4. Each of the four countries should consider aligning their existing post-registration career frameworks for learning disabilities nursing to clearly articulate the knowledge and skills required by learning disabilities nurses at all levels and across all settings. These developments could be utilised across sectors (with appropriate adaptation) to give a coherent career framework



Progress to date:

- This recommendation is largely dependent on UK level activity. However, some initial activity has been undertaken in relation to post registration education within Wales.
- Some nurses are undertaking the MSc Professional Practice at the University of South Wales following either the Learning Disability or Vulnerable Person pathways
- In the north some nurses are undertaking a postgraduate taught pathway such as MSc/PgDip/PgCert Advanced Clinical practice or MSc in health and Social Care leadership available at Bangor University
- Within ABMU Health Board a process of alignment between the knowledge and skills identified as essential for posts and educational needs has been undertaken. This has included the established key skills within the Competency Framework for newly registered (BTEC in Positive Behavioural Support) for registered and non registered staff, and nurses to post – registration career Frameworks for LD nurses. This then relates to the KSF and informs personal development reviews encompassing both educational materials and assessment procedures. Learning paths which reflect Knowledge and skills needed by LD nurses at all levels and across community and residential services are therefore available.
- Also within ABMU a locally organised programme of leadership development has been delivered and evaluated. A leadership programme for Band 6 nurses has also been delivered. Qualification Credit Framework (QCF) units are available, along with Credit Qualification Framework Wales (CQFW) units for registered and non registered staff. These credits can be used within a range of different qualification frameworks. The bespoke Accredited Learning (BTEC in Positive Behavioural Support) for registered and non-registered staff has also been re-levelled.
- Hywel Dda Health Board has developed an educational framework for all nursing staff from novice to expert; the framework is currently being signed off through the Learning & Development structure.

Next Steps:

- To use the data gathered via the survey currently being undertaken of RN(LDs) within Wales to identify the level(s) at which post registration education is required. HEIs and Health Boards will need to use this data and that gathered via personal development plans to identify priorities in terms of both subjects and levels required.
- To consider not only the topics and level of educational provision required but also to identify the most appropriate form(s) of delivery.
- To agenda the development and planning of educational provision for a future All Wales meeting
- To roll out within ABMU the leadership programmes to Band 5 nurses.
- To implement and evaluate the educational framework within Hwyl Dda

5. Commissioners and service planners should have a clear vision for how they ensure the knowledge and skills of learning disabilities nurses are provided to the right people, in the right places, and at the right time in a way that reflects the values- and rights-based focus of learning disabilities nurses' work.



Progress to date:

- The commissioned numbers of pre-registration student nurse places has increased in 2013 for both Universities of Bangor and South Wales compared with the previous three years.
- An initial mapping of pre-registration education programmes leading to RN(LD) in Wales has been undertaken to ensure that the values identified in Strengthening the Commitment are

reflected within the curricula.

- Across Wales RN(LD)s are recruited to a range of different roles that encompass residential and community settings and also across sectors
- Nurses working outside of the NHS have access to the Positive Behavioural Support e-learning and other BTEC qualifications offered by ABMU HB.
- Within ABMU a work book has been created to support the development of Band 5 nurses.

Next steps:

- To undertake work to gain greater clarity regarding the staffing and educational requirements of the independent sector. This will include working with the Welsh Independent Healthcare Authority to encourage them to undertake a training needs analysis of their staff.
- To identify opportunities for healthcare assistants to gain access to nurse education
- To contact HSIW and CSSIW to identify areas where RNLDs are employed
- To determine the number of RNLDs working within the prison service and to seek to identify their training needs.

6. Commissioners and providers of health and social care should ensure the skills, knowledge and expertise of learning disabilities nurses are available across the lifespan. This should be enabled through effective collaborative working across health and social care structures.



Progress to date:

- A mapping of the core business of the learning disability services within the Health Boards has been undertaken. Unfortunately this has revealed that none of the Health Boards includes working with children and young people as part of their core business and therefore it is now extremely rare for LD nurses to work with children and young people with learning disabilities.
- In ABMU the Facing the Challenge service supports children whose behaviour challenges and their families. The team includes RN (LD) staff.
- Similarly, BCUHB's Complex Needs Services works with children and their families and there are also several LD Nurses employed by Children's teams across the North Wales region.
- There are some LD nurses working as school nurses and within children's hospices but their numbers are not known.
- Within a number of Health Boards LD nurses are involved in working with young people and their families during the period of transition from children's to adult services. Within ABMU they have a protocol specifically to support RN (LD) nurses in undertaking this role.

Next steps:

- To identify the needs of children and young people with learning disabilities within Wales and where appropriate the ability of RN(LD)s to meet these needs should be promoted. This should include promotion of the potential contribution to commissioners.
- To meet with Jane O'Kane to explore the need for RNLDs within school settings.
- To identify the needs of older people with learning disabilities within Wales and where appropriate the ability of RN(LD)s to meet these needs should be promoted. This should include promotion of the potential contribution to commissioners.
- To explore the potential of identifying the number of people with learning disabilities living in residential / nursing homes for older people.
- To contribute to the current mapping of the prison / forensic population of people with learning disabilities

7. Commissioners and providers of health and social care should ensure that learning disabilities nurses are able to collaborate effectively with general health services, including mental health services, to address the barriers that exist for people with learning disabilities to improving their health. This should include proactive health improvement, prevention, whole-family and public health approaches.



Progress to date:

- In response to an ombudsman's report work has been undertaken to develop a care bundle and pathway for people with learning disabilities admitted to acute care settings. This is being piloted in one area
- Different Health Boards are taking different approaches to seeking to promote better access to healthcare. One HB (BC) has an established health liaison scheme and another is due to commence such a service (AB). Another HB employs a consultant nurse with a remit for this area of work.
- A post has recently been advertised within Hywel Dda HB (funded by Macmillan Cancer Care) for a post to improve collaboration between cancer care and learning disability services across Wales
- Within ABMU Health Board the increased utilisation of patient stories within the Health Board area has been extremely positive.
- Within ABMU Health Board have Community Nurses worked jointly with staff in Palliative Care to develop a pathway for people with Learning Disabilities and the Nurse Consultant is part of a group developing a Dental Pathway for people with learning disabilities.
- Health Fayres are held annually in Swansea and the RNLD's from ABMU work collaboratively to develop these events and take an active part in the facilitation.
- Hywel Dda Health Board is currently revising its structure across the 3 counties this will include the principles of Strengthening the Commitment.
- BCUHB have a Health Liaison team which works collaboratively with primary and secondary care services in North Wales. The team provide quality checks for health screens provided by GPs and are actively involved in rolling out individual Health Action plans. Liaison Nurse work into each of the 3 DGHs. The team have received awards for their uses of accessible information and employ a gentleman with learning disabilities as part of the team.

Next steps:

- To implement the acute care bundle across Wales
- To evaluate the liaison nurse posts in collaboration with colleagues from elsewhere in the UK
- To implement the revised service structure within Hywel Dda HB
- To implement and evaluate the dental care pathway within ABMU HB
- The mental health liaison post within BCUB will be filled
- To collect and analyse patient stories (both good and bad experiences)

8. Commissioners and service providers should ensure that specialist learning disabilities services for complex and intensive needs (including assessment and treatment services across all sectors) employ sufficient numbers of appropriately prepared and supported registered learning disabilities nurses. This highlights the need to support and develop the availability of specialist and advanced clinical skills and knowledge of learning disabilities nurses in all settings.



Progress to date:

- As previously noted some information to progress this recommendation will be captured via the survey referred to above
- Discussions are currently on-going between some HBs and commissioners regarding the how Some HB's are presently having discussions with commissioners on how we can ensure that staff with the appropriate skills and knowledge are available to support people in these specialist settings.
- Within Hywel Dda HB an Autistic Spectrum Disorder (ASD) Service is being developed.
- Hywel Dda HB has National Autistic Society accreditation for the ASD continuing health care unit
- BCUHB is currently planning a new Assessment & Treatment service on the Bryn-y-Neuadd site and reviewing requirements in terms of the skills and knowledge required by the LD Nursing workforce
Hywel

Next steps:

- Hywel Dda HB have appointed a Lead Nurse for the ASD Service and the commitment to NAS accreditation for ASD continuing health care unit will be maintained
- BCUHB to develop new Assessment and Treatment Service to include profiling and meeting the educational needs of staff
- To undertake further mapping of additional / specialist client need and comparison with existing availability of specialist knowledge and skills within the existing RN(LD) workforce. Gaps between need and availability of appropriate support to be identified
- This will be used to inform discussion and planning regarding educational provision including mode(s) of delivery

9. Learning disabilities nurses, their managers and leaders should develop and apply outcomes-focused measurement frameworks to evidence their contribution to improving person-centred health outcomes and demonstrating value for money. This may require a specific piece of work to scope current frameworks.



Progress to date:

- ABHB has commenced discussions to pilot the Health Equalities Framework (HEF) as a means of collecting outcomes data
- Within ABMU HB the HEF is currently being examined and other outcome measures are being sought as means of comparison.
- Also within ABMU HB Band 7 nurses are currently working on service improvement projects as part of an LQI programme within the HB. Examples include the development of an effective Dementia Assessment Tool, examining the effectiveness of using the Mental Health Measure to support people with Learning Disabilities and LLAIS, a project to give a voice to people with Learning Disabilities in relation to their healthcare.
- Assessment and Treatment Outcome Reports , a holistic evidence based treatment process has been developed within ABMU HB and was shortlisted for the RCN Nurse of the Year Award in 2012.
- BCUHB are incorporating the use of Honos-LD within care pathway for Assessment & Treatment services

Next steps:

- To pilot the HEF within ABHB
- To undertake further work within ABMU to identify appropriate framework(s) to determine outcomes of nursing interventions
- To develop a means of assessing outcomes of Health Liaison posts
- To make outcomes measurement a key priority for the All Wales Implementation Group for 2013-14

10. Learning disabilities nurses should strengthen their involvement and links to transformational work, productivity improvement and practice development.



Progress to date:

- Examples of innovative practice have been showcased in a variety of settings including both local and national conferences
- The University of South Wales has completed a participatory research study that has examined people with learning disabilities' views concerning abuse. This project aims to reduce abuse and promote appropriate action where abuse does occur. It has been showcased at local, national and international levels and a campaign is on-going to increase awareness to the key issues
- Nurses within ABMU HB have presented their work on patient stories, linked to experiences into secondary care within the HB, to the Chief Executive, and various other strategic groups.
- Work within ABMU HB has been nominated to the RCN Nurse of the Year Award, and various other awards and recognitions.
- A few ABMU nurses have been put forward for awards within the HB and have been showcased in the HB celebrating excellence events.
- Staff from ABMU HB and the University of South Wales have collaborated to develop a health promotion tool to encourage women with learning disabilities to access cervical screening.
- BCUHB have an award-winning, Nurse-led, Dysphagia service which was cited as an example of good practice by the NPSA
- Within BCUHB NISCHR have just awarded a grant to investigate mindfulness-based interventions for people with LD anger control issues in which there will be nursing involvement
- Nurses from both HBs and HEIs are involved in advising the Welsh Government in relation to a number of strategic developments relating to both policy and practice. They are also involved in similar activities at HB level.
- The Learning Disability Advisory Board that advises the Welsh Government has two members who are RN(LD)s one of whom represents nursing and the other who represents research.

Next Steps:

- Whilst there has been considerable progress in this area transformational work needs to be further encouraged and evidence of impact more widely disseminated. This will be actioned by each Health Board and collated at a national level.
- Within ABMU HB a proforma is being developed and will be circulated to capture all the good practice and innovation that is happening within the directorate. A blog is also being developed to share good practice, the intentions are that this will be viewed via the intranet.
- To submit examples of good practice for inclusion in the UK web resource
- To establish a section relating to Strengthening the Commitment on the CNO web pages

11. Those who commission, develop or deliver education should ensure that all learning disabilities nursing education programmes reflect the key values, content and approaches recommended in this report. They should also ensure that nurses in other fields of practice develop the core knowledge and skills necessary to work safely and appropriately with people with learning disabilities who are using general health services.



Progress to date:

- The first year of the new under-graduate course in Wales has been reviewed to ensure that there is learning disability input for all student nurses.
- The value base of the LD specialist field within these programmes has also been assessed to determine that the value base of Strengthening the Commitment is evident
- The MSc Professional Practice at the University of South Wales offers all students the opportunity to one or both of the modules relating to vulnerability that include a focus on meeting the needs of people with learning disabilities.
- All HEIs involve both RN(LD)s and people with learning disabilities in educating students from other fields of nursing practice and midwifery
- Bangor University also include Radiography, BSc Medical Science and OT students in their sessions for undergraduates
- Within ABMU a Consultant Nurse is employed specifically to focus on increasing access to healthcare and part of this role involves the delivery of education programmes within primary and secondary care.
- The University of South Wales offer LD undergraduate nurses opportunity to undertake BTEC in PBS during their 2nd year.
- Hywel Dda Health Board has developed an educational framework that incorporates learning for acute general hospital staff including registered/unregistered workforce and also experts in specialist LD care. The suite of modules are designed to facilitate the journey of novice to expert in making reasonable adjustments for the delivery of healthcare for people with a Learning Disability; Induction Learning Disability awareness session for all HDHB, a Master class, and a Learning Disability Champions course

Next steps:

- To monitor against this recommendation the new programmes as they move into years two and three of the undergraduate pre-registration course.
- To monitor the uptake of learning disability related courses by non RN(LD) practitioners (HEI's)
- To implement the new framework in Hywel Dda HB from September 2013

12. Updated, strategic plans for pre- and post-registration learning disabilities nursing programmes are necessary for each country of the UK to support flexibility and ensure an efficient and sustainable model of delivery for the long term. This highlights the need for appropriate numbers of places on pre-registration learning disabilities nursing programmes to meet future workforce requirements



Progress to date:

- Agreement has been reached that two specialist LD under-graduate programmes will be maintained in Wales at present
- The number of places commissioned on pre-registration courses for 2013 has increased in both University of South Wales and Bangor University
- Agreement has been reached by ABMU HB with University of South Wales that individuals who have experience of working in LD services and hold level 3 NVQ qualification obtained in LD services and BTEC meet entry criteria for degree nurse training.
- The University of South Wales is developing distance learning materials that will facilitate more flexible entry to under-graduate nurse education programmes.
- The service and education liaison group in North Wales (SLATE) is an established forum to discuss pre and post registration nursing requirements

Next steps:

- To continue to monitor recruitment and retention of student nurses in the context of service demand
- To map the nature and extent of existing post-registration education and to identify gaps (when compared with training needs analysis and service user needs analysis) and most effective means of delivery (to include distance learning and e learning)

13. Education providers and services must work in partnership to ensure that educational and developmental opportunities for nonregistered staff are developed and strengthened and their benefits are evidenced through appraisal systems, and that educational and development opportunities are available for registered learning disabilities nurses to support their ongoing development, reflecting the needs of people with learning disabilities.



Progress to date:

- Health boards are aware of the Cavendish report and have commenced work in response to its recommendations. ABMU HB are developing an action plan to implement the recommendations
- Within ABMU Health Board is committed to staff development and non-registered staff's training needs are identified through annual appraisal and training needs analysis.
- Hywel Dda Health Board have planned to address the needs of non-registered staff as part of the new pathway noted in relation to recommendation 11.
- Hywel Dda HB has a reducing restrictive practice initiative (now in its third year) which promotes the development of appropriate environments of care and a workforce competent in PBS.
- Within HD HB all clinical staff complete PBS certificate or Diploma via EDEXCEL /BETEC workplace and online learning. Live alerts are sent to all clinicians and POVA dept of all relevant incidents allowing timely de brief and learning from incidents. Annual and interim reports are produced on use of restrictive practices and factors influencing its use.
- The service and education liaison group in North Wales discusses educational development across the service. Aspects of pre-registration course are open to registered and non-registered LD staff in the locality. Registered LD Nurses are given the opportunity to be involved in recruiting and teaching/learning of student nurses at Bangor University.
- BCUHB and Bangor University have a lecturer / practitioner post.

Next steps:

- Implementation of the action plan within ABMU HB
- Implementation of educational pathway in HD HB

- Continuation of the reducing restrictive practice initiative within HD HB

14. Services should provide systems to ensure that learning disabilities nurses have access to regular and effective clinical supervision and that its impact is monitored and evaluated on a regular basis.



Progress to date:

- ABMU HB has a policy on clinical supervision and regularly audit the process. This determines frequency rather than outcomes of supervision and has highlighted some disparities in frequency between different areas of the service. Some development sessions regarding supervision are planned.
- Hywel Dda HB has a clinical supervision policy in place throughout services and also Community of Practice in place for practitioners to network and share practice as per its principles
- BCUHB has a policy on clinical supervision

Next Steps:

- ABMU to examine how improvements can be made to ensure that more equitable clinical and professional supervision can be delivered to nurses within the HB.
- Further information to be gathered regarding the 'supervision passport' that is being used in some areas.
- To undertake an audit of clinical supervision across Wales

15. Leadership in learning disabilities nursing needs to be strengthened in practice, education and research settings with robust, visible leadership at all levels, including strategic and national levels. Services must ensure all learning disabilities nurses in clinical practice have access to a dedicated professional lead for learning disabilities nursing. In addition to existing leadership and development programmes, a UK-wide cross-sector project to nurture and develop aspiring leaders in learning disabilities nursing will be led by the four UK health departments.



Progress to date:

- Six students from Wales attended the leadership workshop held in Leeds in July for third year student nurses.
- Representatives from Wales are involved in taking forward this agenda at a UK level
- Nurses within ABMU HB are being supported to attend relevant leadership development workshops outside of the HB.
- ABMU HB Band 7 nurses are currently working on service improvement projects as part of an LQI programme within the HB.
- ABMU HB have developed learning paths for LD nurses which reflect knowledge and skills needed by LD nurses at all levels and across community and residential services. This has included delivery and evaluation of locally organised leadership development programmes for Band 7 LD nurses.
- Within ABMU HB Qualification Credit Framework (QCF) units are available, along with Credit Qualification Framework Wales (CQFW) units for registered and non-registered staff.
- ABMU HB nurses have access to Free to Lead Free to Care Programmes within the HB.
- Within BCUHB LD Nurse have access to Leadership courses, including an Msc in Health & Social Care Leadership

- BCUHB currently has a “Tall Poppies” leadership programme which currently includes an LD Nurse
- Within BCUHB LD Nurse are and have been involved in a range of service improvement forums and activity including Clinical Improvement Groups (CIGs) relating to identified clinical priorities (i.e. Challenging behaviour, Mental health, PMLD and Forensic Issues).

Next steps:

- ABMU HB to develop an implementation plan to roll out leadership skills programme to Band 6 and 5’s.
- To examine at an all Wales level the potential to link new and recently qualified nurses together to share aspects of leadership development
- To circulate the evaluation of the student leadership workshop when available
- To raise concern regarding the reducing number of senior posts in learning disability nursing in Wales

16. Learning disabilities nurses need mechanisms to share best practice and develop the evidence base to continue to advance as a profession. Services must support learning disabilities nurses to participate in appropriate networks. A UK academic network for learning disabilities nursing will be created to support this drive.



Progress to date:

- There has been representation from Wales at each meeting of the UK Learning / Intellectual Disability Nursing Academic Network (LIDNAN) and lecturers from within Wales are taking the lead and/ or involved in a number of the workstreams.
- The University of South Wales hosted a recent meeting of the UK LDIAN and one member of staff gave a presentation. Some practitioners also attended.
- Two staff at the University of South Wales have published a text book concerning *Safeguarding Adults in Nursing Practice*.
- LD nurses within Wales have been active in making presentations at local, national and international conferences and in submitting papers for publication.
- The University of South Wales have held a number of lunchtime seminars in which their own research has been showcased as well as presentations by researchers from other universities. The seminars have been free to attend and have been accessed by people with learning disabilities, student nurses, family members and clinical staff including nurses.
- Two student nurses from University of Bangor took first and second places in the RCN Wales Student Nurse of the Year Awards 2012
- A quarterly LD Research meeting is open to all staff from education, health and social services in North Wales. The meeting is well attended and is where current research ideas/proposals are shared.
- BCUHB have an LD Clinical Effectiveness Group involving LD Nurses.
- Nurses from a number of HBs regularly attend and present at Challenging Behaviour Community of Practice Forum
- Staff from Wales are presenting at the Paperclip Challenge Workshop on 20th September

Next steps:

- Within ABMU a page regarding Strengthening the Commitment is being developed to go on to their intranet.
- To develop a Strengthening the Commitment section on the CNO web pages

17. Learning disabilities nursing research should be extended to ensure practice now and in

the future is evidence based and the impact of interventions can be demonstrated. Services and education providers must ensure that all existing and future schemes for clinical-academic careers have appropriate representation of learning disabilities nursing.



Progress to date:

- This is still at an early stage but over the past 12 months there has been a noticeable increase in practitioners expressing an interest in being involved in research and/ or undertaking research within their clinical area.
- Staff at the University of South Wales have secured research funding and studies are planned relating to end of life care, diabetes self-management and needs of residential support workers when supporting older people with learning disabilities who have increasing health needs. RN(LD) are Principal Investigators in two of these projects and members of all project teams.
- Bangor University has also secured NISCHR funding to investigate the use of mindfulness with people with learning disabilities. There will be nurse involvement in the project.
- The “Question-Aires” (A service-user led research group) in collaboration with staff from Bangor University, LDAN and support from Involving People are developing a study “Do people with a learning disability know what healthy eating is?”. The project has recently obtained ethical approval
- Within Wales 4 RN(LD)s have PhDs and at least three are currently undertaking doctoral studies.
- One clinically based nurse has been successful in securing a Florence Nightingale Scholarship to assist with the funding of PhD studies

Next steps:

- To commence the research studies noted above.
- To commence evaluation of the Macmillan specialist nurse.
- To explore opportunities will to secure further research funding to facilitate collaborative studies between HEIs and HBs.

Delivering This Programme

It can be seen from the information set out above that progress has been made in relation to each of the recommendations and priorities for future work have been identified. However, in identifying this programme of work the implementation group have also noted three key areas of concern that they feel need to be addressed in order to progress the work:

- *Leadership* – it has been noted that in some areas of Wales learning disability services have become part of mental health services and this has resulted in fewer senior nursing posts in learning disability nursing and hence in a diminution of direct influence at senior levels. It is felt essential that there is appropriate, adequate and visible leadership in each area to ensure that the recommendations set out in Strengthening the Commitment are achieved.
- *Clinical supervision* – variations both within and between Health Boards have been noted along with the potential to note frequency of supervision rather than quality of supervision. It is proposed to undertake an audit of provision but it is recognised that greater commitment of resources will be required in order to achieve this recommendation.

- *Contribution across the lifespan* – at present few RNLDs work with children as it is not seen as the core business of learning disability services and not commissioned. However, it is felt that the RNLD has knowledge and skills that could assist children and their families and that their involvement in this area of work should be explored within Health Boards. Similar issues apply to the potential contribution to the care of the growing population of older people with learning disabilities.

Eitem 8

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