Health and Social care Committee
Access to medical technologies in Wales
MT ToR 21 Cedar Evaluation Centre

Scope of the National Assembly for Wales's inquiry into 'Access to medical technologies in Wales'

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About Cedar

Cedar is an NHS evaluation centre, part of Cardiff and Vale University Local Health Board (UHB) and has a collaboration agreement with Cardiff University School of Engineering. Cedar supports decision making in healthcare by providing information and recommendations on:

- Emerging health technologies
- Medical devices
- Diagnostic tests
- Healthcare interventions
- NHS service configuration

NICE Medical Technologies Evaluation Programme

The majority of Cedar's work is funded by the National Institute for Health and Clinical Excellence (NICE). Cedar is an External Assessment Centre for NICE, as part of the NICE Medical Technologies Evaluation Programme. We also work on topics from the diagnostics guidance and the interventional procedures guidance programmes at NICE.

Cedar has expertise and experience in:

- Systematic evidence reviewing – literature searching, critical appraisal and meta-analysis
- Project management
- Engaging clinicians and academics to work with us
- Assessing the ease of use of medical devices
- Standards testing for medical/consumer health devices
- Conducting research
- Health economics
- Statistical analyses
- Report writing (seeking to use plain English)

Cedar has an established history of evaluating medical devices since 1977 for a succession of UK government funded NHS organisations. Today, the expertise of the Cedar team make Cedar a generalist medical technology evaluation centre, able to tackle a wide variety of medical, surgical and general healthcare topics.

Cedar response

Below are responses from individuals within the Cedar team.

Response 1 Grace Carolan-Rees

Medical devices differ from drugs in their manufacture and product life-cycle, regulation, and clinical use. There are currently several processes for accessing medical (non-drug) technologies depending on the nature of the technology, and these processes are not clear. The inquiry should consider access to CE marked medical technologies as these have already satisfied requirements for safety and basic performance.

There should be a distinction between new and innovative technologies compared with those technologies that are established in the market. Medical devices may develop after the adoption phase, with new models brought out. Other manufacturers may enter the established market with 'me too' devices that differ in minor ways from others, but work on the same principles. It would not be useful to re-consider adoption decisions for each new model of a device, but there needs to be an evaluation of additional evidence to determine whether the technology has delivered the improved clinical outcomes and/or cost savings predicted. Therefore the inquiry may need to consider not only which technologies are in scope, but also how to determine whether a new model in an established technology group, or a new market entry with novel design is significantly different, representing a 'step wise' increase in clinical efficacy and/or cost effectiveness.

A related question is whether the inquiry is concerned with access to single technologies or multiple technologies. For example there are several endovascular technologies that may be used instead of surgery for treating varicose veins e.g. laser, foam sclerotherapy and radiofrequency (RF) heating devices. It may be beneficial to consider the endovascular technologies together as a comparator for surgery, allowing clinicians the opportunity to choose their preferred endovascular method.

Medical devices and diagnostics range from consumable single use items at a cost of a few pence each to large capital devices costing of the order of £1million to install, such as an MRI scanner. There are also devices that comprise a reusable unit plus consumables. The reusable unit may have no acquisition cost, but with a considerable cost incurred for consumables. Newer approaches include managed service agreements and there are procurement frameworks for many technologies. Therefore the economics may be complex.

Currently the decision making process is not clear. Who decides? On what basis? Health Boards are in the process of introducing evidence based prioritisation processes for technologies, services and procedures but this is in its infancy. In the present financial climate there may be pressure for evidence based disinvestment, with little chance for new investment. In the absence of a structured decision-making process, uptake of new technologies depends on which clinicians are the most vocal in making a case for adoption.

Cedar response

Evidence for the clinical effectiveness of medical devices and diagnostics is often sparse and of poor quality. Lack of good quality evidence is a barrier to adoption; therefore the inquiry should encompass the issues surrounding evidence generation for medical devices. Clinical trials for new pharmaceuticals are dominated by randomised controlled trials. The processes of randomisation and 'blinding' can be difficult or may be impossible for devices, diagnostics or interventional procedures, and other forms of evidence may be more appropriate. NHS R&D committees must approve research and may view device studies as less worthy or poorer quality science. This attitude contributes to the dearth of clinical evidence. Many of the NHS R&D office procedures are designed for drug trials and do not fit well for devices or interventional procedures. Other types of evidence generation that may be suitable for non-drug research include pragmatic randomised controlled trials, observational studies, and patient registries. Usability and technical factors may also require investigation. Interoperability or compatibility between technologies may be a barrier to uptake, and the usability factors may result in a technology that has been purchased not being used.

Economic evidence is also usually sparse or non-existent for non-drug technologies. The medical technologies evaluation programme (MTEP) at NICE focuses on single medical technologies that show plausible promise that they are clinically more effective and cost-neutral or clinically comparable with standard care and cost-saving. The economic evidence is usually based on a de novo cost model submitted by the product manufacturer or sponsor and is critically appraised by an External Assessment Centre (such as Cedar in Cardiff). The models consider the lifetime costs of the technology compared with standard care from the perspective of the NHS and personal social services. This is a different approach than is taken for drugs, where the economic evaluation is cost-effectiveness analysis or cost utility analysis (cost per quality adjusted life year (QALY)). In contrast to the stance taken by MTEP, new drugs are often adopted on the basis that they bring more clinical benefit but that they also incur additional cost.

The shortage of expertise among decision makers in the evaluation of evidence, particularly economic evidence is not necessarily a barrier to uptake of technologies, but it may be a barrier to good decision making i.e. the wrong technologies may be adopted. This combined with a lack of evaluation after adoption, and inertia could lead to perpetuation of a bad decision. Therefore the inquiry could consider the skills that are required for decision makers and where those skills reside within the NHS and academia in Wales.

Both MHRA as regulator and NICE in developing guidance recognise that different approaches are required when considering devices and diagnostics compared with drugs. For manufacturers and others involved in the whole innovation landscape, the relationships between organisations and the processes at play are difficult to visualise/navigate. There are a number of 'maps' and 'pathways' that have been developed e.g. Association of British Healthcare Industries (ABHI). These may have limited applicability in Wales with divergence from the NHS in England. Therefore information, and preferably a simplified pathway, are key components that must be in place to improve access. Transparency in processes and decision making is fundamental to building opportunities that will benefit patients, the NHS and industry.

Cedar response

The barrier of budget silos and funding models are fundamental factors in the slow adoption in Wales. At the end of financial year there is a mad scramble to purchase equipment to unrealistic timescales when additional funding is released or unspent allocations are identified. It's not good for the NHS or for industry. Budget silos mean that additional expenditure in one service that may release savings in another service is not incentivised. This factor may become increasingly important as more care is delivered in the community setting.

There may be consumer-led demand for some technologies. An example is the 'gamma knife' which has uniquely among radiotherapy technologies achieved recognition and prominence among patients. Potentially consumer demand could lead centres to purchase equipment locally which may be better used in a few specialist centres for safety and value reasons. The inquiry should consider how robust evidence-based responses to consumer demand may be developed. The inquiry needs to address the post adoption evaluation of technologies so that there can be a learning process leading to improved decisions in the future.

Risk management is inherent in the decision making process with regard to adoption of medical technologies. There are risks to adopting a technology and risks to not adopting it. The inquiry could consider how risks are identified, managed and escalated. Some new devices may relate to novel techniques that have steep learning curves for clinicians and may necessitate adoption only where other arrangements are in place for clinical supervision and possibly special licensing or audit arrangements.

Professional resistance is a barrier to adoption of medical technologies. The CardioQ-ODM device is used to monitor fluids during surgery. NICE found CardioQ-ODM (oesophageal Doppler monitor) that the evidence showed that directed fluid delivery using CardioQ reduced the patient length of stay by 2 days. In spite of the strength of the evidence, there remains professional reluctance by some anaesthetists to adopt the technology.

Procurement systems and the supply chain should also be within the scope of the inquiry.

Response 2 Susan Peirce

I have no particular knowledge of the adoption of medical technologies in Wales in comparison to England or the rest of the UK. My research into medtech adoption is based primarily in the English NHS system simply because this is where the technologies I have studied were being used. However, I would expect most of the factors involved in adoption/non-adoption to be the same across most UK NHS organisations.

Uptake & Barriers

There are several organisations and incentive schemes that have been instituted by the English NHS over recent years to overcome perceived barriers to technology adoption. I suspect that more would be gained from examining differences between the learning that went into these and the particular experience in Wales than would be achieved by re-running these pieces of work.

Cedar response

There is a large recent body of work (by the NIHR SDO and others) looking at medtech adoption that would not be worth repeating just to examine the Welsh context for this problem. Rather this body of work should be reviewed by those familiar with the organisation, funding and culture of the Welsh NHS to determine the applicability of these findings.
Adoption of technology by healthcare organisations is not generally conducted in a rational way, although recent increases in financial gatekeeping may have increased the need for justification and procedural transparency in significant procurements. The impact of social/cultural influences should not be neglected even in a culture that states an intention to implement evidence-based medicine. Clinicians and managers are unlikely to be persuaded by empirical evidence that contradicts their gut response to a device or technique. High-level management buy-in, clinical champions, removal of competitor devices/procedures and staff training are all examples of strategies that can significantly improve the uptake of effective technologies which are impeded by the prevailing healthcare culture. The scope of this inquiry should include all potential influences.

Appraisal
Again, the idea of re-learning and then re-inventing what has already been done in the English NHS would be a waste of resources. The scope for this inquiry should be to review what is being done in England, Scotland and N Ireland and define whether there is sufficient difference between these and the Welsh NHS contexts to justify the development of independent procedures. It is important that inappropriate adoption is also considered. This may cover technologies that are not effective and those where adoption may benefit from national/regional planning. Healthcare technologies can prove very disruptive to the structure and organisation of clinical services, e.g. moving treatment closer to the home, requiring new roles or the re-skilling or re-defining of existing ones. Therefore, robust but pragmatic evidence is required to justify such upheaval without going down the route of 'pilotitis' (running evaluations or pilots at every potential adoption site).

Funding
I have little knowledge of the particular mechanisms for healthcare funding in the Welsh NHS.
Summary
I recommend the inquiry review recent learning and established practices/organisations relating to medical technology in other NHS jurisdictions in the context of the Welsh system.

Response 3 Judith White

1) Devices recommended by NICE's MTEP must show cost neutrality or cost saving, but Trusts are not required to follow NICE MTEP guidance. Because implementing new devices/diagnostics often requires a greater initial outlay or investment compared to drugs, managers may be reluctant to follow the guidance issued.
2) Devices may require ongoing expenditure on consumables. Efficacy of device-related treatment is often dependent on the user.

3) Possibly issue around dissemination and acceptance of MTEP guidance amongst clinicians and managers? Are those in charge reading the guidance? It would be useful to see successful stories on savings produced from following guidance.
4) Transfer of services to outpatient setting or the community are often cost-effective measures, and many devices are associated with this. In the case of many specialities, e.g. palliative care, treatment in the community is preferred by patients. However, shifting financial responsibility from secondary to primary care sector could be a huge barrier to implementation.

Response 4 Andrew Cleves

The uptake of medical technology in Wales and the possible barriers to effective new (non-drug) treatments being more accessible to patients

- Barriers can include strong habits formed by clinicians (as was reportedly the case for CardioQ) and a reluctance to change practice. On the other hand where clinical 'innovators' exist we have seen that changes can happen (e.g. Shine)
- Use of some devices may require additional training or may alter the skill mix or shift the emphasis of treatment from one clinical speciality to another, requiring changes to service configuration.
- Without recommendations with national applicability in place, most budget holders (managers or senior clinicians) may wish to see some evidence of efficacy and of a potential cost saving before agreeing to buy anything new (or even continue to fund a service that has been established – e.g. Functional Electrical Stimulation (FES) in Cardiff). For many new treatments there may be no existing case made for adoption by anyone but the manufacturer. There may not be an existing template to make the case for adoption on efficacy & economic grounds.
- The way budgets are organised is often reported as a barrier to uptake of new interventions i.e. if one clinical budget bears the cost of implementing a new intervention (around a particular device) where the economic benefit occurs further along the treatment pathway, in a different clinical budget.
- Existing purchasing contracts with long periods left to run may stifle innovative alternatives that would otherwise bring new advantage (e.g. oxygen compressors for home use instead of deliveries of bottled oxygen – healthcare providers were committed to the latter due to an existing ?national? contract)

The current appraisal processes for new medical technologies, including medical devices, diagnostic techniques and surgical procedures

- NICE has set out a process in MTEP. There is an opportunity for the Strategy Group to avoid doing in Wales what 'doesn't work' within MTEP. A possible example is the problem of appraising a single technology in isolation.
- Also MTEP has an eligibility criteria related to cost for medical devices – i.e. 'do as good a job but cost less' or 'do a better job and cost no more' (than standard care). I think other programmes at NICE consider the 'does a better job but costs more' scenario (e.g. diagnostics?)

Cedar response

- I don't know what appraisal processes are used in Wales or whether they are standardised throughout Wales for medical devices.
- NICE has also undertaken a degree of related information gathering using its External Assessment Centres (EACs) to inform MTEP (taxonomy, manufacturers' data, registries, conducting research etc). Most of the findings would be of interest to the Strategy Group
- We've seen that research with medical devices isn't subject to the exact same governance as drugs
- Maybe a point to make here is that it can be worth investing in a local service to undertake the appraisal process.

The decision-making process in NHS Wales on funding new medical technologies/treatments.

- Wales may have important geographical differences to England whereby devices used in specialist centres may in fact be used in English specialist centres that serve also Welsh populations
- We have seen that Cardiff and Vale UHB has used a prioritisation panel, but I don't think this was for devices alone. We were told that in the absence of a structured decision-making process, uptake of new technologies depends on which clinicians are the most vocal in making a case for adoption.

Research also exists that suggests Wales is lagging behind other UK nations in terms of the use of some devices. We would like to know if this is actually the case and, if so, why

The degree of uptake of technologies would probably require measurement with a targeted approach e.g. identifying a number of specified devices to focus upon in priority areas (i.e. not too many). Some new technologies are linked to registers (to collect safety data) which may also provide uptake data.

I don't know whether there is information in the Welsh purchasing system that would avoid the job of doing new research?