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Is The UK Still Open For Medtech Innovation And Reimbursement?

by Ashley Yeo

Confusing and ineffective channels of innovation adoption and a lack of funding hamper the UK's reputation as one of the world's health care capitals and a driver of care excellence – in spite of its global brands, NICE, MHRA and the NHS itself. But changes that should transform market access are in place and are worthy of close attention in the next two to three years.

- In spite of the major distractions of Brexit, the UK medtech industry recently refocused on its main brief of lobbying for speedy adoption and efficient procurement of innovative medtech, and on a cost basis that allows for the expansion of an industry that generates £18 billion of sales annually in the UK and overseas.
- The UK is often described as a large market *but not a launch market*, and accordingly users and patients risk missing out on timely access to both incremental or disruptive innovation. But three new innovation pathways recommended by the NHS in summer 2016 and the continued integration of the Academic Health Science Networks offer the promise of improvement.
- These and other initiatives are fleshing out the NHS' Five Year Forward View, a plan to adapt affordable delivery to current patient demands with smart new care models. Medtech has a key role to play in the sustainability of the plan.

Funded through direct taxation, UK health care is free at the point of care in the vast majority of cases, and has earned international plaudits, notably in a *Commonwealth Fund* study of 2014. In that international comparison of health care systems of 11 countries, the UK came out on top in nine categories. But it was notably poor in the Healthy Lives category, measuring such elements as infant mortality and quality of health at the age of 60.

The issue for the UK as many see it is the systemic underfunding of health care. UK health care

services are demanded by a population of 65.1 million (June 2015) and growing, and yet the allocation of GDP to health care is studiedly mid-ranking at 9.12% (2014, including private expenditure), and well below the 17.14% allocated in the US (where just over half of expenditure is from private resources), according to the World Health Organization (WHO) Global Health Observatory data repository.

The Organization for Economic Cooperation and Development (OECD)'s comparison of countries in *Health at a Glance 2015* puts the UK in the middle third for health expenditure per capita, and in the bottom third per capita for each of: doctors, hospital beds, MRI units and CT scanners. It is a picture that seems to highlight a different set of superlatives than those used in the Commonwealth Fund study. What is the medtech company supposed to make of these apparent opposites?

The UK Department of Health (DH) would likely call its approach necessary spending efficiencies; however, the National Health Service (NHS) went into acute overspend in 2015-16 – dipping to a record £2.45 billion loss. In fact, at a Westminster Health Forum (WHF) meeting in London in May 2016 it was reported that 65% of NHS providers are in deficit, including 39 Clinical Commissioning Groups (CCGs), which had overspent to the tune of £151 million ($183 million), and that the overall 2015-16 deficit is more like £3.5 billion "in reality." The received wisdom is that for the coming periods 2017-18 and 2018-19, the NHS is set to experience the biggest funding drop in its history.

The NHS provides 85% to 90% of patient care needs in the UK. The strain on its resources prompted NHS chief executive Simon Stevens to quantify a financial black hole of £30 billion that he suggested should be filled by £8 billion of extra government cash and £22 billion of internal productivity and efficiency savings, annually, by 2020-21.

Stevens, recruited from the private sector in 2013, has been quick to appraise the NHS' needs – from budgeting through system transformation through staffing, post Brexit-meltdown. He set out his vision in October 2014 in the groundbreaking Five Year Forward View (5YFV). If his vision fails, it won't be for any lack of application on his part.

In November 2015 NHS England secured a frontloaded NHS funding settlement of £8.4 billion to kick-start the 5YFV. It argues that the plan's success will depend on "intensified prevention and public health, a well-functioning social care system, and targeted revenue and capital funding for service transformation."

But as recently as October 31, 2016, political spats were still raging over whether this cash was actually being made available, incrementally as promised – and what the true amount is.

UK Market Access For Medtech

If all this paints a picture of difficult market access conditions in the UK, it's one with which local manufacturers are accustomed.

The main UK medtech trade industry associations (the Association of British Healthcare Industries – ABHI – for medical devices and the British In Vitro Diagnostics Association – BIVDA) split their time fairly evenly on two major themes: regulatory issues, especially in view of the now-finalized twin EU Medical Device and IVD Regulations (MDR and IVDR); and the problems with and/or lack of the pace in NHS medtech adoption. (Also see "*Brexit: What Now For Device Notified Bodies, CE Marks And The Future MDR/IVDR?*" - Medtech Insight, 30 Jun, 2016.)

And Brexit is a subtext to everything at present. Indeed, for the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), Brexit has become the "the greatest area of thought for the agency at present," agency chief executive Ian Hudson, MD, said at a meeting of industry professionals in mid-September (WHF, London, September 15).

However, for the medtech companies, whether UK-based or foreign, the key preoccupation is selling into the NHS – Brexit-affected as it may well become. Navigating the NHS to get a product, service or procedure into commercial use can be far from straightforward, even with a proven, money-saving innovation. That has been the experience of UK SME Forte Medical Ltd., for instance, which has discovered that engaging with the system can be fraught with problems. (*See sidebar, "Medtechs Bemoan Circuitous Journey To Access UK NHS."*)

NICE Conundrum – Benefits For Medtech?

CE-marked products can be placed on the market in the UK in any setting of care – while the UK remains an EU member state, at least. That alone does not guarantee commercial uptake, however. Products that represent a new care pathway or are radically different or innovative may qualify for a National Institute for Health and Care Excellence (NICE) appraisal – via the Medical Technologies Evaluation Programme (MTEP) or the Diagnostics Assessment Programme (DAP). Unlike the Technology Appraisal (TA) pathway, which mainly serves the drug industry, devices are not selected by NICE, but must be proposed by the company itself.

Medtechs Bemoan Circuitous Journey To Access UK NHS

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Clinical medical device companies can have a hard time before securing any meaningful income from an innovative product they wish to make available to NHS buyers. That has been the experience of Forte Medical, a UK-based SME that has come up against considerable challenges in trying to engage with the NHS regarding its non-touch urine collection system.

Read the full article here

The purpose of NICE guidance is to increase understanding of a technology or procedure. It helps make a proper case with the commissioners of clinical care (the 209 CCGs) and the trusts. But it does not guarantee adoption. There is no link.

The issue of this "NICE disconnect" is constantly raised for public scrutiny by the ABHI. The industry sees in this an unfair treatment for medtech. If a drug undergoes the NICE TA process, it is a mandate to be funded and made available. This does not happen in medtech.

NICE attempted to address this perceived imbalance with its Innovation Scorecard, which is a mechanism by which national clinical directors can assess where innovation is/is not being introduced. Many see it as a worthy idea that has however not had a telling effect and moreover is resource heavy. The feeling is that, its benefits unclear, its days might be numbered, for medtech at least.

NICE has latterly mooted fees for its HTA work on TAs. At present, no fees are planned for medtech, but the sense is that the issue is not entirely off the agenda, even though the consensus is that making charges for guidance that is not linked to payments or uptake would be a difficult step to take.

The ABHI feels that fees of this nature should be a last resort. It is indignant about any suggestion of an additional fee burden on companies whose products are being assessed for public benefit. During a recent consultation that closed in late September, it registered its full objections on principle and on economic grounds. Unless derailed, it seems that TA fees (which do have the potential to impact certain medical technologies and companion diagnostics) will go ahead as of May 2017.

Procurement Under Renewed Scrutiny

Along with adoption and reimbursement, the theme of procurement – securing or purchasing goods and services within the NHS' commissioning of care remit – is another of the elements of the system that can be frustrating to companies.

Procurement of device and pathology services are under renewed scrutiny following publication of the final report of Lord Carter, "Operational productivity and performance in English NHS acute hospitals: Unwarranted variations." Issued in February 2016, its recommended actions aim to save the NHS £5 billion each year by 2020-21.

Indeed, the NHS procurement system in the UK has long been a bugbear of manufacturers – with industry often accusing agents such as the DHL-owned NHS Supply Chain and NHS Shared Business Services of doing little but charging manufacturers for market access. Companies can deal directly with providers, and local deals can happen outside the Supply Chain, but the bottom line for them is being paid properly.

Supply Chain has another 1.5 years of its extended contract to run, after which there will be a new model of UK procurement based around 11 “operating towers” that will be going out to tender. The DH will coordinate and monitor the success of the new system, which is another attempt to standardize products, supply routes, service specifications, commissioning requirements and clinical performance.

The move to evidence- and outcomes-based models of payment are more talk than action right now, but the intent is firm and indeed they are key to Stevens’ New Models of Care (as featured in the 5YFV). They are gathering support and understanding. The sense that the UK is moving slowly toward accountable care organization (ACO)-style systems is palpable. They are being broached at CCG level in the UK, using the new Sustainability and Transformation Plans (STPs).

Lord Prior of Brampton, a junior health minister and one of the new intake in Prime Minister Theresa May's post-referendum government, believes the UK NHS is at the point of no return. "There is no plan B," he told ABHI meeting delegates on November 2, 2016, adding, "we are fully committed to the STP process."

The STPs were announced in NHS planning guidance published in December 2015. NHS organizations in different parts of the country have been asked to collectively develop "place-based plans" for the future of health and care services in their area. Draft plans were submitted in June 2016, and final plans were expected to be completed in October 2016.

These are intended to help local areas deliver the Five Year Forward View vision of greater integrated care, and evolve new models of care that look at whole-system design across health and social care over the next four years.

Tariffs And Reimbursement

If STPs are a welcome move, ABHI market access director Andrew Davies is acutely critical of how medtech tariffs work in the UK. If a company is introducing a new technique, it needs a tariff as the mechanism for providing reimbursement.

But securing a tariff is usually a slow and complex process, especially given limited budgets and the potential for competing therapies to be “defunded” as a consequence. The tariff is also based on figures that are two to three years old, and moreover regional differences mean that local tariffs may be applied, depending on the population needs, which could affect the national tariff. “Getting into the tariff system is hard, and it takes a long time to get reimbursement coding. It also takes a long time for reference pricing to catch up,” says Davies.

In specialized services areas, which commission expensive and/or high-risk products and procedures for use in the inpatient setting, a prioritization system is increasingly referencing benefit and cost-effectiveness. It is a strong indication that evidence-based models are becoming

more important. Davies says it is “crucial that both clinical and health economic evidence are considered; even if a technology is cost-effective, it doesn’t automatically get the green light, as there is always the affordability question.” He adds, “a product can be reimbursed and still not be adopted.”

Three Types of Reimbursement In The UK

The three types of UK national reimbursement for medical technology products were recently listed by industry consultant Arthur Brandwood as follows:

- The Drug Tariff – which is run by the Department of Health – is aimed at consumables and is suitable for prescription-based products (drugs and appliances) used in the community or primary care setting. In this context, Part IX of the Drug Tariff applies. It includes lists of appliances and dressings, incontinence appliances, stoma appliances and chemical reagents that are allowed to be prescribed. GPs are aware that if they dispense an item that is not in Part IX, they will not reimbursed for it.
- The National Tariff – which covers the majority of items used in the acute care setting (see box - *PBR & HRGs – The UK's Own DRGs and Coverage Systems*). The NHS conducts also annual reviews of new treatments and services that it will make available under specialized service commissioning. These are services provided in relatively few hospitals, accessed by comparatively small numbers of patients, and usually located in specialized hospital trusts. It has an annual spending budget of £15.6bn (2016-17) – but only £500m is allocated to "high-cost devices".

PbR And HRGs – The UK's Own DRGs And Coverage Systems

Payment by Results (PbR) is the system used to pay providers for treatments delivered. The levels depend on the complexity of the treatments. PbR covers the majority of acute care settings. If a technology is used in the inpatient setting, it is likely to be covered by PbR.

Technology used in the community or home setting will be commissioned by CCGs under block contracts or, rarer, via a direct procurement model.

The UK system of Healthcare Resource Groups (HRGs), which are similar to DRGs, is currently being updated to become the HRG4+. The current HRG4 system includes 1,500 groups, each covering episodes of care from admission to discharge. It relies on the cost to treat, and if manufacturers can prove that they can save money (by reducing length of stay or supporting local policy), they stand a chance of getting a good tariff. But without cost impact data, a product will not be used in the NHS.

- Capital equipment – which is run at acute trust level, in terms of purchasing.

The UK uses ICD-10 as its national classification of diseases, and OPCS 4 (Office of Population, Censuses and Surveys) for interventions. (The US uses CPT coding.)

Three New Reimbursement Routes For Medtech Innovations

Much to his credit, Stevens is trying different methods and mechanisms to ensure that medtech innovation reaches the UK market. At the NHS Confederation annual general meeting in June 2016, he announced that three channels of access will be the guaranteed routes to get innovation in the market and reimbursed.

This is welcome news. Over the years much breath has been spent and ink spilled over new initiatives that promised to do precisely that, but they all foundered for one reason or another. The Wanless report of 2002, for one, is often evoked for its lucid – and portentous – messages about the need for sustainable funding of health care in order to forestall just the sort of disaster many feel the NHS is now on the cusp of.

Stevens calls it a "new innovation diffusion funding mechanism" that is consistent with the policy direction of the DH's Accelerated Access Review, the final report of which was issued after much delay on October 21, 2016. His new *Innovation and Technology Tariff* presents "for the first time" a clear "route to market" for innovations identified by the NHS England's three new "real-world" assessment programs.

These programs are:

- The NHS Innovation Accelerator (NIA) program, which was launched in 2015 to support individuals to develop and introduce high impact, tried and tested innovations into the NHS. By autumn 2015, 68 more organizations were using NIA innovations than at the start of the program.
- The NHS test beds program (launched at the World Economic Forum in January 2016) – seven "real-world" test beds were set up in January 2016 to evaluate new technologies that offer better care at the same, or lower overall, cost. They will produce evidence of the impact and cost-effectiveness of their innovations in 2018.
- NHS England's Commissioning through Evaluation (CTE) program, which enables a limited number of patients to access treatments that are promising but not yet funded by the NHS, while new clinical and patient experience data are collected within a formal evaluation program.

The NIA is kicking off the plan in 2016-17. The other two routes will follow in 2017-18. These

explicit national reimbursement routes for new medtech innovations should accelerate the uptake of new medtech devices and apps for patients with diabetes, heart conditions, asthma, sleep disorders and other chronic health conditions. Other areas such as infertility and pregnancy, obesity reduction and weight management, and common mental health disorders will also benefit.

The new system is designed to make it easier for clinicians and innovators to get uptake and spread across the NHS. The Innovation and Technology tariff category will remove the need for multiple local price negotiations. Instead, there will be the guarantee of automatic reimbursement when an approved innovation is used. In addition, NHS England can negotiate national "bulk buy" price discounts on behalf of hospitals, GPs and patients.

AHSNs – Are They Up To The Job?

The Academic Health Science Networks (AHSNs) are a relatively new concept and are designed to identify and promote innovation in the NHS. They are described as a bridge to commissioning and facilitators of engagement. There are 15 AHSNs around England. "The NHS is a slow adopter," Rob Berry, head of innovation and research at the Kent Surrey and Sussex (KSS) AHSN," believes, but he adds, "it is what it is, and it is down to companies to adapt their strategies accordingly."

The networks are now attempting to move into a new phase whereby they exploit each other's capabilities better. Berry, speaking at 2016 annual general meeting of BIVDA, stressed that "the UK is not a perfect market, but AHSNs offer support at various stages." They are not just open to UK companies – those from Finland, Singapore and Ireland are already using AHSNs.

Their help may be much needed to prove the case for innovations. The NHS discretionary spend (the budget) doubled between 2000 and 2008, but the NHS has now entered a unique time – one of continual reduction of the spend on the NHS, says Berry.

Accelerated Access Review – Good On Paper

After many months of delay, the UK government-commissioned, independently compiled Accelerated Access Review (AAR) was released in the mid-fall to provide both a structure to, and a tailwind behind, the rapid uptake and spread of medical technology innovation in the UK.

Facts And Figures On NHS And Medtech UK

- NHS England had a budget of £101.7 billion for 2015-16, rising to £119.6 billion by 2020-21.
- £72.5 billion of this was allocated to the CCGs; £10.4 billion to primary care; and

Launched in 2014 (by minister for life sciences, George Freeman), the AAR has the task of recommending the conditions for making innovative medicines, medical technologies, diagnostics and digital products available to NHS patients more rapidly than has been the case. A global medical technology innovation "powerhouse" might result. At least, that is the fond hope of the ABHI.

Industry has signaled its support for the AAR, which supports some actions already underway (via the Vanguards and Academic Health Science Networks – AHSNs) as examples of new care models that can deliver change. (Also see "*UK Accelerated Access Review Can Create A Post-Brexit 'Medtech Powerhouse'*" - Medtech Insight, 24 Oct, 2016.) Some believe the AAR has been released to give a fillip to a UK industry still reeling by the Brexit vote of June 23.

Specifically, it: pledges a renewed NICE focus on medtech, which could lead to an effective route-to-market for key technologies; proposes alignment of national evaluation processes; focuses on "real-world evidence"; supports "commissioning through evaluation"; and aims to use the full potential of the AHSNs to promote innovation adoption, using local networks for local implementation.

£14.3 billion to specialized commissioning.

- There were some 3,268 companies in the UK medical technology sector in 2015, generating a turnover of £18.1 billion (domestic and overseas), employing some 88,000 people directly.
- The top five core product segments in the UK are single-use technologies, IVDs, orthopedic devices, wound care and management, and ophthalmic devices.

Note: Scotland's 5.3 million population is served by NHS Scotland's system of 14 regional boards, seven specialist boards and a central procurement system; Wales' 3.1 million population is served by seven Local Health Boards (LHBs) and three NHS Trusts; and Northern Ireland's 1.9 million population is served by a Health and Social Care Board and five HSC trusts.

Sources: NHS England – Annual Report 2015-16; Strength & Opportunity 2014

Cynics might view it as another worthy NHS/DH initiative that will eventually be superseded. The UK NHS and DH, sadly, have a track record of grand innovation adoption schemes quietly coming to a halt. But right now, enthusiasm for the AAR prevails.

Final Words – A Culture Shift Begins?

Indeed, the UK's "DNA legacy" is to be involved in health care. So says industry consultant Arthur Brandwood. Brexit might yet mean a UK recession. Or maybe resurgence in health care, for the UK remains a big market for medtech, if not exactly a launch market in the way German

and the US markets are.

For the UK, there are potentially very tough times ahead, and Brexit has no doubt made companies, already nervous about broaching market access in the UK, even more trepidatious. But the AAR, and 5YFV represent positives for those innovators that have technologies that can make a difference to the system efficiencies and patient care.

Equally encouraging, NHS England and NHS Improvement recently published the NHS Operational Planning Guidance, which, for the first time, cover two financial years. The 2017-18 and 2018-19 guidance enables NHS trusts and commissioners to plan for the years ahead, underpinned by a two-year tariff for NHS patients and a two-year NHS Standard Contract. The guidance was also published three months earlier than normal, to allow local leaders more time to plan their priority areas such as cancer, mental health, learning disabilities, primary care and urgent and emergency care.

Are these elements, coupled with Stevens' new reimbursement channels, enough to change perceptions about the UK? The UK has the global health care brands – NICE, MHRA and even the NHS itself. But maybe that raises expectations of performance in the local market in terms of innovation adoption, procurement and reimbursement. These expectations are not entirely born out in reality, or at least not yet.