MEDICAL TECHNOLOGY AND INNOVATION

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What is the Medical Technology Group?

The Medical Technology Group (MTG) is a coalition of patient groups, research charities and medical device manufacturers working to improve access to medical technologies for everyone who needs them. Medical technology gives value for money to the NHS, patients and taxpayers but uptake of medical technologies in the UK is not as good as it should be. MTG is interested in a variety of clinical areas but has a common objective in securing patient access to the best diagnostic, imaging, surgical and supported living technology.

For more information and contact details visit www.mtg.org.uk

A message from Barbara Harpham, Chair of the Medical Technology Group:

This edition of the bulletin focuses on linking healthcare decision making such as commissioning and procurement decisions to the ambition to secure long term value. This is something that the MTG would like to see all CCGs and local providers explore to ensure value for money and improve outcomes for patients. The commissioning of specialised services by NHS England – influenced by clinically led reference groups – also presents an opportunity for the NHS to realise the value that medical technology can offer. There is also an article from James Palmer, Clinical Director of Specialised Services, NHS England, on how he and his colleagues are meeting this challenge.

As always with the NHS, the service specifications published earlier this year are a mixed bag and the MTG will work with NHS England and clinicians to improve these specifications in future years. We support the duty NHS England has to demonstrate equity of access. Nationally-followed specifications and policies should help eradicate regional variation and disparity. However, it is crucial that it is best practice and patient pathways that allow for patient access to the latest and most appropriate technologies.

James Palmer spoke at an MTG event in June where he explained other duties that NHS England has, including a requirement to balance the budget. Many feel that this challenge is equal to that laid down by the Nicholson Challenge. We know that medical technology can help and we highlight several examples in this bulletin. The NHS will only make savings and deliver on the need to improve outcomes – outlined by the NHS Outcomes Framework – by ensuring commissioning and procurement decisions are made with long term value in mind. This means altering pathways and service delivery rather than arbitrarily rationing procedures as we hear is happening with common procedures such as hernia repair, hip and knee replacements and cataract surgery.

The MTG Work Foundation report published in 2011 illustrates many of these points. It shows the enormous potential of medical technologies in improving clinical, societal and economic outcomes. Insulin pumps are portable devices worn continuously on the outside of the body which deliver insulin to people with diabetes in a way which is much more physiological than multiple daily injections. Our report shows that if the number of pump users was increased to 12% in line with NICE recommendations, savings just on consultants' visits and hospital admissions would add up to between £37.2 million and £62.5 million per year. However, all too often, in the past, silo-budgeting has stopped one part of the NHS investing in new technology or procedures because the savings are realised in another part of the system.

Last month the Department of

Continued on P2>

The Medical Technology Group
Improving patient access to medical technology

Continued from P1>

Health published a Procurement Strategy which is another attempt by Ministers to make efficiencies with non-pay NHS spend. Like with commissioning, there is a need to balance short-term cost savings with changes to care pathways and the introduction of technology innovations that, with the right incentives, could lead to sustainable medium and long-term savings. An arbitrary insistence on reducing prices by 5% here and 10% there will not have the desired effect. Furthermore, any system put in place for transparent and fair price-benchmarking must enable comparisons on a like-for-like basis. The MTG will work to ensure parliamentarians and policy makers are aware of our views on this strategy.

I hope that you find this bulletin interesting and informative – if you have any feedback, please do contact us through melissa@pbpoliticalconsulting.com.

Medical Technology Week

The MTG are organising a Medical Technology Awareness Week from 4th to the 8th November 2013. We will involve MPs and Peers, clinicians, NHS staff and patients in promoting the need for better and more consistent access to medical technology across the NHS. We want to get people talking about medical technology!

On the 6th November there will be a reception at the House of Commons – between 12.15pm and 3pm – where we will showcase medical technology and hear from patients on how technology has changed their lives. It will be your chance to show parliamentarians, NHS England and others how important patient access to medical technology can be.

On the Friday of Medical Technology Awareness Week we will be demonstrating the value of medical technology to MPs in their constituencies. We will organise visits to hospitals and meetings with CCGs, clinicians and patient groups.

If you want to get involved in Medical Technology Awareness Week by attending the House of Commons reception on Wednesday or engaging with your MP on the Friday, please email melissa@pbpoliticalconsulting.com.

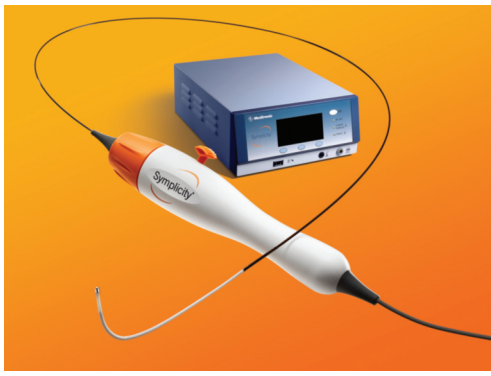
Cost effective interventions that can prevent Heart Attack or Stroke – Renal Denervation

It is estimated that 500,000 people have resistant hypertension in the UK. These are patients who have raised blood pressure despite treatment with three or more anti-hypertensive medications. For these patients the risk of stroke, myocardial infarction or another cardiovascular event is considerable. As well as the risk of death, the likelihood of significant morbidity following a cardiovascular event is also high.

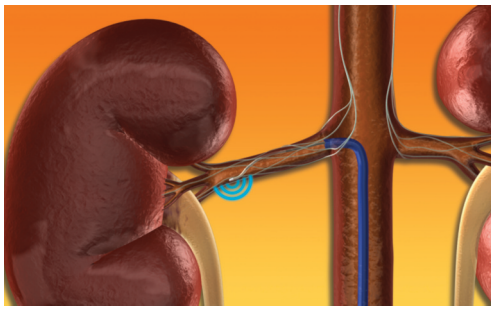
Until recently, there was no treatment available for these patients. A new less invasive surgical technique, renal denervation that utilises a catheter delivery system, offers a treatment option for these patients.

The costs to the NHS and to wider society of cardiovascular and vascular events, caused in part by hypertension, are considerable. For example stroke is the largest cause of adult disability1, with many sufferers of stroke becoming dependant on care, with levels on the Modified Rankin Scale of 3-5 which indicates a level of disability defined as moderate to severe, which requires at least some assistance with daily living[1]. It is estimated there are approximately 1,000,000 people in the UK living with the effects of stroke, half of which are dependent on other people to help with everyday life[2]. Stroke is believed to cost the economy in England ~ £7 billion per year, made up of £2.8 billion cost to the NHS, £2.4 billion cost of informal care and £1.8 billion cost of lost productivity and disability[3].

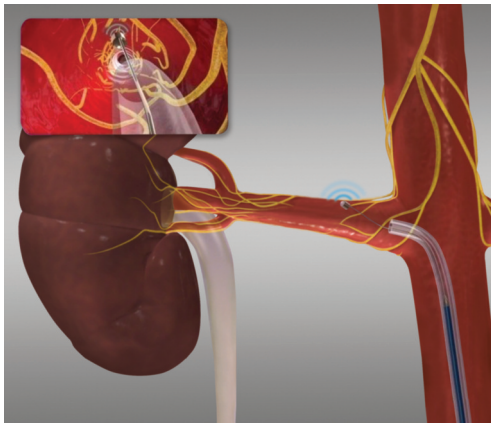
Reducing systolic blood pressure (SBP) and diastolic blood pressure (DBP) by 10 mmHg, a reduction often required in treatment-resistant hypertensives, could halve the risk of cardiovascular events and strokes. Studies have shown that for the vast



The Renal Denervation system consists of a flexible catheter with a radio frequency (RF) electrode tip and a generator that supplies the RF energy to the renal artery



The procedure starts distal to the aorta and consists of multiple site specific ablations moving in a proximal direction.



The helical positioning of these ablations is designed to disrupt overlying renal nerves whilst minimising damage to the renal artery.

[1] Nayak, S. http://theneuroradiologyjournal.it/volume.aspx?ID=199&anno=2011
[2] National Audit Office. http://www.nao.org.uk/publications/0506/reducing_brain_damage.aspx
[3] Mant J, Wade DT, Winner S. Health care needs assessment: stroke. Health care needs assessment: the epidemiologically based needs assessment review, first series. 2nd edn. Stevens A, Raftery J, Mant J, et al., editors. Oxford; Radcliffe Medical Press: 2004. pp. 141–244.

majority patients with resistant hypertension, the new renal denervation procedure can result in a reduction in blood pressure of up to 30 mmHg sustained out to 2 years of follow-up, without significant adverse events.

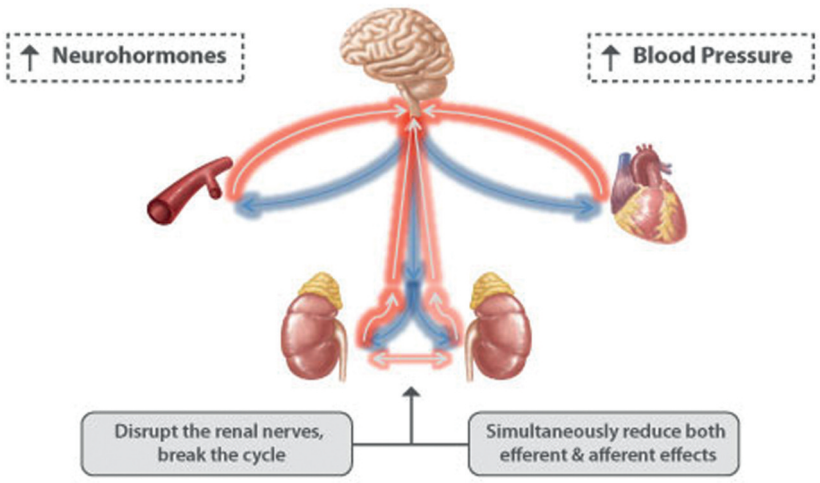
People with hypertension typically have an overactive sympathetic nervous system, a condition that raises blood pressure and contributes to heart, kidney and blood vessel damage. This innovation is used to reduce or quieten the sympathetic nervous system by disrupting the renal nerves . Once positioned in the renal artery, the device delivers low-power radio-frequency energy to deactivate the surrounding renal nerves. This, in turn, reduces activity of the sympathetic nervous system, which reduces blood pressure. The catheter that does this is then removed at the end of the procedure.

The therapy has proven to be clinically effective with over three years of clinical data showing substantial and sustained blood-pressure reduction, without serious adverse events, in patients with resistant hypertension, this has also been demonstrated in a clinical setting with over 6000 procedures performed globally The multi-centre SYMPLICITY HTN-1 study enrolled patients from Australia, the United States and Europe who had persistently elevated blood pressure despite treatment with an average of 5.0 medications. This trial demonstrated that the significant reductions in blood pressure achieved using renal denervation treatment are sustained through 24 months. Similarly impressive results have been shown from the subsequent HTN-2 multi-centre study.

Renal denervation has also been shown to be a cost effective therapy. Using the model preferred by NICE, which compares the lifetime costs and quality of adjusted life years for renal denervation together with three or more anti-hypertensive medications, compared to treatment with just the three or more anti-hypertensive medications, the results are favourable. The analyses is based on the HTN-2 multi-centre study demonstrates a ratio of £6,855/QALY which is well within the boundaries of cost-effectiveness determined by NICE.

Finally, the technology also supports NHS policy objectives. Domain One of the NHS Outcomes Framework identifies an overarching indicator of preventing people from dying prematurely and specifically references under-75 mortality from cardiovascular disease. Renal denervation could contribute significantly to achieving considerable progress against this indicator. It was considered to be of such potential value for patients, the NHS and the UK Life Sciences industry it was referenced in the 'Investing in UK Health and Life Sciences' report.

Despite this convincing case – the NHS has not yet adopted the technology at anything resembling pace or scale. NHS England has decided to commission the procedure through a new initiative called 'commissioning through evaluation' which will put a cap on the number of procedures that can be performed at a limited number of centres while further evidence for wider adoption is collected, (due to the delays in commissioning by evaluation the number centres actively performing this procedure far exceeds the proposed cap) While we wait and see what this will mean for patient access in the medium or long-term, the reality for patients with resistant hypertension today is that patients are being denied this technology – and the NHS is missing out on a potential money saving technology.



Adapted from Schlaich MP, et al. *Hypertension*. 2009;54:1195-1201.

Procedure Description

- The catheter is introduced via the femoral artery using equipment and techniques similar to those used for other catheter-based interventions of the renal artery such as angioplasty or stenting
- The catheter is positioned in the renal artery under fluoroscopic guidance with tip of the catheter initially positioned in the distal region of the main renal artery
- At this point a generator is activated and radiofrequency energy is automatically delivered to the artery for two minutes
- Following this treatment, the catheter is rotated and withdrawn proximally several millimetres to the next treatment site and once in position, the energy delivery is repeated
- This process is continued, resulting in a series of discrete treatment sites (typically four to six) along the renal artery
- The delivery of energy to multiple discrete focal treatment sites minimizes the risk of formation of a flow limiting constriction
- The procedure is then repeated in the contralateral renal artery

NHS England and specialised commissioning

James Palmer – Clinical Director (Specialised Commissioning)

It was a great pleasure to meet with representatives of the Medical Technology Group (MTG) this summer, and discuss NHS England's new responsibilities for specialised commissioning. An open dialogue between industry, patients and NHS England is crucial, and I hope that the MTG will play an important role as this continues to happen.

I appreciate the opportunity to set out in this article some of our goals in relation to specialised services. These are the services that are provided in specialist centres that are able to recruit staff with appropriate expertise and are accessed by comparatively small numbers of patients. NHS England has produced 128 national service specifications and 43 commissioning policies to support the commissioning of these services.

An important principle is clinician involvement in commissioning – this is especially true in the case of medical devices. Seventy four clinical reference groups (CRGs) have been developed to provide NHS England with clinical advice regarding these specialised services, and to develop the service specifications and commissioning policies that will allow NHS England to commission these services through local area teams. Clinicians – working with industry and patients – are best placed to identify and endorse innovations. CRGs will be responsible for identifying and promoting best practice, scanning the horizon for new treatments and pathways, and ensuring that decisions are made that deliver value for the NHS as well as improving patient outcomes.

Another priority for NHS England is to create a consistent, robust and evidence-based approach to commissioning across the UK. I know that ensuring patients have access to appropriate medical technologies wherever they live in the UK is one of the MTG's campaigning priorities. Until now, there has been wide variation in how each region discharges its commissioning responsibilities. This has resulted in inconsistencies in the management of the commissioning cycle e.g. budget setting, contract negotiation, performance management and the development and application of service specifications, commissioning policies and quality standards. Annually reviewed national service specifications and commissioning policies should help to reduce regional variation. Patient access to medical technology should be consistent from Newcastle to Newquay – from Dover to Doncaster.

Finally, service specifications and commissioning policies must be patient centred and outcome based. The delivery method for this is the NHS Outcomes Framework. NHS England must ensure that service specifications and commissioning polices deliver improved outcomes across each of the five domains of the Framework. I was pleased to hear that the MTG – working with parliamentarians – are working on showing how the adoption of certain medical technologies will help deliver against indicators across each domain of the NHS Outcomes Framework. I hope the MTG will share this work with NHS England and relevant CRGs.

I know that there are questions around some technologies where CRGs have determined that there is a lack of evidence for them to be routinely commissioned. A new 'commissioning through evaluation' (CtE) approach is intended to support directly commissioned specialised procedures or services where there is currently insufficient evidence of relative clinical and cost-effectiveness to be routinely commissioned by NHS England, but where there is believed to be genuine 'promise' as a potential future treatment option. Procedures or treatments agreed as part of the CtE programme will be commissioned on a limited basis as part of a formal evaluation project, with patient selection criteria, provider selection criteria and evaluation measures developed with a range of stakeholders including patients and clinical experts. Findings will then be used to inform future substantive commissioning policy decisions. NHS England envisage that the initially proposed CtE programme should be open to patients by the autumn.

The treatments and medical devices we are considering for this new approach include Mitraclip – a device used in the repair of heart valves; renal artery denervation for the treatment of chronic high blood pressure, and selective dorsal rhizotomy, a treatment aimed at reducing spasticity in children with cerebral palsy. NHS England is still working up the detailed costings for this programme but, in general, investment for these treatments is expected to be set at the level of historic national health service expenditure (such as equivalent to expenditure during 2012-13), and will vary from treatment to treatment.

The success of this new approach of commissioning specialised services will be determined through partnership between NHS England, industry and patients. NHS England and CRGs need advance notice of new innovations and help in understanding how they will change patient pathways and service delivery. However, inappropriate lobbying will not be welcome – we are looking for collaboration and partnership. CRGs also need patient and carer involvement. There are patient representatives on each CRG and there is an ongoing process to become involved. It is for patient groups and carers to come to NHS England and register to be involved.

Working to deliver an approach that will enable better patient outcomes through innovation and keeping within budget – which should save the NHS money – is the most exciting part of my new job. I am always open to hear from industry, patients, parliamentarians and NHS staff to help inform NHS England's role in commissioning specialised services.

NICE must get it right on Cardiac Resynchronisation Therapy

A person has heart failure if their heart is unable to pump sufficient blood to meet their body's needs. Causes range from hypertension, congenital heart disease, to a heart attack or a virus.

Patients suffering heart failure develop increasing breathlessness and fatigue when carrying out daily activities – and ultimately at rest. Consequently, ability to work is greatly impaired along with health and quality of life. Untreated, heart failure has a survival rate similar to cancer - and over a third die within 1 year of diagnosis.

Heart failure eventually affects 3 in every hundred women, and 4 in every hundred men. It imposes huge costs on the NHS, accounting for 5% of all emergency hospital admissions and 2% of all NHS hospital bed days.

Implantable devices now have an established role in treatment of patients. Implantable cardioverter defibrillators (ICDs) jolt the heart back into its natural rhythm when it goes out of rhythm. Cardiac resynchronisation therapy devices (CRT-Ds) help pace the heart to enable it to pump blood more efficiently and include a defibrillation function, offering protection from sudden cardiac death.

Stephanie from Sunderland is an example of the benefits. She is a member of the Cardiomyopathy Association - an MTG member. She was 22 when she collapsed, looking and feeling awful. She was rushed to hospital with severe heart failure. Over the next five years she was treated at her local hospital but had several more collapses and emergency admissions to hospital with severe heart failure. She was told it was so serious she to avoid becoming pregnant.

It was only after she was given an ICD that her heart function began to improve and she started to feel much better. The improvement was so great that by the time her ICD was due to be replaced, doctors decided she no longer needed one. "With appropriate care, treatment and support, things can get better," she says.

A large body of high quality evidence already supports the safety and efficacy of ICDs and CRT-Ds. Recently, in a unique collaboration by medical device manufacturers, 12,000 heart failure patients were followed over a period spanning seven and a half years - in 13 individual randomised clinical trials.

The results were dramatic. Patients who received CRT-Ds and ICDs had a death rate 25% to 45% lower than those who instead took the best available drugs. For patients with mild to moderate heart failure (NYHA classes I, II and III), ICD and CRT therapy reduced monthly admission rates to hospital by 20% to 35%. The effect on patients with severe heart failure (NYHA class IV) is even more pronounced, with CRT offering reduction of about 40% in monthly admission rates.

NICE is currently reviewing ICDs and CRT-Ds. New and improved guidance could help improve implant rates and ensure the credibility of NICE and the UK as a centre for medical technology innovation. At the moment, the UK falls embarrassingly far behind other countries in provision of implantable devices for heart failure patients, the UK remains in the lower quartile of European averages.

For ICDs current NICE recommendations are 100 implantations per million people and for CRT-Ds the figure is 130 per million. However, the UK is still not at this number with the latest figures showing an implant rate of 76 per million for ICDs and 116 per million for CRT-Ds. This has serious serious implications for the health of many patients in the UK. As a result, heart failure is killing people, lowering quality of life and the UK is spending a lot of money treating it badly. We must all hope NICE gets it right.

Medical Technology Group members

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AntiCoagulation Europe
ARMA
Arrhythmia Alliance
Arthritis Care
Atrial Fibrillation Association
Association of British Healthcare Industries
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Bladder and Bowel Foundation
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The Medical Technology Group at Westminster

The MTG has been working with parliamentarians for a period of time now in order to raise awareness of the benefits of medical technology for patients, the NHS and the wider British economy. Last year the MTG, along with some parliamentarians, published a report, entitled Delivering Equity of Access: What needs to change?

This year the MTG are looking to follow up on its previous inquiry at Westminster and investigate how greater access to medical technology could help deliver NHS objectives contained within the NHS Outcomes Framework. The NHS Outcomes Framework is the mechanism from which the Government hopes to improve outcomes in particular areas. It will also hold the Government and NHS England to account for the performance of the service.

The NHS Outcomes Framework is separated into five domains. Our report will aim to show how greater patient access to medical technology will help the NHS achieve against some of the indicators that has been set for each domain.

The five domains are as follows:

- Domain One – preventing people from dying prematurely
- Domain Two – enhancing quality of life for people with long-term conditions
- Domain Three – helping people to recover from episodes of ill health or following injury
- Domain Four – ensuring people have a positive experience of care
- Domain Five – treating and caring for people in a safe environment and protecting them from avoidable harm

The MTG is currently looking for suggestions and examples of technology which can be assessed against indicators within the framework. We will be issuing a call for evidence and organising workshops in each domain.

If you feel you can contribute please do get in touch with the secretariat for the Group through melissa@pbpoliticalconsulting.com.