

MEDICAL TECHNOLOGY AND INNOVATION

The Bulletin of the Medical Technology Group

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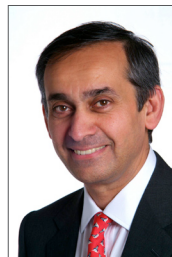
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What is the Medical Technology Group?

MTG is made up of patient charities, research charities and developers and manufacturers of a range of medical technologies. With a wide range of members — from Arthritis Care and Heart Research UK to international companies such as Boston Scientific and Medtronic — we are interested in a very broad range of issues but have a uniting interest in securing patient access to the best diagnostic, imaging, surgical and supported living technology.

The Health Innovation Council A Welcome Addition to the Department of Health

Andy Taylor, Director – Healthcare Policy, Association of British Healthcare Industries Ltd



Lord Ara Darzi

In July 2007 the Government asked Lord Ara Darzi, one of the world's leading surgeons, to conduct a wide-ranging review of the NHS. His interim report, published in October 2007, stressed the importance of innovation in the NHS. Accordingly, the Health Innovation Council (HIC) was established.

HIC is charged with developing a strategy for speeding and embedding innovation across the NHS. With 'medical devices' as one of its workstreams, HIC should promote better use of new technology. Chaired by Lord Darzi himself, HIC includes key individuals from the NHS, academia and industry.

HIC has apparently recognised that the NHS has a problem with innovation: whilst it has

made good progress in recent years on the R&D side, adoption remains limited.

There is good reason to be encouraged by the goals of the Darzi Review and its recognition of the need for substantial and accelerated reform of the NHS to reflect changing needs, challenges and, in particular, opportunities afforded by advances in technology. These can profoundly impact both outcomes and productivity in an environment of increasingly constrained human resources which will be likely to generate rapid inflation of scarce clinical and nursing staff costs. However, if the goals of the Darzi Review and subsequent reforms are not to be undermined, it is essential that procurement is aligned with the strategic and operational goals of local health economies. At the moment, there are conflicting directions in NHS procurement: regional and local level initiatives have the potential to involve clinicians in innovation; at the national level, however, structures are focused on financial goals rather than on longer-term value. There will need to be changes in procurement if Darzi is to make progress.

Department of Health backs Innovation and Technology

The Department of Health announced the launch of two Healthcare Technology Cooperative (HTC) pilots in February 2008. These pilots are intended to improve the receptiveness of the wider health and social care systems to innovation, and to boost the development of new technologies and products.

These pilots are intended to improve the receptiveness to innovation... and boost the development of new technologies and products

The drive to improve innovation in healthcare technologies is an agenda which the recently launched Health Innovation Council is also designed to progress (see above). HTCs will bring together clinicians, patients, scientists, and industry professionals to develop new technologies and products to solve currently unmet patient needs.



A view from Whitehall



A view from the Front Line

Screening Programme & Innovative Technology

A View from Whitehall

Provided by the Department of Health

The Prime Minister announced in his speech to the NHS in January, the introduction of an Abdominal Aortic Aneurysm (AAA) screening programme for men aged 65. Once implemented the programme is expected to save approximately 700 lives within the first 10 years, rising eventually to 1,600.

The screening programme will also improve the patient experience by developing information and support materials to enable men to make informed choices about whether they wish to undergo screening or possible surgery if an AAA is detected.

Most men will only need to be screened once, when they are 65. The screening test is a ten minute ultrasound scan providing a painless, safe and reliable method of measuring the size of the aorta. Most men (95%) will have an aorta within normal limits and will not require another screening test in their lifetime.

If a small AAA is detected, this will need to be monitored with regular scans to see if it increases in size. The patient's GP will also be informed of the result. Follow up with the patient will also be important to discuss blood pressure management, dietary and lifestyle changes and, if required, smoking cessation services.

If a larger AAA is detected, the man will need to discuss with a surgeon the advantages and disadvantages of having an operation to repair the AAA. Patients will need full information so they can make informed choices as to whether to undergo elective surgery.

Work is now underway by the national programme team, who will work with stakeholders to plan implementation. They will be putting in place quality assurance and monitoring, setting national standards and training staff. It is anticipated that the programme will be operational in all SHAs over the next five years.

A View from the Front Line

*Celia Riga BSc MRCS, Nick Cheshire MD FRCS
Imperial College Healthcare NHS Trust, Regional
Vascular Unit, St Mary's Campus, London*

Lucky Alfonso Albert Adams, a 70-yr old wine taster from Kent was diagnosed with a 7cm abdominal aortic aneurysm (AAA) that was picked up incidentally on ultrasound for a bladder condition. The risk of aneurysm rupture and death was estimated to be 20% in 12 months. He underwent successful endovascular repair of his aneurysm (EVAR) with a stent-graft and was discharged home less than a week later.

In the UK, 7% of men over 65 years have an AAA, a condition accounting for approximately 5,000 deaths per year. Most aneurysms remain asymptomatic until rupture, when mortality can be as high as 90%. Detection of asymptomatic AAAs allows for elective repair, which carries a significantly lower risk. Ultrasound screening has been shown to halve the number of aneurysm-related deaths over five years, reduce emergency ruptured aneurysm workload by 70% and disruption to elective theatre-lists and ITU/HDU beds. The additional operative burden per surgeon is less than one extra case per month.¹ Screened patients also have better opportunities for secondary prevention, including hypertension control and smoking cessation. With recent advances in endovascular grafts, imaging and innovative operative techniques, EVAR has become an attractive alternative to open repair. EVAR significantly reduces peri-operative mortality and has comparable outcomes at three-year follow-up, especially in smaller AAAs such as those picked up by screening.² This new procedure is minimally invasive involving two small groin incisions under regional anaesthesia, with a shorter hospital-stay, and faster return to normal activity.

Imperial College Healthcare is the UK's first Academic Health Science Centre, and is engaged in a study looking at outcomes after stenting for early-stage AAAs. The combination of innovative technologies and early AAA detection has great potential to save the lives of hundreds of British patients with minimal risk from their surgery.

References

¹ MASS Group.
The Multicentre Aneurysm Screening Study (MASS) into the effect of abdominal aortic aneurysm screening on mortality in men: a randomised controlled trial.
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² EVAR Trial participants.
Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomized controlled trial.
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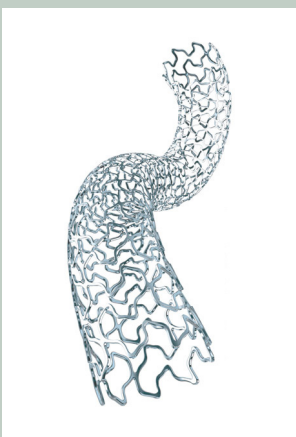


As a mother who tried for two years to secure funding for her four-year-old, Julia explains:

"We struggled with every type of injection regime. Melissa started pumping nearly two years after diagnosis — and our lives began again."

"If I had to sum up in one word the difference a pump has made to our lives I would have to say: liberating."

NICE's recommendation on drug-eluting stents and its involvement in pricing



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Access to insulin pump therapy backed by guidance review

By **INPUT** — patient led support group for people using insulin pumps

The National Institute for Health and Clinical Excellence (NICE) has reviewed its guidance for the use of insulin pump therapy amongst people with Type 1 diabetes, making it easier for children aged 12 and under to access the treatment.

INPUT feels that the updated guidelines for children under 12 are much more appropriate, and welcomes the recommendation that they no longer need to have failed multiple daily injections before being considered for a pump. Insulin pumps provide a sophisticated insulin delivery system. Provided the patient is willing and able to use the insulin pumps

effectively, they can help patients maintain control over their diabetes.

Five years on from the original NICE recommendations, there remains a pronounced variation in access to this therapy — something which the Department of Health's Insulin Pump Group worked to reduce in 2007. INPUT hopes this review will further improve the situation. Ensuring the implementation of these guidelines is more consistent than previously is vital.

For further information, please visit the NICE website: <http://www.nice.org.uk/> or contact John Davis at INPUT on: input@care4free.net or 01590 677911

*Mark de Belder
President, British Cardiovascular
Intervention Society*

The inter-reaction between physicians who identify clinical problems, and healthcare technology partners who seek their solutions, is essential for progress in medicine. The safety and efficacy of percutaneous coronary intervention (PCI) has improved dramatically over the last decade and, with drug-eluting stents (DES), one can say to most patients that the need for additional intervention or bypass surgery has fallen to about 1 in 20 patients.

In 2003 NICE recommended that DES should be used in vessels with a reference diameter less than 3mm or in lesions longer than 15mm. NICE has recently caused a ripple of excitement in the interventional cardiology community by coming out with a first draft review suggesting that we should not use DES in the UK because they are not cost-effective but then has done a complete U-turn and produced a final draft guidance identical to the 2003 guidance. However, on this occasion, it has stated that this is dependent on a price premium between DES and standard 'bare metal stents' (BMS) being less than £300.

Why should doctors care about the price of stents? They certainly have to get involved with cost-effectiveness when told that they are about to be denied the use

of a very effective treatment. The British Cardiovascular Intervention Society (BCIS) and the British Cardiovascular Society (BCS) strongly disagreed with initial recommendation and jointly submitted evidence as well as a cost-effectiveness analysis which was at variance with the results of the economic analysis that NICE commissioned.

However, both the BCIS and the BCS elected not to appeal against the final guidance as they concluded that from the clinical perspective the status quo was being maintained. One company has formally appealed. This appeal will be heard in mid-April. Thereafter NICE will release its guidance. We do not know the details, but there are limited grounds for such an appeal — one of which is that NICE has over-stepped its powers. It is not NICE's responsibility to set the price of products and although it is not overtly doing this, its insistence on a very low price premium is virtually forcing the issue. Is NICE changing its processes? Is it exploring value based pricing? But again, why should clinicians care? We will care if this impacts on the health industry's level of investment in future research and development programmes. Hopefully a sensible compromise can be found that allows us to deliver effective and cost-effective treatments to patients and yet allows industrial partners to continue to engage with the hugely necessary research work that will produce tomorrow's treatments.

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What is the Health and Social Care Bill?

Introduced to Parliament November 2007 by the Secretary of State for Health, Alan Johnson, the *Health and Social Care Bill* aims to modernise and integrate health and social care.

There are four main policy areas of the Bill:

1. **Creation of the Care Quality Commission (CQC)** bringing together existing health and social care regulators into one regulatory body
2. **The regulation of Health Professionals in the health and social care workforce** to enhance public and professional confidence in the system
3. **Measures to enhance Public Health Protection** focusing on serious diseases caused by infection and contamination
4. **The creation of Health in Pregnancy Grants**, one-off payments to expectant mothers, to help with the costs of a healthy lifestyle

Part of the new regulator's role is to "make recommendations for improving economy, efficiency and effectiveness" in the provision of health and social care.

MTG hopes that this could include:

- Giving consideration to savings across all governmental spending departments and economic gains throughout the UK
- Accounting for improvements to patient care likely to arise through its recommendations, in so far as these take advantage of medical technology

We look forward to exploring the new opportunities which this modernisation may afford. The Bill is currently being debated at Committee Stage in the House of Lords which we are following with interest.

More information about the Bill may be found at: <http://www.parliament.uk/>

Technology Showcase: Insertable Cardiac Monitors



Atrial fibrillation (AF) is the most common form of arrhythmia (or heart rhythm disturbance) and affects up to 1% of the UK population (4% in the over 65s); it absorbs almost 1% of the NHS budget.

As a condition that fluctuates, it is important that clinicians are able to look beyond the symptoms or snap-shot-data and see the full picture. Offering continuous monitoring 24 hours a day, the new technology Insertable Cardiac Monitors (ICMs) provides an exciting development in the management of this condition. ICMs automatically record detected episodes of irregular heart

rhythms and provide accurate, long-term monitoring of AF. The devices allow clinicians to monitor the progression of AF and the effectiveness of any treatments administered. Meanwhile they ensure patients have the necessary information to make informed decisions and see their doctor as and when necessary.

With an overall incidence of stroke in AF patients of approximately 5% per year, the condition is a significant cause of mortality in England. Developments in the management of this condition may help support the government achieve its aim to reduce death rates from coronary heart disease, stroke and related disease by at least 40% in people under 75 by 2010.

For further information please contact: info@atrial-fibrillation.org.uk

SAVE THE DATE: MTG Parliamentary Showcase: Monday 23rd June 2008 3pm-6pm
An exciting opportunity to learn more about the group and medical technologies