ABBOTT VASCULAR RESPONSE TO THE NHS CHIEF EXECUTIVE’S INNOVATION REVIEW

Abbott
Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. With vascular disease as one of the world’s leading causes of death and disability, Abbott Vascular (AV) offers innovative technologies that are designed to transform how physicians treat the disease and to improve patient care.

New and innovative medical technologies
New and innovative technologies can be hard to define. For the purpose of this consultation response we have focused on the constraints and limitations experienced in the adoption and diffusion of technologies that have been awarded a CE mark, have significant Randomised Control Trial (RCT) data but do not have a defined reimbursement code or structure.

From our own experience with MitraClip1 and associated soundings, AV is concerned about the lack of a coherent process for evaluating, funding, adopting and diffusing specialised technologies across the NHS.

Adoption of technology
Abbott recognises that moves have been made to improve the way in which medical technologies are assessed, adopted and diffused in the UK, through NICE’s Medical Technology Advisory Committee (MTAC) and other programmes such as iTAPP. However, significant limitations remain. For example, the emphasis placed on equivalent or reduced cost can be restrictive for a new product where the number of procedures has not been sufficient to make such calculations with confidence. There also remains a bias in favour of new technologies that treat larger patient populations. A product such as AV’s MitraClip, which treats a smaller group, is often unsuited to assessment by NICE and other relevant bodies in the early phase of therapy development.

Innovation in specialised services
Innovation in specialised services has been an important source of innovation for the health service as a whole. Developments such as laparoscopic surgery and percutaneous procedures, pioneered in specialised settings, are now improving patient outcomes and reducing lengths of stay across the NHS as a whole.

Status quo
For new technologies that have obtained a CE mark and have supportive trial data but without a defined code or reimbursement structure, adoption of technology is challenging and diffusion even more so. Industry often relies on “new technology money” which is set aside by individual hospitals. By funding a small number of

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1 The MitraClip system is a catheter-based therapy intended to reduce mitral regurgitation (MR). This less-invasive mitral valve repair therapy is adapted from the open surgical double-orifice technique, and increases the options for select MR patients, may reduce the symptoms of heart failure (HF), and may improve quality of life: [http://www.abbottvascular.com/int/mitraclip.html](http://www.abbottvascular.com/int/mitraclip.html).
procedures the hospital is able to build up an experience base, which is then used as justification to apply for funding from specialised commissioning groups (SCGs) on a ‘named patient basis’. AV’s experience is that there are significant and worrying shortcomings bound up with this process. In particular:

- A hospital’s success in developing an experience base for a new technology is largely related to the size of the hospital’s new technology fund, rather than clinical capability.
- The decision whether or not to fund a new/innovative technology on a named patient basis varies significantly across the specialised commissioning groups. This means that hospitals who have committed to developing an experience base and then fail to receive funding for further treatments often end up wasting money, deterring future initiatives.
- The decision whether the hospital will be funded to carry out procedures on a named patient basis is affected by the nature of the relationship between the hospital clinicians and the commissioners as much as clinical outcomes and involves little, if any, strategic planning.
- Hospital’s “new technology funds” are an unsatisfactory method of funding new technologies, encouraging companies to sell their device into as many hospitals as possible. This behaviour has three significant results: a) it prevents clinicians from performing a sufficient number of procedures to ensure the best outcomes; b) SCGs are subsequently inundated with requests from multiple centres to fund patients for that new procedure; and c) it results in poorer clinical outcomes for patients.

Commissioning
The status quo has led to industry relying on hospitals for initial funding. The result for commissioners is that they are often the last to know about developments in new and innovative technologies. This makes horizon scanning for new technologies difficult and commissioners often find themselves funding new devices on an ad hoc basis, which makes it difficult for commissioners to accurately forecast the cost of new technologies.

Recommendations
AV’s experience is that other Western European countries have more comprehensive funding arrangements for the prompt uptake of innovative technologies. AV recognises that not all approaches to innovation are suitable for the NHS but suggests that some valuable lessons can be learned. The NUB (Neue Untersuchungs- und Behandlungsmethoden) process in Germany was introduced as a mechanism for allowing innovation into the G-DRG\(^2\) system. Under NUB individual hospitals make applications for technologies that are new to the German system and thus have no pricing code under G-DRG. If a hospital’s application is approved then a top-up is paid to the hospital allowing them to use the new device. Approved technologies are subsequently monitored centrally and if the device delivers good patient outcomes and sufficient cost difference the product may be integrated permanently.

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\(^2\) G-DRG is the system which reimburses hospitals for inpatient activity.
A process more along the German lines would provide some of the strategic oversight needed to improve the adoption and diffusion of new medical technologies within the NHS. Countries such as Denmark, Sweden and Finland have also proved ready to provide funding for MitraClip at a level sufficient to support what we see as the desirable minimum volume of two procedures per centre per month, while experience is being gained.

The current reorganisation of the NHS will see specialised commissioning arrangements move from 10 specialised commissioning groups to a nationally aligned team sitting within the NHS Commissioning Board. AV believes that this reorganisation provides an ideal opportunity to address the unsatisfactory situation found in the NHS.

Based on our experience with MitraClip, AV would like to make the following recommendations to ensure patient safety and optimal clinical outcomes:

- **Establish an innovation fund for specialised life sciences** as part of the NHSCB’s responsibility for directly commissioning specialised services. This would enable the Board to show leadership in the field of innovation and facilitate the involvement of commissioners at an early stage of product deployment. The fund would be open for specialised services, products and technologies covered by the Secretary of State’s mandate. Principles for the fund should be developed with a variety of partners including clinicians, commissioners, patients and industry, with a focus on ensuring equitable access and improved outcomes based on clinical need and efficiency. A fund set at 2% of the Board’s anticipated budget for specialised services would seem appropriate.

- **Limit the number of ‘first wave’ specialist centres** to develop a therapy based on available clinical data. New technologies with a greater evidence base would have a greater number of centres, subject to other considerations below.

- **Define the volume of patients to be treated by each centre** to ensure the learning curve is minimised, and clinical outcomes optimised. The benefit of this model is that costs can be precisely defined and controlled whilst creating the best chance of clinical success.

- **Agree on parameters to prospectively audit/monitor patients** treated with the new therapy. This is required to help refine patient selection and speed up the understanding of the role of the new technology in the absence of further RCT data that may be underway. A User Group of doctors from first wave centres should be created to monitor clinical outcomes and develop guidelines for best clinical practice.

- **Define in advance the point at which ‘second wave’ centres should be initiated** to support growth and development of the therapy/technology. Those regional hospitals that have the required service and skill to support the new therapy and who have referred a predetermined number of appropriate patients to first wave centres will be obvious candidates to become second wave centres.

In the past, innovation has suffered from a tendency for clinicians, commissioners and companies to operate in varying degrees of isolation from
one another in a fragmented system, with patients losing out as a result. The NHS reforms for specialised commissioning have the potential to usher in a much more coherent approach with clearly defined routes to deliver the benefit of new technology to patients, in areas like cardiology, linked to the proposed innovation fund.

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Do you want to be kept in touch with the next steps in this process? Yes

Do you want to be included in a wider community of interest? Yes