How *In Vitro* Diagnostics can realise cost savings and improve patient outcomes for the NHS

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The Department of Health estimate that 4% of the NHS budget is spent on the provision of pathology services which contribute about 70% of the information used in making clinical decisions. This already represents a great value for money proposition but it is clear that there are opportunities for achieving even more than this.

In Vitro Diagnostics, or IVDs, are the tests performed on clinical samples to provide information for diagnosing and screening for disease. The tests can also be used to monitor therapy or rule out putative diagnoses and have an increasing role to play alongside drugs. There are a growing number of diagnostic dependent drugs which should only be prescribed for patients where a parallel test has shown the drug will be effective for that patient based on the genetic make-up of the individual or the disease they are suffering from. It is likely that many more drugs will routinely be used with IVDs in this way in the future, particularly for cancer. There also will be IVDs which show if an individual is responding to a specific therapy.

Of immediate concern is the ability of IVDs to play their role in cost savings for the NHS over the next few years. Pathology services have been in the headlights of the QIPP initiative of the Department of Health since its inception in September 2009. QIPP is the acronym for Quality, Innovation, Prevention and Procurement, an ongoing project to identify budgetary savings while maintaining health outcomes and patient safety. In the final report of the review of pathology services by Lord Carter of Coles (from 2005-2008) it was identified that there could be significant savings made by the re-design of pathology services. There has been a tremendous amount of work done in England in the last eighteen months to do just this, led by the National Clinical Director for Pathology Services, Dr Ian Barnes. This has seen improved utilisation of networked laboratories and a range of other innovations including the joint venture between Guys and St Thomas's NHS Trust and Serco to provide a more commercialised service under the name of GSTS Pathology. This is a model which is starting to appear across the country in other hospitals and there are also other private providers with an interest in doing similar activities.

However that is the work being done to streamline and improve efficiency of the service. Of the total expenditure on pathology, just under a quarter of the money is actually used to purchase the reagents and equipment to perform the testing. So industry has recognised that it also has a role to play in making cost efficiencies and this is something which BIVDA and its member companies have viewed as a real opportunity for our sector. We have long been concerned that the laboratory is usually viewed as an overhead by hospital management and that the tests provided are mere commodities. This is far from the truth and IVD companies in the UK have been very eager to participate in the QIPP initiative by providing examples on tests which can save money and improve patient outcomes. For medical technologies this is largely being achieved through the iTAPP programme. iTAPP is

the Innovative Technology Adoption Procurement Programme and is being run by the Procurement, Investment and Commercial Division of the Department of Health (PICD) and now under QIPP. It is an activity reviewing submissions from industry for technologies with potential for costs, systems and patients benefits, were they to be more widely adopted. iTAPP is working also with NHS Technology Adoption Centre on developing adoption strategies. There are currently 100 different medical device and IVD technologies being examined with a top tier which alone could represent savings in the hundreds of millions of pounds annually.

However adoption of new IVD technology is very complex due to how the money moves around the NHS. For example, Payment by Results incentivises hospitals to perform invasive tests or procedures which could be replaced by a more minimally invasive test using blood or another biological sample. Sometimes these aren't pleasant but, as an example, providing a faecal sample must be less upsetting to individuals than having to go through a colonoscopy unnecessarily. There is also an increase in patient safety by using less invasive technology. So there is an urgent need for hospital finance managers to re-engineer their systems so that testing is provided to allow greater saving in other areas.

Increasingly testing is being done outside of the laboratory using technology developed by IVD manufacturers to be smaller, often portable, straightforward to use but still utilising the science within the equipment that is used in a laboratory setting. It is now relatively common for much testing to be done in wards, operating theatres, critical care units etc within a hospital. The best scenario for this is where the testing and related equipment is centrally managed by the pathology staff so that they can ensure the correct maintenance, staff training and quality assurance is used. It also offers better financial management as the same equipment can then be provided across the hospital site rather than each department making their own procurement decisions in an area where they will have less expertise than their scientific colleagues.

Another area for improvement is in the utilisation of testing in the community setting to prevent referral to hospital in many cases. This is already making significant savings in some areas of England – for example in the East of England where many GPs use a point of care test for D-dimer to rule out a diagnosis of deep vein thrombosis in people presenting with clinical signs of this condition. This saves the cost of an admission when the condition is not present and speeds up treatment for the people who may have DVT when they reach hospital. Another example is in the management of people with chronic obstructive pulmonary disease (COPD) who are often admitted to hospital at night when there is often no real clinical reason to do so. Portable blood gas meters can now allow a fingerprick of blood to be tested in the patient's home by a community nurse or paramedic and if the gas levels are normal then the patient can be reassured and settled without being taken into hospital. As confidence in the use of these technologies grows and with adoption being supported appropriately then patient outcomes and care can be increased while saving money on hospital admission and interventional procedures.

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