MAKING BRITAIN HEALTHY: UTILISING THE INNOVATION *IN VITRO* DIAGNOSTICS CAN PROVIDE TO THE NHS

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The Department of Health has estimated that 70% of clinical decisions are linked to diagnostics. For years, patients have seen the benefits brought by innovative *in vitro* diagnostics, and they will continue to see many more in future.

Every time we see a patient brought into A&E on television, whether in a fictional programme or real-life documentary, one of the first things a doctor will do to treat them is to rattle off an order for tests using incomprehensible acronyms – U&E's, FBC, LFT FBC etc.* These represent a whole battery of very mundane but essential tests which are required to flesh out the clinical picture of what is happening in the patient's body, and are examples of just some of the *in vitro* diagnostics (IVDs) now commonplace in healthcare.

IVDs are tests performed on samples of body fluids or tissue, unlike *in vivo* diagnostics (x-rays, imaging etc) where the patient actually needs to be present for the test to be performed on them. Despite their name, IVDs are not only used for diagnosis but in a wide range of health contexts including: ensuring safety of the blood supply by determining blood type and screening for infectious agents; monitoring therapy; as a tool for managing chronic disease; screening the population (or at-risk sectors of the population) for disease. For doctors, even ruling out a possible cause can be as helpful as an actual diagnosis.

As in all the life science sectors, there have been significant advances made for IVDs over the last forty years. Until 1970 most tests were made and performed in NHS pathology laboratories, using very labour intensive bench-top techniques. During the 70s and 80s it became much more normal for routine tests to be bought in as commercial kits of reagents (chemical solutions used to detect the presence of a biological substance) with a validated protocol to follow – the "convenience ready meals" of day-to-day testing. In this heyday, the UK industry was at the forefront of global R&D with companies like Wellcome Diagnostics and Amersham International.

Just as advances in digital technology revolutionised home computing, the advent of automated testing transformed pathology. Think about how incredible it now seems that in 1981 Bill Gates could say "640k of memory ought to be enough for anyone." There has been a similar leap forward in diagnostics. Today, most of the NHS laboratory workload is fully automated. This means more samples can be tested better and faster, and analysis time has been reduced from around a week to less than a minute.

Alongside the advances in technology we have seen a rapidly increased menu of tests evolve to provide more and more information to support clinical decision-making. There are now tests involved in every

disease process, with new biomarkers being identified constantly.

U&Es and FBC tests aren't especially cutting edge or exciting in and of themselves, but without the information they provide a clinical team would essentially be working in the dark. There are technology changes happening today which are right at the cutting edge of science and will become as routine as the U&Es over the next few years. Most of these advances are happening in two areas: point of care testing and personalised medicine.

Already many of the most essential tests can now be carried out in the hospital, actually at the bedside using point of care testing. While the science behind these is as complex as laboratory-run tests, the IVD industry has developed the technology to allow reliable, simple to perform and accurate tests to provide information with minimal delay in a critical setting such as in an intensive care unit or A&E department.
Increasingly, point of care testing is now being used in communities to diagnose and monitor patients away from hospitals and reduce readmissions. These tests appear more expensive than a laboratory test if examined only on a cost per test basis, but in a whole system context they can be both more cost effective and more beneficial to patients. With advances in fields like telemedicine, we will see this use extended further to allow monitoring of people with long term chronic conditions in their homes without the need for constant outpatient clinic appointments at a hospital.

Personalised medicine describes the process when a diagnostic test is used alongside a drug. These tests can be used to identify which patients will actually benefit from being prescribed a therapy – for example, a HER2 test to see if a breast cancer patient has the gene that allows the drug herceptin to have an effect – or monitor the use of the therapy and adjust dosage. When the knowledge of the human genome is overlaid onto this we begin to see truly amazing possibilities for the future regarding truly personalising medicine and targeting treatment for individuals. This also brings additional safety by minimising adverse reactions to drugs and, of course, saves money by preventing the prescription and use of drugs where they will not work. Already, we are at the point where drug companies are planning how they can provide a diagnostic test alongside a new drug.

IVDs also have the possibility to save money now for healthcare. This can be achieved by using tests to reduce the number of patients having not just unnecessary drugs, but also invasive and more expensive tests. For example, there is a simple test, Calprotectin, which differentiates between organic bowel disease and symptoms of irritable bowel, which is normally identified through a colonoscopy. Correct implementation of this test could stop up to 50% of patients currently being referred for unnecessary procedures and over £100 million to PCTs across England. The knock-on benefit of this would be that appointment slots for colonoscopy would be released. This would in turn release capacity to allow access for patients with bowel cancer symptoms, and perhaps could mean that the screening age for people for bowel cancer could in turn be lowered enabling more cancers to be diagnosed early. However, in order to realise all these benefits from a single, simple and inexpensive test (typically less than £20), the way funds are managed will need to be re-engineered, as will mindsets in the NHS. In this example the saving would be to the PCT by reducing the number of colonoscopies they pay a hospital trust to perform, but the trust would have to increase the laboratory budget in order to provide the test – impacting on the hospital's income and costing it more when it should be costing it less.

IVDs are constantly evolving to provide new tests and new ways of using existing tests to improve health, ensure patient safety and bring cost efficiencies to healthcare in the UK. The availability of diagnostics to identify target populations for drugs will rationalise therapy and enable the best value for money from the drugs budget. And point of care testing will bring real benefits to people by enabling more monitoring and disease management to be carried out in the convenience of their communities with less disruption to their daily lives.

*Urea & Electrolytes, Full Blood Count, Liver Function Tests – detailed explanations of these tests can be obtained at www.LabtestOnline.org.uk