

THE AGE OF DIAGNOSTICS: The increasing role of in vitro diagnostics in modern healthcare



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**“...the upcoming
years may well be
known as the age
of diagnostics”**

Janet Woodcock MD Director of
the Centre for Drug Research &
Evaluation, US FDA

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conditions and treatment is increasingly
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In vitro diagnostics (IVDs) are an integral part of the investigative journey any clinician must embark upon for a patient. Blood, fluids or tissue are examples of the human samples required to perform such tests. They are the clues required to flesh out the clinical picture of what is happening inside a patient's body. Yet, despite their name, IVDs are not just used to diagnose. IVDs are used to test the safety of blood supplies by determining the blood group, they are used to screen for infectious agents and rule out possible causes of disease. The role of IVDs in monitoring conditions and treatment is increasingly important. Tests can be utilised to catch changes in health for patients managing long term conditions – hypoglycaemia in patients with diabetes, for example – and they can also be used to determine whether a treatment is working or failing. Whichever situation warrants their use, IVDs generate the information required to decide on an appropriate course of action.

Previously, diagnostic testing always occurred in the hospital. A GP would refer a patient to a hospital specialist if they required a test. The specialists were effectively the gatekeepers

of hospital resources. We have now seen a shift in how diagnostic tests are administered. By 1990 semi-automated analysers appeared, making tests simpler and faster. Rapid manual tests (the most familiar example of this format being the pregnancy test) or miniaturised instrumentation allow tests to be performed to lab standards at the 'point of care' (POC). This means a GP can rule out Chlamydia or HIV with a swab or drop of saliva, while the presence of drugs can be detected in the emergency room. Appropriate action can be decided upon in minutes.

Across London, a successful 'direct access' diagnostic scheme is in place. Mobile, fixed or community-based facilities enable GPs to make direct referrals for tests without the need to visit a hospital specialist. This reduces the need for hospital outpatient appointments and reduces time between the presentation of symptoms and

diagnosis: saving both money and lives.

POC tests are not the only way in which tests are creeping out of the lab and closer to the patient. While in acute care, there are a number of routine tests which are performed in order to measure the patient's metabolic processes. Blood sodium and gas levels are routine but essential much in the same way as a GP taking your blood pressure or temperature. These can now be performed on the ward or even at the bedside. The value of bringing IVDs closer to the patient is in not having to wait for referrals, then for results to come back from labs. For many patients, the most value can be found in minutes. Also, more intrusive tests can be avoided and money can be saved.

The future, then, sees diagnostics in the homes of patients managing and self monitoring long term conditions from the home – while using



technology to share data with clinicians. Patients with diabetes are already monitoring their blood glucose levels in order to adjust their diet and lifestyle accordingly, keeping them out of hospital. It will soon be a reality for HIV patients to monitor the effectiveness of their antiretroviral drugs from home, making sure that time consuming visits to clinics only occur when they are truly necessary. In a time when efficiency is so important for the NHS, keeping patients out of hospital beds as much as possible is incredibly important. IVDs look set to have a huge role in this essential paradigm shift in modern healthcare.



Diagnostics also look set to predict the likelihood of a patient developing a disease. By identifying the biomarker neutrophil gelatinase-associated lipocalin (NGAL), diagnostic tests can predict the likelihood of the development of kidney disease after cardiac surgery. Cancer has been the main focus of this kind of research for quite some time, with researchers working towards genetic cancer predictions from small tissue samples.

If we look again into the future – perhaps to BIVDA's 40th anniversary – we see diagnostics coupled with drugs. Rather than merely making the initial diagnosis, which leads to the prescription of drugs, the diagnostics will be working out the best kinds of drugs for patient sub-populations. We call these 'companion diagnostics' and they will eventually be used to predict the effectiveness of a specific drug. The Technology Strategy Board (TSB) is currently

researching which groups of patients will benefit from generic drugs such as Metformin. Metformin (for people with diabetes) has a high success rate when prescribed to the correct patient sub-population, but it produces severe side effects for others. The vision for research such as that by TSB is that one day, with a prick of the finger, doctors will know which patients they can prescribe to. The benefit for patients is obvious and the cost savings to the NHS will be significant too.

So in the age of diagnostics, IVDs are no longer behind the scenes. They are the GP's first port of call and part of the day-to-day routine in the home. The white goods next to a hospital patient's bed are not washing

machines but blood gas analysers. They are also at the heart of R&D, making sure that tumours are genetically predictable and pharmaceuticals specifically targeted. Bringing diagnostics further forward in the patient pathway saves precious minutes and money. The sooner a patient is diagnosed, the sooner clinicians can start to think about what will make them better and if they can be kept out of hospital then the resources of our healthcare institutions can breathe a sigh of relief. These are pressing issues in a time when our population is ageing and efficiency savings must be made. In the age of diagnostics it will be diagnostics that help us to decide what will make the difference.

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