

Bond Digital Health - contribution to position paper (BIVDA)

Introduction

Across the world, diagnostics has often played second fiddle to treatment, but then the pandemic came. Diagnostics have taken a centre stage and have been endorsed by the WHO Director General as one of the most effective pandemic control methods at our disposal. This is because isolating positive cases immediately slows the spread of Covid-19, as evidenced by research.

Rapid testing and mass testing have become the norm – and the general population is more informed and accepting of IVD than ever before. And because of the pandemic, the benefits of digitised rapid testing have become abundantly clear to the public too:

- Results in real time
- Aggregation of disease-related data in real time
- Macro and micro-level insights, in real time

Or in other words, because of digitisation, there is a new ability to be able to identify, deal with and stamp out infectious disease rapidly.

But should the benefits of digitised IVD be seen as a pandemic-related phenomenon only? Or is now a great time to think bigger, think ahead – and seize an opportunity that could transform all healthcare?

IVD is, after all, capable of detecting many types of disease and factors relating to health. Cancers, hormone levels, deficiencies – and a lot of other health information – can be detected early and cost-effectively via IVD.

The end of the pandemic won't be the end of this. We face many global health challenges that the wider adoption of digitised IVD tests can have an impact upon, from disease outbreaks (such as ebola and Zika virus) and early detection of cancers to antimicrobial resistance.

Mass testing is likely to be with us for many years to come – and as it becomes the norm for Covid-19 control, it is likely to become the first line of defence in all disease control. We believe digitised IVD has the potential to become the first line of defence in all disease control. And we believe it has the potential to reshape healthcare and social care delivery.

But to realise its full potential, it has to leverage the full capabilities of digitization.

A more resilient health system

Even before the pandemic healthcare systems were stressed. People are living longer – and while the treatments they're able to receive are improving all the time, they can be expensive. Because of this, some systems were under huge pressure with a lot of tension between health and social care.

The IVD industry and the new rapid testing methods have a huge and important role to play in this because of their ability to identify root causes at speed.

Building a system that collects and aggregates diagnostic data in real time is a relatively cost-effective way to have the potential to save millions of lives, and make savings.

The shift in thinking and culture this would necessitate is profound. It represents a fundamental shift to prioritising diagnostics – and prevention – rather than placing all emphasis on treatment.

An early diagnostics culture

Where there is big, robust data, epidemiology can have greater impact – with the potential to reduce incidences of disease by highlighting:

- Disease in earlier stages
- The environmental and underlying health conditions that pre-dispose individuals to disease
- Opportunities to intervene
- Opportunities to develop earlier-stage treatments and interventions (eg: prostate cancer)

Early diagnostics could also become self-reporting. The NHS is already trialling the use of home smear testing. Home colon cancer testing is also approved. Privately, sales of self-testing kits are growing. If all these tests became digitised, diagnosis could be made earlier. But what healthcare providers could also develop is deep, real-time understanding of areas and patients who need additional support – as well as an ability to better plan and target effort.

Regulatory landscape

Even though there isn't a single overarching body for digital health in the UK, more health agencies have started to recognise the importance and value of digital health.

Last month NHSX unveiled a new “simpler and faster” assessment process to help give staff, patients and the public confidence that the digital health tools they use meet NHS standards. The new [Digital Technology Assessment Criteria](#) (DTAC) is described as ‘a rapid process that can be completed in days’.

NICE, the National Institute for Health and Care Excellence, has released an [‘evidence standards framework](#) for digital health technologies, which aims to ensure new technologies are clinically effective and offer economic value.

The MHRA (Medicines and Healthcare products Regulatory Agency) last year updated its [guidance](#) on medical device standalone software including apps. The guidance is likely to force developers to re-assess regulatory status and classification of their products under the medical devices regulations.

How can Government and Industry work together?

In the US, the FDA is already mandating that non-laboratory tests incorporate digital reporting capability. We also believe that regulation has a role to play in the future of IVD.

However, to truly realise the potential of IVD, we need to start thinking of it as a vehicle for – and agent of – improved wellbeing and reduced healthcare costs, particularly at a time when the NHS is under enormous strain and waiting lists are reaching record levels.

We simply cannot sustain a healthcare culture that places so much emphasis on treatment. Currently, many feel disconnected from their own health and the outcomes of their behaviours and habits. When they fall ill, diagnosis can take a long time. Treatment is often an unavoidable next step – and the lines between healthcare and social care are blurred, expensive and fraught. In other words, a treatment-focussed approach inevitably kicks the “care” part of healthcare ever-further down the road. And the further down the road you go, the more expensive and difficult delivery becomes.

If, on the other hand, you flip the thinking and instead prioritise mass testing – which has now become a much more affordable and viable option – you give yourself the ability to:

- Understand the conditions that underpin disease
- Take action earlier
- Improve outcomes across the board

With everything we have learned through the pandemic – along with improvements in connectivity and technology that have happened over the past 12 months – we have an opportunity to shift gears. We can begin to build a healthcare system that prioritises early, real-time diagnosis, rapid intervention – and deep, rapid understanding of the conditions that lead to disease and its spread.

If we start to think about healthcare in terms of prevention, rather than simply as “cure”, then we can begin to realise much-needed:

- Improvements in the nation’s health and wellbeing
- Cost efficiencies – because prevention can be cheaper than cure
- Empowerment of individuals to better understand their own health and to take control of it (for example, with diabetes)
- Better understanding of common health and wellbeing concerns (for example, fertility)
- Empowerment of healthcare providers by providing them with up-to-the-minute insights into the people and environments that are more likely to experience health problems – and the ability to better plan resource allocation

This, of course, represents a potentially radical rethink of the way we plan, deliver, prioritise – and even define – healthcare. We need to see digitisation not simply in terms of a nice-to-have – but a necessary component of all IVD.

Given the impact a shift of this nature could bring about, an industry-wide, government-funded initiative could become an important part of the picture. Just as multiple players in the aircraft industry are taking part in a joint, government initiative to create the zero-emission aircraft of the future, we believe a joint initiative on the future of diagnostics in healthcare would accelerate positive change.

It's clear that we cannot go back to the treatment-first mentality of pre-pandemic days. We must seize the opportunity to embrace digital transformation in IVD and to put it at the heart of the health agenda and our thinking – and we must do it quickly.