BIVDA

IVDs: Transforming Patient Pathways

The Digital Revolution

Industry View

British In Vitro Diagnostics Association (BIVDA)

This paper is provided to policy makers to ensure that the digitisation of In vitro Diagnostics (IVD) and the breakthroughs, experiences and collaboration resultant from the Coronavirus Pandemic are not limited to being a short-term phenomenon. The last year has demonstrated that the IVD industry has the ability and capacity to transform healthcare through an early diagnosis culture which prevents the public from becoming patients.

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Foreword

BIVDA (British In Vitro Diagnostics Association) is the national industry association for the manufacturers and distributors of in vitro (IVD) products in the UK, representing almost 200 organisations including multi-nationals and SME's.

Our members are continuing work to provide quality tests with differing methodologies, such as PCR, Rapid Antigen, Lateral Flow Device, Point of Care and Serology. Companies are also developing non-invasive tests and molecular multiplexing for identification of Covid-19 alongside the seasonal respiratory infections.

Rapid, mass testing has become part of life and the general population is more informed and familiar with IVD than ever before. The benefits of digitised testing have become clear to the public with results in real time and to public health professionals with the aggregation and insights of disease related data. There is now an embedded ability in the UK to identify, address and control disease which did not exist before.

Background

The focus on Diagnostics has increased significantly due to the outbreak of SARS-CoV-2 first detected in China in December 2019 and the recognition that testing is at the forefront of control measures in public health. The challenges across the world forced the development of digital technology and concepts of self-testing and remote use of diagnostics directly to the public. The change in the way testing and data is managed through "democratised" diagnostics has changed how personal health can be tracked and improved for the future.

The benefits of digitised IVDs should not be seen as a pandemic-related phenomenon only, this is an opportunity that could transform all healthcare for the population.

The science and technology available within the IVD industry and pathology networks in the NHS is capable of detecting many types of disease and factors relating to public health. Cancers, rare diseases, chronic diseases, as well as infectious diseases can be detected early and cost-effectively via IVD.

Addressing National Need

• The UK needs to balance health and social care.
• The UK needs to ensure future pandemic preparedness and control measures.
• The UK needs to address anti-microbial resistance.
• Commerce and society need a rapid means of effective testing to provide passporting for entry to facilities, airports, stadia, offices, schools, universities and the like to be able to confirm that entrants are virus free, paramount to an efficient economic recovery.
• Individual members of the public need to have the capability to test themselves cheaply and regularly to ensure that they can use passporting, facilitate foreign travel, and can take appropriate measures such as self-isolation.

Lateral Flow Tests (LFDs) are being used in the latter two categories but are not the complete solution.

The end of the pandemic won't be the end of this transformation. There are many global health challenges that the wider adoption of digitised IVD tests have the potential to have an impact upon, from disease outbreaks (such as Ebola and Zika virus), early detection of cancers and surveillance of antimicrobial resistance. The issue of antimicrobial resistance is a serious threat to public health and treatment and digital community surveillance coupled with advances in genomics and advanced medicines is a major part of the future of healthcare.

Mass testing in the community is likely to be with us for many years to come for not only Covid-19 when it is endemic but current risks for example, influenza and other respiratory diseases as well as future pandemic preparedness. As it becomes the norm for Covid-19 control, it is likely to become the first line of defence in all disease control and has the potential to reshape healthcare and social care delivery.

But to realise the full potential of community, mass testing it has to leverage the full capabilities of digitisation.

The solution is to realise that a healthcare culture which places such emphasis on treatment rather than prevention and intervention is not sustainable and that IVD testing is the mechanism to achieve improved well-being and reduced healthcare costs.

Health System Resilience

Even before the emergence of the SARS-CoV-2 pandemic, healthcare systems were stressed. The global population is living longer and while the treatments available for a wide range of diseases, both critical and chronic such as Cancer, HIV, Diabetes and Auto-immune diseases are improving all the time they can be expensive. Because of this, some systems, including the UK, are under huge pressure with pressures on finance and resources between health and social care and the provision of care for hospital patients and the community

When individuals fall ill, diagnosis can take a long time, and the treatment options which are the unavoidable next step are more expensive and difficult as disease progresses. The impact of this is often a disconnection between health, outcomes and behaviours and habits.
Testing has now become a much more affordable and viable option due to the advancement of technology and scientific breakthroughs between academics, universities and industry. Advanced testing will make it much easier to understand the conditions that underpin disease, to take action earlier and improve outcomes for patients.

The UK can build on its world class healthcare system to prioritise early, real-time diagnosis and rapid intervention. It can also use its data to develop a deep, rapid understanding of the conditions that lead to chronic long term health issues to improve overall public health, but also to be an enabler and tool for future pandemic preparedness and the spread of acute infectious disease. It will be paramount to ensure that the world class digital capability and data of the UK is protected through policy to ensure competitiveness and leadership globally. Being able to contextualise diagnostic tests and being able to contextualise the data collected from medical devices & IVD with other sources and sensors is a potential area of consideration for the industry. The data is not only critical to clinical outcomes in the UK but is commercially valuable to both government and companies internationally.

How we can capture the single dimension provided from a connected IVD test and bring other factors in through passive data collection that maybe give added dimensionality and deeper insights is an important area, for example vital signs data merged with continuous monitoring capability.
Healthcare should be thought about in terms of prevention rather than cure and this will then drive, improvements in the nation's health and wellbeing, deliver cost efficiencies, empower individuals to better understand their own health and to take control of it (for example, Diabetes) and provide a better understanding of common health and wellbeing concerns (for example, Fertility).
Healthcare providers will be empowered by access to and have the ability to better plan resource allocation.

Digitisation needs to be considered as an essential component of this preventable approach and of IVD product development. The development of digitally enabled diagnostics is a huge cost to the industry and reimbursement for digital products is critical for the industry.

Recommendations

• Government allocate public resources – funding and consented data access - to digital technologies.
• MHRA to provide a smoother regulatory landscape for digitally enabled diagnostics through UK regulation and greater cooperation between Industry, Academia and the NHS for data and data management.
• An ethical framework for individual consented patient data use by industry, the NHS and for public health.

A Culture of Early Diagnosis

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.

While the NHS is making progress on the digitisation of care, with the NHS App and online records, this is by no means universal; to realise the integrated care system, patients and clinicians need to have instant access to comprehensive medical histories and testing results across the full range of healthcare settings. Easy access to this data has proven to be vital in organising the Covid-19 vaccination programme based on priority and medical need – and with patient consent could be a valuable tool in medical research, keeping people out of hospital and managing people at home (self-management).

By democratising diagnostics through digital technology, in order to ensure the quality and be in a position to use the data generated by the public, a new set of enablers will be required to ensure that the public can provide the data easily and an affordable or no cost. A major effort is also required to ensure that hardware is compatible across care settings, which has not been the case to date, with a myriad of different operating systems and system models being used across the NHS. 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 across the healthcare system.

Recommendations

• A major funded effort to ensure IT systems across the NHS can ‘talk to each other’ and share diagnostic data quickly and simply.
• A new strategy for trialing greater digital home testing by the public.
• Ensuring patients have easy access to their full medical records via the NHS app.

Lateral Flow Testing, Certification and Personal Health

Lateral Flow Testing

Lateral flow devices (LFDs) have served a valuable purpose during the pandemic by identifying infections and acting as a screening device. The use of LFD's in several settings, professional and now more so, from a home use perspective are becoming readily available to the lay user. Additional Lab based testing exists for mass testing use cases where turnaround times of >6 hours can be accommodated.

More accurate LFD tests are needed longer term to screen people are required that will allow all parts of society to return to work, events, mass gatherings and travel in a safe and controlled manner. LFD's should be used a tool to ensure that individuals can swab, test, report and certify themselves where the declaration and images are analysed through digital innovation which can be deployed at scale and accessible to all.

Better, quicker LFD self-tests, specifically self-tests by design rather than adapted tests intended for assisted testing by professionals have been developed by BIVDA members and other UK manufactures under the Rapid Antigen Testing Consortium with robust data and evidence for regulatory approval. Test and manufacturing capacity is being scaled up so that the UK becomes self-sufficient in managing the current pandemic and any future ones that may materialise. These products should be used by the UK as the development of such LFD tests have been within strict existing regulatory frameworks which provides confidence in the performance and integrity of the data to gain the approval for providing personal diagnosis for health monitoring data that is captured, analysed using, electronic devices, such as smart phones, tablets and computers.

Beneficial features of these LFD tests include:

- Immediate results
- Higher specificity.
- Affordable for regular testing.
- Digitally compatible.
- No training required and focus on the lay (self) user
- capable of testing more than one epitope at a time e.g. multiple variants of one virus or two or more respiratory viruses, and:
- Easy to store, stock, track and trace.

Certification

Industry partners have been working at pace to demonstrate how digital innovation can support LFD devices with the Lay user in mind.

Ultimately, each part of the overall solution needs to work seamlessly with the other parts, the LFD needs to be recognised and compatible with the specific Health Certificate Solution and then the results must be recognized and validated by Gatekeeping Solution, where the developers of these products have no other connection than being part of Network of Trust, Safety and Security.

There are 3 initial pillars for digital innovation

QR Codes: An agreed data structure for QR codes for LFDs to be issued, tracked and maintained by an active repository

ID: An agreed method of ID registration, verification and authentication to be accessible and shared across partner members

Status Tracking: An agreed method of recording and storing LFD test status to be accessible and shared across partner members

There are many organisations developing health pass or Covid-status certificate systems that aim to cover a wide range of use-cases, some are UK focused and others are operating across international borders. The government needs to set regulations that make sure minimum data standards and interoperability standards are in place to enable a diverse, functional, secure and inclusive ecosystem. Not every potential use case is equally critical (entering a café versus international travel, for example), and the stringency of measures is likely to change over time as local prevalence and risk change. Regulations need to reflect this while reducing risks including identity abuse, inappropriate public health practices and unfair access.

Government needs to facilitate the safe and inclusive use of these systems by setting broad, minimum standards which participants must meet to be able to issue an accredited Covid-19 status certificate; ensuring international interoperability; and, if necessary, use legislation to stop illegitimate discrimination.

Covid-19 Status Certificate (CSC) platforms must be able to verify identity and create data or ‘evidence’, while maintaining privacy and security and they need to operate in a range of use-cases. In each, there are inputs such as what Covid protocols are in place, what evidence is required to meet them and how to generate evidence; and there are outputs such as verified evidence and Covid status.

The Rapid Antigen Testing Coalition has mapped the operational processes that need to be in place for CSC providers to create valid inputs and verified, interoperable outputs which should be adopted

The key considerations are laid out below, following the specific areas the Cabinet Office Call for Evidence requests undertaken during this period of the pandemic.

Clinical / medical considerations

- Given inevitable uncertainty around appropriate medical guidelines for safe access to shared spaces, Industry supports the World Health Organisation view that a risk-based approach needs to be taken.
- The Rapid Antigen Test Consortium's core expertise lies within the Rapid Lateral Flow Device (LFD) Testing arena, however, "Data In" ('evidence') can also be acquired more widely from PCR Test Results and Vaccine Status etc.
- CSC systems need to encompass multiple evidence types to cope with clinical uncertainty and ensure maximum access across the population.
- Rapid Antigen Test Consortium has a detailed view on ensuring the integrity of LFD use.

Legal considerations

- To build trust in the standards there needs to be acceptable level of minimum standards of data protection. Clearly GDPR, COPPA, CCPA, ID 2020 compliance will be essential. May well need to mandate specifics around what compliance looks like. If we are trusting each member of the consortium to follow a 'code of conduct' how do we protect against a rogue company or validate data security of our members.
- Self-test declarations and Opt in/Opt Out Terms need to be defined allowing choice.

Operational / delivery considerations

- A broad direction of travel for government policy needs to be clearly communicated so that providers can invest and develop solutions with some level of confidence, and start building a functioning, interoperable network. Only providing this at the last minute will lead to delays and suboptimal systems.

Considerations relating to the operation of venues that could use a potential COVID-status certification scheme

- With minimum standards in place (with a high bar) for identity, privacy and security, and with safeguards in place for non-discriminatory access, we believe that a multiplicity of providers will cater for appropriate use cases. If, for example, a pub wants to introduce an access system, then it should be allowed to do so, so long as it is not discriminatory.
- As with any public event, the government has a say in what protocols need to be in place for safe operation. A CSC standard will allow events and other uses a system that can implement whatever standards are required for low-risk operation.

Considerations relating to the responsibilities or actions of employers under a potential COVID-status certification scheme

- Employers have a duty of care to provide a safe work environment. A CSC ecosystem provides the tools for employers to provide and monitor this. Current top-down, one-size-fits-all policy cannot adapt to the changing needs of employers as the pandemic evolves
- Providing regular testing via LFD's creates a safe and trusted environment where public can feel secure on any individuals Covid Health Status.

Ethical considerations

- Time limitation requires that all measures should be temporary and limited in scope as systems are deployed, decommissioning also needs to be in place to understand how to exit these measures.
- The use of data should be proportional to the need. This includes surveillance.
- Data collection and retention should be fully compliant with GDPR protections.
- Data is for the purposes of this support and should not be commercialised or otherwise passed on without consent.
- Data and processes should be transparent and easy to understand for the lay person.
- Independent oversight should be considered to ensure that the system is trusted by the public.
- Minimum retention of data for the purposes of pandemic response, unless required for future epidemic planning and research.

Equalities considerations

- Any verification service must be frictionless in that all equality settings must be accommodated removing any barriers to entry and use. The Consortium are currently defining several personas that need to be developed and verified
- Testing and validation should be robust, secure and easy to navigate, including for those without access to smart phones or other technology.

Privacy considerations

- There are many legal considerations when dealing with personal identity systems and the gathering of personal identifying information (PII). Any regulatory framework the government introduces needs to set minimum identity standards, with frameworks from GDPR, COPPA, CCPA, ID 2020 a useful starting point.
- It may well be that different types of app will need to adhere to differing levels of Data Security compliance – for example a pass for international travel will require a higher level of ID security than, for example, a cinema pass. However, there are significant risks introducing a market for identity solutions and full consideration needs to be given to the minimum standard.
- The Good Health Pass collaboration has set out an initial framework for health passes around the world to ensure privacy (and ethical) considerations are embedded in a pass system. It has done this with the crucial outcome of interoperability at the core. RATS has mapped its suggested framework to the Good Health Pass and has widespread agreement with its approach. See Appendix A.

Personal Health

Over the last year, people have become adept at using their mobile phones and computers for GP appointments, sending testing data for Covid-19 for surveillance and conditions such as diabetes through to their clinicians. To bring care closer to the patient and make primary care services functional and sustainable during any future pandemic, this emerging trend should be encouraged.

A 70% drop in demand for some tests in 2020 correlates with undiagnosed or un-managed conditions. The advances in testing achieved this year means patients no longer need to visit a hospital for simple diagnostic tests which can be done at home or in a community setting.

Making collection of data passive where the patient, end user has minimal involvement in the data pathway is important. This could potentially be one of the benefits of 5G technologies. Not because of the higher data rate but also because they simplify setup and connectivity which is a major barrier to adoption.

Another element worth considering is how to overcome Digital App fatigue as, the number of Apps is growing and planning how to better manage barriers like is required to and working with developers to ensure the data is obtainable across different platforms. Encouraging public integrity for results needs to be considered, an example of which is the incentive for self-isolation on symptoms and a positive test. Financial reparations are of course unsustainable, but how can the public be incentivised to report accurately?

To truly benefit from a digital transformation, Data must be taken from a broad perspective, and not limited to LFD's or digital apps. The Laboratory Information Systems contain data from hospital and private laboratory testing, yet the question of consent and the use of this data is a fundamental lynchpin of making the data work.

Whilst a lesser impact in the UK than the US, data given freely by patients for improved healthcare, and prevention of pandemic or endemic disease preparedness cannot be used for commercial purposes, or to disadvantage people in terms of health insurance, treatment or societal restrictions. The balance must be reached, and this should be through aligned regulation. The debate in the UK is on-going and the deadline for opting out is approaching, this is also a significant area of consideration in the Life Sciences vision, but the MHRA must be at the forefront of global strategy.

Cost to healthcare of infrastructure to align acute and community data as well as upgrades associated with digital technological advancements could become a barrier unless a clear funding stream is adopted across the healthcare setting, industry and the public. Companies that produce data should be provided support to enable data to be captured due to cost limitations. Anonymised Data could be used for R&D for machine learning trials and precision medicine.

Consideration should also be given to consent as neither UK companies nor global organisations have been able to easily access Covid-19 samples from UK samples for commercialisation of research and development. This is largely due to excessive process and paperwork, unclear ethical guidance and a restrictive regulatory landscape.

It is already the case that hardware is obsolete and that the NHS Covid App is not compatible with some older models of smart phones and tablets – and it is currently separate from the NHS App used to book appointments, order prescriptions and access medical histories. Building a network that collects and aggregates diagnostic data in real time is a relatively cost-effective way to have the potential to manage

public health and make savings, these savings can be re-invested in the infrastructure required to maintain a steady flow of easy to submit data, and easy remote access to extract the data.

The plans and mechanisms that are assisting in the management and surveillance of the pandemic response through democratised diagnostics could be expanded to manage other health data and any potential limitations or legislative issues addressed to ensure consent and privacy is paramount.

There is no complete body responsible for health data, with responsibility falling across the Department of Health, Hospitals, academia, NHSX and NHSE/I, National institute for Health Protection and MHRA. This requires engagement and data sharing on secure platforms and learning to join up the "Big Data" to maximise the impact on public health. Data needs to be standardised and coded to analyse the differences between self-tests, laboratory tests, analysers and community input. There is some work underway in universities, but this needs to be universal across the UK.

Digitisation is a radical overhaul of processes and systems in the NHS and would bring the NHS and the public together to modernisation. This is an ambitious and holistic task and the UK diagnostics industry is asking for a set of enablers to deliver a world class digitization of health services to prevent the public becoming patients over the long term by data driven health decisions.

Recommendations

- Greater compatibility between NHS and third-party Apps to ensure easy information flows and data capture.
- Reform of consent regulations to allow for greater availability of patient samples and data for research purposes.
- A single body responsible for coordinating health data, in-patient and community with a standardised data type and code.
- Keeping potential healthcare use in mind when rolling out the 5g network, ensuring that all healthcare settings including social care settings benefit from implementation.
- Strong collaboration between Government and IVD industry players to develop and promote 2 sets of standards:
    - Minimum data standards to be shared between industry and NHS digital applications
    - Interoperability standards to enable useful interaction across industry and NHS digital applications.
- Ensure that all UK solutions work seamlessly at scale with European and Worldwide organisations allowing all aspects of Testing, Result reporting to be openly shared in a secure and safe manner through opt in controls.

Appendix A – Covid Certification

The Seven Key Challenges to Interoperability

1	**Consistent User Experience**
	Good Health Pass implementations must use the same conceptual models, core terminology, interaction triggers (e.g., QR codes, deep links), consent models, and certification marks
2	**Standard Data Models and Elements**
	Good Health Pass implementations must collect, process, and transmit a standard set of data elements
3	**Credential Formats, Signatures, and Exchange Protocols**
	Good Health Pass implementations must use a standard set of credential formats, digital signature algorithms, and exchange protocols
4	**Security, Privacy, and Data Protection**
	Good Health Pass implementations must meet baseline security and privacy requirements that enable holders to maintain full control of their personal data
5	**Trust Registries**
	Good Health Pass implementations must be able to quickly and safely verify authorized issuers and verifiers
6	**Rules Engines**
	Good Health Pass implementations must have the option to securely and privately interact with authorized rules engines to accommodate variations in policy and regulations
7	**Identity Proofing and Binding (Authenticity of the Holder)**
	Good Health Pass implementations must implement standard methods for verifying the authenticity of the holder at specified levels of assurance

- **(A)** = Manufacturing, QR Coding, GS1 coding
- **(B)** = Verification / Identification / authentication / privacy
- **(C)** = Test execution, output and reporting
- **(D)** = Interoperability

	A	B	C	D
1	x		x	
2		x	x	
3			x	x
4	x	x	x	
5	x	x	x	x
6			x	x
7		x	x	