Diagnostics: Building capacity and capability in the UK

On 12 October 2021, the Academy of Medical Sciences and the Royal Society held a symposium on *Diagnostics: Building capacity and capability in the UK*. It brought together scientists from industry and academia, experts from the wider scientific community and patients with lived experience to explore advances in the diagnostics sector and the opportunities and challenges of building capacity and capability within the UK. Key implications from the event discussion are summarised below.[1]

Seizing new opportunities for diagnostics

The diagnostics sector

- **The COVID-19 pandemic has led to significant investment** in diagnostics laboratories, staff, manufacturing and logistics. Huge data sets have been collected, combined and opened up to research, and collaborations have flourished between the NHS, academia and industry. **Building on these investments and seizing momentum could invigorate the wider diagnostics sector.** Success will depend on the development of new diagnostics, the rapid adoption of innovation, new NHS diagnostics capacity, an expanded workforce, and improved manufacturing and supply chains in the UK.

Users

- Combining decentralised testing and digital health presents an opportunity to reduce healthcare costs, improve healthcare, and streamline its delivery. To be acceptable to consumers, such tests must be simple and intuitive to use, while for professionals the tests must perform to the same high standards as laboratory-based tests, with results that can be uploaded into electronic health records.

Patients

- **It is essential that diagnostic approaches respect the needs, values, preferences, and circumstances of patients.** Without this, novel approaches such as home-based testing may fail. Novel diagnostics should be patient-centric at all stages of development and adoption.
- **Diagnostic approaches must be inclusive**, lower or remove barriers for use and acceptance of tests, and be flexible in how results are disclosed to accommodate patient preferences.
- **Some tests – such as those for infections like COVID-19 – are suitable for point-of-care or home testing,** while others need a healthcare professional to engage with the patient so that crucial life-affecting decisions are made in consultation. It is vital that diagnostics are used appropriately to ensure they are trusted by patients and the public.

[1] These do not necessarily represent the views of all participants at the event, the Academy of Medical Sciences, or its Fellows.

Innovation in diagnostics

Rapid diagnosis

- **Point-of-care COVID-19 testing has enabled rapid therapeutic intervention** and protected the health of the public and patients as they move throughout the NHS, social care and wider society. These simple, **easy-to-use tests do not require specialised staff** and similar technology can be used to identify acute respiratory infections, acute diarrhoea and genital infections. They may therefore offer a cost-effective way to triage patients or manage infections in public health settings.
- **Existing technologies, used in other fields, can also be applied to rapid diagnostics**. For example, the analysis of volatile organic compounds (VOCs) is now being developed as a triage test for oesophageal, gastric pancreatic and colorectal cancers – diseases where early diagnosis is particularly important – with promising early results. These could open up a new era for early detection and diagnosis with significant implications for reducing deaths from certain cancers.

Imaging, AI and digitisation

- Unlike molecular tests for infections that give a clear positive/negative result, image-based diagnostics – for example the radiological images of cancers – require clinical interpretation. **New computational methods and artificial intelligence (AI) can be used to analyse such images,** supporting triaging of patients based on their risk. This could free up clinician time to spend more time directly with patients.
- **Image digitisation and AI algorithms are also being applied to the analysis of solid specimens, such as from cancer biopsies.** The algorithms assist clinical interpretation and guide therapies, help get results back to patients more rapidly, and can provide novel insights into the biology of disease. Challenges to the rollout of this technology include the volume of data generated, and issues with the interoperability of systems.

Advancing innovative diagnostics into clinical practice

Funding

- The early stages of diagnostics development are often funded through Government and charitable research funders, with academic research feeding a pipeline of products and companies. This pipeline is supported by university translation offices, by Government support such as through Innovate UK, and by venture capital investment. Public and charitable funding is therefore vital to the sustainability of the diagnostics sector.
- For investors, diagnostics are often seen as carrying just as much investment risks and clinical trial regulations as medicines, but also sometimes lacking a clear path to commercialisation and adoption. **Bringing stakeholders together can help to define this path, with academics articulating the function and impact of the diagnostic, and these being validated with patients and clinicians.**
- The teams involved are also crucial to success – **an essential part of venture capital decision-making is whether the right team is in place to drive a technology forwards.** Team science and collaboration across industry, academia and the NHS is essential to a healthy and innovative diagnostics sector.

Approval and adoption

- Diagnostics cover a range of different areas and technologies – including genomic tests, tests for blood-borne infections or proteins, and imaging. A 'one-size fits all' approach can be difficult, especially considering the types of clinical data that need to be collected and validated. **Clear evidence requirements and well-established clinical trial methodologies can support confidence to pursue novel approaches, especially in**

areas considered 'high-risk', such as rare diseases where the potential market is smaller.

- Keys to successful adoption include early engagement with end users – patients, the public and clinicians – and having a well-defined, realistic market. While the NHS is the end point for many new diagnostics, the UK is only 3% of the global healthcare market and there is the potential to sell into other markets. As such, **a clear route to adoption is essential to ensure the UK does not miss out on innovative diagnostics.**

Find out more

The Royal Society: Symposium webpage
https://royalsociety.org/science-events-and-lectures/2021/10/tof-diagnostics

The Academy of Medical Sciences: Diagnostics-related FORUM events

- February 2018: Early detection and diagnosis of cancer (workshop)
- October 2020: The COVID-19 testing response (roundtable)
- December 2020: Precision prevention for modifiable health risks (workshop)
- March 2021: Building a sustainable UK diagnostics sector (workshop)
- October 2021: Building capacity and capability in the UK (this symposium)
- December 2021: Lessons from COVID-19 applied to antimicrobial resistance (workshop)

Reports can be found at: https://acmedsci.ac.uk/policy/forum/forum-reports