Lead Biomedical Scientist Tony Cambridge states that decentralised testing and diagnostics are vital for the future of the health service.

he delivery of healthcare across multiple territories has never been under more scrutiny than it is in the COVID-19 era. Due to the challenges posed throughout the pandemic, it has become apparent that patientcare models need to be transformed in order to successfully manage common conditions outside of the hospital setting.

COVID-19 may, in the future, be seen as the catalyst for significant change, delivering new models of care in decentralised settings. It may also highlight

where opportunities have previously been missed to introduce technologies and pathways that disrupt traditional care delivery. A renewed focus on delivering healthcare where and when it is required, should now be high on the list of priorities for executives and managers within health organisations.

Increasing hospital resource may not be the answer

The redesign of the healthcare landscape has seen integrated care systems emerge, defining the responsibilities of general practices, community services and social care. A realisation that increasing hospital-based diagnostic resources is not the answer is now firmly settling in. This leaves community-based diagnostics in a strong position to address the problems that health services face in terms of growing waiting lists, delays to care, escalating costs, and poor outcomes.

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A model that is gaining increasing attention is community diagnostics, whereby testing is provided closer to the patient, creating an improved experience for the clinician and individual. Community diagnostic hubs will need to be introduced in order to create a network of decentralised care that acts in partnership with secondary care





15

organisations. Primary care networks should be engaging with local pathology networks in order to develop the governance and resource required to deliver transformation on this scale. Diagnostics offered closer to the patient are in no way designed to undermine the service provided by pathology laboratories, but to enhance it, and safeguard optimal care for the patient.

Used in an appropriate way, decentralised testing can reduce pressure on support services, such as pathology and phlebotomy, by redirecting workload to other workstreams, preserving the laboratory testing for specialist and urgent hospital cases.

The commercial health sector

Clobal diagnostics companies are in a strong position to support this transition, with many technological solutions already in existence that may provide the answers. These organisations are also in a position to listen to the demands of service providers, who are calling out for simple, accurate tests that require little specialist training to use, but can provide the clinical information rapidly and in environments that suit the patient and clinician needs more readily.

Medical devices that can easily integrate into a rapid diagnostics healthcare system will be favoured over those requiring more user interaction or software development to ensure they communicate with existing IT systems. The future must see patient results captured in a complete electronic patient record accessible to clinicians caring for the individual regardless of the setting.

There are many solutions on the market, from established global diagnostics companies through to relatively new start-ups. One thing is for sure – performance data must be compelling and robust in order for adoption to be fully considered. Setting up a network of testing hubs is a challenge few have been willing to accept. The success of this model is dependent on a multiorganisation approach to delivery of care using the best model for patients and clinicians. Executives and healthcare leaders across the care landscape need to engage in the process, drive change, and promote improvements through openness and co-operation across clinical services.

The time feels right to deliver

We have been here before, but advances in technology and easy adoption of medical devices make the model all the more attainable than in previous times.

Media attention, political pressure and the outcry for change make this an extremely exciting time as to what healthcare might look like in the next few years. One important consideration is that we must all benefit from transformation, from patients to providers.

Before COVID-19 there were active discussions exploring ways to alleviate the pressure on overcrowded emergency departments, hospital congestion and patient flow. The postponement and cancellation of elective procedures must end, with growing waiting lists a concern for those managing capacity in secondary care. The impact of cancelled procedures is wide-reaching, affecting the patient's wellbeing as well as the



financial element for cashstrapped organisations. The management of patients presenting at entry points to hospital care could conceivably be provided in the community,

if access to the right tests of sufficient quality at the right time, could be assured.

Many initiatives to improve the health of the population have failed and we now need a new approach to detecting abnormalities early. We now need a healthcare system that is responsive to the needs of the clinician, the expectation of the patient in the 21st century and robust and accurate enough to support diagnosis and instigate treatment plans without hospital involvement. What is required is patient-centred quality improvements.

The power to disrupt

Point-of-care (POC) diagnostics can be part of the solution. Where previously there have been obstacles to POC testing adoption, its utility during the pandemic has shown the true power of the technology to disrupt traditional pathways of care, improve diagnostic accessibility and enhance patient and clinician experience.

The impact on the healthcare economy must be assessed, as there are financial savings and cost avoidance related to provision of testing that avoids secondary care attendance, reducing admissions and reducing length of stay.

Common illnesses must be detected at the earliest opportunity. Patient awareness of the availability of diagnostics is central to them seeking medical advice at the first presentation of symptoms. Education of the population as to what to look out for, and seek guidance for, must be improved. The information gathered at this point can identify pathological conditions before they advance to a stage where hospital care is required. Patients with advanced symptoms invariably



POTENTIAL BENEFITS OF DECENTRALISED TESTING

- Where normal results are obtained, significant delays are removed, patient stress is reduced and unnecessary prescriptions avoided
- Further follow-up appointments could be reduced, or prioritised if indicated
- Only indicated pathology tests will be requested, reducing unnecessary testing
- Treatment plans introduced earlier, based on identifying conditions at earliest opportunity. This will influence the progression of medical conditions
- Hospital referrals avoided
- Emergency department attendances reduced
- MIU and local care centre attendance
- increased appropriately and proportionately Hospital admissions and bed days reduced.

assured that when they are hospitalised they will not have their health compromised or complicated further.

Technology now allows for multiple tests on the same platform (multiplexing) at the same time, offering flexibility where some systems were previously inflexible. Analysers are now suitable for use with a number of different sample types, taken from paediatric to adult patients with no clinical effect on the accuracy of results. Those healthcare professionals working in the POC specialty will be well aware of the need to have simple, user-friendly devices available. Devices and tests that require calibration, pre-analytical sample steps, complicated maintenance or confusing interpretation of results, are not popular and risk causing bottlenecks for patient flow when slick processes are required to

"We need a system that is responsive to the needs of the clinician and patient expectations"

ensure efficiency. This is where the involvement of an experienced team of POC professionals is essential in the selection and implementation of these diagnostic solutions. Pathology networks must develop the governance required in order to ensure safe delivery of the service. Quality and proficiency standards must be adopted and integrated into the day-to-day management of the service, with all personnel involved in

providing diagnostic results aware of the requirement for continuous excellence, safety always being paramount.

Clinician-patient experience

Patient choice is central to the success of redesigned healthcare pathways, but, importantly, the clinician choice and experience is equally essential. During the COVID-19 pandemic the use of virtual consultations was a necessity in response to the control of infection, with exposure to potentially contagious patients minimised. With clinicians now reverting back to face-to-face interaction with patients there is an opportunity to develop the interface they have with those individuals in their care. This extends to improved choices around diagnostics where decentralised solutions can now

require more intense treatment, sometimes across multiple specialties, which can drive up the cost of care significantly. A swifter resolution through early intervention will lead to improved outcomes and improve the healthcare economy.

Conditions considered to be prime candidates for early identification and prevention of referrals include: pulmonary embolism/deep vein thrombosis, acute cardiac disease, diabetes, chronic obstructive pulmonary disease/asthma, heart failure, international normalised ratio/ anticoagulation, cancer, urinary tract infection, acute and chronic renal failure, chest infection/cough/lower respiratory tract infection, cardiovascular disease and sepsis.

Imagine improving early detection of diabetes or cardiovascular disease before they become debilitating. Think of the impact that early detection of cancers might have on those individuals and their families. Consider detection of sepsis or accurate diagnosis of bacterial/viral infections using rapid tests in the same visit and what that means to halting the progression. Starting patients on the correct medication and care plan as directed by diagnostic results will reduce ineffective prescribing and assist practitioners in making crucial care decisions.

One of the most significant challenges we are faced with is quickly identifying the organism with which a patient is infected, with the degree of accuracy to ensure other individuals are not put at risk by false negative results. The winter is now upon us, which will see common symptoms of suspected infection present at every emergency department and GP surgery across the country. Using rapid diagnostics within specially designed environments that isolate the individual until the result is available would help combat the cross-infection that has been all too common in hospitals over recent years. Hospital-acquired infections must be eliminated and patients should be

provide laboratory-quality results.

- Patients have more awareness and knowledge of available technology and treatments
- Promoting personalised care for patients
- Increased patient choice
- Shared decision making (clinician and patient)
- A sense of control for patients over their treatment programme.

The healthcare economy would benefit from patients receiving their results and care plans in one visit, with follow-up appointments and phlebotomy sessions avoided when a POC solution is in use. The impact on the patient's mental health and wellbeing cannot be underestimated here, and the worry avoided through not having to wait for results is a key improvement that rapid diagnostics can offer.

Depending on the results obtained for patients, clinicians can make decisions much earlier, commence treatment plans, change medications, or rapidly refer a patient to specialist care, if necessary. The impact on prescribing patterns also needs to be estimated as a move towards personalised care will undoubtedly change the way in which medications are used.

The improvements could be inestimable, providing care where the patient needs and expects it, identifying the tell-tale signs of ill health at the earliest opportunity. Obtaining this health picture is the gateway to arrest the progression of some of the most common health conditions experienced by a large cross-section of society. The use of many common medications may be avoided entirely.

Delivering the model

It is these financial improvements that will offset the considerable investment in resources needed to expand diagnostic testing in the community. Locations need to be identified and designed to be able to operate as a standalone unit, with everything needed to support the patient, accommodate the clinical staff and healthcare professionals, as well as support the technological requirements of the service.

The governance of these services must be assured by local and national pathology experts operating in networks to deliver the intended outcomes. It is essential that these services are safe and are delivered within a quality framework that follows national guidance on the safe use of medical devices, and meets international standards for quality and competence, such as applicable ISO standards.

Organisations who buy into this approach to care may wish to start small, conducting pilots in the community aimed at testing the appetite to adopt the model across carefully selected areas. It is clear that the success of any pilot will be dependent on the initial design, the commitment from clinicians and managers to utilise the test results, record the decisions made, and assess the impact through monitoring patient outcomes. Capturing this information in a single IT system that has the capacity to readily transform the information into meaningful data will help conclusions to be drawn, and benefits to be demonstrated in a way that promotes wider adoption.

"The future is not set. The challenge is being accepted by progressive organisations." Pilot studies need adequate resourcing. Planning and providing the following elements are key to the successful delivery of the study.

- Support from the pathology POC teams to conduct device validation work, monitor performance and establish governance processes
- Release and backfill for POC/pathology clinical and managerial leads assisting the trial
- Identify influential supporters within the community clinical teams
- Additional support staff for the duration of the pilot
- Training and equipment support from the manufacturers/distributors
- Connectivity of community-based devices to secondary care middleware, or a community data manager
- Adequate healthcare professional staff at each pilot site to conduct testing and ensure upkeep of equipment.

These services have already been adopted in isolated areas of healthcare in the UK and globally. Now is the time to standardise the model, share successes, and challenge health leaders to evolve alongside the diagnostics solutions now available and in rapid development. Invest now, invest wisely.

The future is not set. The challenge is being accepted by progressive organisations. The focus now needs to be fixed on establishing the model, gaining and sustaining momentum, and proving the concept through health monitoring of the general population by way of big data.

Tony Cambridge is Lead Biomedical Scientist in the Pathology Management team, Blood Sciences and Point of Care Testing, at University Hospital Plymouth NHS Foundations Trust. He is also Managing Director of Thornhill Healthcare Events and Consultancy. For more opinions on decentralised testing and diagnostics, turn to the Big Question on p.20.