Rapid detection of infection

Point-of-care testing, in the form of lateral flow testing for SARS-CoV-2 antigen, has become familiar to many during the ongoing COVID-19 pandemic. Here, **Carolyne Horner** discusses the diversity of point-of-care tests (POCTs) available for the rapid detection of infection and the key issues relevant to their uptake by UK healthcare.

Since the emergence of the SARS-CoV-2 virus and ongoing COVID-19 pandemic, awareness of infectious diseases and the need for rapid diagnostic tests has never been higher. While a defined timeframe for a 'rapid' diagnostic test is lacking;[1] most would agree that provision of results to the end user within two hours would qualify.[2]

Broadly speaking, a diagnostic point-of-care test (POCT) is "testing that is performed near or at the site of the patient, with the result leading to a possible change in the care of the patient."[3] However, definitions vary and there is an ever-growing list of alternative names for point-of-care (including, rapid diagnostics, near patient, satellite, decentralised, remote or patient centred testing). Point-of-care and near-patient testing tend to be used interchangeably, whereas other terms are more bespoke according to requirements. Given the level of variation associated with POC testing, a grading system based on the location and person completing the test has been suggested (Table 1).[1]

In addition, the World Health Organization (WHO) proposed that an ideal POCT, especially one suitable for use in low resource settings, should achieve the assured criteria and be affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free and deliverable to end users.[4]

Diversity among POCT

The true benefits of a POCT are realised when the test is completed outside a standardised laboratory environment by someone who is not laboratory trained. By their nature, POCTs are simple to operate and require limited expertise to complete, they have a low number of processing steps, equating to minimal hands-on time, and have easy-to-interpret results.

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Fig. 1 A molecular panel syndrome-based point-of-care test (BioFire FilmArray Torch System, showing the panel kit, pouch loading station and analyser).

There are many POCTs available for the detection of infection, ranging from simple dipstick-type tests to molecular-based syndromic testing (Table 2 and Figures 1-4). Even for detection of the same infection, vast differences exist between POCTs, some of which are listed below:

- Is it a standalone test, such as a dipstick or lateral flow?
- Is it simple or complex in terms of analyser/additional equipment requirements?
- What is the target analyte: pathogen-specific or surrogate marker of infection, such as a change in immune response?
- What are the range of analytes detected: single or multiple analyte detection or molecular syndromic testing?
- What is the technology of detection: antigen, immunoassay, or molecular?
- How easy is sample collection: finger prick blood, nasal swab?
- What is the time to result: <5 minutes to <2 hours?

Understanding the diversity among the POCTs available for detection of infection is important when interpreting the results of systematic reviews, the conclusions of which frequently acknowledge considerable heterogeneity in studies eligible for inclusion,[5] making recommendations for clinical practice difficult, due to the level and quality of evidence available. Variations among POCTs also become important when anticipating and addressing barriers to implementation.[1] For instance, POCTs suitable for a GP consultation are likely to be different to those suitable in an emergency department, in terms of the time-to-result, range of pathogens detected, cost of the analyser/test. ▶

Rapid detection

POCTs for rapid detection of infection are applicable across the breadth of healthcare provision. Screening for infection using POCTs in community settings, such as pharmacies or care homes, may provide diagnostic support and reassurance for those patients in which the infection is likely to be self-limiting, with symptoms that can be managed at home, who do not require a healthcare appointment.[6,7]

In primary care, POC testing can support clinical decision making in one of three ways: by screening for infection (a rule in/rule out scenario), informing the need for referral to secondary care, and monitoring disease progression.[8]

Other areas of healthcare where POCT for rapid detection of infection could provide additional benefit to existing clinical practice include on the way to hospital via ambulance,[9] during 'digital' consultations,[10] or when targeting hard-to-reach groups.[11]

Inevitably, some patients will require assessment and management within the hospital setting. Use of POCTs in the emergency department or acute assessment unit has been shown to offer a rapid triage solution for respiratory tract infections.[12,13] Once admitted to hospital, POCTs are available to aid infection prevention decisions in order to prevent transmission of pathogens associated with healthcare-associated infections, such as influenza,[14] methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridioides difficile*, or norovirus.[15]

POC testing for rapid detection of infection offers benefits in the following areas:

- Patient triage according to severity of illness and urgency to be seen
- Improving patient workflow and reducing backlog
- Appropriate use of limited resources, including laboratory resource
- Informing and improving antimicrobial prescribing and reducing selective pressure for the development of antimicrobial resistance.

POCT selection

Currently, there are >300 commercially available SARS-CoV-2 antigen lateral flow assays.[16] With this many tests available, how is a healthcare provider to choose the test that offers the best performance, value for money, robust supply chain etc?

One valuable source of information is the relevant Target Product Profile (TPP). A TPP outlines an extensive list of desired characteristics and minimum acceptable criteria of a target product, in this instance a diagnostic test, ranging from intended use to performance characteristics.[17]

In the UK, the Department of Health and Social Care (DHSC) sought to address the increasingly large number of commercial lateral flow antigen devices available on the market by commissioning a time-limited SARS-CoV-2 test development and evaluation programme, that comprised three phases of testing:[18]

- Phase 1: a desk-top review, including of manufacturers' claimed performance and instructions for use,
- Phase 2: controlled laboratory testing indicating the robustness, specificity, sensitivity, and other desired characteristics of the tests,
- Phase 3: testing of a larger sample set (at least 1,000 true negatives and 200 true positives, plus samples from PCR-confirmed positive cases identified by the Lighthouse Laboratories).

Since its establishment in August 2020, the programme has evaluated over 140 lateral flow devices: approximately 30% of the tests met the standards for Phase 2 and 43 tests passed Phase 3a testing.[19]

According to new regulations, The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021, it is now a legal requirement for all antigen and molecular COVID-19 detection *in vitro* diagnostic devices intended for sale in the UK to pass UK government validation. All COVID-19 detection tests available for purchase on the UK market must meet a minimum performance standard, currently assessed by desk-top review, followed by a proposed laboratory validation.

Fig. 2 An analyser-based point-of-care test (Aidian QuikRead go CRP)

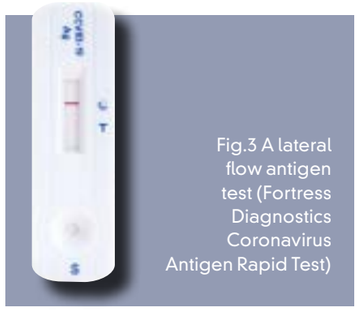

Fig.3 A lateral flow antigen test (Fortress Diagnostics Coronavirus Antigen Rapid Test)

As the results of all tests that pass the desktop review requirements will be published, it is expected that this process will provide stakeholders with the necessary information to make an informed decision when choosing a test.[20]

Currently, this validation process is only required for SARS-CoV-2 antigen and molecular tests; however, the Royal Statistical Society Diagnostic Tests Working Group recognised "the inadequate state of current processes for evaluating and regulating medical tests". Their comprehensive report makes recommendations covering aspects of study design, regulation and transparency, providing a framework for how diagnostic tests need to be evaluated to generate robust evidence that decision makers can trust.[21]

Importance of data

Unlike the evaluation of new therapeutic drugs and other clinical interventions, which are the subject of large randomised controlled trials, diagnostic tests are rarely evaluated in the same robust way. Often diagnostic accuracy studies do not include a pre-defined hypothesis and sample size calculations are omitted. In order to improve the quality of diagnostic accuracy study design and subsequent interpretation of results, minimum acceptable criteria need to be defined.[22]

As a consequence of the lack of standardised methodology for evaluation, systematic reviews of POCT for rapid detection of infection are frequently limited to a small number of studies eligible for inclusion.[5] Heterogeneity in the clinical syndromes assessed (i.e., respiratory tract infection is a broad clinical syndrome) and study design makes drawing strong conclusions difficult. Without this robust level of low risk of bias, high quality evidence, it is difficult to make evidence-based recommendations for POCT within clinical guidelines/algorithms and progress the test into clinical practice.

	Location			Operator	
Grade	Hospital	Laboratory	Other healthcare facility	Healthcare Professional	Example
1A	✓	✓	X	✓	Satellite Laboratory
1B	✓	X	X	✓	ED, ICU
2A	X	X	✓	✓	GP surgery
2B	X	X	X	✓	Care home
3	X	X	X	X	Self-testing at home

Key: ED, emergency department; ICU, intensive care unit; GP, general practice.

Table 1. How different point-of-care testing situations may be graded, according to location and person completing the testing.[1]

Evidence for the use of POCTs in the rapid detection of infection is commonly in the form of small-scale, short-term, pilot or feasibility studies.[23] Very often these studies stop when funding runs out and while results may be presented at a meeting or conference, they may not be published as peer-reviewed manuscripts. This 'bottom-up' approach has limitations and is unlikely to lead to much advancement. A 'top-down' approach whereby central organisations drive adoption of POCT at a national level may yield more widespread results.[23]

Across UK healthcare, a complex, interacting group of stakeholders, such as regulators, industry, commissioners, policy makers, laboratory services, POCT teams, clinicians, and patients, all have an interest in POC testing, and their motivations and priorities need to be considered.[23]

A disparity exists between information that is reported from an academic and industry perspective compared with information that is considered pertinent by clinicians, or policy and decision makers.[23] Characteristics most often reported in diagnostic accuracy studies are those relating to test performance (such as sensitivity, specificity, negative and positive predictive values) and turnaround time.

Clinical utility (defined as the "extent to which a correct (treatment) decision, as based on the POC test result, has added value in clinical outcomes") and data associated with risks (defined as "the impact of a [wrong] treatment/advice based on a [wrong] test result"), workload, reimbursement, and relevant legislation are rarely reported but are the test characteristics of most value to the clinician and other decision makers.[24]

Given the diversity of POCT available for rapid detection of infection and the range of healthcare provision in the UK, it is important to choose the most appropriate POCT for your setting/population.[2] Success may be measured in different ways depending on desired outcomes of implementation.

While clinical practices are standardised to a certain degree, each clinical setting is as unique as the patients it serves, therefore, a POC workstream that is successful in one location may not work for another. To illustrate this point, two studies that evaluated the same POCT (FilmArray BioFire with the respiratory panel) in different clinical practices are presented.

The first study, a randomised control trial comprising 720 patients, used the FilmArray BioFire, a molecular syndromic POCT, to aid diagnosis of acute respiratory tract infection in the acute medical unit and emergency department of Southampton General Hospital during two successive respiratory seasons (pre-COVID-19). Outcomes assessed were the proportion of patients who received antibiotics while hospitalised (up to 30 days), duration of antibiotics, proportion of patients receiving single doses or brief courses of antibiotics, length of stay (LOS), antiviral use, isolation facility use, and safety. Using the molecular POCT, there was strong evidence ($p < 0.0001$) for improved turnaround time of result (FilmArray: 2.3 hours [mean 1.4]; laboratory-based: 37.1 hours [mean 21.5]), and an increase in the rate of influenza detection and appropriate antiviral use. However, routine use of molecular POCT for respiratory viruses did not reduce the proportion of patients treated with antibiotics.[13]

The same respiratory molecular POCT was evaluated in a much smaller, feasibility study in primary care comprising four GP practices over 6 weeks (n=93 samples tested). Clinical diagnosis was changed for 19 patients and eight patients were contacted regarding a change to their treatment plan according to the POCT results; however, the turnaround time to result (65 minutes) did not suit a routine GP consultation. Lack of targets for common bacterial causes of respiratory tract infection was also seen as a shortcoming of the molecular POCT.[25]

Fig.4 Urine dipstick (Roche Combur-Test)

Barriers to adoption

Despite the number and variety of POCTs available for rapid detection of infection, implementation has been slow.[24] Financial, cultural, organisational, and logistical factors are often cited as barriers to implementation rather than failure of a POCT to deliver a result in a particular setting.[23,26,27]

Costs associated with introducing POC testing and lack of funding are frequently identified as barriers to implementation.[23,27,28] and it has been acknowledged that UK healthcare needs to develop ways to ensure funding is transferred to appropriate areas in order for POCT to be implemented successfully.[29]

The cost per POCT is usually presented as more per test compared with centralised laboratory testing; however, this simplistic approach does not take into account the complexity of healthcare provision and possible longevity of POCT outcome. Nor does the low cost of centralised laboratory testing take into account the pre- and post-analytical steps and costs associated with the delay in results compared with POC real-time results.[28]

The availability of high-quality health economic data for the use of POC testing in an acute setting is lacking.[30] However, the introduction of POC testing should not always be expected to be cost saving. An increase in costs associated with rapid detection of infection may be justified when better prognosis, longer life expectancy, a reduced need for hospitalisation, and reduced risk of serious life-threatening complications are all possible outcomes. The economic impact for adopting POC testing needs to assess both the immediate ▶

impact of implementation, such as direct clinical benefits for patients, but also the longer term, indirect benefits to healthcare and society.[26] It has been suggested that the NHS needs to consider the introduction of POC testing in terms of value proposition.[28]

Implementation

A carefully planned, meticulously executed strategy for implementation is needed if the full benefits of POCT for rapid detection of infection are to be achieved while avoiding harm.[31] Failure to do this and the risks could outweigh the benefits.[1]

There is a wealth of information available to inform POCT strategy development:

- Official Medicines and Healthcare Products Regulatory Agency (MHRA)[32] and National Institute for Health and Care Excellence (NICE) Medtech Innovation Briefings,[33–35]
- Various checklists and frameworks,[2,36,37]
- Expertise in NIHR diagnostic centres.[38]

In summary, POC testing is a decision-making tool for real-time patient management, it is not a replacement for a thorough clinical examination or full complement of laboratory tests. Rather, POC testing can act as a screening tool to identify those patients who require further investigations and interventions and those who do not. In the wake of the COVID-19 pandemic, opportunities have emerged for POC testing for rapid detection of infection.

It is not a lack of demand for POCT that is limiting progress with implementation, rather financial constraints, such as appropriate funding/reimbursement models, and a reluctance to change existing workflows when time is already stretched and pressure on services is high.

Due to the complex, interacting nature of the many facets of UK healthcare, a one-size POCT implementation approach is unlikely to be realistic; however, by investing in POCT for rapid detection of infection, the benefits and long-term savings to the NHS have the potential to be phenomenal. CSJ

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Type	Dipstick	Lateral Flow	Lateral Flow	Immunoassay	Immunoassay - multiple targets	Molecular – single target	Molecular - syndromic
Example	Roche Combur-Test	Fortress COVID-19	FebriDx	Aidian QuikRead go	MeMed BV	Abbott ID NOW	BioFire FilmArray
Technology	Chromatogenic	Immuno chromatogenic	Immuno chromatogenic	Immuno turbidometric	Immunoassay	PCR	Multiplex PCR
Time to result	1-2 mins	10 mins	10 mins	<5 mins	NK	≤20 mins	≤60 mins
Analyser required	No	No	No	Yes	Yes	Yes	Yes
Cost*	£	£	£	££	££	££	£££
WHO ASSURED	Yes	Yes	Yes	No	No	No	No
Pathogen-specific	No	Yes	No	No	No	Yes	Yes
What is detected	Molecules (e.g., glucose, bilirubin) or cells (e.g., WBC, RBC)	Antigen or antibody	CRP and mXA	CRP	TRAIL, IP-10, CRP	Genes for specific pathogens	Genes for a wide panel of pathogens
Clinical syndrome	UTI	aRTI	aRTI	Bacterial/viral differentiation	Bacterial/viral differentiation	aRTI	RTI, GTI, sepsis, meningitis

KEY: *Cost (cost per test and associated analyser) has been arbitrarily categorised as follows: £, inexpensive; ££, moderate; £££, expensive; WHO ASSURED: World Health Organization criteria: Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free and Deliverable to end users; UTI, urinary tract infection, aRTI, acute respiratory tract infection; GTI, gastrointestinal.

Table 2. Characteristics of a selection of point-of-care tests used for the rapid detection of infection.

About the author

Carolyne Horner is the scientific lead at Una Health, a role in which she provides scientific and clinical expertise to the team. She has a Bachelor of Science (Biological Sciences) from the University of Leicester and a Ph.D from the University of Leeds. Carolyne trained as a clinical scientist (Microbiology) at Leeds Teaching Hospitals NHS Trust where she worked for over 15 years before moving to the British Society for Antimicrobial Chemotherapy to work as a clinical affairs officer. Carolyne's areas of interest are antimicrobial resistance and surveillance, diagnostic stewardship and education of these subjects.