

Will COVID-19 be the coming of age for point-of-care testing?

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BACKGROUND

As countries deal with the COVID-19 pandemic in varying ways, one area of agreement is the need to test for the COVID-19 virus in as many people as possible. Beeching *et al* have rightly pointed out that ‘tests cannot be interpreted if they are not available’.¹ However, as reported in the UK media, access to COVID-19 (viral) testing has been limited for some sections of the population including healthcare professionals and carers. There have also been long delays in getting the results back to the person being tested. This has now been addressed by increasing the number of specimen collection stations and the use of home collection kits, although the return of results can take several days.

LEARNING FROM COVID-19 TESTING EXPERIENCE

As we now move into the next phase of getting the economy restarted, the number of tests required will increase significantly, underpinning the test and trace service. More and more employers and business owners will be asking the question ‘Do any of my employees or customers have COVID-19?’; there has also been a call for testing at the borders, as international travel recommences. This will further stimulate the demand for convenient and timely testing; Beeching *et al*¹ argued the need for rapid near patient testing, a point also made by Sheridan reviewing the developments in fast, portable diagnostic tests for COVID-19.² We refer to this as point-of-care testing (POCT) since the intention is to act on the result (the care element) immediately. POCT recognises the immediacy of the question being asked both in spatial and temporal dimensions.³

With the immediacy of the COVID-19 pandemic and the sheer number of people that require testing (virus or antibody),

it is relatively easy to demonstrate the benefit, and therefore the value, of POCT to a wide spectrum of what we might call customers or stakeholders in the COVID-19 care pathway. Thus, in addition to a range of healthcare professionals wanting to know the COVID-19 status of the person in front of them, both of them and their employers need to know their own status with regard to suitability for work. COVID-19 status does not only impact on patient disposition and treatment decisions, but also on decisions related to workload and resource management. Furthermore, the clinical diagnostic decisions regarding patients may be required at home, with determining the need for referral to hospital—especially in the rural setting, or at the local general practitioner practice. All of these decisions including questions relating to suitability for work, require test results to be available quickly. Examples of testing scenarios where a COVID-19 result is required quickly are illustrated in [table 1](#).

Interestingly, POCT has already been implemented in Australia for COVID-19 testing for virus detection to address the needs of the aboriginal community,⁴ and mining companies in Australia are also using POCT to help restart their industry.⁵ Trials are now being reported on the evaluation of new POCT technologies for virus detection in a range of settings, for example, the care home.⁶

BARRIERS TO ADOPTION?

The likely implementation of POCT for COVID-19 management prompts the question as to why POCT is not used more routinely, given the technologies have been available for several decades.⁷ One barrier to use is the concern regarding analytical performance of POCT devices not matching that of the laboratory. This is very relevant to COVID-19 as there is doubt about the performance of many



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Discussion

Table 1 Illustrating some of the scenarios in which a question of COVID-19 status is being asked and where decisions need to be made quickly

Enquirer	Patient/customer	Setting	Question
GP	Person at home	Home	Referral to hospital?
Carer	Care home resident	Care home	Isolation required?
Paramedic	Caller	Ambulance	Which entrance to hospital?
Emergency doctor/nurse	Emergency patient	ED	Which ward for referral?
Employer (healthcare)	Healthcare worker	Home or place of work	Is he/she fit to work?
Employer (education)	Teacher	School	Is he/she a risk to pupils?
Employer (public transport)	Driver	Bus depot	Is he/she a risk to the public? Is he/she a risk to co-workers?
Employer (industry)	Engineer	Factory	Is he/she a risk to co-workers?
Employer (agriculture)	Fruit picker	Fruit farm	Is he/she a risk to co-workers?
Professional sport club	Sports person	Major football club facility	Are other players being put at risk? Can he/she play in the team today?
Any employee above	Any employee above	Any workplace	Can I go to work today?

Each scenario is described in terms of the questioner, the subject of the question, the setting in which the question has arisen and an example of the question for which a result will enable a decision to be made. All of the scenarios in the upper portion of the table require clinical, organisational and resource management decisions. All of the scenarios in the lower portion focus on two major objectives (1) to get the economy started and (2) to avoid triggering a second wave, and further spread, of infection.
ED, emergency department; GP, general practitioner.

of the lateral flow devices being offered for antibody testing.⁸ The importance of the accuracy of COVID-19 virus tests has also been highlighted in relation to the absence of a recognised ‘gold standard’ method.⁹ However, this issue can be resolved by requiring development of methods to published specifications with local, independent verification of the device performance against an established laboratory reference method before adoption. Thus, continuing technology developments result in POCT devices with improving analytical performance to the point where they match the performance of laboratory devices, such as with blood electrolytes and glycated haemoglobin (HbA1C) measurement.^{10 11}

Such improvements in analytical performance have also occurred in devices detecting infectious diseases, such as influenza, where the deployment of small devices measuring virus by various amplification technologies can provide more sensitive and specific measurements than lateral flow type devices. These developments and their deployment to achieve improved outcomes are discussed by Yarbrough *et al* highlighting the benefits of the improved sensitivity of the test reducing the number of false negatives in addition to improved decision-making on patient disposition and antibiotic stewardship.¹² POCT has also been deployed for hepatitis C testing and shown to be clinically effective, improving access to testing and better linkage to care.¹³

Another key barrier to the adoption of POCT has been the perceived high cost of the test, when compared with the low cost per test achieved using a centralised laboratory service. However, this limited perspective appears to ignore the cost incurred getting the specimen to the laboratory, the analysis time and the time

taken to communicate the result back to the requester, and their combined effect on delay in decision-making. Thus the delay will adversely impact on all stakeholders, including time wasted, greater anxiety, delay in treatment, inefficient use of healthcare resources, for example, length of stay in facility, as well as a greater cost to employers and society with a slowing of industrial economic recovery. The benefits downstream of testing can more than defray the initial higher cost of the test itself.¹⁴ However, the evidence to demonstrate the full benefit of POCT testing is rarely collected as reimbursement is only based on the cost of producing and delivering the test.¹⁴ It is perhaps noteworthy that the National Institute for Health and Care Excellence is looking at the economic modelling of POCT devices for viral detection and serology.¹⁵

CONSIDERATION OF THE BROADER BENEFITS OF RAPID TESTING

One way to identify the value of any testing is to borrow the concept of a value proposition, widely used in industry, and apply it to healthcare.¹⁴ While acknowledging that healthcare is a complex industry, the value proposition enables clarity to be brought to the contribution of each of the stakeholders involved in delivering care and all the benefits described above that will accrue to these stakeholders/customers. We would argue that these stakeholders can all be the ‘consumers’ of testing who will all have different questions and expectations of better outcomes. Such outcomes can be quite diverse and include those of convenience and time savings for some of the stakeholders. Thus, a study of the implementation of POCT for HbA1C in primary care showed that, in addition

to improved glycaemic control and patient satisfaction, there was a significant reduction in patient visits and phlebotomy requirement as well as office administration.¹⁴

Management of the COVID-19 pandemic is going to result in a lot of customers/ stakeholders and patients, experiencing the benefits of POCT for the first time. They might rightly ask why more of their testing cannot be performed in a similar way. The answer is it can, if healthcare providers look beyond just the cost of producing a test result, and consider the broader value proposition of POCT, recognising the benefits to all those involved in care delivery. Will the experience with POCT for COVID-19 virus testing lead the way to new models of healthcare delivery, as well as helping to address the vexed question of value for money in healthcare?

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REFERENCES

- 1 Beeching NJ, Fletcher TE, Beadsworth MJB. Covid-19: testing times. *BMJ* 2020;369:m1403.
- 2 Sheridan C. Fast, portable tests come online to curb coronavirus pandemic. *Nat Biotechnol* 2020;38:515–8.
- 3 Kost GJ. Geospatial hotspots need point-of-care strategies to stop highly infectious outbreaks: Ebola and coronavirus. *Arch Pathol Lab Med* 2020. doi:10.5858/arpa.2020-0172-RA. [Epub ahead of print: 16 Apr 2020].
- 4 Australian Department of Health. World first rapid COVID-19 testing to protect Aboriginal and Torres Strait Islander communities. Available: <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/world-first-rapid-COVID-19-testing-to-protect-aboriginal-and-torres-strait-islander-communities>
- 5 ABC News. Mining companies keen to drive widespread testing and research for coronavirus. Available: <http://www.abc.net.au/news/2020-05-01/mining-companies-drive-widespread-COVID-testing-research/12205018>
- 6 Martin JE. CICERO - A Care Home Study of COVID-19. Available: <https://clinicaltrials.gov/ct2/show/NCT04453553#contacts>
- 7 St John A, Price CP. Existing and emerging technologies for point-of-care testing. *Clin Biochem Rev* 2014;35:155–67.
- 8 Mallapaty S. Will coronavirus antibody tests really change everything? *Nature* 2020;580:571–2.
- 9 Watson J, Whiting PF, Brush JE. Interpreting a covid-19 test result. *BMJ* 2020;369:m1808.
- 10 Mirzazadeh M, Morovat A, James T, *et al*. Point-Of-Care testing of electrolytes and calcium using blood gas analysers: it is time we trusted the results. *Emerg Med J* 2016;33:1–6.
- 11 Sølvik Una Ørvim, Røraas T, Christensen NG, *et al*. Diagnosing diabetes mellitus: performance of hemoglobin A1c point-of-care instruments in general practice offices. *Clin Chem* 2013;59:1790–801.
- 12 Yarbrough ML, Burnham C-AD, Anderson NW, *et al*. Influence of molecular testing on influenza diagnosis. *Clin Chem* 2018;64:1560–6.
- 13 Fish S. Hepatitis C point of care testing: what is its impact on testing and linkage to care? Available: <https://www.catie.ca/en/pif/spring-2017/hepatitis-c-point-care-testing-what-its-impact-testing-and-linkage-care>
- 14 Price CP, St John A. The value proposition for point-of-care testing in healthcare: HbA1c for monitoring in diabetes management as an exemplar. *Scand J Clin Lab Invest* 2019;79:298–304.
- 15 National Institute for Health and Care Excellence. Exploratory economic modelling of SARS-CoV-2 viral detection point of care tests and serology tests. Available: <https://www.nice.org.uk/guidance/indevelopment/gid-dg10038>