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

Christopher P Price 1 , Andrew St John 2

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’. 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 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. 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.

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, and mining companies in Australia are also using POCT to help restart their industry. 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.

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. 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
of the lateral flow devices being offered for antibody testing. 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. 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 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. POCT has also been deployed for hepatitis C testing and shown to be clinically effective, improving access to testing and better linkage to care.

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.

However, the evidence to demonstrate the full benefit of POCT testing is rarely collected as reimbursement is only based on the cost of producing the test. 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.

### 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. 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.\textsuperscript{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?

\textbf{Contributors} Both authors have worked together on two of the main topics featured in this manuscript. They conceived and researched the topics relevant to COVID-19 together and contributed equally to the writing and revision of the manuscript.

\textbf{Funding} This research was supported by the National Institute for Health Research (NIHR) Community Healthcare MedTech and In Vitro Diagnostics Cooperative at Oxford Health NHS Foundation Trust. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care. This paper is part of the work of the International Federation of Clinical Chemistry and Laboratory Medicine and World Association of Societies of Pathology and Laboratory Medicine Committee for the Value Proposition in Laboratory Medicine.

\textbf{Competing interests} CPP has read and understood BMJ policy on declaration of interests and declares the following interests: CPP chairs an advisory committee for LumiraDx for which he is remunerated. He has no financial interests in the company. AstJ has read and understood BMJ policy on declaration of interests and declare that he has no competing interests.

\textbf{Patient consent for publication} Not required.

\textbf{Provenance and peer review} Not commissioned; externally peer reviewed.

This article is made freely available for use in accordance with BMJ’s website terms and conditions for the duration of the COVID-19 pandemic or until otherwise determined by BMJ. You may use, download and print the article for any lawful, non-commercial purpose (including text and data mining) provided that all copyright notices and trade marks are retained.

ORCID iDs

Christopher P Price http://orcid.org/0000-0003-2980-9818
Andrew St John http://orcid.org/0000-0001-7564-2823

\textbf{REFERENCES}


\textbf{Discussion}