Preparing for the next pandemic: lessons learnt from the implementation of point-of-care SARS-CoV-2 testing in an emergency department

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ABSTRACT

Point-of-care testing (POCT) provides rapid, accurate results that facilitate diagnosis and patient management. POCT for infectious agents allows timely infection prevention and control interventions and informs decisions around safe patient placement. However, POCT implementation requires careful governance as they are primarily operated by staff with limited prior education on laboratory quality control and assurance processes. Here, we describe our experience implementing SARS-CoV-2 POCT in the emergency department of a large tertiary referral hospital during the COVID-19 pandemic. We describe collaborative governance between pathology and clinical specialities, quality assurance, testing (volume and positivity rates), impact on patient flow and focus on lessons learnt during implementation that should be incorporated into revised pandemic preparedness planning.

INTRODUCTION

Rapid laboratory diagnosis of SARS-CoV-2 is essential for hospital management of COVID-19. In addition to aiding clinical decision-making, testing facilitates timely infection prevention and control (IPC) and informs decisions around safe patient placement.[1] During the pandemic, a variety of SARS-CoV-2 testing platforms were developed which varied in turnaround time (TAT) and the volume of samples analysed. High-throughput batch-based molecular platforms were the backbone of testing for many laboratories, however, they were associated with longer TATs compared with commercial rapid platforms or point-of-care tests (POCTs).[2 3]

The cobas Liat system (Roche Molecular Systems) is a fully automated POCT molecular testing platform which utilises real-time PCR for SARS-CoV-2/influenza A/B detection within 20 min.[4] The faster TAT compared with laboratory-based testing is of obvious appeal, while maintaining comparable accuracy and sensitivity, with up to 100% concordance.[2 5–9]

In our institution, onsite SARS-CoV-2 PCR laboratory-based testing commenced on 16 March 2020, using the high-throughput Roche Flow platform with an average TAT of between 15 and 17 hours. Contemporaneously, a SARS-CoV-2 assay became available for the Cepheid GeneXpert XVI platform and the GenMarkDx ePlex platform allowing more limited laboratory-based rapid PCR testing, with a reduced average TAT of 7–11 hours (including transport time to laboratory). Due to concerns regarding cross-infection risk from admission of asymptomatic or presymptomatic patients to multioccupancy accommodation, universal SARS-CoV-2 admission testing (UAT) was introduced in June 2020 and continued until the end of August 2022.[10]

Initially, laboratory-based SARS-CoV-2 testing was performed between 08:00 and 20:00 hours daily. As a single laboratory scientist covered the out-of-hours period, samples received after 20:00 hours were tested next day. This generated delays in patient placement decisions overnight from the emergency department (ED). As the pandemic progressed, alongside COVID-19, non-COVID-19 ED presentations increased compounding pressure on the laboratory to produce faster SARS-CoV-2 results. To improve TAT, the cobas Liat POCT system was introduced in our ED on 8 December 2020.

We retrospectively reviewed the use of POCT in the ED for COVID-19 diagnosis from implementation until cessation of UAT. This corresponds to the first to the fifth (current) wave of COVID-19 in Ireland.[11] We describe testing volume, positivity rates, impact on patient flow and lessons learnt that are relevant for future pandemic preparedness and implementation of POCT in clinical areas.

METHODS

Beaumont Hospital is an 820-bed adult tertiary referral hospital in Dublin, Ireland, providing specialty and acute care services to a catchment area of 290 000 people, including specialised services such as neurosurgery, acute haematology/oncology and renal transplantation. Of 820 beds, only 136 are single rooms, 77% with en suite facilities, and 12 of these are airborne isolation rooms. The hospital has an on-site laboratory with a laboratory information management system (LIMS), order communications system (OCS), patient administration system (PAS) and paper-based medical records.

Governance and staff training

Two recently appointed POCT laboratory scientists led on implementation under the supervision of a consultant clinical microbiologist and under the governance of the laboratory directorate. Dedicated nursing staff with responsibility for the POCT process were identified and a testing pathway was

agreed by hospital management. Training in cobas Liat analyser use, IPC/personal protective equipment (PPE) use and decontamination protocols was provided by the POCT team to 57 staff members: 24 laboratory-based and 33 clinical staff.

POCT infrastructure, testing process and results reporting

A dedicated POCT room with controlled access adjacent to the ED was identified and equipped with two analysers and appropriate equipment. A quiet and uncluttered environment was maintained to reduce potential errors during testing and permit safe PPE doffing. On completion of a test, a printed report was generated which was cosigned by the nurse performing the testing and the staff member in receipt of the result. The printed report was filed in the patient's paper healthcare record.

Creating the electronic record involved additional steps as our LIMS has no native support for POCT results. POCTs were first ordered on the OCS, which automatically generated a LIMS sample label and barcode. Results were then held in a Roche middleware programme (cobas IT Middleware) and periodically reviewed by the medical laboratory scientists during that day. The samples were then 'received' and verified on the LIMS to create the OCS electronic record. Processed samples were retrieved daily by a microbiology laboratory scientist, who was also responsible for restocking the testing room. These samples were then held for a further 7 days (if negative) in the microbiology laboratory.

Quality assurance

Retesting of POCT samples in the laboratory was performed regularly as part of an internal quality assurance process. The POCT platform was enrolled in two separate External Quality Assurance (EQA) schemes; Randox Quality Control for Molecular Diagnostics (QCMD) for SARS-CoV-2 and Irish External Quality Assurance Scheme (IEQAS) for influenza A/B. In November 2021, Labquality EQA Scheme via IEQAS became available which combined both SARS-CoV-2 and influenza A/B testing.

False positive detection and the FDA warning

Due to the potential for false positive results associated with cross-contamination when using open systems, training for clinical staff included recognition of potential false positive results. In March 2021, the US Food and Drug Administration (FDA) issued a warning regarding possible false positive results on the cobas Liat platform.[12] This warning was highlighted to clinical and laboratory staff. Thereafter, additional vigilance was required to ensure that any potential false positive results were identified, and patients not placed in a COVID-19 cohort bay until confirmed as positive by additional testing in the microbiology laboratory.

Potential false positive results were flagged to the clinical microbiology team (CMT) if:

- Two or more consecutive samples yielded positive results.
- More than one target was detected.

If a sample was flagged as a potential false positive result, then the sample was immediately retested in the microbiology laboratory and the clinical team contacted to correlate with the clinical findings. If discordant results were generated from laboratory testing, a repeat sample was requested for same-day retesting and a final decision made based on reviewing the results in totality.

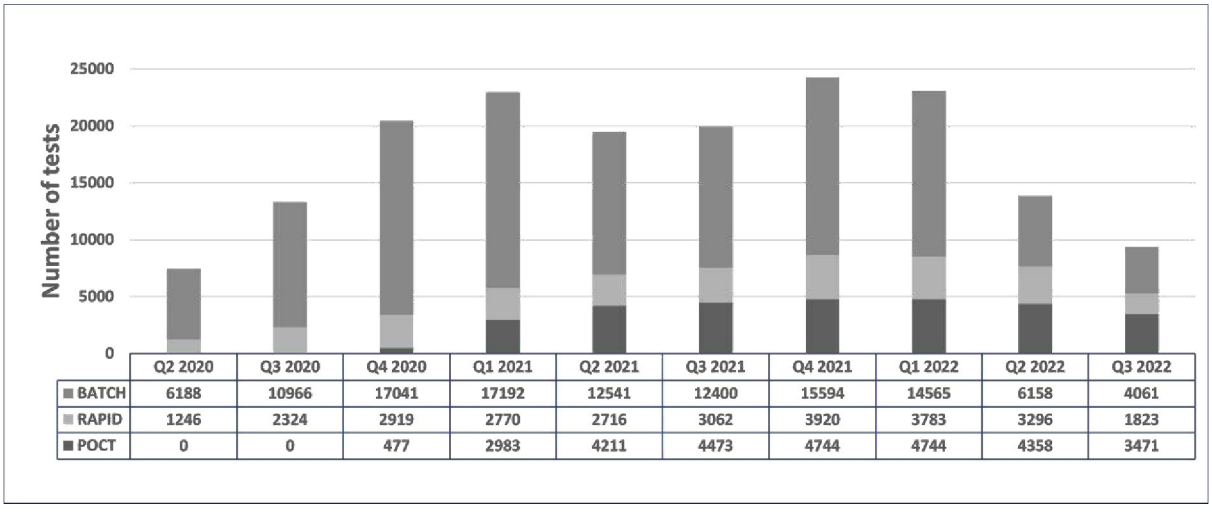
Use of POCT analyser

We conducted a retrospective review of the use of the Roche cobas Liat POCT analyser in our ED. Testing volumes from 16 March 2020 to 31 August 2022 on three different platforms were analysed: (1) POCT, (2) laboratory-based rapid platforms (Cepheid GeneXpert or GenMark Dx ePlex) and (3) laboratory-based batch testing (Roche Flowflex). The indication for POCT testing (symptomatic or not) and the time of testing (between 08:00 and 20:00 hours, or outside routine laboratory testing hours) were analysed.

RESULTS

In total, 174 026 SARS-CoV-2 PCR tests were performed in our institution between 16 March 2020 and 31 August 2022. Of these, 28 764 (18.8%) were carried out by POCT (figure 1), of which 14 643 (51%) were performed outside of routine laboratory testing hours (figure 2).

Of 28 764 POCT results, 2557 detected SARS-CoV-2 RNA (average monthly detection rate 8.9%, range 0.7%–14.3%), the majority (80%, n=2038) from symptomatic patients. Eighty-seven (0.3%) results were reported as 'invalid' or 'unsuitable' (n=46 and 41, respectively).



	Q2 2020	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022
BATCH	6188	10966	17041	17192	12541	12400	15594	14565	6158	4061
RAPID	1246	2324	2919	2770	2716	3062	3920	3783	3296	1823
POCT	0	0	477	2983	4211	4473	4744	4744	4358	3471

Figure 1 SARS-CoV-2 testing volume by testing platform in Beaumont Hospital, Dublin from Quarter 2 2020–Quarter 3 2022. Batch, Roche Flow platform; POCT, point-of-care testing, Cobas® Liat platform; Rapid, Cepheid GeneXpert XVI platform/GenMark Dx ePlex platforms.

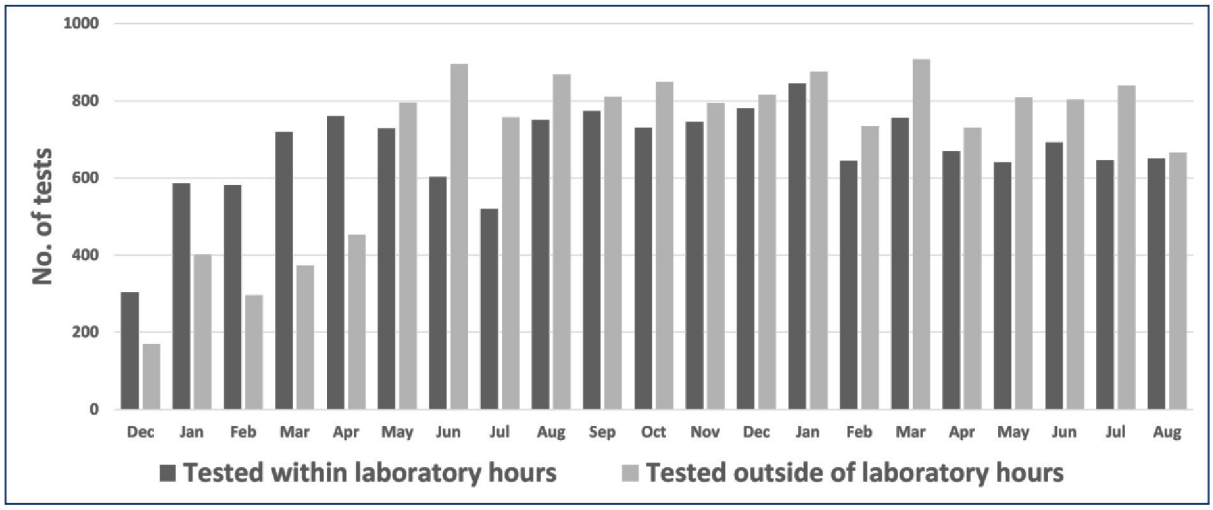


Figure 2 SARS-CoV-2 point-of-care testing volumes in Beaumont Hospital, Dublin performed during laboratory working hours (08:00–20:00 daily) and out of laboratory working hours (20:00–08:00) between 8 December 2020 to 31 August 2022.

FDA warning

From March to July 2021, there were 113 positive SARS-CoV-2 POCT results reported, 8 of which warranted further investigation as they were not confirmed on repeat testing. These samples were referred to Roche for further testing and 2 (1.7%) were confirmed as true false positives.

Patient flow

As demonstrated in figure 3, POCT implementation led to an initial reduction in 'time-to-bed' for admitted patients despite an increase in the volume of admissions. This was demonstrated for both COVID-19-related and non-COVID-19-related admissions. However, this reduction was not maintained into 2022.

DISCUSSION

Introduction of POCT in the ED resulted in an increased testing capacity of 120% over the course of the pandemic. Specific data on TAT was unable to be accurately analysed due to limitations in our IT system. There was a significant time-lag between sample ordering and final result authorisation due to the need for the laboratory staff to authorise all results on the middleware system. This occurred only during routine laboratory working hours. However, given that one in five SARS-CoV-2 tests were performed on the POCT and over half of these were performed outside routine laboratory testing hours, these results were available earlier for clinicians and hospital management than if tested in the laboratory. This facilitated safe patient placement and patient flow, with an initial reduction in time to bed for admitted patients, although this was not maintained. The reasons for this are complex and likely relate to increasing hospital activity as the pandemic progressed, including increasing ED and outpatient attendances. In addition, there were logistical challenges in patient placement: as the overall number of COVID-19 patients decreased, hospital activity and complexity of admissions increased. There was a move away from large COVID-19 cohort wards to single-room isolation and smaller cohorts due to the need to ensure maximal bed occupancy. Nonetheless, though the time to-bed placement was not maintained, without POCT, there

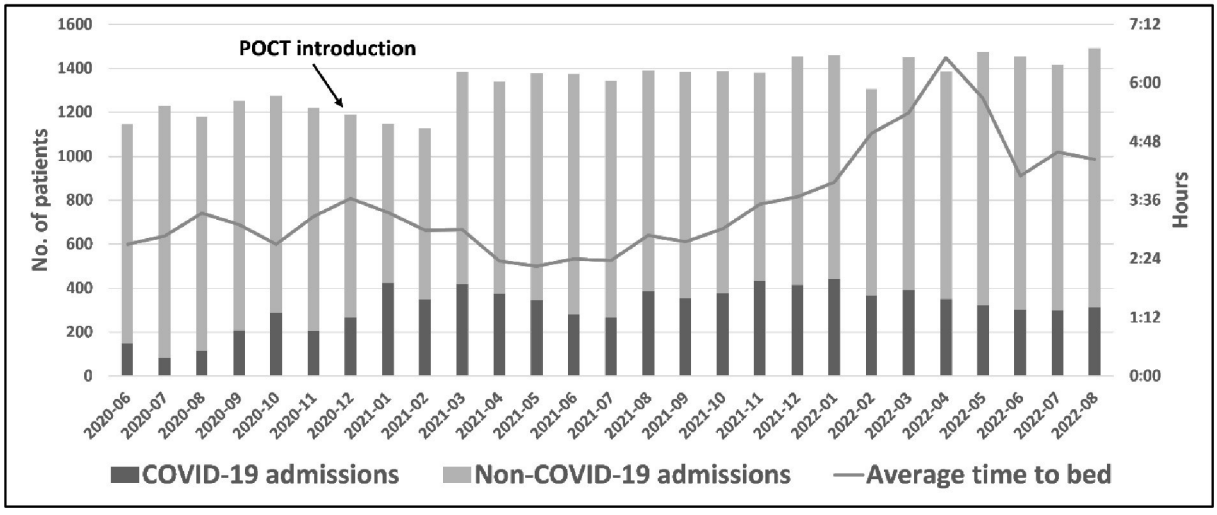


Figure 3 Volume of COVID-19 and non-COVID-19 emergency department admissions in Beaumont Hospital, Dublin between 1 June 2020 and 31 August 2022. Average time to bed: the line denotes the average time in hours taken for patients to be moved from the emergency department to a bed on an inpatient ward. POCT, point-of-care testing, Cobas Liat platform.

would have been significant delays in testing of ED patients with resultant IPC risks of cross-transmission while awaiting results. Importantly, POCT facilitated 24/7 COVID-19 diagnosis in the ED and enabled the out-of-hours laboratory scientists to concentrate on urgent non-COVID-19-related diagnostics.

The proportion of invalid results (0.3%) is lower than the 0.7%–3.75% previously reported.[2 5 13] However, previous studies have been smaller, with a total of 1418 samples tested (range 160–814). When combined with our results the overall rate of invalid results was 0.4% (118/30 182).

Our experience implementing POCT during a pandemic highlights several important issues relevant for future pandemic planning. One of the biggest challenges was that testing was performed by clinical staff without previous training in laboratory practices or an appreciation of quality control and quality assurance procedures.[14] Staff engagement and training were significant challenges given that POCT implementation occurred during the second pandemic wave when community rates were high with a resultant strain on hospital staff and resources.[11] We believe that establishing clear governance and leadership under the laboratory directorate, definition of roles of clinical and laboratory staff and ensuring open communication between laboratory and clinical staff was key. This ensured that clinical staff had access to experienced scientists who could troubleshoot and address any issues that occurred during implementation in real time. POCT scientists led clinical staff education and training and establishing quality management processes. This ensured that testing aligned with existing IPC pathways and effective communication and investigation of non-conformances and maintenance of quality control occurred.

Another issue relating to POCT use involves the inappropriate use of limited resources and demand management. In our experience, ensuring that appropriate testing pathways were adhered to was challenging, particularly when supply of kits became limited. POCT was introduced specifically for testing symptomatic patients presenting to the ED, although it was subsequently expanded to include asymptomatic patients. In-patients and staff continued to be tested with laboratory-based testing platforms. Unsurprisingly, once staff became aware that POCT provided the fastest TAT, non-ED samples began to be tested by POCT. These requests generally came from senior staff members attempting to circumvent the agreed testing pathways in order to get a more rapid result. At times POCT staff felt pressurised into performing these tests despite knowing that it meant a delay in the testing of ED samples and was not aligned with agreed testing pathways. Consequently, POCT use was regularly monitored by the CMT who provided feedback to staff and senior management highlighting the importance of adherence to agreed testing algorithms which prioritised ED samples to ensure optimal patient flow and IPC practices.

The issue of potential false positive results on the cobas Liat platform was highlighted by the FDA in March 2021. This led to an increased workload for the POCT team, clinical and laboratory staff, and the clinical microbiology service to ensure that any potential false positive results were identified and managed/investigated appropriately. This issue was finally resolved in July 2021 when a software update was released for the cobas Liat platform. Our review during this period showed that there were a low number of actual false positives, with only two results not confirmed by Roche.

In addition, there were multiple occasions where the analysers in use malfunctioned and required replacement. Each new machine required revalidation, placing a further strain on the POCT team.

POCT result documentation is integral to clinical decision-making and ensuring accuracy/traceability of results.[14] The cobas Liat system provides a printed copy of the POCT report which is available immediately and facilitates appropriate IPC action and patient management. However, this manual transfer of results allows for error and makes tracing/verification of results difficult. Therefore, it was critical that POCT results were interfaced with the hospital LIMS and OCS. One of the greatest challenges pertained to the hospital's IT infrastructure which has no native support for POCT results. This required an additional step which occurred during routine laboratory working hours only; microbiology laboratory scientists were diverted from other duties to manually verify POCT results resulting in a lag time between testing and result visibility on the PAS.

Our experience is limited as POCT was for a single centre, and this analysis was retrospective in nature. However, as it occurred during the course of a pandemic, our experience provides real-world experience of how POCT platforms can be implemented successfully under strenuous working conditions and provides a scaffold by which other centres can approach POCT introduction.

The COVID-19 pandemic has required laboratories to employ a dynamic testing response to the public health crisis. POCT platforms provide rapid results facilitating faster patient management and IPC actions. However, POCT requires careful implementation, appropriate governance, and ongoing staff education to be most effective. Our experience demonstrates the key role that pathology specialities play in POCT implementation and shows that when used appropriately they are a powerful tool for response to a pandemic. Implementation is a multidisciplinary process and could not have occurred without laboratory-based leadership and governance, senior management support and ongoing collaboration between the POCT team, clinical microbiology staff, senior management, patient flow, IPC, IT and nursing departments.

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