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Quality improvement project to reduce beta-D-glucan turnaround times in an NHS pathology network

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ABSTRACT

Beta-D-glucan (BDG) is a cell wall component of many fungi, detecting this in patients' serum permits early diagnosis of invasive fungal infections, particularly in patients with haematological malignancy. In critically ill patients in an intensive-care unit, where the prevalence of invasive fungal infection is lower, the high negative predictive value of BDG facilitates withholding or discontinuation of empirical antifungal therapy, contributing to antifungal stewardship. However, for the results of BDG testing to impact patient management, they need to be available within a clinically useful timeframe. The South West London Pathology (SWLP) network routinely sent samples for BDG testing from hospital trusts in our area to the UK Health Security Agency Mycology Reference Laboratory (MRL) at Bristol for analysis. In 2021, the mean turnaround time (TAT) was more than two times the 5-working-days standard stated in the SWLP user handbook. In this quality improvement project (QIP), we identified that the greatest delay was the MRL posting hardcopy reports. We investigated electronic reporting, first for all patient samples, and then only for intensive-care patients. However, we found that information technology (IT) and staffing limitations meant this was not viable. We then investigated commercial solutions and identified an innovative assay, which enabled the implementation of in-house BDG testing that was a good fit with our available staffing resource and laboratory environment. Our aim was to achieve at least 90% of BDG results authorised within 5 working days of sample receipt. Our QIP improved performance on this from 0.88% to 92.8% and reduced the mean TAT from 11.6 to 2.5 days and at lower unit cost. The change has been well received by our laboratory staff, and our pathology operational leads have had very positive feedback from our clinical teams and our antifungal steward.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Demand for beta-D-glucan (BDG) testing has increased significantly following its inclusion in several clinical guidelines. Despite this, conducting BDG tests has remained largely confined to specialist reference laboratories and has been associated with prolonged turnaround times (TATs).

WHAT THIS STUDY ADDS

⇒ QI methodologies have been applied to pathology services to reduce TATs and improve patient outcomes. However, to our knowledge, there is no previously published QI work in microbiology to improve TATs for BDG testing.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ We demonstrate that quality improvement can often be limited by systems employed by external organisations, and local adoption of technological innovations can circumvent this.

PROBLEM

1,3-beta-D-glucan (BDG) is a cell wall component of many fungi, including *Candida*, *Aspergillus* and *Pneumocystis* species. The detection of BDG in patients' serum enables early diagnosis of invasive fungal infections (IFIs), particularly in haematological malignancy patients where the prevalence is higher than in other patient groups. In critically ill patients, where the prevalence of IFI is lower, the value of BDG testing is its high negative predictive value, potentially enabling the withholding or discontinuation of empirical antifungal therapy where, for example, there is a risk of invasive Candidiasis following complicated abdominal surgery or gastrointestinal perforation.[1] The English Surveillance Programme for Antimicrobial Utilisation and Resistance reported that, in 2021, the highest antifungal prescribing rates were in intensive care, followed by haematology.[2]

In 2019, NHS England recognised the importance of antifungal stewardship (AFS) by including it in the Commissioning for Quality and Innovation scheme, aiming to counter the related problems of financial burden on the National Health Service (NHS) of inappropriate antifungal use and emergence of antifungal resistance.[3] The NHS spends more than £80 million annually on antifungal agents, with inappropriate use making up £11–25 million.[4]

As a part of an AFS programme at St. George's University Hospital NHS Foundation Trust to reduce inappropriate use of antifungal agents (associated with significant costs and side effects), improve patient outcomes

and limit the emergence of resistance, the stewardship team identified long BDG turnaround times (TATs) as a significant issue. BDG tests were sent to the Mycology Reference Laboratory (MRL), resulting in a median TAT of 12 days.[5] Lack of availability of rapid diagnostics and lack of resources (especially staffing) have been identified as the most frequent barriers to AFS in England.[6]

The driver diagram[7] in online supplemental figure S1 lays out our quality improvement project (QIP) logic. Our main project goal was attaining the 5-day TAT stated in our network's handbook for ≥90% of BDG samples. This had been attempted previously, described in change ideas (CIs) A and B in the Strategy section below. CI C was a renewed attempt in October 2023 to reach the target within 6 months.

To provide a systematic structure to this QIP, we used the Model for Improvement (MfI). This poses three questions: 'what are we trying to accomplish?', 'how will we know a change is an improvement?' and 'what changes can we make that will result in improvement?'.[7 8] CIs were tested through successive plan–do–study–act (PDSA) cycles, learning from successes and failures to refine further changes.

The MfI has been used in QIPs to improve performance in NHS hospital clinical sciences, in physical sciences,[9] physiological sciences[10–13] and life sciences,[14] including TAT in pathology services.[15–17] However, in microbiology, there is little published quality improvement (QI) work outside of preanalytical sample pathways.[18–21] To the best of our knowledge, there has been no QI work published on BDG testing.

BACKGROUND

Measurement of serum BDG concentrations has diagnostic and AFS value in haematology and intensive-care patients. The high negative predictive value of BDG has been shown to reduce inappropriate antifungal treatment by as much as 90%.[22 23] While no national TAT performance target exists for serum BDG test, there have been several reports suggesting that long TATs from reference laboratories were limiting their AFS value. Following the reports of median TATs of around 10 days for tests referred to the MRL, in 2021, the MRL conducted an analysis and found that their TATs were consistently<24 hours, with 98.8% of results available within their published 3-day TAT target, calculated from the time of sample receipt at the MRL to their result reporting.[6 24–26] However, this does not reflect the total TAT experienced by service users since it omits the transport of samples to the MRL and return of results to the sender.

BDG testing became accepted in clinical practice through peer-reviewed publications and inclusion in several clinical guidelines,[24 27–31] and the National Institute for Health and Care Excellence has proposed that BDG may be used to guide antifungal therapy discontinuation in patients testing negative.[32] Despite demand for BDG testing increasing more than 100-fold in England between 2010 and 2020, performing BDG testing has remained largely confined to specialist laboratories.[33] A 2017 United Kingdom (UK) survey of laboratory testing capacity found only 5% provided local BDG testing; the remainder sent samples to the MRL.[34] Reasons included technical complexity of available assay technology and the need for facilities to prevent contamination with environmental glucans. Potential for contamination has led to triplicate sample testing, significantly increasing costs. Furthermore, the traditional BDG assay requires the inclusion of several quantitation standards, making it cost-effective only if there are sufficient samples to run full batches.[32] Therefore, laboratories with lower demand (smaller catchments) would have longer TATs.

Another of the relatively most frequent tests we sent to the MRL was galactomannan (also known as Aspergillus antigen, another fungal biomarker). We implemented in-house testing for galactomannan in 2021, as a technically simple assay had become commercially available.

MEASUREMENT

Figure 1 shows a high-level process map of the BDG testing pathway prior to our QIP. The process begins with samples arriving at the South West London Pathology (SWLP) Central Pathology Reception along with other pathology samples from our five hospital sites. Here, they are sorted into pathology disciplines. Samples for BDG testing are transferred to the Serology reception, where they are unbagged, numbered and placed onto racks. Samples are booked onto the Laboratory Information Management System (LIMS) and centrifuged. If no additional serology tests are required, samples for BDG are placed onto the referral rack and collected daily by a biomedical support worker and taken to the microbiology referral bench. When other serology tests are also requested on a sample, these are processed first. On the referral bench, samples are aliquoted into small tubes, hand labelled, sealed and packaged. The sample is logged on the referral database and packaged samples are taken to the collection point by 16:00 each day, from where they are collected and transported overnight the 100 miles to the MRL in Bristol. Once tested at the MRL, a hard copy of the authorised report is posted back to us. Postal reports are collected daily from the post room, opened, date stamped and placed in the biomedical scientist (BMS) reporting tray. Reports are collected from the tray and entered onto the LIMS by a senior BMS, transcription of which is checked by a second BMS. The LIMS autoauthorises negative results; positive results are authorised by clinical staff. BMS periodically generates a list of incompletes highlighting samples for which the result is outstanding and contacts the MRL to chase these, which are then posted to us. Authorised reports are placed in a tray for collection by the administrative team, who barcode, scan and upload the result to our DART information system for permanent storage.

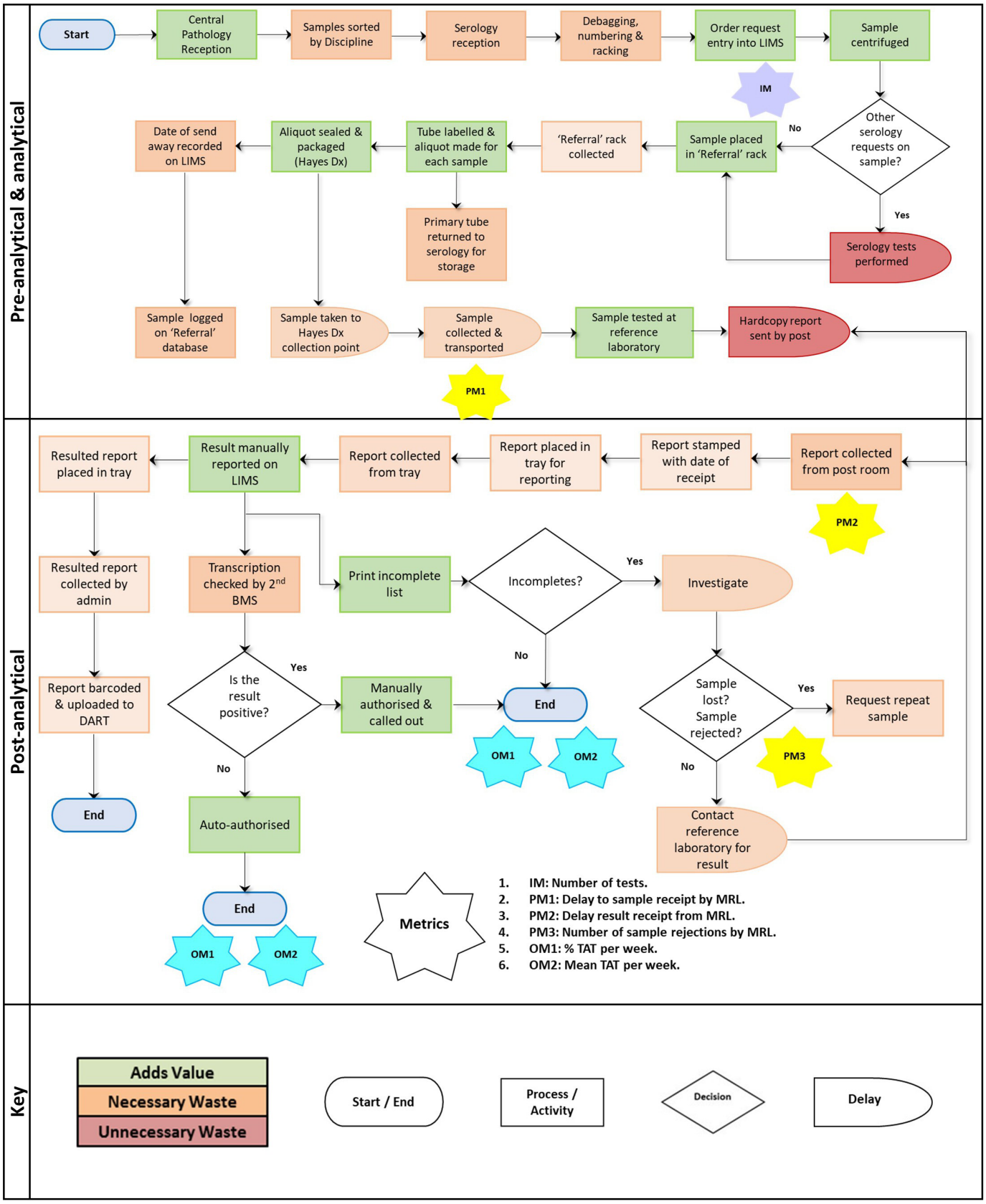

Figure 1 Process map. BMS, biomedical scientist; IM, input metric; LIMS, laboratory information management system; MRL, mycology reference laboratory; OM, outcome metric; PM, process metric; TAT, turnaround time.

Conducting root cause analysis (RCA), we investigated TAT data for April 2021 (72 tests). Online supplemental figures S2 and S3 show the breakdown and Pareto chart.[7 8] The largest delay occurred between the report being authorised by the MRL and receipt of this report by SWLP, with 78% taking≥4 days to arrive. The second largest delay was the time between the receipt of samples by SWLP and receipt of samples by the MRL. Samples received on Friday were sent to the MRL the following Monday for delivery on Tuesday. Therefore, it was unsurprising for the time between SWLP sample receipt and MRL receipt to be up to 5 days; 74% of samples were received within this timeframe. These wastes, waiting for transport and the transport itself, were clearly waste in 'lean' workflow terms.[7 8]

A TAT target for BDG testing of 5 working days had been previously published in the SWLP user handbook, based on a rapid TAT being required for optimal impact on AFS. However, a system of measuring and monitoring TAT performance had not been set up. For this QIP, we chose≥90% achievement of this 5-working-days TAT target as our main goal. This is consistent with the performance targets for other tests we conduct in the microbiology department.

Therefore, we set our outcome metrics (OMs) to be the proportion having a TAT within 5 days (OM1), with a target of≥90%, and the mean weekly TAT (OM2), with a target of≤5 days. We defined the TAT as the time between SWLP sample receipt and result authorisation using LIMS data.

We analysed 12 months of TAT performance data (1 July 2020–30 June 2021) to give an initial baseline on these metrics. The last 13 weeks of these data are shown on the left-hand side of figure 2 (baseline A) in statistical process control (SPC) format.[7 8] We tried three approaches (CIs A, B and C) over the course of 3 years. Considering the length of this period and the consequent number of datapoints, figure 2 shows three sets of baselines each 13–26 weeks, with breaks in the X-axis before baselines B and C.

Each baseline demonstrates that we failed to meet the OMs, with<1% of TATs within 5 days (vs the target of≥90%) and mean TAT>10 days (vs the target of≤5 days). Workload is a potential confounder, so we also show the weekly number of BDG tests at SWLP as an input metric (IM).

We set the two largest contributors to TAT, identified by RCA above, as process metrics: PM1 for the waste from dispatch to the MRL and PM2 for the waste from return of results. Our LIMS did not capture these timestamps. We labouriously analysed the scanned forms from April 2021 (n=70 BDG requests). Baselines were: PM1=3.0 days and PM2=3.9 days.

Given the immense budget challenges in the NHS, any net increase in unit cost could be problematic. We set this cost per test (including staff time and consumables involved in preparing, packaging/posting samples to the MRL, MRL charges and staff time for results processing) to be OM3 and calculated a baseline unit cost of £81.13.

As shown in online supplemental figure S1, sample rejection contributes to this cost. The MRL's BDG assay is a colourimetric test, so samples may be rejected if they are yellow, turbid or lysed. In baseline C, approximately, 11% of samples were rejected for these reasons (PM3=11%).

DESIGN

I (lead author, MS) have been working closely with a Consultant in Infectious Diseases at St. George's University Hospital, which has a special interest in diagnosing and managing patients with fungal infections, to improve the provision of fungal diagnostics at SWLP. Several laboratory and clinical staff, plus other operational team members, were interviewed to discuss where, in the BDG testing, pathway delays were occurring and develop the process map in figure 1.

We established a small team to discuss possible changes to test. We appreciated that sending tests to the MRL meant that there would be processes outside our control that could limit the effectiveness of our changes.

CI A: access MRL reports electronically for all BDG samples

To remove the wait for hardcopy reports from the MRL by post, we explored the possibility of electronic reporting. The MRL does not have the facility to securely email reports; instead, individual members of our staff could obtain logins for the MRL portal. They then could generate a worksheet from our LIMS of outstanding BDG results, log in to the MRL and search their portal for each individual report. The MRL's stated that mean TAT from sample receipt to report authorisation is ≤1 day; thus, factoring in overnight transport of samples from us to them, reports should be available on the portal within 48 hours of referral to us.

CI B: access MRL reports electronically for only intensive-care BDG samples

Due to the barriers encountered with electronically accessing BDG reports (see Strategy section), we reduced our ambition to instead focus just on adult patients in intensive care (approximately, 40% of requests). Here, timely results can have the greatest clinical impact.[1] We could also seek to involve Specialty Registrars (SpRs, resident medics undergoing specialty training).

CI C: in-house BDG testing

As shown in figure 2, this article covers three phases of improvement efforts over 3 years. In each phase, we considered the feasibility of bringing BDG testing in-house. On each occasion until the last (which started in late 2022), we judged it infeasible. The commercially available solutions were technically complex, thus requiring more staffing resources and the availability of clean facilities to prevent contamination with environmental glucans, which we were unable to accommodate. In addition, due to this risk of contamination, the assays available at the time were often run in triplicate, even in specialist laboratories, which significantly increased costs. In addition,

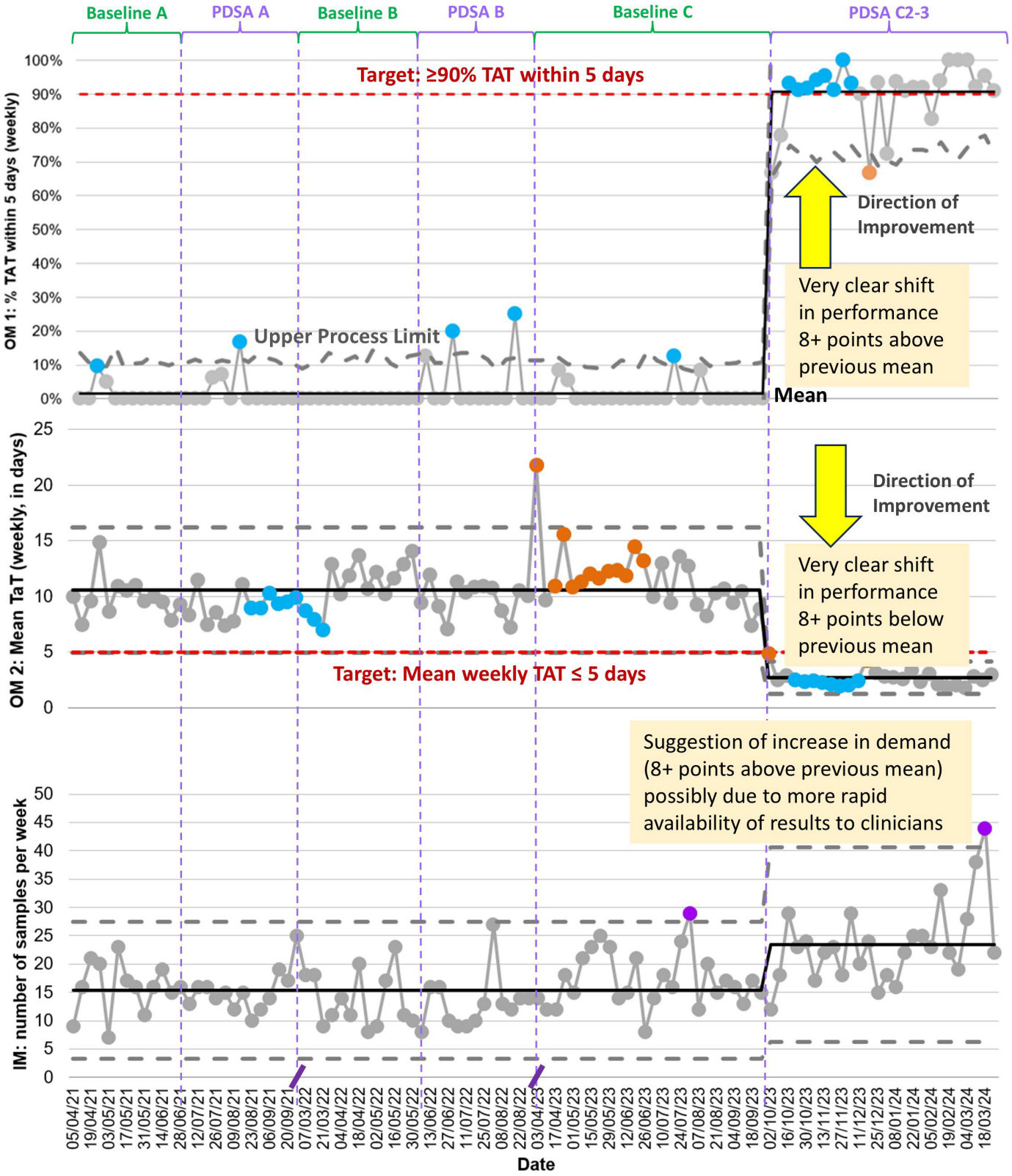

Figure 2 Stacked SPC charts of key performance metrics OM1 (weekly percentage TAT within 5 days) and OM2 (mean weekly TAT) with the number of samples tested each week as an IM. Due to the length of time between each PDSA cycle, separate baseline data are also presented prior to the implementation of each change with prior breaks in the timeline. Coloured data points are periods of unusually good or poor performance or unusual demand. IM, input metric, OM, outcome metric; PDSA, plan–do–study–act; SPC, statistical process control; TAT, turnaround time.

these assays required the preparation and inclusion of several quantitation standards in each batch, making it cost-effective only if there are sufficient samples to run full batches (as, eg, in reference laboratories). Thus, we chose to carry on sending samples for BDG testing to the specialist laboratories like 95% of laboratories in the UK at the time.

Following the failure of the first two CIs to demonstrate a viable means of attaining our targets, we decided to look again at this. We conducted an options appraisal of commercially available BDG assays to identify potential solutions that may make in-house BDG testing feasible, aware that there had been recent advances offering random access (ie, not requiring batching of samples in order to be economically viable) and relatively technically simple workflows that could be conducted and reported by lower grades of staff. Furthermore, the recent transfer of other assays to higher throughput automated platforms elsewhere in the department as a part of separate contract review work freed up laboratory staff and space.

We drew up a specification and evaluated five commercially available solutions against this. The Fujifilm Wako BDG assay fulfilled all the specification criteria; however, we would need acceptance of a business case and satisfactory local assay verification results.

As a part of the business case, we built a financial model, based on 2022/2023 prices and staff costs, and 2021 workload. In summary:

The capital outlay for the instruments would be £13 150 excluding value-added tax (VAT) (relatively cheap in the context of scientific equipment). Staff hands-on time and new expertise would be minimal, and the assay workflow would be easily incorporated into the routine laboratory setting. We suggested that staff at Agenda for Change Band 4 and above can perform this test, with technical validation and reporting performed by Health and Care Professions Council (HCPC) registered staff at Band 5 and above. Due to the simplicity of the system, there would be no additional annual maintenance costs. A saving would be that the Fujifilm Wako BDG assay is not colourimetric, so the 11% rejection (requiring repeat samples) due to samples being compromised for colourimetric testing should be eliminated. (There was also a scope for the system to be interfaced with LIMS, although we did not opt for this.)

We spread the capital outlay over a 7-year lifespan and used the 2021 workload (1217 samples per year). Including VAT, reagent and consumable costs, staff time and factoring in quality control and quality assurance processes as well as some wastage (10%) and laboratory overheads (19.37%), we calculated a cost per test of £67.14 compared with the cost of sending samples to the MRL (MRL direct unit cost, postage and packaging, and staff time to prepare samples for testing and reporting of results) of £81.13. This would be an estimated cost saving of approximately £17 000 per year.

STRATEGY

In this project, we tested three CIs over five PDSA cycles (summarised in table 1) and planned another.

PDSA A: access MRL reports electronically for all BDG samples

We obtained MRL portal logins for relevant members of our staff and trained them on searching the portal to locate reports. Electronically accessing MRL reports for all patient samples was tested from 5 July 2021. As shown in figure 2, we observed no material improvement in TAT, OM1 (TAT within 5 days) remaining about 1 or 2% (vs the 90% target), and OM2 (mean weekly TAT) remaining about 10 days (vs the 5-day target). This change was unsuccessful and so abandoned. Reasons were principally lack of staff time to generate daily worklists and interrogate the electronic portal for each outstanding result.

The way in which results are available from the MRL is unique among reference laboratories. Despite being a part of the United Kingdom Health Security Agency (UKHSA), they do not use the same electronic reporting system. The system used by the other UKHSA reference laboratories has a user-friendly interface that notifies users by email on a daily basis of new reports. When logging into the system, the new reports are immediately apparent to users. The MRL system is antiquated and not able to email users when new results are available. Users need to log in and search the portal for the results by patient. Therefore, users need to draw up a list of samples sent to the MRL with results still outstanding and manually search for each patient to see whether their results are available. Further barriers encountered included the electronic portal requiring access via the now-obsolete internet explorer 11 browser, frequent issues with portal logins and slow responses from the MRL IT team to resolve these.

PDSA B: access MRL reports electronically for only intensive-care BDG samples

To determine viability with this reduced scope, we started a trial on 6 June 2022 with intensive care at a single hospital site within the network, which accounted for 60% of intensive-care BDG requests. A microbiology SpR attending the daily intensive-care ward rounds collected the samples for testing and returned them to the laboratory for the same-day referral. Having recorded the patient details, the SpR then would daily log on to the MRL portal to access the reports.

As shown in figure 2, again no material improvement in TAT was observed. When just the test site's intensive-care BDG samples were analysed in isolation, OM1 did appear improved (from 0% to 11%) and OM2 reduced from 11.6 days to 8.8 days, but still far from our targets.

We determined that this approach was not sustainable and was, thus, abandoned. It was not a core part of the SpR role, so there were gaps in coverage due to sporadic leave following periods on-call, lack of adequate handovers and

Table 1 Summary of PDSA cycles

PDSA cycle	Plan/Prediction	Do	Study	Act
Baseline	Define metrics and targets and assess performance OM1: percentage of results each week authorised within 5 days (target 90%) OM2: mean weekly TAT (target 5 days) PM1: mean delay to receive samples at MRL PM2: mean delay to receive results from MRL PM3: sample rejection rate IM: demand for BDG testing at SWLP		OM1: 0.88% OM2: 11.6 days OM3: £81.13 PM1: 3.0 days PM2: 3.9 days PM3: 11% IM: 15.8 per week	
A1	Access MRL reports electronically for all patient samples against 'outstanding' BDG report worksheet. OM1: ≥ 90% OM2: ≤ 5 days	Staff reference laboratory portal logins obtained and training provided.	OM1: 2.02% OM2: 9.2 days IM: 15.2 per week (not robust changes under SPC rules)	OM1 and OM2 not met. Idea abandoned as not sustainable due to a number of barriers.
B1	Access MRL reports electronically just for patients in intensive-care wards by microbiology registrar at one hospital site. OM1: ≥ 90% OM2: ≤ 5 days	Registrar collected samples on daily ward round and accessed reports on reference laboratory portal daily.	OM1: 4.09% (ICU 11.1%) OM2: 9.9 days (ICU 8.8 days) IM: 15.1 per week (not robust changes under SPC rules)	OM1 and OM2 not met. Idea abandoned as not sustainable due to a number of barriers.
C1	Conduct options appraisal for in-house BDG testing, develop and submit business case.	Create specification, evaluate solutions, determine workload, deliver business case.	Appears viable on technical and cost-efficiency grounds. Predicted cost saving and improved TAT.	Business case created and accepted.
C2	Implementation of in-house BDG testing with Fujifilm Wako BDG assay, ratify laboratory verification, go live—eliminating waste of dispatch and postal return. OM1: ≥ 90% OM2: ≤ 5 days OM3: £67.14 Develop and implement IQC scheme (Preventative measure—no baseline data).	Ratification of verification report, go live on 2 October 2023. Collect patient positive samples, dilute, aliquot, store and test.	OM1: 92.8% OM2: 2.5 days OM3: £13.99 reduction in cost per test. PM1 and PM2: 0 days (eliminated) PM3: 0% (eliminated) IM: 23.4 per week (vs 17.2 in baseline C) IQC stable, measurement uncertainty acceptable. Technical performance as expected.	OM1 and OM2 met, change retained. Cease use of MRL. IQC successfully implemented. Monitor for changes in assay performance.
C3	Develop and implement EQA scheme (Preventative measure—no baseline data).	Approach another London network to participate and distribute first round of samples.	First distribution received in April 2024. 100% qualitative agreement.	Sample exchange successfully implemented. Determine criteria for quantitative agreement.

Continued

Table 1 Continued

PDSA cycle	Plan/Prediction	Do	Study	Act
C4	Improve capability to meet the 5-day TAT target. OM1: ≥ 95%	Investigate samples with TAT>5 days for further improvement.	Potential improvements identified.	Implement improvements and monitor for impact (planned QI work).

BDG, beta-D-glucan; EQA, external quality assurance; HCPC, Health and Care Professions Council; ICU, intensive care unit; IM, input metric; IQC, internal quality control; ISO, International Organization for Standardization; IT, information technology; MRL, Mycology Reference Laboratory; NHS, (United Kingdom) National Health Service; OM, outcome metric; PDSA, plan–do–study–act; PM, process metric; QI, quality improvement; SPC, statistical process control; SWLP, South West London Pathology; TAT, turnaround time; UKHSA, United Kingdom Health Security Agency; VAT, value added tax.

frequent SpR rotation. Furthermore, some hospital sites in the network did not have microbiology SpRs.

PDSA C1–3: in-house BDG testing

Our first test was to determine whether we could get a business case for the Fujifilm Wako BDG assay accepted and internally verify the adequacy of the assay in our department in terms of accuracy, precision and reproducibility. This was PDSA cycle C1. We prepared and submitted our business case to the finance team for review and ratification, then obtained final approval from the medical director, director of operations and managing director. We conducted scientific verification in October 2022. The assay was performed in accordance with the manufacturer's claims and our acceptance criteria. The results were ratified in a departmental service review meeting. After a 12-month delay due to a host of reasons (an internal review of managed-service contracts; the build, test and roll-out of a new LIMS; restructuring of laboratory workflows to make room for the BDG test instrument and the laboratory merging with another trust), we finally proceeded to implement in-house BDG testing on 2 October 2023 (PDSA C2). The supplier of the test/instrument provided full onsite training to a number of staff at different bands, and an internal competency programme was introduced in accordance with current departmental processes.

To routinely monitor the quality of the assay, we instituted weekly internal quality control (IQC) testing in accordance with International Organization for Standardization (ISO) 15189:22 standards for medical laboratories. Ideally, there would be third-party commercial material for this purpose, but there were no suppliers of such material. Therefore, we set up a system of creating IQC material by pooling and diluting residual positive patient samples to a level that was no more than two times the assay cut-off of 7 pg/mL. 20 aliquots were initially tested to determine the mean and SD. One aliquot was tested weekly for a period of 4 months to determine the stability of the IQC material and determine the measurement uncertainty. A mean of 11.758 pg/mL and SD of 0.630 pg/mL were obtained. The expanded uncertainty was calculated by multiplying the standard uncertainty (ie, SD) by a coverage factor (k) of 2 to give a value of 1.26 pg/mL. As a result, we estimated that 95% of samples with a measured value around 11.758 pg/mL would have a range of ±1.26 pg/mL (measurement uncertainty).

No external quality assurance (EQA) scheme existed for BDG testing against which to benchmark performance. The manufacturer of the Fujifilm Wako BDG assay distributes samples to the users of the assay annually, collects the results and informs users of individual performance, but gives no indication of performance compared with other users. To overcome this, in February 2024, we established a sample exchange programme with the microbiology department of another London pathology network already using this assay. This involves the exchange of three anonymised samples four times a year for testing by both laboratories. Agreement on qualitative results ('positive' vs 'negative') is essential, with discrepancies resolved by repeat testing. As PDSA C3, the first distribution of EQA samples was in April 2024, consisting of two negative and one positive sample; qualitative agreement was obtained for all three. The mechanism for determining agreement on quantitative results (concentration in pg/mL) will be determined after four rounds of sample exchange (ie, spring 2025).

As shown in figure 2 and table 1, shortly after we commenced in-house testing, we achieved our targets (OM1: ≥90% of BDG results authorised within five working days of receipt and OM2: mean TAT≤5 working days). We have had no samples rejected (PM3=0) since the change (vs 11% previously due to colourimetric assay issues).

RESULTS

Through this QIP, we improved the proportion of BDG sample results authorised within 5 days of receipt (OM1) from below 1% to 91% (figure 2, top) and improved the weekly mean TAT (OM2) from 11.6 to 2.7 days. If we exclude the first 2 weeks of PDSA C2 (as a transition period) and the week up to Christmas 2023 (the orange special cause (non-random poor performance) point),[35] OM1 was 92.8% and OM2 2.5 days.

We can see that BDG workload was largely stable prior to the move to in-house testing at PDSA C2 (IM, bottom SPC chart in figure 2). SPC rules for a shift[35] suggest that BDG demand increased by over 50% at around this time. We have nevertheless sustained the improved

performance on our OMs. This increase in demand may be a consequence of results being available to clinicians within a timeframe useful for their decision-making about antifungal therapy for their patients.

It is unlikely that the SARS-CoV-2 pandemic and its aftermath had a significant impact on BDG TAT performance, as although the UKSHA MRL reported a 300% increase in BDG testing requests, driven by increasing awareness of the possibility of COVID-associated pulmonary aspergillosis in critically ill patients, they reported a reduction in their (internal) TAT compared with prepandemic levels during this challenging period.[33]

We have achieved a huge improvement to our BDG testing service, but we note that the SPC chart for OM1 (figure 1, top) indicates that, though we achieve 90% on average, we are not statistically capable of doing this reliably every week since the lower dotted grey line (the lower process limit that indicates the extent of random variation) is at around 70%. (The middle graph indicates that we are capable of meeting the OM2 target of weekly mean TAT≤5 days.)

We continue to seek to improve performance on OM1, with a more-demanding stretch target being ≥95% TAT within 5 days. To this end, we have continued RCA. In the 6 months following the start of PDSA C2, excluding the two initial weeks and Christmas week (as above), 40 of the BDG, 555 samples (7.2%) had a TAT>5 days. Delayed BDG result authorisation occurred in 27.5% of these cases due to galactomannan (another fungal biomarker) also being requested for that sample. As noted in the Background section, galactomannan testing was previously also referred to the MRL, but brought in-house in 2021 using a simple lateral flow device in an attempt to circumvent the same issues regarding MRL TATs. Galactomannan is currently only tested in-house once a week, in a different section of our laboratory, due to increased workload following a recent contract with another NHS Trust impacting the staffing resource in this section. This is the red-shaded delay for other serology tests towards the upper right of the process map in figure 1. Following discussions with laboratory and clinical leads, we plan to colocate galactomannan and BDG testing in the same laboratory section. This is planned as PDSA C4, subject to the purchase of additional small pieces of laboratory equipment and staff training. However, staff changes and workload are also major barriers to implementing and analysing this further refinement of CI C.

While we are confident that the unit cost of BDG samples is now robustly lower, the annual saving may be lower than the £17 000 predicted. That figure was based on the 2021 demand of 1217 tests. However, subsequently, demand has been lower: 2022 731; 2023 854 and 2024 1099 (predicted based on figures to 30 September 2024). This is possibly due to fewer critically ill COVID-19 patients with suspected COVID-associated pulmonary aspergillosis, although the demand is now increasing. The simplicity of the test workflow permitted rapid acceptance and adaptation into the existing laboratory workflows by staff already performing similar tests. With the send-away process, Band 7 BMS staff were responsible for reporting the results received from the MRL, but these senior staff had little protected time for this due to their other responsibilities. The in-house testing of BDG can be run by lower grade staff, who have had time released by automation of some other tests. This makes staffing sustainable and more available than previously.

The test instrument is compact and has proved to be easy to use and without the need for time-consuming maintenance. Since going live with in-house testing, we have experienced no technical issues with the instrument or performing the assay. Ongoing satisfactory performance on IQC and sample exchange demonstrates the sustainability of quality of the assay results.

There has been no observed detrimental impact on other services provided within the section of the laboratory performing BDG testing. In fact, by colocating serum galactomannan and BDG testing, we expect to further improve the services for both of these assays. This will also alleviate staffing pressures in the laboratory section currently performing galactomannan testing. Implementation of this was delayed at the time of this QIP due to unrelated changes elsewhere in the department.

Work is planned to determine the impact of this QIP on AFS by investigating antifungal prescribing in intensive-care pre- and postchange to in-house testing and also on demand optimisation for BDG testing to ensure that testing is requested appropriately.

BDG testing has been brought in-house from the MRL, as we had done earlier for galactomannan. We would like to extend this to the third test we most frequently sent to the MRL (though also low volume in absolute terms): antifungal susceptibility testing for yeasts. While manual/semiautomated systems are available, we have not yet found a commercial solution or panel that will run on our existing equipment, that is viable in terms of staff resource and purchase cost, and our service-level agreements have compounded this. However, this remains under review periodically.

LESSONS AND LIMITATIONS

We tested three CIs in this QIP, the first two of which had no effect on improving our OMs. CIs A and B tried to improve the existing process by accessing MRL results electronically. Neither of these CIs was successful due to limitations of both the MRL's portal and SWLP staffing resource. It is disappointing that poor and fragmented IT in the NHS is a common barrier to efficient workflows.

CI C, setting up in-house BDG testing, only became possible once suitable and cost-effective technical solutions were commercially available. Once implemented, CI C was readily adopted by laboratory staff and our pathology operational leads received very positive feedback from our clinical teams and antifungal steward.

Increasing centralisation of pathology services into NHS pathology networks and innovation in laboratory

diagnostics has permitted the cost-effective repatriation of some of the testing previously sent to reference laboratories. While our laboratory provides microbiology services to several hospitals across South West London and Surrey, it is based at a large London teaching hospital that provides specialist infectious diseases services and often deals with complex and relatively rare types of infections. However, the increasing use of invasive procedures and immunosuppressive regimens for the treatment of a wide range of conditions is resulting in fungal infections becoming more common, for example, the 100-fold increase in demand for BDG testing at the MRL noted in the Background section. These increasing volumes, along with technical developments, will increase the viability of widening in-house testing for more NHS pathology service users. We are aware of several NHS pathology networks that have also implemented this same BDG assay. A simple financial model, as outlined in the Design section, can be used to estimate the break-even point where the volume of tests locally would make in-house testing viable.

This project gave me (MS) their first opportunity to use newly acquired QI knowledge and apply the MfI framework, which proved to be a useful approach they will use in future projects. Several factors led to the extended length of time over which this project was conducted, including available staffing resource due to turnover; managed-service contract review; build, test and roll-out of a new LIMS; restructuring of laboratory workflows to make room for the BDG test analyser and the laboratory merger with another trust. We noted plans to continue trying to improve our BDG pathway, including a planned PDSA C4, and that, as often in the NHS, staffing and workload are constraints on this.

CONCLUSION

There is increasing demand for fungal diagnostic testing in microbiology, and most of this work has been performed by central reference laboratories. The need for these results to be available to clinicians within a timeframe to usefully inform patient management and enable good AFS led us to explore ways to improve TAT using QI approaches. Due to limitations with accessing reference laboratory results and the demand this put on our staffing resource, we concluded that it was not feasible to improve the send-away BDG service, so we ultimately implemented in-house testing once a suitable commercially available solution became available. This enabled us to rapidly achieve our main goal of providing≥90% of results within the 5-working-day TAT target and at lower unit cost. Ongoing QI work suggests opportunities to further improve our in-house BDG testing, and these are being investigated.

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