original article

Implementation of total laboratory automation at a tertiary care hospital in Saudi Arabia: effect on turnaround time and cost efficiency

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BACKGROUND: Total laboratory automation (TLA) is a relatively new way of improving the management of high volume clinical laboratories. TLA may reduce staff, reduce operating costs, decrease testing time and provide enhanced process control.

OBJECTIVES: Establish a cost efficient TLA that is less labor intensive, improves productivity and reduces turnaround time (TAT).

DESIGN: Implementation of TLA for random glucose and troponin-T as sentinel tests to compare change in TAT.

SETTING: Tertiary hospital with high volume of laboratory tests.

METHODS: Routine patient samples for random glucose and troponin-T were used to capture TAT. Information on staff grades and schedules before and after implementing the TLA, and cost of contracts to deliver the service were collected.

MAIN OUTCOME MEASURES: TAT, cost efficiency, and reduction in labor.

RESULTS: The consolidation of contracts resulted in a reduction of 28.8 million SAR in direct costs. Staffing cost was reduced by 1.14 million SAR with less senior staff required; there were reductions in staff at both senior and junior level. The overall TAT for all tests was reduced by 32% in 2016 (after TLA implementation) compared to 2012 (before TLA implementation). The median TAT for random glucose tests was reduced by 21% (to 55.7 minutes in 2016 from 70.1 minutes in 2012). Evidence of test optimization by exploring the impact of stat tests, auto-dilutions and reruns on the overall TAT of the TLA is shown by comparing troponin T TATs after reclassifying stat tests (in 2016) to routine (in 2017). At the 75th percentile, there was a 27% reduction in TAT when comparing August 2016 to March 2017 with a 19% reduction in median TAT.

CONCLUSION: By moving from stat to routine assays, the TAT was reduced, which is counter-intuitive. The use of stat assays slowed down the performance of the TLA. A careful review of the mix of assays should be conducted to maximize performance and to ensure that the system delivers what is required.

LIMITATIONS: Room for improvement by systematically analyzing and reviewing the impact of making minor changes that could have significant impact on TAT.

CONFLICT OF INTEREST: None.

Total laboratory automation (TLA) is relatively new way of improving the management of high clinical laboratory workloads, but there is scant literature to support wide adoption in Saudi Arabia. Due to reductions in financial and human resources, many laboratories have merged services with fully automated, connectable laboratory analyzers leading to the creation of automated core facilities. The evolution of automated core facilities has been delivered successfully in clinical chemistry and hematology.[1-3] The early adopters of such consolidation of services have demonstrated that implemented changes resulted in less staff, reduced operating costs, more rapid testing and better enhanced process control.[4]

The Department of Pathology and Laboratory Medicine (DPLM) provides a full suite of diagnostic services to King Faisal Specialist Hospital and Research Centre in Riyadh, Saudi Arabia including a reference laboratory service. The laboratory services support the complex needs of highly specialized and demanding clinical facilities for organ transplantation and oncology. Before initiating the project, the DPLM provided 13.5 million tests in 2012 with a growth rate of 7% year over year. Of these tests, more than 3 million were processed through areas of the laboratory that lent themselves to being part of an automated core facility that was targeted for an automation solution. We were asked by hospital administration to grow and be able to transform to a not-for-profit commercial entity, generating revenue and transforming from a cost center to a profit generating center.

To transform the service to a new model required in-depth analysis of the current and historical situation. Armed with this data, the DPLM leadership teams were able to create a strategic plan with aligned project streams and named individuals who were responsible for key areas of the project. At all stages of the transformation the focus was on quality, with the ethos being that a relentless focus on quality would decrease costs and result in the liberation of resources, which were trapped by suboptimal processes. These 'trapped' funds could then be used to self-fund income generation plans. We present the results of a plan that started in 2010 to imbed lean principles and business process re-engineering to drive the realization of a new strategic plan and to consolidate the existing services and grow the potential for self-funded income generation. We report on the impact of the automated core facility, focusing on chemistry and immunoassay tests.

METHODS

After more than 4 years of planning and preparation, a vendor and equipment were selected for the automation of hematology, chemistry and serology, which represented 73% of the total DPLM tests. The contracted vender implemented 1) the cobas 8000 modular analyzer series from Roche Diagnostics Middle East for chemistry, serology and preanalytical sorting of postanalytical storage devices; 2) Sysmex XN for hematology with a full slide maker and stainer and sample storage on a single track; 3) Cellavision for automation of morphology of blood films; and 4) Stago Evolution with Stago R Max for coagulation. These instruments were aligned to create an automated core facility, or TLA, which encompassed preanalytical processing, automated chemistry, immunoassay, serology, infectious diseases and postanalytical storage. The TLA was connected with middleware for various IT activities. The middleware interfaced with the hospital information system (Cerner Millennium). We report on the impact of TLA, focusing on chemistry and immunoassay. In October 2012, the DPLM began to implement the TLA, which went live partially in 2013 and was completed in 2016. The contract consolidation that underpinned the TLA was crafted to deliver on the following core objectives: cost efficiency, reduced labor intensity, matching capacity and demand with the appropriate grade of staff based on the skill-mix, increase productivity and capacity, and reduce turnaround time (TAT) and improve predictability (reduce variation). The plan for transformation was created in terms of milestone deliverables by teams with named individuals who were responsible for key project streams. The cadences of meetings were set as follows: daily for key tasks and challenges, weekly for updates and monthly for project steering reviews and input.

Data for analysis and comparison was captured on TAT for tests performed on the TLA, staff grades and schedules before and after implementing the TLA, cost of contracts to deliver the service, and subsequent opportunities to improve outcome by setting rules for auto-dilutions, re-runs and choice of an assay as stat or routine. Time stamps were compared before and after the TLA implementation with routine tests for random glucose and troponin-T chosen as sentinel tests to compare TATs. These two tests were chosen as sentinel tests because they are common, high volume examples for both routine and stat service. Routine tests are reported within 120 minutes and stat tests within 60 minutes in the main laboratory. Whisker boxplots present TAT by receipt hour of the day for 2012 and 2016 for random glucose tests. We also compared data points between 2016 and 2017 for the combined TAT for all tests (clinical chemistry, serology and immunoassay), when an optimization project was instigated to explore additional benefits that could be yielded by reducing the number of auto-dilutions,

re-runs and to quantify the impact of stat assays on TLA performance. The DPLM provides laboratory diagnostics services from satellite laboratories and the main lab where the TLA is located. Troponin-T is provided as a stat test in the emergency laboratory; this test is also provided on a routine basis in the main laboratory on the TLA. We reviewed the type of assay kits in the TLA (stat and routine) and measured the impact of changing assay mix on TAT. This data was then used to establish key performance indicators at the busiest time of the day, when the TAT was poorest.

The financial impact of the transformation was calculated for direct costs such as staff grade and number of staff required before and after, and cost of delivering the physical solution such as reagents and service costs. We moved from individual contracts to a guaranteed price per reportable result (GPPRR) contract. In a GPPRR contract, the cost of calibrators, controls and analyzers are factored into a test price and volume data is submitted to initiate payment to the vendors. In a GPPRR financing model, the risk and initial outlay is borne by the vendor and funds are paid retrospectively.

RESULTS

There was a steady increase in volume of work from 2012 to 2017, with an average increase of 7% year over year growth, with greater than 17.9 million test results forecasted for 2017 (**Figure 1**). An analysis of workload distribution indicated 11AM as the busiest time of day for random glucose tests in 2012 and troponin T in 2016, as reflected by the median TAT values at that time. The data are in keeping with the current service level agreements for stat (horizontal line at 60 mins) and routine (horizontal line at 120 min) (**Figures 2 and 3**). The median TAT for random glucose tests was reduced by 21% from 70.1 minutes in 2012 to 55.7 minutes in 2016 (the data set was not truncated).

There was a 32% reduction in combined test TAT for all tests performed on the TLA (clinical chemistry, serology and immuno-assay) before 2012 and after 2016 the TLA implementation (**Figure 4**). Given the narrowing of the minimum and maximum TAT ranges in 2016, the predictability indicates that service level agreements (1 hour for stat and 2 hours for routine testing) were met in 2016.

During the month of August 2016, TATs for 1047 troponin T samples from time of collection to result were a median (IQR) of 64.9 (44.2-105.5) minutes (**Figure 5**). After reviewing and changing 11 of the stat kits to routine in the TLA in March 2017, the TATs for 1064 troponin-T samples were a median (IQR) of 52.4 (39.5-76.8) minutes (**Figure 6**). At the 75th percentile, there was a 27% reduction in TAT when comparing August 2016 to March 2017 with a 20% reduction in median TAT. At the busiest time of the day for the laboratory (11:00 am), there was an improvement in median TAT of 63 minutes, 141 down to 78 minutes which is a 45% reduction. In addition to changing assay kits from stat to routine, we also removed unnecessary auto-rerun rules which had been set historically. The theoretical TAT of stat assays ranged from 4-7 minutes as compared to routine tests of 10 minutes (for a range of common tests including glucose, urea, total protein, and amylase). Changing from stat to routine assays counter-intuitively reduced the TAT.

The financial impact of the TLA was achieved by contract consolidation (5 contracts reduced to 1), headcount reduction (6 less full time staff required), staff skill mix change (fewer senior staff required) and enhanced medical value with the ultimate goal of more efficient use of clinical staff time. The changes in staffing yielded a cost improvement of 1.14 million SAR per year while consolidation of contacts resulted in a direct cost reduction of 28.8 million SAR.

DISCUSSION

The DPLM has been accredited by the College of American Pathologists every year from 1984 and was the first medical laboratory in the Middle East to be accredited by this body. The complex nature of TLA requires intensive management from the beginning

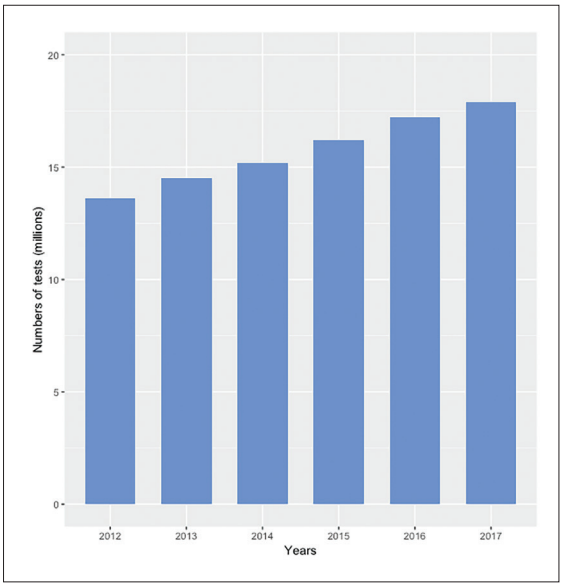

Figure 1. Test numbers annually from 2012 to 2017 in the Department of Laboratory Medicine (2017 is projected, based on numbers as of 1 September 2017). The workload increased by 7% (year on year growth).

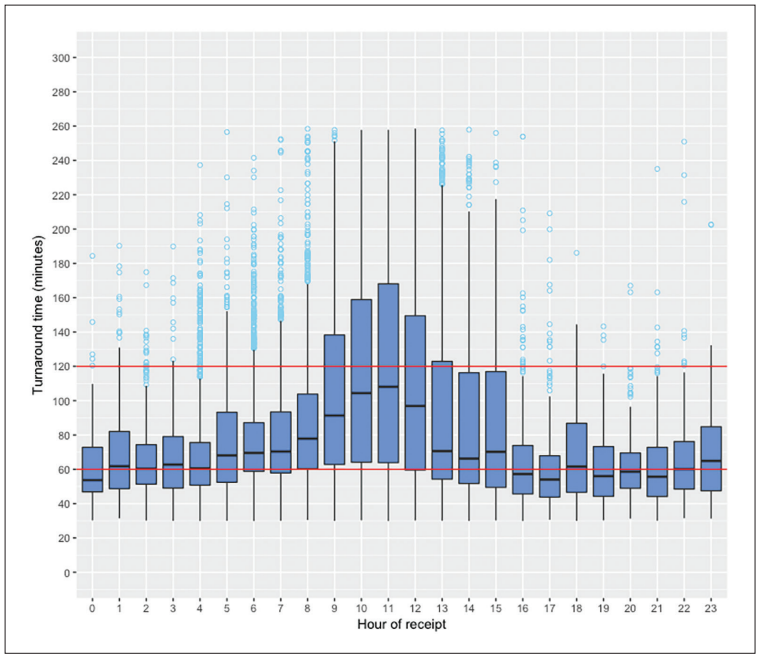

Figure 2. Random glucose turnaround time during March 2012 (before the installation of total laboratory automation) from sample collection to result availability. The horizontal lines are 60 (stat) and 120 minutes (routine) (median, interquartile range, blue circles=outliers).

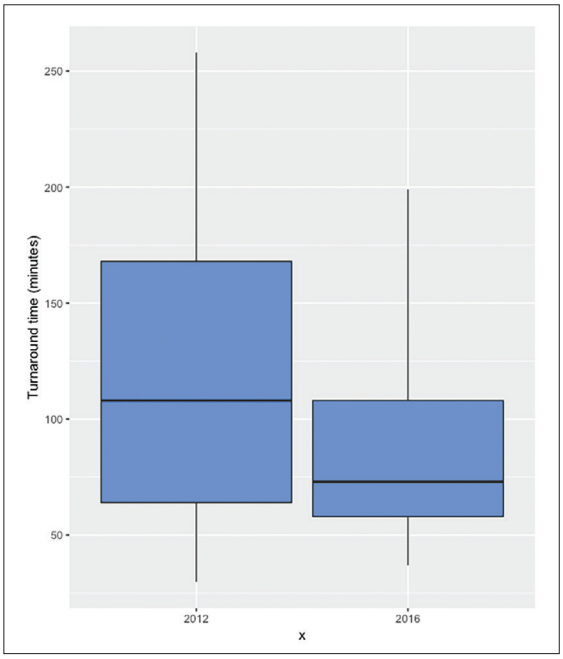

Figure 4. Turnaround time and improvement in predictability for all tests performed on the TLA (clinical chemistry, serology and immuno-assay) before 2012 and after 2016 implementation of total laboratory automation (median, interquartile range, and outliers).

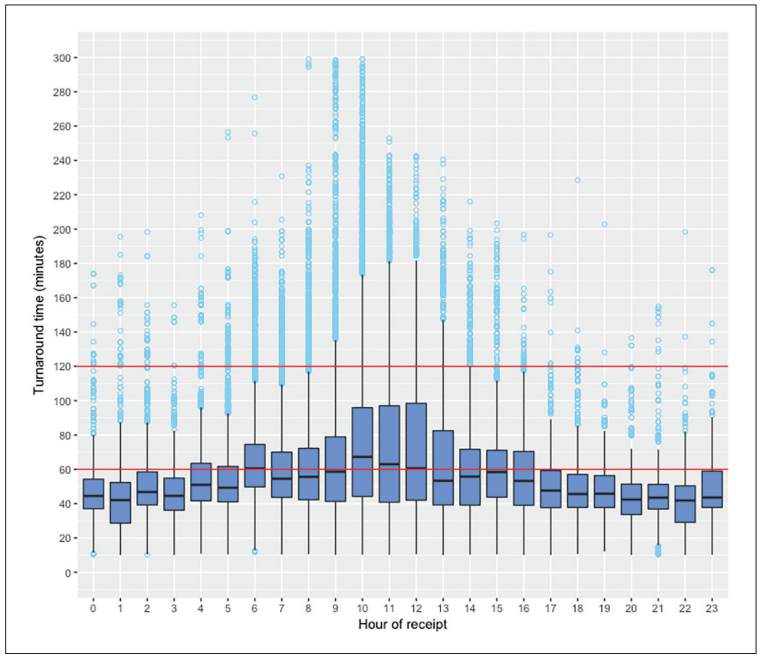

Figure 3. Random glucose turnaround time during March 2016 (after the installation of total laboratory automation) from sample collection to result availability. The horizontal red lines are 60 (stat) and 120 minutes (routine) (median, interquartile range, blue circles=outliers).

to end of the process, ensuring that the benefits and risks of actions (or inaction) can be thoroughly assessed to provide optimal service delivery. The delivery of a TLA was embraced by the department because of the significant and obvious benefits of improvements in quality, TAT, reduction in hands-on staff time and improvements in end-user satisfaction. It was critical to model and evaluate the potential impact of a TLA in a large production environment to manage the risks associated with change. While vendors offer support by way of simulation tools, it is important to explore real world examples of actual delivery. Not all laboratories will benefit in the same way; size matters as does complexity requirements. It is well documented that in small volume production environments, front loading an analyzer produces a result more quickly than does loading an automated track.[2] Our focus was on quality in a high volume production environment; so we kept desired outputs in focus and created performance metrics so that we were able to measure the impact of our actions and correct course where necessary, using data to drive decision making. Hawker describes practical considerations to consider to be thought through before embarking on a TLA consolidation project;[3] many of these are intuitive and were considered in our design plan.

Informatics functionalities were key considerations

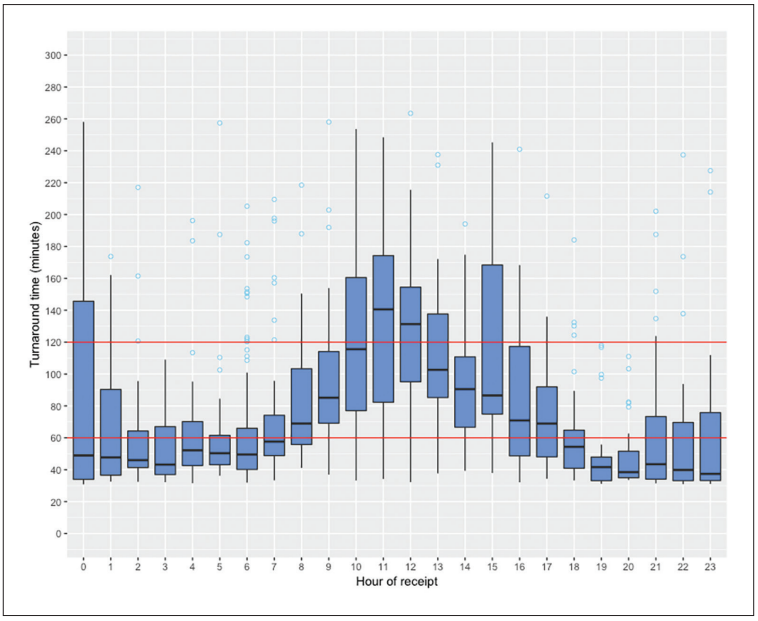

Figure 5. Troponin T turnaround time in minutes by hour of the day for the month of August 2016. The horizontal red lines are 60 (stat) and 120 minutes (routine) (median, interquartile range, blue circles=outliers).

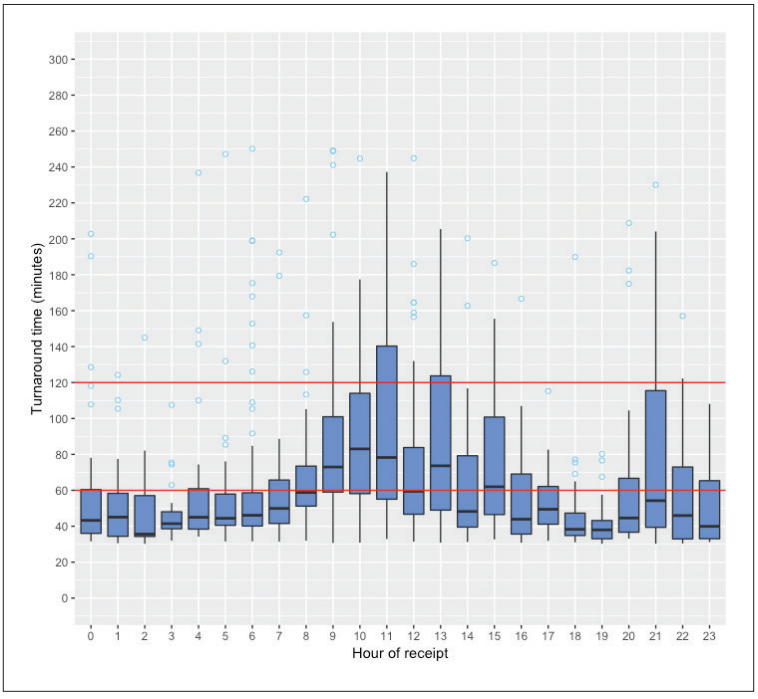

Figure 6. Troponin T turnaround time in minutes by hour of the day for the month of March 2017. The horizontal red lines are 60 (stat) and 120 minutes (routine) (median, interquartile range, blue circles=outliers).

in our final selection as we viewed IT solutions as enablers in the development of robust services within a highly complex laboratory environment. By embracing technologies such as electronic requesting (since 1992) and using automated document control systems (using SoftTech software) we had many process variables minimized so that we were able to focus on the quality aspects of the services. Our experience in electronic requesting is similar to that of Dogether et al[4] who describe clearer, more accurate, and understandable information being yielded when automation is adopted (where only a third of their forms were readable prior to the implementation of an IT solution); informatics capabilities are foundational for robust end-to-end value stream management.

In the middleware we built comprehensive logic rules such as delta checks (comparison of the current result(s) to the previous result(s) from the same individual using a specified cutoff value) and reflex testing to enable auto-verification/auto-validation of results which enables the staff to focus on abnormal results and more complex tasks. Lou et al describe the benefits of auto-verification, but they describe a negative impact on the TAT from sample collection to reporting.[5] We had a 32% reduction in TAT and improvement in predictability from before (2012) and after (2016) TLA implementation, which included the implementation of auto-validation rules. Our findings are in-keeping with Li et al who reported improvements in TAT and a better handling of abnormal results which led to an improvement in patient care.[6] We routinely process 4600 blood tubes through our TLA per day. Effective workload management using technology yielded free staff time, which was spent on activities that add maximum medical value. In addition to savings in direct costs, by improving predictability and reducing TAT, we increased the medical value of the service provided, which has contributed to more timely diagnosis, treatment and discharge. The efficiency of clinical staff was enhanced because they had confidence that the result would be there on time, which reduced phone calls about the status of results as the service became more predictable. A TLA, with integrated robotics and IT solutions, is becoming crucial to simplify operations, both reducing manual reliance and maximizing patient safety. The percentage reduction in TAT by percentiles indicates that even after going live with a TLA for more than 4 years, that there was still room for improvement by systematically analysing and reviewing the impact of making minor changes that may have significant impact on TAT.

Dolci et al asked whether stat tests still matter.[7] We have worked to improve our TAT (32% reduction in median TAT overall from sample collection to result availability) but are now at the stage of diminishing returns. Therefore, we have identified other approaches (using Six Sigma methodology) and have active programs underway to move towards a service whereby routine will be 1 hour (95% of all tests completed in 60 (±5) minutes. Once we achieve this, we will move from a 2-tiered stat and routine service to 1 service that is 1 hour (on time every time). Our goal is to eliminate the need for a stat service, but we are not there yet.

Transformation of services is a long journey which requires focused discipline. Our experience with the transformation to a TLA has been positive, resulting in effective and efficient service delivery while enabling huge potential for additional work and income generation, with the keys to success being strong leadership, robust change management and clear performance metrics. Our data have demonstrated that by moving from stat to routine assays, the TAT was reduced, which is counter-intuitive; the use of stat assays slowed down the performance of the TLA. A careful review of the mix of assays should be conducted to maximize performance and to ensure that the system delivers what is required.

Table 1. Troponin-T specific data comparing TAT in minutes before and after changing 11 assays from stat to routine (August 2016 and March 2017).

	2016	2017	% reduction
Minimum	31	30	3%
25th percentile	44	39	11%
Median	65	52	19%
75th percentile	105	77	27%
Maximum	263	250	5%
Total count	**1047**		

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