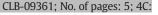
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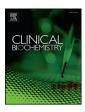
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Evaluation of the impact of a total automation system in a large core laboratory on turnaround time

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ABSTRACT

Background: Growing financial and workload pressures on laboratories coupled with user demands for faster turnaround time (TAT) has steered the implementation of total laboratory automation (TLA). The current study evaluates the impact of a complex TLA on core laboratory efficiency through the analysis of the In-lab to Report TAT (IR-TAT) for five representative tests based on the different requested priorities.

Methods: Mean, median and outlier percentages (OP) for IR-TAT were determined following TLA implementation and where possible, compared to the pre-TLA era.

Results: The shortest mean IR-TAT via the priority lanes of the TLA was 22 min for Complete Blood Count (CBC), followed by 34 min, 39 min and 40 min for Prothrombin time (PT), urea and potassium testing respectively. The mean IR-TAT for STAT CBC loaded directly on to the analyzers was 5 min shorter than that processed via the TLA. The mean IR-TATs for both STAT potassium and urea via offline centrifugation were comparable to that processed by the TLA. The longest mean IR-TAT via regular lanes of the TLA was 62 min for Thyroid-Stimulating Hormone (TSH) while the shortest was 17 min for CBC. All parameters for IR-TAT for CBC and PT tests decreased significantly post-TLA across all requested priorities in particular the outlier percentage (OP) at 30 and 60 min.

Conclusions: TLA helps to efficiently manage substantial volumes of samples across all requested priorities. Manual processing for small STAT volumes, at both the initial centrifugation stage and front loading directly on to analyzers, is however likely to yield the shortest IR-TAT.

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1. Introduction

Laboratory automation has been the cornerstone of many clinical laboratory services since the mid 1970s and over the decades this field has witnessed major technological transitions. Further advancement in conceptual design has emerged into a functional system known as 'total laboratory automation' (TLA). The ability to integrate all steps of sample processing from pre-analytics through to post-analytics via sophisticated mechanics and software is what characterizes TLA. A greater scope of efficiency is realized by the ability to consolidate analyzers from multiple disciplines onto a single system providing a seamless core laboratory. The consequential benefits of such a system

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reach far beyond just laboratory services and include amelioration on both the quality and economic levels. With financial constraints on the rise in healthcare systems, such investments are much needed. The use of these TLA systems is therefore expanding due to the growing recognition of their value in improving the efficiency of laboratory services [1–4].

The Department of Pathology and Laboratory Medicine (DPLM) is part of the Nova Scotia Health Authority Central Zone (NSHA-CZ) that provides services to nine hospitals and dozens of community health centers. It consists of one primary laboratory located in the Victoria General Hospital (VGH) of the Queen Elizabeth II Health Sciences Centre (QEII HSC) as well as four Rapid Response Laboratories located throughout the Zone. The QEII HSC is a large acute tertiary hospital and provincial referral center. It consists of two hospital sites: the main one being the VGH which houses non-emergency and specialized inpatient units and outpatient clinics. The installation of a comprehensive TLA multidisciplinary system in May 2015 at the VGH site was a major project that took over two years to complete. Since then, the impact of this system on improving turn-around time (TAT) and overall efficiency of laboratory services is becoming increasingly more apparent.

Angeletti et al. [1] recently reported on the TLA that had been newly installed in their laboratory in Rome, Italy. This TLA combined chemistry,

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Abbreviations: TAT, turnaround time; TLA, total laboratory automation; DPLM, Department of Pathology and Laboratory Medicine; NSHA-CZ, Nova Scotia Health Authority Central Zone; QEII HSC, Queen Elizabeth II Health Sciences Centre; VCH, Victoria General Hospital; LIS, laboratory information system; IR-TAT, In-lab to Report Turnaround Time; IOM, input/output module; CBC, Complete Blood Count; PT, Prothrombin time; OP, outlier percentage; TSH, Thyroid-Stimulating Hormone; ED, Emergency Department; ICU, Intensive Care Unit.

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hematology and coagulation analyzers, yet its size and complexity did not appear to be comparable to our system. The VGH automation layout described here could possibly be the largest and most complex of such systems reported to date. The present study evaluates the efficiency of our state-of the art automation system within a large core laboratory, by analysis of the TAT for STAT, urgent and routine samples. These results may provide valuable information and benchmarks for other laboratories that plan to implement a TLA system and also guide vendors on improving newer generations of automation systems.

2. Materials and methods

2.1. Laboratory setup

The VGH laboratories are located within a multi-storey building which comprises all pathology divisions. Prior to the implementation of the TLA system, most inpatient and outpatient samples were registered and processed in the accessioning area located on the main entry floor. Samples were then delivered to the testing site of each division, namely Hematology, Immunology, Microbiology and Clinical Chemistry, all on separate floors. In early 2013, the establishment of a core laboratory with TLA as a major and critical component was initiated in an effort to create a multidisciplinary layout encompassing previously mentioned divisional analyzers with enhanced efficiency of sample processing and testing. In May 2015, the complete layout of the TLA system was achieved, and the integrated automation system currently processes over 1.8 million tubes and produces over four million test results per year.

2.2. Total laboratory automation system

The initial step towards this huge project was the installation of the accelerator APS a3600 total automation track system (Inpeco SA, Lugano, Switzerland) in an open plan renovated area. Analyzers from the various laboratory disciplines (Chemistry, Immunology, Microbiology, Hematology and Coagulation) were constructed around and linked to the track. The layout and brief description of the TLA and each component connected onto the track system are shown in Table 1. The data management system (DMS) receives the orders from the laboratory information system (LIS, Cerner Millennium) and monitors the state of operations of the associated modules of the TLA. Results from the analyzers are then relayed to and managed by Instrument Manager Middleware (Data Innovations) that is interfaced with the LIS.

2.3. Data on turnaround times

To evaluate the efficiency of the APS a3600 TLA, data were collected for the In-lab to Reporting turnaround time (IR-TAT) from the time when samples were loaded onto the input/output module (IOM) to the time when results were verified by the LIS. Five representative analytes: potassium, urea, Thyroid-Stimulating Hormone (TSH) and Complete Blood Count (CBC) were selected for this purpose. Examining these particular tests ensured that five different test principles were captured, each generated by the different types of analyzers that were connected to the TLA track in varying distances. The analysis of IR-TAT was carried out based on data for the post-TLA period of January 2016–March 2016. By this time the definitive automation layout had been reached and general stability of the whole system and processes had been achieved.

In order to comprehend the impact of TLA on IR-TATs, comparison studies on the IR-TAT of CBC and PT testing during pre- and postautomation periods were performed. The corresponding pre- automation period that IR-TAT was examined for these tests was from October 2013– December 2013. The choice of this timing corresponds to the fact that the new analyzer platforms for these tests commenced January 2014, before TLA was implemented.

Table 1

TLA layout and brief descriptions of each component connected to the TLA.

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Module	Description/unit	Number
Input/output module	720 samples loading/unloading capacity; processing 800 tubes/h; identification of the type of tube, barcode reading, interaction between operator, automation through a graphical interface, and tracking operations in progress in the tubes	2
Centrifuge module	Processing 320 tubes per hour; 4500 RPM for 6 min; automates the centrifugation of the samples	3
De-capper module	Processing 600 tubes per hour; automates removal of screw caps and pressure caps from the tubes	2
Re-sealer	Processing 800 tubes per hour; allows an automatic heat seal of the tubes with aluminum foil after the analytic process	1
De-sealer	Processing 800 tubes per hour; automates removal of seal from the tubes that need to be rerun	1
Tube storage module	Automated refrigerated storage capacity 15,360 tubes; stores tubes, processed automatically, which can be recalled at the request of a user and discarded after a default and configurable time.	2
BIM (bulk Input module	Processing 1000 tubes per hour; automated sample input processing	1
Aliquoter	Processing 500 tubes per hour; provides the possibility to aliquot and generate secondary tubes from the primary tube	1
Track section	Processing 3600 tubes per hour; U turn track allows rapid divert module; total tube traveling distance is 97 m long and traveling time is 9.5 min. Entire TLA occupies an area of 3000 sq ft.	1
Architect c16000	General chemistry analyzer	3
Architect i2000	Immunoassay analyzer	5
Sysmex XN1000	Hemotology analyzer	3
ACL TOP 700 (IL)	Coagulation analyzer	2

Prior to the implementation of TLA, samples for Hematology tests were delivered to the division, the specimens were then manually scanned confirming receipt by the testing site and the receipt time was recorded in the LIS. Therefore, the receipt to reporting TAT for CBC and PT tests corresponded to the IR-TAT of the samples that were processed by the TLA when this system came into place. During the pre-TLA periods, sample check-in, centrifugation and loading onto analyzers were all performed manually, according to the priority of the test requested. The laboratory TAT from phlebotomy to reporting had then been monitored accordingly, to determine if the goals dictated by our protocols are being met, namely: 1 h for STAT, 3 h for urgent and 8 h for routine samples and an outlier percentage rate <10% for each type of priority.

After implementation of the TLA system, a distinct workflow was set for each of the three priority requests:

- STAT: samples for CBC testing are manually scanned for check-in to the core laboratory, and then directly front loaded on to the analyzers. Samples for Chemistry tests (potassium and urea) are centrifuged offline and then loaded on to the priority lanes of the IOM of the TLA. Samples for STAT PT testing are treated the same as the urgent samples, described below.
- 2. Urgent: samples are loaded onto the priority lanes of the IOM and the TLA is programmed to prioritize these samples for uploading on to the track and for centrifugation. This process is applied to analytes such as STAT PT as well as urgent requests for potassium, urea, CBC and PT.
- 3. Routine: samples are loaded on to the regular lanes of the IOM; this applies to all routine requests including all those for immunoassays, such as TSH.

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