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Improving Laboratory Turnaround Time in a High Throughput Medical Laboratory

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Abstract

One measure of efficiency in a diagnostic laboratory is promptness in producing results. With this in mind, turnaround time (TAT) has become a conspicuous indicator reflecting a lab's efficiency. Delays in TAT in a high throughput laboratory such as Quantum Diagnostics were identified in July 2017.

Aim: This study aims to investigate the root cause of the delay and develop corrective actions to improve work processes that could potentially improve TAT.

Materials and Method: Urgent and non-urgent tests TAT which includes H. pylori and EBV tests alongside routine biochemistry were collected from July 2017 till January 2019. Prior to August 2017, samples were run for biochemistry tests on Cobas 8000 (Roche Diagnostics, Germany) prior to processing serology H. pylori (Immulite 2000, Siemens) and EBV (Snibe, BMS) tests. Delayed TAT was identified to originate from a holdup at the biochemistry section. Work processes were then reorganized to prioritize serology tests first, where samples were loaded on respective analyzers and transferred to the biochemistry analyzer immediately upon aspiration of samples. In addition, installation and activation of 1) p512 pre-analytical system, 2) two Cobas 8000 modules and upgradation and installation of additional endocrine modules was done to improve throughput time.

Results: Percentage TAT achieved for urgent and non-urgent tests were 39.75% and 60.57% respectively in July of 2017. Subsequent TAT achieved in the following months from September 2017 to January 2019 has demonstrated significant improvement in QI which the percentage TAT achieved for urgent and non-urgent was 95.5% and 90.0% respectively in January of 2019.

Conclusion: Lab indicators are important to identify poor work processes and formulating plans to overcome them improve TAT significantly.

Keywords: Turnaround time; TAT; Urgent tests; STAT; Key performance index; KPI; Lab indicators

Abbreviations: TAT: Turn Around Time; EBV: Ebstein-Barr Virus; QI: Quality Indicators; TTAT: Total Turn Around Time; LTAT: Laboratory Turn Around Time; LIS: Laboratory Information System; RPR: Rapid Plasma Regain Test; IDS: Information Delivery System; CCM: Cobas Connection Modules.

Introduction

Clinical laboratory is a significant component in aiding healthcare providers in the diagnosis, management and assessing outcome of disease of patients based on the tests requested by the health care providers on their patients' specimens [1]. These results must be available and accessible whenever they are needed by the healthcare providers [2]. The precision, accuracy and timeliness in releasing results to clinicians are vital to ensure that patient gets the best care possible. Clinical laboratories are very data driven through various Quality Indicators (QI) which tend to be more focused on accuracy and precision of test results through the monitoring of internal quality control as well as external quality assurance data. Because so much emphasis is directed towards these aspects of quality, timeliness of reporting tend to take second place.

Clinical laboratory assesses timeliness through its turnaround times (TAT). Clinicians consider TAT from the time the test is ordered to results reporting, whereas laboratory professionals usually use specimen receipt to reporting of results as the TAT [3]. A study done by the College of American Pathologists, CAP Q-Probes, in 1998 reported 41% of the laboratories defining emergency TAT as the interval between sample arrival and result reporting, 27% defining it as the time from test ordering to reporting of the results and 18% defining it as the interval between sample collection and result reporting [4].

Total TAT (TTAT) of an assay is defined as the time interval from test request to the clinician's awareness of the results [5]. Laboratory TAT (LTAT), on the other hand, can be defined differently depending on test type (urgent vs. routine), analyse, and institution. However, it is generally defined by the time interval from the point of accessioning to the time the results are released. "Accessioning" in this context is defined as the reception of specimens at the laboratory either by scanning of barcoded samples as "received" or manually registering the

specimen onto the laboratory information system (LIS), whereas "result time" is defined as the release of finalized validated results into the LIS.

Of the TAT definitions, TTAT is an ideal QI of a clinical laboratory. However, significant limitations prevent its use in assessing a laboratory's efficiency. The lack of full control over phlebotomy and specimen transport make it difficult for the laboratory to monitor and address delays caused during this preanalytical stage that takes place outside of the laboratory. In addition, ordering times are unable to be captured from the various medical centres and clinics in various states of the country. These factors limit the implementation of monitoring TTAT and therefore, a LTAT monitoring is more practical and is one that Quantum Diagnostics laboratory adopts.

Quantum Diagnostics is a high throughput laboratory receiving, on average, 8000 samples per day from all parts of Malaysia, and running an estimated 160,000 biochemistry tests daily. The laboratory consists of six major departments which include Preanalytics, Biochemistry, Microbiology, Haematology, Molecular and Histology and Cytology departments. The one-stop service aims to allow its customers to receive test results in a timely manner which has been established at 2 and 4 hours for urgent and non-urgent tests respectively. These TAT targets have been established based on the large samples received daily as well as the various locations the laboratory services. Based on this high sample volume and from various clinical centres nationwide, TAT appears to be one of the key indicator of the laboratory's efficiency, apart from other QI such as quality assurance, internal quality controls and sample rejection.

The target LTAT for both urgent and non-urgent tests in Quantum Diagnostics is set at 2 hours and 4 hours respectively. LTAT was monitored in July of 2017 where it was noted that the targets set by the laboratory management was not achieved for both urgent and non-urgent tests in the biochemistry department. Therefore, the objective of this study was to determine the cause(s) of the delayed, instigate appropriate actions to address this, and assess the effectiveness of the action plan.

Material and Methods

Work processes in the laboratory prior to intervention

Sample accessioning: This study was conducted in Quantum Diagnostics core laboratory in Petaling Jaya, Selangor, receiving on average of 8000 samples per day from various medical centres/clinics. The core laboratory provides chemistry, immunochemistry, haematology, microbiology, molecular, histopathology and cytology laboratory results to various medical centres and clinics in all states of the country. To provide a more appropriate TATs for time-critical specimens, the laboratory has separated receiving and processing of urgent and routine samples. The core laboratory receives an average of 400 urgent samples and 7600 routine samples per day with majority delivered by proper transporting procedures by the laboratory's own courier team. Every sample received at the lab has a request form provided together with it which the doctor would indicate if the sample is required to be processed as urgent or non-urgent. If the request form was indicated as urgent, then the specimen will be prioritised by the dedicated specimen receptionist. Urgent samples are labelled with pink barcodes and the routine samples are labelled with white barcodes. This is to ease traceability of urgent samples amongst the large number of routine samples. Every barcode label has a corresponding lab number which is labelled on the sample and the respective request forms.

Workflow for urgent tests: Urgent samples are scanned on the urgent tracker prior to placing the samples on the department's allocated urgent tray. Urgent trackers are used to trace for any delays in the movement of urgent samples from department to department. Samples without rapid plasma regain tests (RPR) will be handed over directly to the Biochemistry department from the specimen reception. However, if an RPR test is requested, the sample will be handed over to the Microbiology department first for RPR before redirecting to the Biochemistry department to analyze the remaining biochemistry tests. Upon sample arrival at the Biochemistry department, urgent samples are first checked on the LIS (Laboratory Information System) to identify and sort samples with H. pylori and Ebstein-Barr virus test (EBV) requests. Following this, the samples are then loaded onto the analyzers manually in the following sequence: 1) Cobas 8000 (Roche Diagnostics, Germany) analyzer for biochemistry test analyses, 2) SNIBE (BMS, USA) analyzer to test for EBV and 3) Immulite 2000 (Siemens Healthcare, USA) for H. pylori tests. Results are then transmitted to the LIS for validation and any reruns or dilutions for biochemistry tests are managed by the middleware.

Workflow for non-urgent tests: All non-urgent (routine) samples are handed over to the microbiology department first to perform RPR. The microbiology lab staff scans the corresponding lab numbers to the samples on the LIS to generate an RPR worksheet. Based on the RPR worksheet generated, lab staff would then be able to segregate samples with and without RPR requests. Samples without RPR test requests will directly be handed over to the biochemistry department for biochemistry analysis on the Cobas 8000. Samples with RPR test requests will undergo RPR prior to being redirected to the biochemistry department for biochemistry analysis.

Lab staff in the biochemistry department then checks for pending tests for serology and H. pylori where the corresponding samples are then identified and transferred to the Immulite 2000 and Snibe platforms respectively. Upon completion of the tests, results are transmitted to the LIS for validation. Completed samples are then sent for manual archiving.

Monitoring of LTAT: On a weekly basis, LTAT data is extracted from the LIS which captures specimen accessioning to test reporting within the laboratory. Statistical analyses are done by the LIS to derive percentage of achievable LTAT targets. These data are reviewed during operational meetings. The laboratory management established an LTAT target of 95% of results completed within the time interval. It was identified that LTAT did not achieve this target in July of 2017 for tests running within the biochemistry department.

Interventions to address delayed LTAT: The department proceeded to conduct an investigation by mapping out the work processes from reception of the samples to the biochemistry analyzers until results were released and identifying potential areas that contributed to the delay in process. Following this exercise, it was discovered that the main holdup was at the biochemistry section for routine samples where samples sent to run for combined biochemistry and microbiology tests were directed to the microbiology section first for RPR before redirecting them to the biochemistry section for the remaining tests (Figure 1). The delay for urgent samples were due to the prioritization of biochemistry tests before directing the samples to be analyzed for H. pylori and EBV on the Immulite 2000 and Snibe automated analyzers respectively.

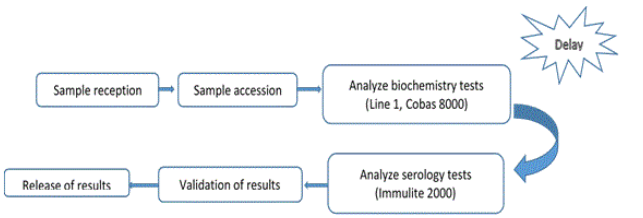

Figure 1: Flow diagram of samples from accessioning to release of results prior to corrective actions.

Several intervention phases were put in place to improve the work processes within the biochemistry department in an effort to achieve LTAT target (Figure 2). The first intervention phase was to reorganize work processes to prioritize H. pylori and EBV tests, where samples were loaded on respective analyzers and transferred to the biochemistry analyzer immediately upon aspiration of sample. In addition, three Cobas 8000 analyzers were set to run biochemistry tests simultaneously and an upgrade of the immunoassay module from e620 to e820 were done to improve analytical throughput of immunoassay testing of urgent and routine samples.

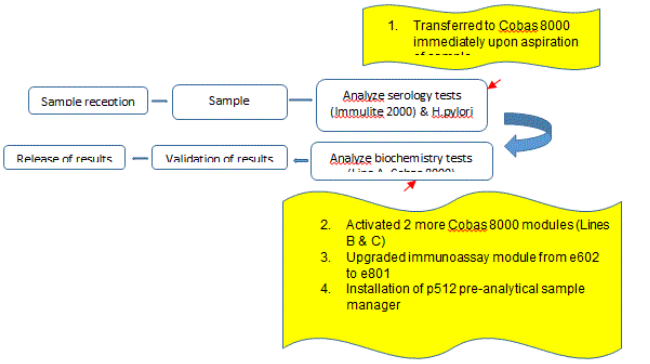

Figure 2: Flow diagram of samples from accessioning to release of results following implementation of corrective actions highlighted in yellow.

The second intervention was the implementation of real-time LTAT through a screen monitor for urgent tests which classifies the samples at the 2 hour, 1 hour, half hour or critical mark. This was executed in November of 2017 and allows the lab personnel to closely monitor the urgent LTAT and assists them in identifying potential delays in LTAT and takes the necessary actions to prevent this. A copy of the urgent request form will be handed over to the customer care agent by the specimen reception staff who will key in the details of the urgent tests on Quantum's IDS (Information Delivery System) where the urgent lab numbers will appear on the urgent monitor for the respective departments to monitor and resolve the urgent tasks within 2 hours. If the lab numbers are not resolved within 2 hours, then those lab numbers would be highlighted in red on the monitor screen which requires immediate attention.

The third intervention took place in July of 2018 where, following several discussions with the key vendor, the implementation of total laboratory automation was initiated with the installation of a cobas p512 pre-analytical system, cobas infinity middleware and a cobas connection module (CCM) which linked the samples from the sorter to the analyzers. This exercise took approximately three months to optimize and stabilize. The final intervention phase took place in January 2019 where an additional installation of the Cobas 8000 immunoassay module, e801, was carried out to improve throughput of immunoassay tests.

Data collection and analysis: This study was conducted between the months of July 2017 and January 2019 to determine the difference in LTAT prior to and post intervention. LTAT was determined for urgent and non-urgent tests requesting for biochemistry and serology tests (H. pylori and EBV). LTAT was calculated from the time of sample accessioning to the time samples were validated and released. Data were keyed into a google sheet and mean LTAT was calculated for each month. LTAT for July 2017 reflects the turnaround time prior to corrective actions whilst August 2017 to January 2019 LTAT reflected turnaround time following the implementation of corrective actions.

Results

Tables 1 and 2, and Figure 1 highlights the LTAT of urgent (LTAT targeted at 2 hours from sample accessioning) and routine tests (LTAT targeted at 4 hours from sample accessioning) during the months of July 2017 until January 2019. Quantum Diagnostics Laboratory's goal was to achieve a minimum of 95% attainable LTAT for both urgent and routine samples. From the results, it was observed that since the implementation of the interventions, there was a steady improvement in LTAT from August 2017 till January 2019 for both urgent and routine samples. The overall cumulative percentage increment since the execution of these corrective actions was 29.45% and 55.75% for urgent and routine samples respectively.

Year	Month	Routine (%)	%Δ from baseline	Urgent (%)	%Δ from baseline	Total routine samples	Total urgent samples
2017	July	60.57	-	39.75	-	1521383	171251
	August	69.85	9.28	54.07	14.32	1531377	173825
	September	67.95	7.38	78.4	38.65	1286418	145598
	October	69.26	8.69	74.39	34.64	1482861	175720
	November	70	9.43	86.2	46.45	1424688	187446
	December	74.8	14.23	85.2	45.45	1445979	188188

2018	January	81.8	21.23	88.2	48.45	1484080	218423
	February	89.5	29.23	93.6	53.85	1081422	174902
	March	81	20.43	85	45.25	1777417	232839
	April	85.46	23.89	91.04	51.29	1594303	238935
	May	83.9	23.33	86.27	46.52	1225530	229091
	June	90	29.43	92.15	52.4	1292946	190029
	July	81.19	20.62	91.32	51.75	1798517	251238
	August	89.78	29.21	96.1	56.35	1749244	258811
	September	90.45	29.88	96.09	56.34	1619327	203525
	October	86.75	26.18	92.35	52.6	1885221	242375
	November	88	27.43	93.49	53.74	1665147	231492
	December	89	28.43	94.4	54.65	1907226	290398
2019	January	90	29.43	95.5	55.75	1796812	294263

Table 1: Percentage of LTAT achieved from July 2017 to January 2019 for routine and urgent tests in Quantum Diagnostics laboratory.

Month	**Pre-analytics configuration**	**Analytics configuration (units)**			**Total throughput**		
		ISE	CC	IM	ISE	CC	IM
					Tests/hr	Tests/hr	Tests/hr
March 2018		C501 (2)	C501 (2)	E602 (4)	3600	5200	680
May 2018		C501 (3)	C501 (3)	E602 (4) E801 (1)	5400	7800	1150
June 2018							
July 2018	CCM p512						
August 2018							
September 2018							
October 2018							
November 2018							
December 2018							
January 2019				E602 (4) E801 (1)	5400	7800	1280
February 2019							
March 2019							

Table 2: Intervention phases implemented to improve the LTAT.

Discussion

Quality can be defined as the ability of a service to satisfy the needs and expectations of the customer [6]. Medical laboratories have traditionally restricted the scope of quality to focusing on imprecision and inaccuracy goals. Therefore, they take pride in being data driven to reflect precision and accuracy of test results. Clinicians however, are interested in service quality, which encompasses total test error, availability, cost, relevance and timeliness [7]. Delays in TAT tend to lead to immediate complaints from users while adequate TAT goes unremarked [8].

TAT is one of the most noticeable signs of a laboratory service and is used by many clinicians to judge the quality of laboratory service [9]. Achieving TAT that is both acceptable by clinicians and achievable by the laboratory is vital to ensure efficiency of patient care. However,

striking this balance can sometimes be challenging. Like most laboratories, Quantum identifies and monitors several QI regularly to ensure quality standards are provided to its customers. Among the laboratory QI the laboratory prioritizes is the LTAT.

Although there are differences defining TAT for clinicians and laboratory personnel as well as differences in opinions relating to the clinical outcomes of an improved TAT, the causes of any delay in TAT should be identified and addressed. Assessing both intra-laboratory and extra-laboratory TAT would be the ideal approach. However, such data are often not available and the laboratory should use the data that can be gathered easily, reliably and on an ongoing basis. Intra-laboratory TAT (LTAT) may be the easiest to define, using start points of specimen accessioning (or registration) and end points of result availability to requester [10]. This was how Quantum Diagnostics defined its TAT.

Quantum Diagnostics laboratory management identified failure to achieve the LTAT target of 95%. The target was set high to ensure efficiency of the service provided by the laboratory. Instead of lowering the target of 95% to a lower, more achievable goal that complies with College of American Pathologists (CAP) recommendations (within a time interval of 90% and 95%), [11,12] the laboratory management decided to actively identify areas of improvement within the work processes to meet the existing LTAT target instead. Mapping of the work processes for urgent and routine tests identified a bottleneck at the biochemistry section where majority of tests are run on the Cobas 8000 analyzer. This prompted the following corrective actions: 1) reorganizing the work processes to prioritize serology tests for urgent requests before redirecting samples to the biochemistry analzyers, 2) implementing a TAT real-time monitoring through a large monitor to enable close monitoring of urgent tests TAT, 3) installation and activation of another two Cobas 8000 biochemistry analyzers to be run simultaneously with the existing module, 4) installation and activation of an upgraded, higher throughput immunoassay module (e801) to run immunoassay tests alongside the existing module (e602), 5) installation of the p512 pre-analytical sample manager system with infinity middleware and 6) educating laboratory staff on the importance of meeting the designated LTAT and the new work processes initiated to improve it. Following the implementation of these interventions, LTAT was seen to gradually improve from August 2017 to October 2017 with an increment of 8.69% and 34.64% for routine and urgent tests respectively. It was noted that further LTAT improvement was observed for urgent tests upon the installation of LTAT real-time monitoring screen (14.23%).

In May of 2018, the installation of the CCM track system, infinity middleware and the p512 pre-analytical sample processing system was carried out. This succeeded in significantly increasing the percentage of tests achieving the target LTAT from 83.90% to 90.00% for routine tests and 86.27% to 92.15% for urgent tests. Subsequent to this, the mean percentage of achievable LTAT was 87.7%, for routine and 93.1% for urgent tests. Although the LTAT did not persistently achieve greater than 95%, the gradual increase in achievable LTAT reflects the ongoing improvement in the work processes within the department. It is also worth mentioning that the challenges faced to achieve this target include:

1) Limitation of the CCM track system which could connect all the Roche analyzers but unable to link other analzyers such as Snibe (BMS) and Immulite 2000 (Siemens Healthcare).

2) Sharing of samples for analysis of microbiology tests such as RPR before sample is handed over to the biochemistry section to run serology and biochemistry tests on their automated platform.

3) Samples have to be manually transferred to the p512 pre-analytical system for archiving.

This study highlights the importance of identifying and monitoring QI to ensure immediate identification of any indicators not achieving their targets. It also underscores the significance of good working partnership between the laboratory and its key vendors to ensure QI goals are met and that any failed indicators are addressed jointly. In order to achieve this, it is important that the vendor is in line with the quality standards set by the laboratory and shares similar sentiments with the laboratory to maintain these standards. This synergistic partnership between Quantum and its vendor enabled efficient implementation of improvement plans by ensuring the smooth transition from having one line of Cobas 8000 to activating a second Cobas 8000 line to run simultaneous biochemistry tests in addition to upgrading the immunoassay analyzer from e601 to e801. In addition, the gradual implementation of laboratory automation showed a vast improvement in LTAT, particularly in a high throughput laboratory such as Quantum Diagnostics. From the results, there was a noticeable improvement in LTAT achieved since the addition of the pre-analytical system p512, infinity middleware and CCM, which consolidated the analytical platforms. The implementation of consolidated automation and interfacing instruments has been suggested by Horowits (2005), to improve TAT and patient safety [11].

Future development within the department to further improve the LTAT include the complete hand-over of RPR to the Biochemistry Department from the Microbiology Department which minimizes sample sharing, thought to also affect TAT efficiency. In addition, the activation of RPR on the Cobas 8000 analyzer is predicted to further reduce time of analysis.

Conclusion

Establishing a close working relationship with key vendors in developing a dashboard that could capture routine and urgent LTAT along with validation statistics and critical results alert can improve monitoring of these critical data and subsequently improve efficiency of the laboratory. TAT monitoring is the ideal choice of activity that has been illustrated that the laboratory's commitment to providing a high quality service.

Mapping out work processes helps in determining the root cause of delays in TAT. In this retrospective study, we identified a failure in achieving LTAT target which was then extensively investigated through the charting of work processes and identifying areas within the process that can be reorganized, updated or intervened to reduce processing time. Synergistic partnerships with key vendors that are in line with the laboratory's performance index are vital to ensure efficiency of any improvement strategies.

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