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Corrective Steps in a Total Laboratory Automation: Experience of a University Laboratory

Total Laboratuvar Otomasyon Sisteminde Düzeltici Adımlar: Üniversite Laboratuvarı Deneyimi

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ABSTRACT

Aim: The Intra-laboratory Turnaround Time (IR-TAT) serves as a significant measure of overall laboratory efficacy. This study sought to augment laboratory operational productivity and diminish IR-TAT by instating a Total Laboratory Automation (TLA) system, executing stat testing, integrating an additional autoanalyzer, and modifying the sample type.

Material and Methods: The evaluation of IR-TAT was conducted both through the mean TAT and Outlier Percentage (OP), comparing data before and after automation. Seven tests were utilized for this comparison, including Albumin, Alanine Aminotransferase (ALT), Urea, Potassium, Beta Human Chorionic Gonadotropin (β-hCG), Troponin I, and Thyroid Stimulating Hormone (TSH). Statistical analysis was performed using the t-test in the Open Epi program.

Results: Post TLA implementation, IR-TAT demonstrated improvements in routine biochemistry samples. However, a statistically significant elevation was observed in IR-TAT for urgent samples (except β-hCG and TSH), and for β-hCG and TSH within routine samples. To rectify this, stat testing was initiated specifically for the Emergency Department. These stat tests were processed in a separate autoanalyzer outside of TLA, and the sample type for Troponin I was transitioned from serum to plasma. Consequently, a decrease was observed in the mean IR-TAT for stat tests ($p<0.001$).

Conclusion: The TLA system deployed in our institution has effectively optimized the management of high volumes. Implementing corrective measures such as the inclusion of stat testing and altering the sample type have resulted in definitive improvements in IR-TAT. To maximize the benefits derived from TLA, it is crucial to identify existing issues and implement appropriate corrective measures.

Key Words: Analytical Techniques and Equipment, Automation, Laboratory Organization and Management

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ÖZET

Amaç: Laboratuvar içi test sonuç verme süresi (L-TSS), laboratuvar performansının önemli bir göstergesidir. Bu çalışma, Total Laboratuvar Otomasyonu (TLO) kurulumu, stat test uygulaması, TLO dışına ek bir otoanalizör eklenmesi ve numune türünün değiştirilmesi ile L TSS'yi azaltmayı amaçladı.

Materyal ve Metod: L-TSS'ın değerlendirilmesi, otomasyon öncesi ve sonrası veriler karşılaştırılarak hem ortalama TSS hem de Aykırı Değer Yüzdesi (AD) aracılığıyla gerçekleştirildi. Bu karşılaştırma için yedi test (Albümin, Alanin Aminotransferaz (ALT), Üre, Potasyum, Beta İnsan Koryonik Gonadotropin (β-hCG), Troponin I ve Tiroid Stimülan Hormon (TSH)) kullanıldı. İstatistiksel analiz OpenEpi programında t-testi kullanılarak yapıldı.

Bulgular: TLO uygulaması sonrasında rutin biyokimya numunelerinde L-TSS'de iyileşme gözlendi. Ancak acil numunelerde (β-hCG ve TSH hariç) ve rutin numunelerden β-hCG ve TSH'de istatistiksel olarak anlamlı artış gözlendi. Bunu düzeltmek için Acil Servise özel stat test uygulaması başlatıldı. Stat testleri TLO dışında ayrı bir otoanalizörde çalışıldı ve Troponin I için örnek tipi değiştirildi. Sonuç olarak stat testlerinde L-TSS'de azalma ($p<0,001$) gözlendi.

Sonuç: Kurumumuzda kurulu olan TLO sistemi, yüksek hacimlerin yönetimini etkili bir şekilde optimize etmiştir. Stat testlerin eklenmesi ve örnek tipinin değiştirilmesi gibi düzeltici tedbirlerin uygulanması, L-TSS'de iyileşmelere yol açmıştır. TLO'dan elde edilen faydaları en üst düzeye çıkarmak için sorunları belirlemek ve uygun düzeltici önlemleri uygulamak çok önemlidir.

Anahtar Kelimeler: Analitik Teknikler ve Ekipman, Otomasyon, Laboratuvar Organizasyonu ve Yönetimi

INTRODUCTION

Automation is considered one of the most important breakthroughs in the recent history of laboratory diagnostics. Rapidly developing technology, microprocessors, and computers have enabled the production of automated instruments in which repetitive human operations are limited and workflow is performed faster and more efficiently. At first, automation was brought to the analysis phase, which is the main job of the laboratory, in the calculation of test results and transferring them to patient reports. As computers and robotics were developed, data processing capacities were increased, and automation could be applied to wider steps. Further advancement has emerged into a functional system known as 'total laboratory automation' (TLA) (1-3).

Laboratory services are an essential component of quality healthcare delivery and require adequate equipment for the quality of work and the safety of staff, patients, customers, and visitors. Over the past decades, test requests have progressively increased for several reasons, such as the aging population, an increase in chronic disease prevalence, the discovery of new and more effective biomarkers, and a general rise in healthcare demand. Clinical laboratories have used technological advances to meet test efficiencies against increased demand (2).

In a model of TLA, many analyzers performing different types of tests on different sample matrices are physically integrated as modular systems or physically connected by assembly lines. Many steps of sample processing from pre-analytics (check-in, centrifugation, aliquoting) through to post-analytics (storage and disposition) are automatically performed physically connected in workstations (3).

Although the main business area of clinical laboratories is the analysis phase, the main service is to deliver the analysis results to the clinician or patient by obtaining the analysis results in an accurate, reliable, and timely manner. Turnaround time (TAT) is a measure of timelines and is widely used as a key indicator of total laboratory performance. Clinicians depend on the best TAT to achieve early diagnosis and treatment (4,5). TAT is defined as therapeutic TAT when it includes

the time from the test order to the beginning of a therapeutic intervention based on the test result (5,6). To set the time from ordering and including specimen collection as well as time for transport to the laboratory are difficult to control. However, laboratories prefer to use intra-laboratory TAT as a quality indicator. The intra-laboratory TAT includes all the laboratory activities starting from scanning the barcode sample as "received, to the final report accessible to the clinicians (7,8). The expectations of implementing laboratory automation were to improve patient outcomes and clinician satisfaction; contain escalating workloads at minimal cost; better use manpower sources; eliminate sources of error in pre-analytical processing; improve the working atmosphere and biosafety of staff through reduced sample handling and manual process; reduce staff frustrations for repeat and add-on testing.

The aim of our study was to evaluate the intra-laboratory TAT of our central laboratory after TLA implementation (October-December 2016) and to compare it to that in the pre-automation period (October-December 2015). Here we also provide our institutional experience of corrective ideas (stat implementation, change of sample type for Troponin I, and using an analyzer other than TLA for stat tests) of some of the potential advantages and limitations of TLA. This paper gives an overview of our experience with automation implementation in the clinical laboratory.

MATERIALS AND METHODS

The study was performed at the Central Laboratory of the Manisa Celal Bayar University Hospital, Turkey. It is a tertiary care 420-bed hospital in Turkey. The Clinical Biochemistry Laboratory has approximately 5 million test numbers per year and provides a wide range of analyses for the diagnosis and management of inpatients and outpatients. In anticipation of a projected increase in workload, our clinical laboratory has streamlined and standardized its work processes and established a TLA with the deployment of linked analyzers (chemistry and immunoassay models), pre- and post-analytical modules.

Prior to the implementation of laboratory automation, the laboratory layout included five analyzers for sample processing, the pre-analytical and post-analytical areas were managed with laboratory personnel. After centrifugation, samples were delivered to the open space analytical area of the laboratory, where the technical staff manually loaded tubes to the specific instruments (3 x Advia 1800 clinical biochemistry analyzer and 2 x Centaur XP (Siemens Healthcare Diagnostics, Tarrytown, NY, USA)). The samples were removed from the refrigerator by technical personnel when the analytical phase ended.

Beckman Coulter Power Processor Laboratory automation systems (Brea, California, USA), setup was completed in about one month and started operating in June 2016. It is a modular system designed to automate pre-analytical, analytical, and post-analytical processes. Our system combines multiple analysis tools into a single workstation, allowing the application to blood tubes. The system was expected to automate sample processing for the general clinical biochemistry and immunoassay.

In-patient samples delivered to the laboratory are received by technical staff dedicated to the pre-analytical phase that, after screening for any pre-analytical errors, introduces samples into the automation Power Processor. Along the automation Power Processor, multiple analyzers for sample processing are located as follows: 2 x centrifuge modules, the decapper module, the aliquot module, 2 x Beckman Coulter DxI 800 (Brea, California, USA) immunoassay analyzer, and one Beckman Coulter AU 5821 (Brea, California, USA) clinical biochemistry analyzer, the recapping module, the storage module. Our automation layout has been schematized in Figure 1. As seen in Figure 1, it was very difficult to place the TLA system

due to the lack of physical space. This congestion created a separate difficulty as it created difficulties in use.

There is an urgent priority rack for alternative uploading on to the input module rack. The TLA couldn't have another privileged way to differentiate urgent samples from the routine specimens at the pre-analytical phase because it doesn't have any alternative platform or centrifuges that could recognize urgent specimens.

Therefore, two amendment steps were developed in May 2017. First, the stat test panel implemented isolated the urgent and routine test panels giving additional privileges to the samples from the Emergency Department (ED). Second, Using Li-Heparin tubes for Troponin I test. Stat samples are centrifuged offline and then loaded on to the analyzers. Stat biochemistry specimens were analyzed outside TLA with Beckman Coulter AU680 (Brea, California, USA). Laboratory staff were directed to load stat hormone and Troponin I specimens in front of all other samples on the loading rack directly. The other samples as urgent and routine are processed via the TLA.

TAT in our laboratory is defined by the time interval from samples arriving in the laboratory, to the verification of results in the laboratory information system (LIS). Data was collected for the in-lab for reporting turnaround time (IR-TAT) from the time when samples were accepted by the laboratory till the results were verified. The percentages of samples completed within the target TAT is used as the performance indicator.

Seven representative analytes were selected for this purpose: Albumin, Alanine Aminotransferase (ALT), Urea, Potassium, Beta Human Chorionic Gonadotropin (β-hCG), Troponin I, Thyroid Stimulating Hormone (TSH).

To better understand the advantages TAT obtained through automation implementation pre- and post-automation periods and stat test panels were ranged as follows: October to December 2015 for pre-automation period, October to December 2016 for post-automation period, and July to September 2017 for the stat tests.

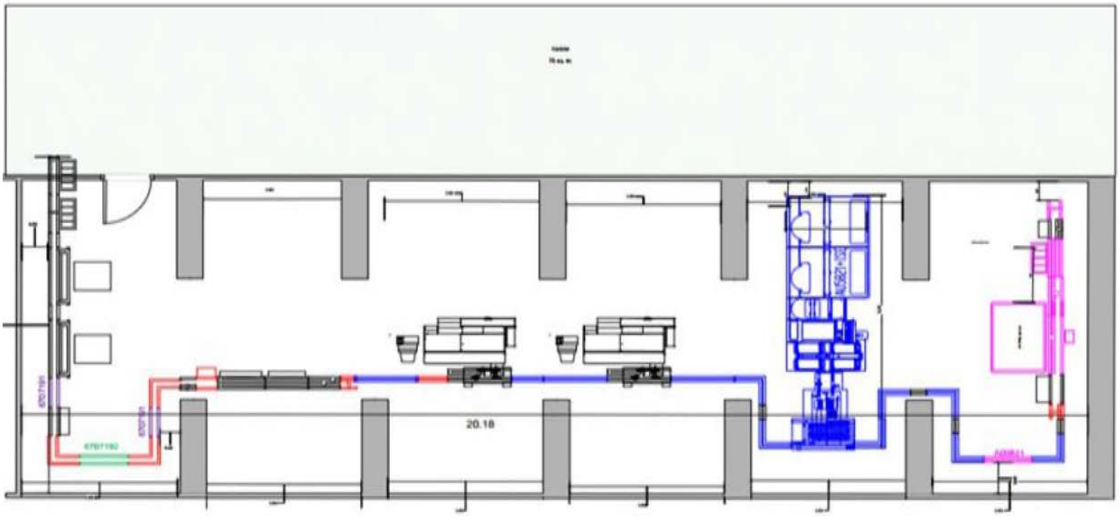

Figure 1. Map of the definitive automation layout (Power Processor, California, USA) and position of the instruments included along the automation line at the laboratory

The target means IR-TATs for stat samples were established to be 1 hour from the Emergency department, 2 hours for urgent samples, and 4 hours for routine samples from the sample check-in to the final report production. Acceptable outliers of percentages (OP-TAT) at target hours are determined as <10% (90% results reported in target hours).

Laboratory TAT data was extracted from the laboratory information system (LIS) retrospectively. Intra-laboratory TAT includes all of the laboratory activities from the scanning of the barcode sample as "received" to the final report accessible to the clinicians. Mean, median, standard deviation (SD), and outliers of percentages (OP) were obtained using the Microsoft Excel program. Statistical analysis was performed using the 95% confidence interval t-test in the OpenEpi (version 3.01) program. p values ≤ 0.05 were regarded as significant. Permission was obtained from the ethics committee of Manisa Celal Bayar University to share the study (no:20.478.486-2017).

RESULTS

We currently report the analysis of the TAT for stat, urgent, and routine exams every month to the Department of Quality Management. The hospital has established a maximum reporting period (measured by TAT): 1 hour for stat tests, 2 hours for urgent, and 4 hours for routine.

The volume of analytes processed by the TLA

During the study period, the test volume of the seven analytes increased by 12% in 2016 compared to that in 2015. When the volumes of routine and urgent analytes are examined separately; there was a decrease of 4.9% in the volume of routine analytes and an increase of 32.8% in the volume of urgent analytes. While 46% of all tests were urgent in 2015, this ratio changed to 54% in 2016. In Table 1, a volume of seven analytes processed both urgent and routine in the laboratory during the study periods are shown.

Effect of implementation of TLA on IR-TATs for urgent and routine samples

Data on mean and percentages of IR-TATs for Albumin, ALT, Urea, Potassium, β-hCG, Troponin I, and TSH are shown for urgent samples in Table 2 and for routine samples in Table 3. All urgent samples were loaded onto the priority lanes of the TLA. In urgent samples, the shortest mean IR-TAT was 50.4 min for Troponin I, followed by 61.2 min and 62.7 min for potassium and urea respectively. The longer mean IR-TAT of 75.8 min for TSH. The lowest values for OP-TAT at 60 min and 120 min were 21.2% and 3.3% respectively for Troponin I, while the highest values were 62.1% and 11.8% for TSH testing.

The longest mean IR-TAT in routine samples was 133.6 min for TSH, while the shortest was 104.4 min for Urea, as seen in Table 3. OP-TAT at 240 min for biochemistry analytes in this study was < 1.5%, whereas for hormone analytes it was <7%.

IR-TAT Comparison between the pre and post-automation periods

Data for comparison of the mean of IR-TATs and percentages of outliers of IR-TATs (OP-TAT) between pre- and post-TLA for seven analytes is shown in Table 2 and Table 3. Contrary to expectations, mean IR-TAT increased for urgent tests after TLA. An increase was observed especially in biochemistry tests. There was no statistically significant difference in the mean IR-TAT of β-hCG and TSH analytes in urgent samples after TLA.

Table 1. Volume of the seven analytes processed during the study periods

Analyte	Routine (n)		Urgent (n)	
	Oct-Dec 2015	Oct-Dec 2016	Oct-Dec 2015	Oct-Dec 2016
Albumin	19.957	18.105	17.220	23.082
ALT	25.834	24.221	21.765	29.326
Urea	24.913	23.122	22.409	29.803
Potassium	18.833	18.961	23.644	29.953
β-hCG	1467	1211	589	888
Troponin I	1042	1222	3050	4786
TSH	12.930	12.958	180	161

ALT, Alanin Aminotransferaz; β-hCG, Beta Human Chorionic Gonadotropin; TSH, Thyroid Stimulating Hormone.

Table 2. Mean Intra-Laboratory Turnaround Time (TAT), Outlier Percentage (OP) at 60 min and 120 min for urgent (all urgent examples of the hospital) analytes during the study period before and after TLA.
Pre-TLA: October-December 2015, Post-TLA: October-December 2016.

	Pre-TLA			Post-TLA			p values
Urgent Exam	**Mean TAT (min)**	**OP-TAT 60 min (%)**	**OP-TAT 120 min (%)**	**Mean TAT (min)**	**OP-TAT 60 min (%)**	**OP-TAT 120 min (%)**	
Albumin	48.8	20.6	2.2	64.9	40.4	7.4	<0.001
ALT	47.4	19.0	2.0	62.8	38.2	6.8	<0.001
Urea	47.2	18.7	2.0	62.7	38.1	6.7	<0.001
Potassium	47.0	18.3	1.9	61.2	35.8	6.3	<0.001
β-hCG	67.4	49.2	9.0	68.7	50.6	7.0	>0.05
Troponin I	48.6	17.6	3.0	50.4	21.2	3.3	0.025
TSH	68.0	42.2	12.2	75.8	62.1	11.8	>0.05

TLA, Total Laboratory Automation; ALT, Alanin Aminotransferaz; β-hCG, Beta Human Chorionic Gonadotropin; TSH, Thyroid Stimulating Hormone.

Table 3. Mean Intra-Laboratory Turnaround Time (TAT), Outlier Percentage (OP) at 120 min and 240 min for routine analytes during the study period before and after TLA. Pre-TLA: October-December 2015, Post-TLA: October-December 2016.

	Pre-TLA			Post-TLA			
Routine Exam	**Mean TAT (min)**	**OP-TAT 120 min (%)**	**OP-TAT 240 min (%)**	**Mean TAT (min)**	**OP-TAT 120 min (%)**	**OP-TAT 240 min (%)**	**p values**
Albumin	109.9	36.4	2.4	105.6	31.7	1.5	<0.001
ALT	110.1	36.5	2.4	105.0	31.1	1.4	<0.001
Urea	109.6	36.5	2.3	104.4	30.7	1.3	<0.001
Potassium	111.2	37.2	2.8	104.5	30.7	1.5	<0.001
β-hCG	115.1	39.1	2.2	122.8	38.9	5.8	0.006
Troponin I	110.2	35.4	2.3	112.5	34.1	4.7	>0.05
TSH	120.4	44.6	2.5	133.6	47.4	7.0	<0.001

TLA, Total Laboratory Automation; ALT, Alanin Aminotransferaz; β-hCG, Beta Human Chorionic Gonadotropin; TSH, Thyroid Stimulating Hormone.

Table 4. Comparison Mean Intra-Laboratory Turnaround Time (TAT), Outlier Percentage (OP) at 60 min of urgent (urgent examples from outside the emergency department) and stat (urgent examples of emergency department) samples during the study period (July-September 2017).

Analyte	Urgent Exam		Stat Exam		p values
	Mean TAT (min)	OP-TAT 60 min (%)	Mean TAT (min)	OP-TAT 60 min (%)	
Albumin	86.0	61.5	38.8	7.6	<0.001
ALT	88.8	64.2	38.1	7.1	<0.001
Urea	87.5	63.1	38.0	7.0	<0.001
Potassium	82.0	56.9	38.1	7.1	<0.001
β-hCG	78.6	65.7	61.2	44.5	<0.001
Troponin I	49.3	19.0	41.9	9.7	<0.001

ALT, Alanin Aminotransferaz; β-hCG, Beta Human Chorionic Gonadotropin.

In routine samples; Albumin, ALT, Urea, and Potassium analytes showed a decrease in mean IR-TAT and OP-TAT values post-TLA. β-hCG, Troponin I, and TSH analytes showed an increase in mean IR-TAT and OP-TAT. There was no statistically significant difference in the mean IR-TAT of Troponin I analytes in routine samples after TLA.

Stat tests for the ED

In 2016, 23% of all urgent samples were from the ED, and the remaining urgent samples were from polyclinics and inpatients. Unexpected volume increase (32.8%) and higher mean IR-TAT in urgent samples compared to the previous year required the prioritization of the ED. As a corrective action for the ED, the application of stat tests has been implemented. After the application, the test volume distribution was observed as 49% routine, 47% urgent (urgent examples from outside the emergency department), and 4% stat (urgent examples from the emergency room). Stat samples were not included in the TLA system and the sample type for Troponin I was changed from serum to plasma. Data for comparison of mean and percentages of outliers of IR-TATs between stat and urgent samples are shown in Table 4. IR-TAT values of stat tests improved significantly. Mean IR-TATs for Albumin, ALT, Urea, Potassium, β-hCG, and Troponin I all decreased with stat testing in July-September 2017; It was detected as 38.8, 38.1, 38, 38.1, 61.2 and 41.9 minutes, respectively. In the same study period, the mean IR-TATs of urgent samples increased compared to the 2016 data. An increase was observed especially in biochemistry tests. When outliers were examined at 60 minutes, all stat tests except for β-hCG were observed to be <10%. However, the outliers for the urgent tests were <10% for all tests at 180 minutes. The trend of OP-TATs 60 min of ED's tests at the three periods have been schematized in Figure 2.

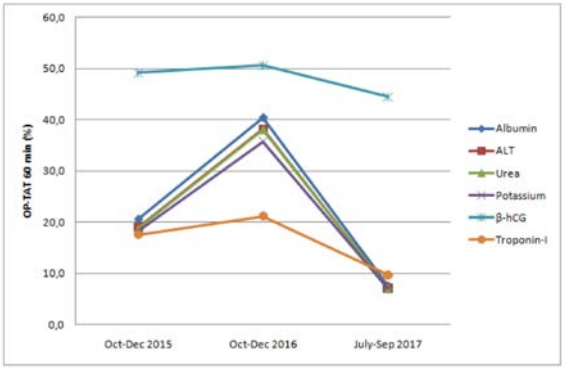

Figure 2. Percentage of outliers at 60 min (OP-TAT 60 min) registered at three periods for the emergency service' exams. (Pre-TLA: October-December 2015, Post-TLA: October-December 2016. After stat test implementation: July-September 2017).

DISCUSSION

The multifaceted developments of technological innovations had a profound impact on clinical laboratories (2). Automation is considered as one of the most

important breakthroughs in laboratories, where business volume has increased over the past decades (9). Thanks to automation, many analyses can be performed in a short time with a small number of personnel and a reduction of errors can be achieved. Integrating multiple diagnostic specialties into a single track improves the efficiency, organization, standardization, quality, and safety of laboratory testing (10). The process of standardization provides tangible benefits on the quality of the total testing process, thereby reducing the risk of diagnostic errors (11). One of the advantages of TLA is that it reduces the number of blood tubes required for testing. The same serum tube can be used for multiple clinical chemistry and immunochemistry tests. The reduced sample number also generates a lower impact on biological waste disposal, resulting in additional economic savings (12). Many studies have shown that an efficient TLA model can successfully reduce laboratory costs (13,14). Laboratory automation is necessary for laboratories with medium to large capacity because as the test number increases, the economic benefit of automation increases as well (14). The resulting benefits of such a system are improvement at both the quality and economic levels.

On the other hand, developing a model of TLA also presents some potential problems: represented by higher initial costs, enhanced expenditure for supplies, space requirements and infrastructure constraints, increased generation of noise and heat, and higher risk of downtime. Space requirements and infrastructure constraints are major issues for implementing TLA (10). The investment for implementation of TLA is associated with an initial rise in costs for new system installation and for new hardware. A large model of TLA would also require a higher level of maintenance. The higher the complexity of the system, the greater the risk that a system failure will have serious consequences on laboratory operations. The possibility of manually loading samples into the analyzers in an emergency should always be maintained (15).

Despite innovations in technology, TAT remains a hot topic among clinicians and the laboratory as it directly impacts patient care. Therefore, TAT is considered an important indicator of laboratory quality (4,7). Much evidence suggests that laboratory automation can improve sample management and laboratory efficiency by reducing TAT (3,7,16). The benefits of automation have been documented in various examples from around the world. Unfortunately, there are few references to less successful TLA implementations and documentation of the first month's post-TLA.

In the current study, TAT was analyzed before and after laboratory automation implementation to evaluate the impact of automation. Data reported demonstrate that in the first post-TLA period expected TAT improvement was not achieved for some analytes.

Our first and foremost question was whether the TLA was efficient in processing urgent samples. Contrary to expectations, mean IR-TAT increased for urgent tests after TLA (Table 2). 32.8% volume increase of urgent samples may have affected the results of IR-TAT. The larger the test number the higher the risk of creating bottlenecks (17). Factors such as increasing test numbers, staff competency with regard to handling urgent samples, and inexperienced staff in the face of a new system contributed to this situation. Rapid and accurate laboratory tests are essential to support clinical decision-making since most clinical decisions are based on laboratory results. Doctors in the outpatient clinics in our hospital requesting urgent tests are a necessity. However, it is not an easy task, to continuously manage it due to the pre-analytic factors. There is no clear line on what is urgent and every clinician can make an urgent test order. However, it is challenging to respond to urgent requests for individual samples from outpatient clinics because the laboratory handles all hospital

samples in the same TLA system. This high demand for urgent tests makes the situation inefficient in terms of the laboratory, as it may delay the processing of most samples.

Although we believe that manual processing at both the initial centrifugation stage and front loading of samples directly onto analyzers would possibly incur the shortest IR-TAT, TLA is still the best overall solution when there is a large volume of urgent samples and a shortage of staff. For this reason, it is necessary to develop rules and criteria that allow emergency samples to bypass other samples by making a detailed analysis of the workflows within the system (18).

In routine samples; Albumin, ALT, Urea, and Potassium analytes showed a decrease in mean IR-TAT and OP-TAT values post-TLA (Table 3). Rapid analytical phase of these tests and automated process standardization contributed to these results. β-hCG, Troponin I, and TSH analytes showed an increase in mean IR-TAT and OP-TAT (Tables 2 and 3). Increasing test numbers and re-running for dilution at high values may have contributed to this situation.

One of the most important challenges to ED in Turkey is the problem of overcrowding. One of the major factors contributing to overcrowding is prolonged TAT (19). So optimal management of emergency testing is a critical issue in laboratories using TLA. Our data showed that the exclusion of the stat samples from the automation line produced a better TAT. However, these samples have to be manually stored after the analysis is completed which is a process requiring the active participation of the laboratory staff. Stat implementation for ED was a good solution, as the TAT target for ER samples failed with the current TLA system. Although the number of samples coming from the ED has increased, the quality of service we provide to the ED has increased thanks to the separation of stat samples and the use of additional devices. Similarly, a study by Singer at all. shows that TATs were significantly reduced by the introduction of the stat lab. With the majority of TATs meeting the target of equal to or less than 30 minutes. This allows urgent tests to be performed more efficiently than before (19,20).

For the Troponin I assay, changing the sample type (from serum to Li-Heparin plasma) and moving it independently from other samples to the instrument had a positive effect on TAT (Table 4, Figure 2). One of the major limitations after TLA has been related to barcode reading. Poor labeling techniques and poor-quality barcode labels have caused interruptions in automation. Correct positioning of the barcode labels is important to ensure minimal interruption.

Staff were initially frustrated by pauses in automation due to a lack of understanding of TLA operations in both hardware and software, unfamiliarity with new workflow processes, and system errors. It was surprising to see that system errors increased after TLA (such as code 0: barcode error, code 2: stopper error). However, regular meetings with the vendor and technical support team were helpful in improving our understanding of TLA, and applicable solutions were produced. As we overcame the problems, it was noted that system errors and TLA downtime decreased. In the following months, the features of automated sample retrieval, reruns, and specimen tracking were much appreciated by the staff. The standardized workflow increased staff morale over time as staff experience increased. Additionally, TLA increased personnel safety by automating the entire laboratory workflow, especially in the post-analysis phase, thereby eliminating all manual actions that could potentially increase biohazard exposure and risk of injury. This has become especially important during the COVID-19 pandemic.

As Archetti C et al noted in their study, the number of technical personnel required to perform the same test number was reduced

when the workflow became stable and setup problems were partially resolved (14). Technical personnel were shifted to other areas needed in the laboratory.

It was not possible to examine the effect of TLA on TAT alone because other changes were made during the same time. For example, both the physical lab layout and the workflow process were reorganized to optimize workflow efficiency.

The measurement drives much of the day-to-day decision making and laboratory information plays an increasingly dominant role in modern medicine (21). Continuous improvement is one of the most important building blocks of the quality management system. The aim is to constantly fix the system with small changes and to ensure that it works in the safest way. The Deming Plan-Do-Check-Act (PDCA) is a checklist of the four stages that you must go through to get from "problem faced" to "problem solved" The PDCA cycle shows how to achieve continual improvement in any process. This is the continual improvement process, and in the laboratory, this process is applied to all procedures and processes in the path of workflow. Using the PDCA cycle we have been able to implement the corrective actions needed step by step in our laboratory (22).

Laboratory efficiency should be increased with workflow analysis. For maximum benefit from TLA; after the installation, the observed problems should be identified and corrective actions should be taken step by step. Process evaluations should be made at weekly and monthly meetings; problem resolutions should be made to make the most of the rapidly advancing technology. This system has optimized performance in terms of managing high volumes and complexity by streamlining critical steps. The implemented TLA in our institution had a significant positive impact on the management of high volumes of both urgent and routine patient samples. However, the longer IR-TAT of urgent samples yielded a need for stat implementation with manual processing at both the initial centrifugation stage and front loading directly on to a new analyzer. A particularly encouraging finding was that routine biochemistry testing improved significantly after TLA compared to pre-TLA data, despite increased test number and a period of adaptation to a new system. Step-by-step corrective strategies such as stat implementation and change of sample type resulted in definite IR-TAT improvement.

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REFERENCES

1. Lam CW, Jacob E. Implementing a laboratory automation system: experience of a large clinical laboratory. J Lab Autom 2012;17(1):16-23.
2. Dolci A, Giavarina D, Pasqualetti S, Szőke D, Panteghini M. Total laboratory automation: Do stat tests still matter? Clin Biochem 2017;50(10-11):605-11.
3. Lalongo C, Porzio O, Giambini I, Bernardini S. Total automation for the core laboratory: improving the turnaround time helps to reduce the volume of ordered STAT tests. J Lab Autom 2016;21(3):451-8.
4. Howanitz JH, Howanitz PJ. Laboratory Results: Timeliness as a quality attribute and strategy. Am J Clin Pathol 2001;116(3):311-5.
5. Angeletti S, Cesaris MD, Vitali S, Bernardini S, Dicuonzo G. Monitoring and improvement of intra laboratory turnaround time at the University Hospital Campus Bio-Medico in Rome. Biochim Clin 2014;38(2):115-20.
6. Hawkins RC. Laboratory turnaround time. Clin Biochem Rev 2007;28(4):179-94.

7. Angeletti S, Cesaris DM, Hart JG, Urbano M, Vitali MA, Fragliasso F, et al. Laboratory automation and intra-laboratory turnaround time: experience at the University Hospital Campus Bio-Medico of Rome. J Lab Autom 2015;20(6):652–8.
8. Kilgore ML, Steindel SJ, Smith JA. Evaluating stat testing options in an academic health center: therapeutic turnaround time and staff satisfaction. Clin Chem 1998;44(8):1597–603.
9. Ebubekir B, Nurinnisa O, Nurcan KB. Automation in the clinical laboratory: integration of several analytical and intralaboratory pre- and post-analytical systems. Turk J Biochem 2017;42(1):1–13.
10. Lippi G, Da Rin G. Advantages and limitations of total laboratory automation: a personal overview. Clin Chem Lab Med 2019;57(6):802-11.
11. Yeo CP, Ng WY. Automation and productivity in the clinical laboratory: experience of a tertiary healthcare facility. Singapore Med J 2018;59(11): 597-601.
12. McPherson RA. Blood sample volumes: emerging trends in clinical practice and laboratory medicine. Clin Leadersh Manag Rev 2001;15(1):3–10.
13. Hawker CD, Roberts WL, Garr SB, Hamilton LT, Penrose JR, Ashwood ER, et al. Automated transport and sorting system in a large reference laboratory: part 2. Implementation of the system and performance measures over three years. Clin Chem 2002;48(10):1761–7.
14. Archetti C, Montanelli A, Finazzi D, Caimi L, Garrafa E. Clinical laboratory automation: a case study. J Public Health Res 2017;6(1):881.
15. Young DS. Laboratory automation: smart strategies and practical applications. Clin Chem 2000;46(5): 740–5.
16. Chung HJ, Song YK, Hwang SH, Lee DH, Sugiura T. Experimental fusion of different versions of the total laboratory automation system and improvement of laboratory turnaround time. J Clin Lab Anal 2018; 32(5):e22400.
17. Xie C, Chen Y, Wang Z. Design of an incremental and open laboratory automation system. Zhongguo Yi Liao Qi Xie Za Zhi 2015;39(4):268–71.
18. Yang T, Wang TK, Li VC, Su CL. The optimization of total laboratory automation by simulation of a pull-strategy. J Med Syst 2015;39(1):162.
19. Singer AJ, Viccellio P, Thode HC Jr., Bock JL, Henry MC. Introduction of a stat laboratory reduces emergency department length of stay. Acad Emerg Med 2008;15(4):324–8.
20. Kim KY, Lee SG, Kim TH, Lee SG. Economic Evaluation of Total Laboratory Automation in the Clinical Laboratory of a Tertiary Care Hospital. Ann Lab Med 2022;42(1):89-95.
21. Plebani M. Quality in laboratory medicine and the Journal: walking together. Clin Chem Lab Med 2023;61(5):713–720.
22. World Health Organization. Laboratory Quality Management System Handbook. Geneva;2011.