DxA 5000: Intelligent Automation that increases efficiency.

ABSTRACT

Background: Between October 2019 and November 2022, we collected and analysed baseline operational metrics at the Hospital Universitario de Poniente diagnostic laboratory (Almeria, Spain), to accurately detail the efficiency of the pre-analytical workflow.

Objective: To conduct a clinical laboratory observational impact study by comparing and analysing "Turnaround Times" (TATs) before and after the installation of the Total Laboratory Automation (TLA) DxA 5000 system.

Methods: Data was collected on specific metrics within the laboratory pre-analytical workflow: direct observations of manual handling within the pre-analytical processes such as sample receipt, transport, sorting, and preparation; time studies of pre-analytical workflow and systems; and Laboratory Information System (LIS) capture of testing

timelines. Additionally, we performed literature searches to seek independent data and observations on the potential impacts of introducing TLA systems into clinical laboratories settings.

Results: The integration of the TLA DxA 5000 system simplified processes and increased staff safety by reducing manual handling of samples by 77%. Furthermore, CCIA pre-analytical TAT before the installation of DxA 5000 system was 1h 31min 12 sec; which afterwards improved to 19 min 35 sec. This represents more than one hour reduction in pre-analytical time, corresponding to a 78.53% performance improvement. Additionally, the final test result TAT was reduced from 2h 47 min 58 sec to 1h 21 min 14 sec, corresponding to reports being delivered to clinicians ~1 ½ h quicker, with 51.64% increased performance. Furthermore, from sample load until the final test result was available, CCI samples were handled 20.93% faster; and haematology tubes got their results ready for review 15 min earlier after DxA 5000 installation.

Conclusions: Independent literature and observations during the study, supports the belief that adopting TLA DxA 5000 system has the potential to improve safety in the clinical laboratory, by reducing manual handling interventions. The observed data demonstrates that the TLA DxA 5000 system can support enhanced hospital care by delivering laboratory clinical results faster.

INTRODUCTION

Because medical decisions are partly based on laboratory findings, a clinical laboratory is the pillar of a multispecialty hospital and its health care services [1,2]. In fact, according to Ngo et al., [3] even though it is not possible to use a single number to categorize the frequency with which laboratory tests inform medical decisions, it is possible to quantify the frequency with which laboratory tests occur in patient encounters. Based on electrical records from the Virginia Commonwealth University Medical Centre, most inpatients (98%), approximately half of emergency department patients (56%) and nearly one-third of outpatients had laboratory tests performed during their healthcare visits (29%) [3].

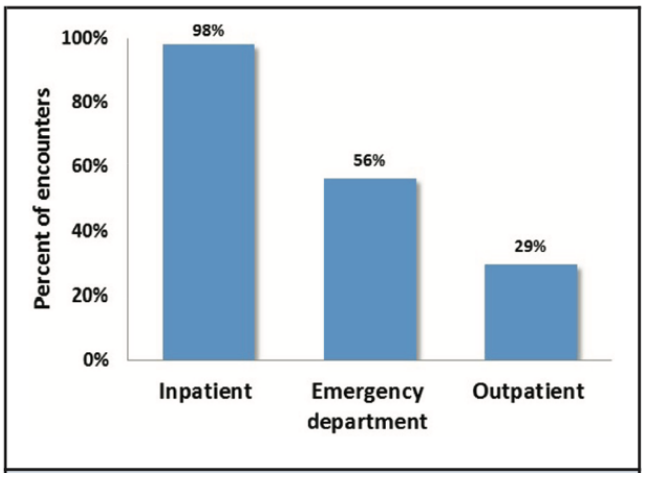


Figure 1 – Percent of different types of patient care areas for which at least one laboratory test was ordered in Virginia Commonwealth University Medical Centre to inform medical decisions (based on Ngo et al., "Frequency that Laboratory Tests Influence Medical Decisions", in The Journal of Applied Laboratory Medicine, 2017).

Clinical laboratory results must be accurate, precise, and well-timed. As such, timeliness or "turnaround time" (TAT) is a benchmark measure of laboratory performance and a quality indicator of the effectiveness and efficiency in the testing process – which, eventually translates into patient and clinician satisfaction [4].

TAT terminology originated in the shipping and airline industries as the time that passes from docking/landing until take-off – which, ultimately incurs costs on the airline (e.g., airport fees). This term is now routinely used in medical laboratories as "a parameter of a clinical laboratory's efficiency, defined as the time between ordering a test, or submitting a specimen to the lab, to the reporting of the results" [5]. While the Interlaboratory Quality Assurance (IQA) and External Quality Assessment (EQA) programs validate the quality of the clinical tests performed, focusing on precision and accuracy; TAT assures a speedy, dependable and cost-effective solution [6].

The TAT procedure in a clinical laboratory setting can be divided into three phases: (1) pre-analytical (order to preparation), (2) analytical and (3) post-analytical (reporting to action) [7]. In each phase, there are critical points for TAT analysis that can be used to examine the efficiency of the process and can comply with a uniform study on the efficiency of a Total Laboratory Automation (TLA) system, like the DxA 5000 system. As such, data collection on sample receipt, transport, sorting, and preparation, together with Laboratory Information System

(LIS) capture of testing timelines conform with the requirements needed for a scientific study of the efficiency of a TLA.

With this in mind, Hospital Universitario de Poniente's diagnostic laboratory in Almeria, Spain, was used for an observational clinical laboratory impact study of "before versus after" TLA system installation. This reference public university hospital, founded in 1997, operates under the Health Service of the Regional Government of Andalusia, Spain, serving a region of 270,000 inhabitants according to the Spanish Institute of National Statistics 2021 report. Prior to the DxA 5000 TLA system installation, the clinical laboratory had a mixture of Auto*Mate*/Power processor sample systems from Beckman Coulter and a separate coagulation system. Staff were responsible for pre-selecting samples for processing, with several manual interactions throughout the workflow that possibly undermined the performance of the testing. We aimed to understand where the workflow could be streamlined not only in terms of time performance, but also in terms of reducing the manual handling episodes the laboratory personnel needed to undertake, to potentially improve safety.

METHODS

Study design

Data was collected on October 2019 (“before” study setting) and August 2022 (“after” TLA DxA 5000 system setting). External personnel observed pre-analytical processes that ranged from courier delivery through sample delivery (i.e., sample “hand-off”) to sample load and analytical processes, over a three day-period during first shift operations. Data collection efforts focused primarily on tracking individual sample tubes to determine the following: (1) the number of “touch-points” (i.e., staff manual handling of samples-tubes) that occurred with each sample prior to analytical activities; (2) detailing the cycle time (CT) to process samples through pre-analytical processes; (3) capturing “testing timeline” of individual samples from receipt to loading and through resulting across Clinical Chemistry Immunoassay (CCIA), Haematology and Coagulation testing disciplines.
In the “before” study setting, the core lab testing systems included the following:

- CCIA: track-connected Beckman Coulter UniCel DxI 800 and AU 5800 platforms integrated via Beckman Coulter Power Processor;
- Haematology: Free-standing Beckman Coulter UniCel DxH 800 platforms;
- Coagulation: Instrument Laboratory (IL) ACLTOP 500 systems.

Routine samples arrived via courier. Sample reception staff were responsible for sample processing tasks (remove samples from totes); sort sample by sample type/test discipline; centrifuge samples as required (CCIA & Coagulation); Operate Auto*Mate* pre-analytical systems (CCIA & Hematology); and load processed samples to the different analytical systems /areas.

In the “after” study setting, external personnel observed pre-analytical processes from courier delivery through sample loading onto the DxA 5000 system by the reception staff.

Statistical Analysis

Statistical data analysis was made with mean values calculated from the raw data obtained throughout the three day-period of data collection in the two settings. A paired T-test was computed to determine with a 95% confidence interval the statistical difference in terms of total minutes before and after the installation of the TLA DxA 5000 system.

RESULTS

DxA 5000 system conducted to process simplification with reduced manual handling of samples.

As represented in **Figure 1**, staff had 13 manual handling events throughout the global workflow before the installation of DxA 5000 system. Afterwards, the staff only had three manual handling occasions after the initial reception of the samples, which represents a 77% improvement in terms of the number of times samples had to operated (i.e., load or unloaded into different racks).

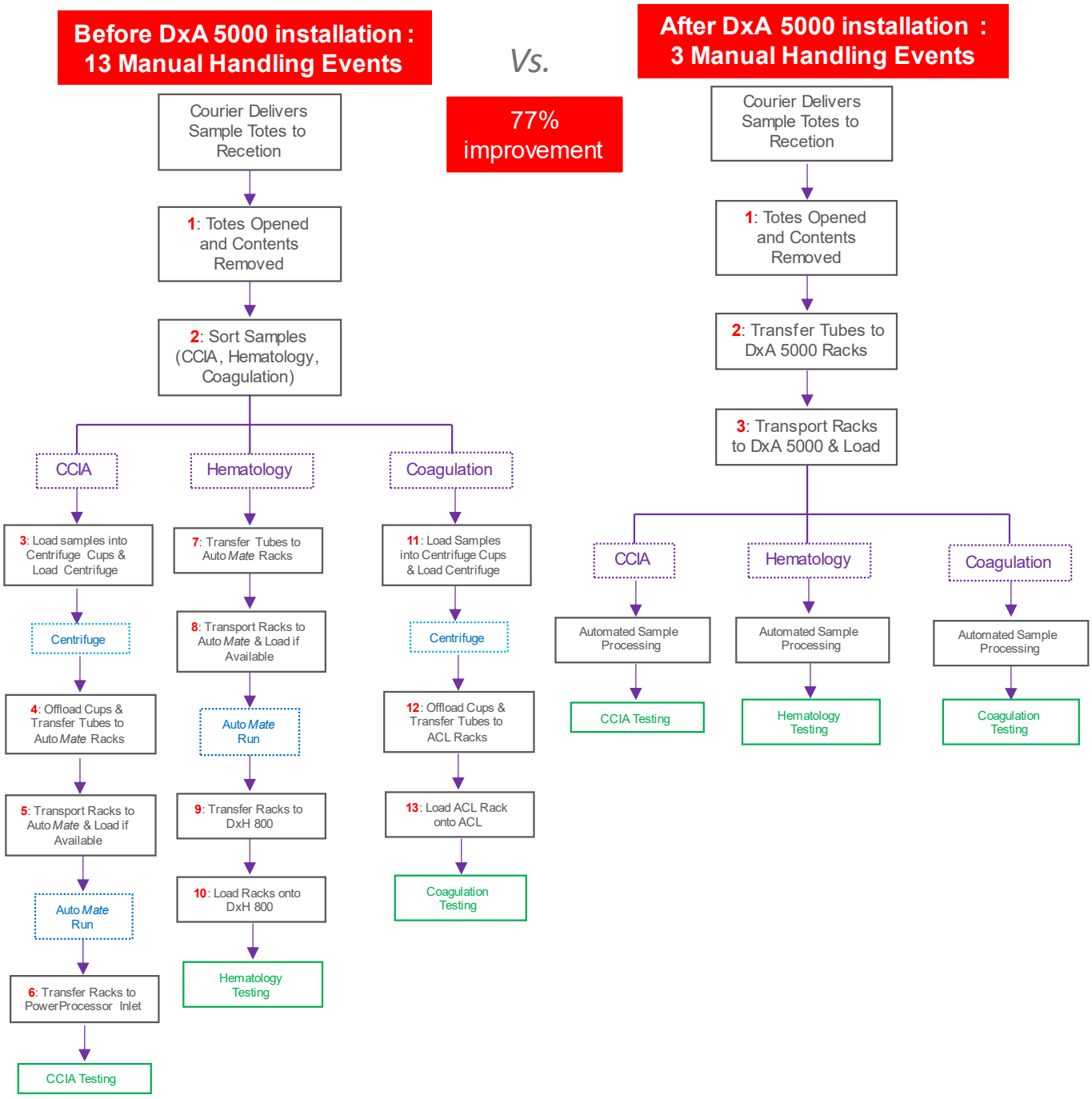


Figure 1 – Global workflow: "Before" (left panel) versus "After" DxA 5000 installation (right panel) in terms of manual handling of samples.

DxA 5000 system allowed Cycle Time compression

As represented in **Table 1**, in 2019 CCIA pre-analytical TAT before the installation of DxA 5000 system was 1h 31min 12 sec; which, improved to 19 min 35 sec, with more than one hour reduction in time, corresponding to a 78.53% performance improvement. Furthermore, TAT until the final test result was reduced from 2h 47 min 58 sec to 1h 21 min 14 sec, corresponding to almost 1 ½ h of time saved and a 51.64% performance improvement. Additionally, once TAT was analysed from sample load until the final result is available, CCI samples were handled 16 min 19 sec faster, with an associated 20.93% improvement in TAT. In relation to Haematology samples, these were analysed in 20 min 50 sec after the installation of DxA 5000 system, showing an improvement of 41.89% in time savings. Coagulation results are available in 32 min with the new TLA.

In pre-analytical haematology, there was ~15 min reduction in time, corresponding to 30.58% improvement; albeit in coagulation there was less than 1% improvement. In relation to the TAT until the final test result was available, haematology samples were processed 27 min 34 sec faster, with a 33.17% improvement in TAT.

Table 1: TAT Comparison

TAT: Pre-Analytical	Before (h:min:sec)	After DxA 5000 (h:min:sec)	Time Saved (h:min:sec)	Improvement (%)
CCIA	1:31:12	0:19:35	1:11:37	78.53%
Hematology	0:49:42	0:34:30	0:15:12	30.58%
Coagulation	0:21:11	0:21:03	0:00:08	0.63%
TAT: Pre-analytical to final result	**Before (h:min:sec)**	**After DxA 5000 (h:min:sec)**	**Time Saved**	**Improvement**
CCIA	2:47:58	1:21:14	1:26:44	51.64%
Hematology	1:23:06	0:55:32	0:27:34	33.17%
Coagulation	NA	0:53:12	NA	NA
TAT: Sample Load to final result	**Before (h:min:sec)**	**After DxA 5000 (h:min:sec)**	**Time Saved**	**Improvement**
CCIA	01:17:57	01:01:38	00:16:19	20.93%
Hematology	00:35:51	00:20:50	00:15:01	41.89%
Coagulation	NA	00:32:09	NA	NA

Table 1 – Cycle time compression: TAT comparison before and after the DxA 5000 installation during pre-analytical phase, TAT until the final test result and TAT from sample load until final test result is available.

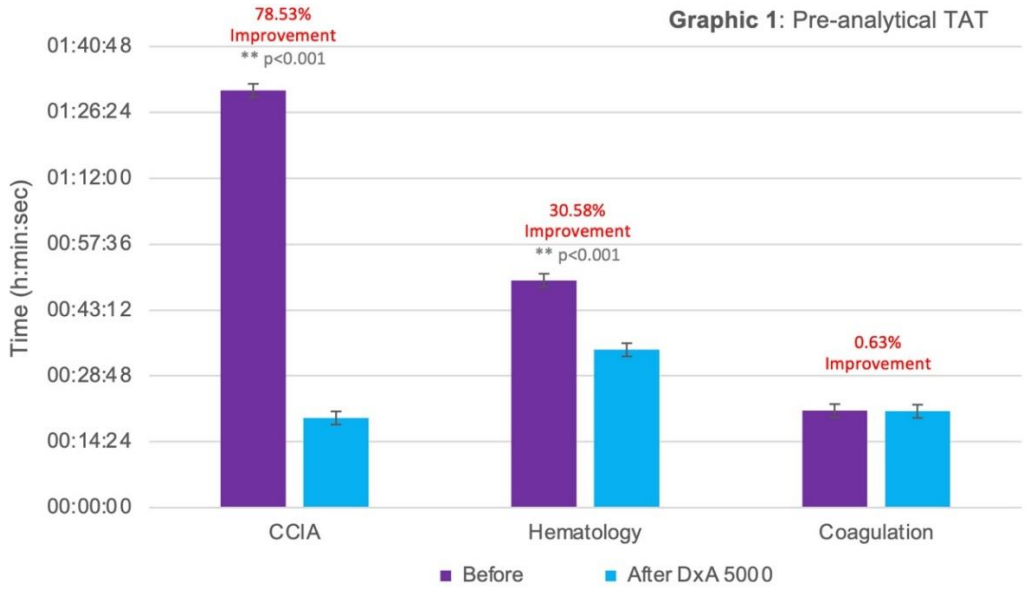
TAT: Pre – Analytical defined as tube arrival in lab to sample load on analyser or connected cutomation.

TAT: Pre-Analytical to final result defined as tube arrival in lab to final sample result.

TAT: Sample load to final results defined as sample offload from Auto*Mate* or scan at connected automation to final sample result.

DxA 5000 system Reduced pre-analytical cycle time.

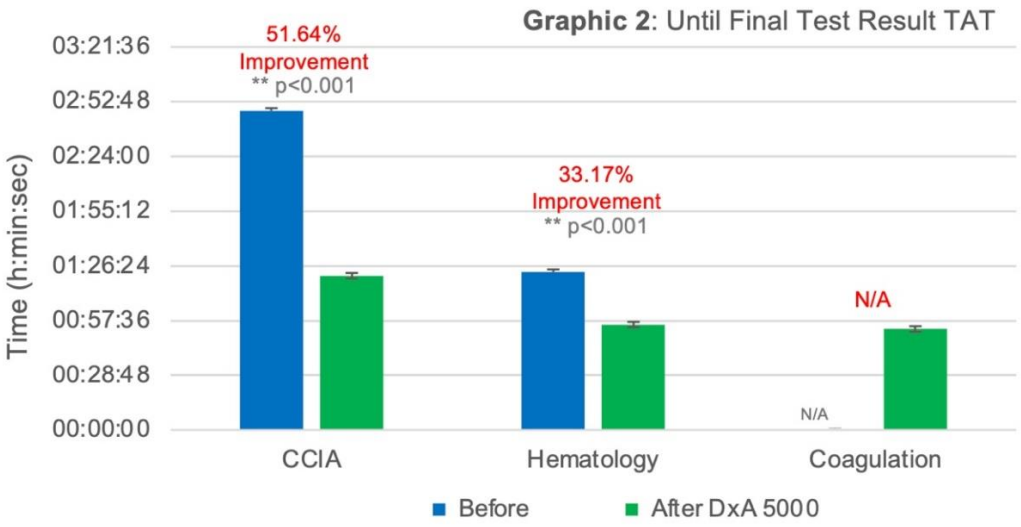
As shown in **Graphic 1**, with the installation of DxA 5000 system there was a clear improvement in laboratory performance in the processing and analysis of CCIA test samples, with a time reduction of more than one hour. In haematology samples, the effect is not so pronounced, but there is still an improvement of 15 min before and after the installation.



Graphic 1 – Pre-analytical Turnaround Time (TAT) before and after the DxA 5000 installation.

DxA 5000 system improved testing Turnaround Time from pre-analytical to final result

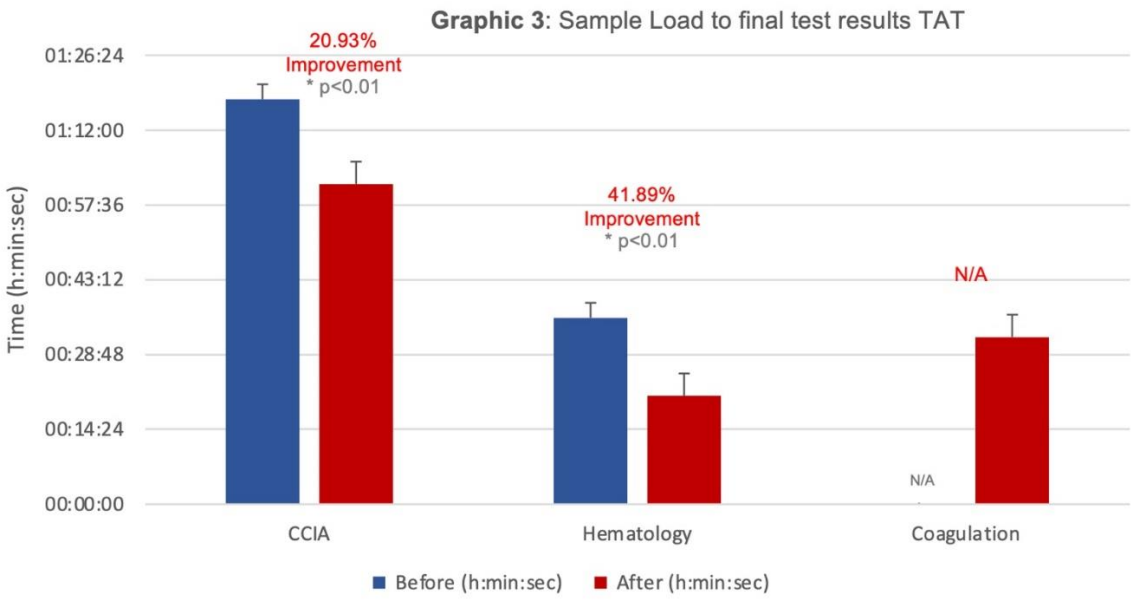
As depicted in **Graphic 2**, CCIA test samples are processed almost 1 ½ h faster after the installation of the DxA 5000 system; with haematology test tubes analysed almost ½ h sooner with the new TLA system.



Graphic 2 – Turnaround Time (TAT) comparison before and after the DxA 5000 installation until the final test result is available for clinical report.

DxA 5000 improved testing Turnaround Time from sample load to final result

As represented in **Graphic 3**, when analysing TAT from sample offload from Auto*Mate* or scan at connected automation until the final sample result is available, there is a 20.93% improvement in the handling of CCI samples. Furthermore, haematological tubes are handled 41.89% faster, with results available in 20 min.



Graphic 3 – Turnaround Time (TAT) comparison before and after the DxA 5000 installation from sample loading until the final test result is available for clinical report.

DISCUSSION

The clinical laboratory of Hospital Universitario de Poniente, Almeria, Spain, recently implemented a Beckman Coulter DxA 5000 system. Prior to the adoption of the TLA system, the laboratory was operated using different platforms for centrifugation, clinical chemistry, coagulation, and haematology with manual transfer of the processed samples to the different analytical systems / areas. Therefore, this hospital represented an adequate forum to clearly identify the clinical effectiveness of DxA 5000 system; and as such, an observational clinical study was conducted to evaluate the improvement in performance of the laboratory in terms of staff safety and TAT.

At the beginning of the study period, for CCIA test analysis the laboratory processes operated using Beckman Coulter UniCel DxI 800 and AU 5800 platform connected via the Beckman Coulter Power Processor; for Haematology samples, a free-standing Beckman Coulter UniCel DxH 800 platform was used; and, for coagulation, an Instrument Laboratory (IL) ACLTOP 500 system was in place. Data for the study were collected in October 2019 and in August 2022 over a three day-period during first shift operations to avoid confounding variables.

Effectiveness was determined by key performance indicators (KPIs) of three turnaround time (TAT) variables: pre-analytical, from pre-analytical until final result available for clinical report; and from sample load until the final result. These TAT variables were considered to be important KPIs, since TAT is a traditional quantitative outcome and is one of the most frequently used indicators for evaluating laboratory performance [6]. To analyse the change in TAT after the TLA adoption, we evaluated the LIS data from the before- and after-TLA periods in order to examine the effectiveness of the new TLA system. The collected data included the test code, test name, and completion time of each test. Workflow analysis was additionally performed to evaluate if staff safety could be increased by streamlining the workflow, with reduced manual handling, using the new TLA. Unlike the LIS data, workflow analysis was conducted from sample registration to archiving to create a sample processing flow chart.

Laboratory automation systems were developed to improve laboratory performance by reducing the number of repetitive tasks that could lead to human errors, as well as standardizing the total testing process [8]. Some studies indicated that one of the main benefits of implementing TLA is the increased staff safety level [8-10]. The present study also showed that this was one of the most effective KPIs. The high level of improvement offered by the TLA DxA 5000 workflow potentially increased staff safety by diminishing the number of events where the tubes needed to be manually handled or loaded into racks. Recently, the importance of staff safety has been particularly emphasized given the impact of the COVID-19 pandemic on substantially increasing the number of high-risk infectious samples to be tested, thereby increasing the risk to laboratory staff [8]. As such, keeping staff away from these samples as much as possible increases their safety and improves hospital care. By automating the laboratory workflow and reducing manual actions that would potentially increase biohazard exposure and risk of injury, TLA systems such as DxA 5000 system can fundamentally reduce the likelihood of mass infections in hospitals. Furthermore, by reducing the number of repetitive manual tasks, skilled staff can concentrate more on tasks that require higher levels of knowledge and experience, such as result verification. In fact, adopting a TLA requires a different skillset from laboratory personnel, such as information technology expertise [8].

The TAT for clinical chemistry samples was reduced by 78.53%, which means that clinicians and patients get their results almost 1 ½ h faster than before. This is a considerable support for the effectiveness of hospital care. Delivering reports quickly and reliably supports an increased confidence, since physicians can respond more quickly to their patient's needs. Furthermore, this optimized TAT not only conducts to an increased clinician's/patient's satisfaction, but also increases the number of samples processed daily, benefiting the diagnostic facility monthly revenue on an operational level.

Even though there has been significant concern that total automation can decrease the need for laboratory personnel at all levels, a recent study showed that with total automation, the number of tests performed per single worker has increased to an average of 1.4 and 3.7 times in the clinical chemistry and serology sections, respectively ($p \leq 0.001$) [11]. Furthermore, it was reported that retirement rates for the clinical laboratory workforce exceeded the number of graduates [12]. As such, TLA may be ideal for laboratories that suffer from workforce shortages but still want to improve their operational workflow. Laboratory automation can increase productivity and improve work scheduling with reduced staff, while providing new opportunities to re-skill and develop all laboratory personnel involved.

CONCLUSION

Laboratory automation shows enormous differences for patient outcomes with a wide range of tests available and a rapid turnaround time, further supporting hospital care. Additionally, it can improve the safety of the clinical laboratory staff, and contributes to the expansion of a central hospital diagnostic facility. A TLA system such as DxA 5000 can effectively optimize laboratory processes and efficiency.

REFERENCES

1. CDC. Strengthening Clinical Laboratories. Division of Laboratory Systems (DLS) U.S. Department of Health & Human Services (2022).
2. Bhatt, R. D., Shrestha, C. & Risal, P. Factors Affecting Turnaround Time in the Clinical Laboratory of the Kathmandu University Hospital, Nepal. Ejifcc 30, 14-24 (2019).
3. Ngo, A., Gandhi, P. & Miller, W. G. Frequency that Laboratory Tests Influence Medical Decisions. The Journal of Applied Laboratory Medicine 1, 410-414 (2017). https://doi.org:10.1373/jalm.2016.021634
4. Dawande, P. P., Wankhade, R. S., Akhtar, F. I. & Noman, O. Turnaround Time: An Efficacy Measure for Medical Laboratories. Cureus 14, e28824 (2022). https://doi.org:10.7759/cureus.28824
5. Chung, H. J., Lee, W., Chun, S., Park, H. I. & Min, W. K. Analysis of turnaround time by subdividing three phases for outpatient chemistry specimens. Ann Clin Lab Sci 39, 144-149 (2009).
6. Hawkins, R. C. Laboratory turnaround time. Clin Biochem Rev 28, 179-194 (2007).
7. Truchaud, A. et al. New tools for laboratory design and management. Clin Chem 43, 1709-1715 (1997).
8. Kim, K., Lee, S. G., Kim, T. H. & Lee, S. G. Economic Evaluation of Total Laboratory Automation in the Clinical Laboratory of a Tertiary Care Hospital. Ann Lab Med 42, 89-95 (2022). https://doi.org:10.3343/alm.2022.42.1.89
9. Lippi, G. & Rin, G. D. Advantages and limitations of total laboratory automation: a personal overview. Clinical Chemistry and Laboratory Medicine (CCLM) 57, 802-811 (2019). https://doi.org:doi:10.1515/cclm-2018-1323
10. 1Genzen, J. R. et al. Challenges and Opportunities in Implementing Total Laboratory Automation. Clin Chem 64, 259-264 (2018). https://doi.org:10.1373/clinchem.2017.274068
11. Al Naam, Y. A. et al. The Impact of Total Automaton on the Clinical Laboratory Workforce: A Case Study. J Healthc Leadersh 14, 55-62 (2022). https://doi.org:10.2147/jhl.S362614
12. Garcia, E., Kundu, I., Kelly, M. & Soles, R. The American Society for Clinical Pathology's 2018 Vacancy Survey of Medical Laboratories in the United States. Am J Clin Pathol 152, 155-168 (2019). https://doi.org:10.1093/ajcp/aqz046

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