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Review Article

Total Laboratory Automation - Is it always a boon?

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Abstract

In this era of automation, successive generations of stand-alone autoanalysers have fully replaced the traditional manual analytical steps in a laboratory. These autoanalysers have highly contributed to increased analytical speed, offered the ability to test high volumes of patient specimens, and provided large assay menus. Development of integrated systems greatly improved the analytical phase of clinical laboratory testing. Further automation has also been developed for pre-analytical procedures, such as sample identification, sorting, and centrifugation, and for post-analytical procedures, such as specimen storage and archiving. All phases of testing have been ultimately combined in total laboratory automation (TLA).

Keywords: Turnaround time, automated instruments, operating cost, quality of testing, system failure.

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1. Introduction

The modern era of automation has brought significant contribution to revolution of many human activities, thus providing unquestionable benefits on system performance.[1] The multifaceted advancement in automation technologies has generated a profound effect on the organization and management of clinical laboratories, whereby many manual tasks have been partially or completely replaced by automated and labor-saving instrumentation. [2, 3]

In total laboratory automation (TLA), most analyzers can perform many different types of tests (i.e. clinical chemistry, immunochemistry, hematology, haemostasis and so forth) and that too, on different sample matrices (e.g. whole blood, serum, heparinised plasma or citrated plasma). These auto-analysers are physically integrated as modular systems or connected by assembly lines (e.g. tracks, belts and other types of conveyers.[4]

Laboratory automation today is a complex integration of robotics, computers, liquid handling, and numerous other technologies".[5] In advanced models of TLA, many pre-analytical and post-analytical steps (e.g. sample input, check-in, sorting, decapping, centrifugation, separation, aliquotting, sealing and storage) are automatically performed in workstations physically connected with the analyzers. All these steps are very efficiently managed by software programs.

So Automation is a customised process that may range from automating only a few steps of the analytical process to total laboratory automation, depending on the needs and resources of each laboratory. As emphasised by Melanson *et al*, selecting clinical chemistry laboratory automation is a complex, time-consuming process.[6] Fully automated low, medium, and high volume analysers are available as independent units. These analysers are designed for a wide range of sample workloads. These may range from small or modest sized benchtop units or large to very large floor models. They routinely employ spectrophotometry for a wide variety of colorimetric and/or immunoassay tests. They often include an ion specific electrode (ISE) module for electrolyte analysis (Na, K, Cl). They can offer a large menu of assays, or may be dedicated to a relatively small number of assays such as test profiles.

Ongoing technological advancements are expected to promote further development of laboratory automation in the upcoming future. This article provides a personal overview on some potential advantages and limitations of TLA.

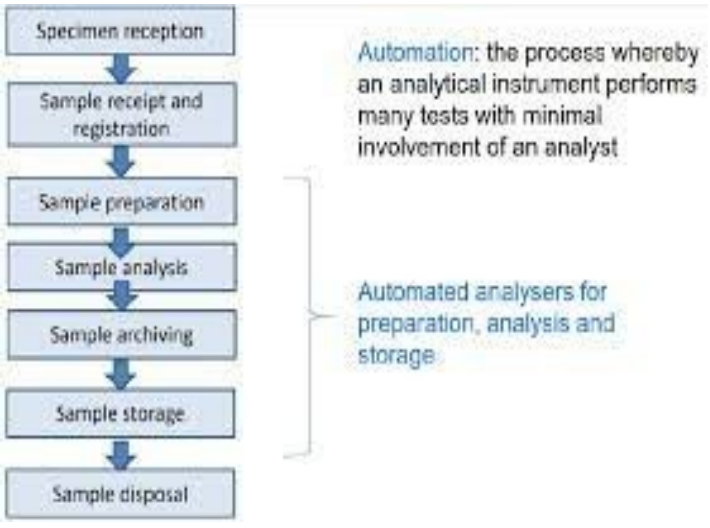

Figure 1: Different steps involved in generation of patient report starting from sample acquisition. Now we can achieve full automation at each of these steps.

2. Potential advantages of TLA

2.1 Lower costs on the long term

An efficient model of TLA can successfully lower the costs of laboratory diagnostics.[7, 8] The net benefit (i.e. the return of investment) is indeed more appreciable on long term when the so-called break-even point is reached. At this stage, the higher initial costs will be offset.[7] Basically, the major economic cost of TLA, results from merging many diagnostic platforms within a consolidated system. But in long term this encompasses a reduction of manual workforce (especially auxiliary and technical staff) which is otherwise needed for managing high volume testing.[8] The financial gains are also attributable to lower pre-analytical and post-analytical expenditures. For example in an automated laboratory, consolidation of the so-called serum working area would actually need collecting a minor number of blood tubes to perform different analyses. This means requirement of smaller storage units for storing a lesser number of specimens after the tests have been completed. However, the economic saving is variable, depending on the final solution of automation adopted and on the relative volume of tests locally performed. Larger is the number of tests, the bigger is the consequent economic revenue of automating many steps of the total testing process.[8]

2.2 Improved efficiency

In TLA, the customizable assembly lines can be well organized to meet specific needs and layouts of different laboratories environment. Several studies now demonstrate that an efficiently designed TLA may be variably effective to reduce turnaround time (TAT). This concomitantly helps to increase laboratory productivity (i.e. throughput).[9, 10] Notably, modern assembly lines can transport a huge number of blood tubes or secondary aliquots at high speed (i.e. between 3000 and 10,000 tubes per hour at a speed of 20–100 m/s), thus considerably offsetting manual transportation.[11]

Yeo and Ng showed that implementation of TLA can help the laboratory to handle huge workload of a laboratory.[12] Such an increased volume of tests may also be accompanied by a notable expansion of the test repertoire. These valuable goals could be essentially achieved by workflow optimization, automatically encompassing diversion or prioritization of samples among the different analyzers.

The modern model of TLA can incorporate several diagnostic lines (e.g. clinical chemistry, immunochemistry, hematology, coagulation and even microbiology). Alongside this line, TLA offers the additional advantage of allowing a combination of modern pre-analytical workstations with analytical platforms.[13] The TLA now enables check-in, sorting, decapping, centrifugation and fully-automated liquid aliquotting of different tubes types and sizes, followed by circulation of automatically labeled secondary aliquots into TLA, thus overcoming the challenge of adapting different analyzers to different types of tubes. The modern generation of laboratory instrumentation is also equipped with advanced software programs, allowing better sample management.

2.3 Improved sample management (e.g. rerun, reflex and add-on testing) and traceability

Information technology (IT) has profoundly contributed to improving medical laboratory work and organization. Some high-risk erroneous activities connected to manual transcribing data have been virtually eradicated. This has also enabled reducing the TAT.[14] It has helped to set decision rules based on predefined criteria. This now allows auto-verification of data and automatic re-analysis of samples with highly abnormal or suspect results. This ultimately contributes to enhance the quality and safety of diagnostic testing.[15,16] The efficiency of performing these important activities is highly increased in laboratories using TLA.

Last but not least, specimen traceability is also consistently increased by maintaining all routine and stat samples within a closed environment, enabling digital traceability of all the processes a tube has been subjected to, from time of delivery to the laboratory; up to storage once testing has been completed.

2.4 Enhanced standardization for accreditation / certification

Keeping all the different phases of the total testing process under control, including extra-analytical activities, is a mainstay of total quality in laboratory diagnostics.[17] It has also become a necessary requirement of International Standards Organization (ISO) 15189: 2012 accreditation.[18] Consolidating different diagnostic areas within the same workspace would require less administrative efforts to develop and update standard operating procedures (SOPs). In TLA, wherein multiple procedures for pre-analytical and post-analytical sample management can be merged when many analyzers are integrated. Notably, TLA also seems profitable for many aspects related to the analytical quality, such as quality specifications of the assays, traceability of calibrators, improved quality and stability of reagents. But laboratory professionals should evaluate all technical planning, including infrastructure before the adoption of a specific model of TLA.

Automation enables increased accuracy and repeatability throughout the total testing process. It lowers the risk of diagnostic errors, especially those emerging from the manually-intensive activities of the pre-analytical phase.[12] Hawker *et al* showed that implementation of a major automation system in a medical laboratory was effective to decrease the number of lost specimens by over 50%.[7] This would grant paramount benefits in terms of standardization, thus simplifying certification and accreditation procedures.

2.5 Improved quality of testing

Some integrated pre-analytical workstations can also automatically perform quality assessment for monitoring specimen integrity (i.e.Haemolysis, icterus, lipaemia (HIL), sample volume, presence of clots or bubbles, serum/plasma indices and so forth).[19] Such improved process will yield enormous benefits on the quality of the total testing process.

2.6 Lower sample volume

One of the previously mentioned advantages of TLA is the opportunity to reduce the number of blood tubes needed for testing. The same serum tube can be used for multiple clinical chemistry and immunochemistry tests due to decrease in sample volume requirement for testing. [20] Indirectly, a reduced sample volume will also generate a lower biological waste disposal. So it also helps in environmental conservation.

Containment of unnecessary diagnostic-related blood loss and prevention of blood drawing-related anemia is especially important in subjects such as neonates, anemic patients or those needing repeated laboratory testing for critical illnesses.[21] The use of lower blood volumes is also important in patients with difficult veins, for whom drawing multiple blood tubes may not be easily feasible. [22]

2.7 Lower biological risk for operators

Worker safety is one of the most important advantages of automating industrial operations. Automated systems not only remove operators from the workplace, but also safeguard them against the risks of performing certain hazardous manual tests. [23]

2.8 Staff requalification and job satisfaction

The minimization of manually-intensive labor is one of the major advantages of TLA, which would then translate into a net saving of staff (both technical and auxiliary) needed for managing laboratory workflow.[7] Hence, this would enable to re-qualify the lab personnel, eliminating manpower and redefining job roles towards value-added tasks such as quality assessment or implementation of new tests (e.g. genomics). This ultimately leads the way towards personalized (laboratory) medicine. [24] With TLA, lab personnel requalification can be intellectually satisfying, thus increasing the morale and productivity of the staff.

3. Potential limitations of TLA

3.1 Space requirement and infrastructure constraints

Space requirements and infrastructure constraints are the major issues for implementing TLA. Accommodating big multiple analyzers and new hardware into a pre-existing environment is a big challenge, especially when the building is not purpose-built for this scope. It is obviously easier to create a new space than renovating an existing one especially when the infrastructure of the building is old. [25] In the latter scenario, when renewing possibilities are limited, the system configuration should be necessarily designed around the local environment, so that analyzers orientation and access for maintenance or repair may be acceptable.

3.2 Increased costs for supplies (i.e. maintenance, energy and supplies)

The implementation of new hardware, essentially represented by pre-analytical workstations, assembly lines and sample storage units, carries significant costs for running the system (i.e. energy and water) and for supplies. A large model of TLA would also require a higher level of maintenance than for manually-operated instrumentation. [26]

3.3 Higher costs on the short term

The investment for implementation of TLA is inevitably associated with an initial escalation of costs for

accommodating the project (i.e. environmental modifications, powerful air conditioners, sound-proofing), for system installation and for the new hardware (e.g. enhanced expenditure for pre-analytical platforms and assembly lines used for connecting separate analyzers). This may be an issue in some facilities, where the budget allocated to the laboratory by the hospital administrations for a new tender is low. [8] Hence, a negotiation with the hospital administration would be necessary to clearly illustrate the possible return of investment achievable by shifting toward TLA. This must be accompanied by a reliable financial planning accountable for expenses and projections of revenues.[26]

3.4 Increased generation of noise, heat and vibrations

The consolidation of many analyzers in the same area (e.g.in the "core lab") will concentrate noise, heat and vibrations in a narrow environment. Hence, this may be perceived as excessive warming and increased exposure to acoustical or electrical noise in the workplace. [25]

3.5 Increased risk of system failure

The higher is the complexity of the system, the greater is the risk that a system failure would generate serious consequences on laboratory functioning. This concept especially applies to laboratories using complex TLA models, where many analyzers are physically connected by assembly lines. Critical system failures, especially involving the assembly lines, would require restoring manual procedures for managing samples.[26] These unfavourable consequences are magnified by a decreased manual workforce and understaffing, as commonly happens with TLA.

So even with TLA, a back-up power supply, hardware, software and semi-automated procedures must always be kept as suitable alternatives for limiting turnaround time (TAT). The possibility of manual sample loading into the analyzers during emergency situations should always be preserved.[26]

In TLA, replacement of manual activities with automation has some major consequences, e.g. rapid deterioration of skills and inefficient resuming of manual functioning when automation should fail. These two aspects are especially important in clinical laboratories, as the transfer of technical skills to the operational environment would then make it challenging. There may the almost irreversible loss of confidence in manual skills, whilst the second, even more challenging, is the lack of manual power (consequent to staff reduction) needed for resuming all those manual activities that have been conveyed to automation (e.g. sorting, centrifugation, decapping, aliquotting or recapping, sample loading and unloading, and so forth). So the system failure may completely paralyse the laboratory, and the laboratory is unable to provide data to the clinicians. This may ultimately jeopardize patients' health.

3.6 Risk of transition toward a manufacturer's driven laboratory

A highly automated clinical laboratory strongly depends on constructive partnership with manufacturers. [26]The establishment of a strategic relationship with suppliers is essential for achieving the goal of an efficient TLA. So tenders should be more accurately defined according to the expected laboratory layout in case of TLA. Full commitment to a single vendor may be an additional risk, as this may pave the way to a manufacturer's-driven laboratory. So this may substantially limit laboratory personnel from organizing and managing their own laboratories.

	Advantages of Total Lab Automation	Disadvantages of Total Lab Automation
1.	Increased processing of diagnostic samples a) Improvement of laboratory workflow b) Better Management of patients reports c) Cost savings in long run	Difficulty in laboratory adaptation to automation a) Staff training b) Expensive equipments
2.	Improved quality and reproducibility of patient results	Increased risk of crash of the automated system (a backup is essential) a) A good support and maintenance is very essential b) Expensive maintenance budget
3.	Reduced time to results a) Decreased hospitalization time b) Reduction in nosocomial infections	Dismiss of staff a) Staff escaping b) boring and lonely work

Source of Table [27]**:** Antony Croxatto, G Prod'hom, F. Faverjon, Rochais Yannick. Laboratory automation in clinical bacteriology: What system to choose? Clinical Microbiology and Infection 2016; 22(3).

4. Conclusions

Automation is one of the most important breakthroughs that have occurred in laboratory diagnostics over the past decades. But in TLA, each laboratory has need of its unique automation modules. So selection of the most suitable (often flexible) model of laboratory automation is a challenging enterprise. TLA has been proven effective to improve efficiency, organization, standardization, quality and safety of laboratory testing. It also provides a significant return of investment on the long-term and enables staff requalification. On the other hand, developing a model of TLA presents some potential problems, mainly represented by higher costs on the short-term, enhanced expenditure for supplies, space requirement and infrastructure constraints, higher risk of system failure, disruption of staff trained in specific technologies, along

with the risk of transition toward a manufacturer's guided laboratory. Hence, the accurate analysis of all these advantages and limitations of TLA should guide laboratory directors to configure a local solution suitable for meeting current testing needs and handling future demands.

Author contributions:

The corresponding author wrote the whole manuscript. The second author contributed to critical review of the manuscript.

Conflict of Interest: None

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