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Review Article

Automation in clinical laboratories: an overview

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Abstract

In the present era, all the sectors are undergoing automation and clinical laboratories cannot be left alone without automation, otherwise they will fail to achieve their goals of delivering good quality patient care services. The objective of present article is to make the clinicians, healthcare providers and laboratory personnel aware and to update their knowledge in terms of automation in laboratories.

Keywords: Clinical laboratories, automation, Indian scenario

1. Introduction

There have been significant changes in clinical biochemistry over last 60 years; particularly last 10 years with the introduction of total lab automation (TLA). Clinical biochemistry has a great influence on clinical decisions and 60-70% of the most important decisions on admission, discharge, and medication are based on laboratory results.[1] As we learn more about clinical laboratory results and incorporate them in outcome optimization schemes, the laboratory will play a more pivotal role in management of patients and the eventual outcomes.[2]

In Indian scenario the clinical laboratories come under unorganised sector and there is no uniformity in techniques, procedures or methods adopted by them. Each clinical laboratory performs independently depending upon the available financial and human resources, its location and the medical needs of the nearby population to which it largely caters including associated hospitals, dispensaries etc. In big cities the clinical laboratories are situated at a distance of about few hundred meters and at other places these are not available even at long distances.

As per National Accreditation Board for Testing and Calibration Laboratories (NABL) criteria[3], the clinical laboratories are classified as under:

- Small Laboratories (below 100 patients/ day)
- Medium Laboratories (101-400 patients/ day)
- Large Laboratories (above 400 patients/ day)

In above laboratories apart from investigation quantum, the spectrum of investigations may vary hence no uniform pattern can be drawn for uniform standardisation of laboratories in terms of its quality.

1.1 Why the automation is required?

In order to obtain high throughput,[2] efficacy and accuracy with minimum expenditure of reagents in limited time and space, automation becomes essential.[4,5] Moreover there will be minimal manpower requirement,[6] minimal human contact with potentially infected materials, thus ensuring individual safety.[7,8,9] Automation of laboratories will be more

productive in terms of economic considerations with minimum expenditure and maximum profit attained, along with provision of the good quality services to the patients.[5,10]

1.2 Advantages of automation:

- Decrease in the turnaround time (TAT) for the investigations. TAT is defined as the time interval from the sample arriving in the laboratory to the verification of the results.[11]
- More useful for doing emergency samples.[12]
- Increase in the spectrum of tests several fold in the limited time and space.
- Accuracy and reproducibility are high in an automated system.
- Less requirement of manpower due to less human intervention and fewer laboratory errors during pre-analytical, analytical and post- analytical processes, make it cost-effective.[13]
- Speedy delivery of reports to the clinician and patients.
- Use of walkaway technology makes it more users friendly.[4,8]
- Generation of waste is also decreased considerably.
- Increased staff safety.
- Better control of the entire process.

1.3 Disadvantages of automation:

- High capital cost in terms of instrument installation and maintenance.[14]
- Dependency on vendors. Delay is inevitable in the cases of non-availability of spares. Moreover, the status of international market may affect the supply of reagents and spares of equipment.
- Reagent kit availability may be a problem. They may give erratic results after some time of use.
- Running cost is very high especially for sophisticated tests because the number of samples is minimal.
- Availability of maintenance of instruments and supply of reagent kits is limited to big cities and not available in remote/hilly areas.
- In cases of breakdown or if the equipment is out of order, alternative arrangements are very costly.[14]

The goal of a successful automation must be to change the way in which work is done in the laboratory and this involves changing not only the tools and processes, but also the job structure and ultimately the way people think about their work.[13] The progress in automation and convergence of technologies are two key factors, which particularly affect how we think about the future of clinical chemistry.[15]

Benefits of automation can be realized in terms of improvements in service to both caregivers and patients.[16-20] Laboratory directors are faced with the challenge to balance cost with the goals of quality services delivered.[21-24] Automation is a customized 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. Technology is also available to automate core laboratories, which combine chemistry and haematology testing for further efficiency. Each laboratory must decide for itself, whether or not automation should be implemented and, if so, when, and to what extent.[25]

2. Recommendations

2.1 Small size laboratory:

Limited automation is recommended in small laboratories. For haematological investigations, fully automated haematology analyser having capability of performing about twelve parameters with throughput of up to 60 tests per hour may be procured.[26,27]

Microwell Enzyme-linked immuno sorbent assay (**ELISA**) strip reader is recommended for hormones, tumour markers etc.

For biochemical tests and other investigations semi-automated instruments are sufficient where reagent and sample mixing is performed manually using micropipettes (table 1). Glass pipettes should be totally discontinued especially for small volumes up to 1 ml. Moreover bottle top dispensers are recommended for speedy and accurate dispensing of reagents. This also avoids cross-contamination.[26]

2.2 Medium size laboratory:

Medium size laboratories can use fully automated instruments. Fully automated haematology analysers with three or five part differential count and capability of performing around 18 parameters with a throughput 60 or more tests per hour is recommended.[18]

Semi-automated microwell ELISA plate reader with washer or chemiluminescent analyser is recommended for hormones, tumour markers etc.

For biochemical investigations, medium size laboratories can use fully automated instruments with a throughput of around 200-400 tests per hour.[19] This instrument should be able to perform serum electrolytes also (table 1). It is recommended to have programmable open loop system so that kits of any company may be used. Alternative back up instrument should always be kept to perform the investigations in cases of major breakdowns, inevitable problems in the maintenance of the main instrument or delay in reagent kit availability.

Wherever possible, online reporting system should be developed for speedy delivery of reports to OPD and inpatient department which may be achieved through LAN (local area network) or internet. This significantly reduces the burden of generation of duplicate reports, which occurs due to errors or delays in retrieval of original reports.

Internal as well as external quality assurance should be part of automation and the staff should have proper qualification and outlook in this regard.

2.3 Large size laboratory:

High speed haematology analysers of high throughput with three or five part differential count is recommended with the capability of performing around 22 parameters.[18,19]

Fully automated microwell ELISA processor or fully automated chemiluminescent analyser with a throughput of 120 or more tests per hour, preferably with walkaway technology is recommended for hormones, tumour markers etc.

For biochemical investigations, fully automated analyser with high throughput and capability to perform at least 800 tests per hour including serum electrolytes is recommended. Also the variety of tests to be performed can be increased several fold (table 1). Such laboratories can go for total lab automation (TLA) with automation in pre-analytical, analytical and post-analytical phases of a sample investigation including:

- Identification establishment through bar code generation for sample collection and using hospital information system (HIS) network.
- Automated centrifugation, although expensive, may be considered the first requirement for efficiency in automation. Pre-analytical automation can reduce labor costs by up to 50% .[28]
- The Intelligent Aliquotter, comprising a serum-level detector and secondary-tube labeller and aliquot unit, has brought about fundamental change in processing of samples in clinical chemistry. Serum aliquoting and transport to different instruments for further analysis and reporting is considered important in TLA.[7]
- One of the priorities in clinical chemistry is rapid access to appropriate information and laboratory information system (LIS) continue to develop to meet this demand. LIS facilitates all aspects of clinical laboratory work from registering of samples to interpretation of data. It has been noted that there is abundance of information in biomedical sciences, which is continuously changing. Laboratory specialists and clinicians need access to scientific-based information anytime and anywhere. Online transmission of data aids in patient's convenience to get report at home, office, hospital and is easily accessible for follow up and treatment. Various forms of personal digital assistant are under trial or in use and such tools have information on reference and critical ranges, interferences, pathophysiology, sample collection and many more.[29]
- Computers are not only capable of running highly automated instruments but also of implementing expert rules to

allow validation of results and their immediate release.[30]

- Video conferencing facility, telemedicine and interactive discussion facility should be available in all large size laboratories.

Table 1: List of instruments recommended for laboratories[#]

	Classification of clinical Laboratories as per NABL.	**For haematological investigations**	**For hormones, tumor markers etc.**	**For biochemical investigations**
1.	Small Laboratories (below 100 patients/ day)	Fully automated haematology analyser with capability of: •12 parameters •throughput of ≥60 tests/hr.	Microwell ELISA strip reader.	Semi-automated instruments.
2.	Medium Laboratories (101-400 patients/ day)	Fully automated haematology analyser with: • 3 or 5 part differential count. •18 parameters • throughput of ≥60 tests/hr.	Microwell ELISA plate reader with washer or chemiluminescent analyser	Fully automated chemistry analyser. • Throughput of 200-400 tests/hr. including electrolytes.
3.	Large Laboratories (above 400 patients/ day)	High speed hematology analysers with • high throughput • 3 or 5 part differential count • 22 parameters.	Fully automated microwell ELISA processor or fully automated chemiluminescence analyser with a throughput of ≥120 tests/hr. with walkaway technology.	Fully automated chemistry analyser with high throughput with ISE • ≥800 tests/hr. including electrolytes.

[#] may be modified as per individual laboratory requirement.

2.4 Important points to be considered:

- Annual maintenance contract (AMC) or comprehensive maintenance contract (CMC) should invariably be available with all the sophisticated instruments.
- For storage of kits, automated temperature regulated refrigerator with digital temperature display and warning alarm should be available wherever possible.
- It is very important to have suitable uninterrupted power supply (UPS) facility made available with all sophisticated instruments.
- Dipstix and Rapid test kits (card test) should be available for the diagnosis of HIV, HCV, HBsAg, Dengue serology, Malaria antigen, Pregnancy test, Cardiac Troponin T, RF, CRP, ASLO etc. in all laboratories.
- The clinical laboratories may cater in the field of pathology, microbiology, biochemistry and immunology.
- Office automation should be done in all laboratories.
- For blood banks, special license should be obtained through government agencies, hence all the due formalities as per the requirement of licensing authority should be completed, which may vary from time to time.

3. Conclusion

Automation of clinical laboratories is need of the hour. Every clinical laboratory should assess their requirement, depending upon the availability of resources. The above information is indicative only and may be modified as per the clinical laboratory requirements based on the clinicians/local population demands.

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