LABORATORY AUTOMATION- TECHNOLOGICAL INNOVATION IN CLINICAL LABORATORY MEDICINE- A REVIEW

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ABSTRACT: Laboratories play a crucial role in the quality health care delivery and diagnosis of disease. Automation of laboratory instruments brought tremendous transformation in the diagnostic laboratories. Laboratory automation is the result of combined efforts of both medical , engineering fields with a common target of improving patient care. Accuracy of the test results and minimizing the turnaround time (TAT), reducing the errors, improving lab safety are the main goals of laboratory automation. The present review article focused on automation of different processes of the laboratory

KEY WORDS: laboratory automation, Auto analyzer.

INTRODUCTION :

Laboratories play a crucial role in the quality health care delivery and diagnosis of disease. Automation is a technological innovation in the field of diagnostic laboratories. Laboratory automation is the result of combined efforts of both medical , engineering fields with a common target of improving patient care. Accuracy of the test results and minimizing the turnaround time (TAT), reducing the errors, improving lab safety are the main goals of laboratory automation.

With automation the analytical instrument performs many tests with only minimal involvement of an operator. Though automation was used only for analytical processes during 90' s ,due to introduction of new technology revolutionary modification occurred in laboratory automation where in addition to analytical process, automation is also used for non-analytical processes (1). Automation of non -analytical processes, using conveyor systems, interfacing analyzers, and

automated specimen processing and storage etc is considered as Non analytical automation (1,2). Combining the pre and post analytical functions with analytic activity is considered as total laboratory automation (TLC) (2,3). The information presented in this study was gathered using various data base such as PUBMED, Science Direct, Scopus and Google Scholar and the keywords used were "laboratory automation", "technology "and "Autoanalyzer".The inclusion criteria were: (1) Articles published in English language; (2) Research or review articles; (3) Published from 2000 to July 2020.

Automation reduces manual interference , decreases human error, decreases the turnaround time , improves accuracy, considerably increases total number of tests done in less time, quality, repeatability ,efficiency , accuracy. Automation also relieves the technologist from monotonous work and aids to focus on other important issues and to use their expertise , Uses minimum amount of sample and reagent, Improves safety and makes it easy for 24/7 operation of the laboratory . However, according to recent studies continuous monitoring of analytical procedure and analytical quality by qualified, well trained technologist and following well defined standard operating procedures are crucial factors to reach the goal (3). The major obstacles for automation are the cost, regular maintenance of the instruments, requirement of qualified laboratory professional and quality control methods.

Masahide Sasaki, Professor and Director of the Department of the Clinical Laboratory at Kochi Medical School, Kochi, Japan , who has been considered as the father of modern clinical laboratory automation created the world's first automated laboratory (1,4,5,6). . He trained a group of medical technologists to assemble conveyor belts and electronic boards and to program robots. His 45 minutes demonstration video on clinical automation in front of around 900 people at the American Association for Clinical Chemistry in Atlanta, GA, in July 1989 caused transformation in laboratory medicine. His spell bound presentation about the possibilities for error reduction, and remarkable decrease in turnaround times gained the attention of the western countries(1,4,5,6). Later revolutionary developments occurred in the field of diagnostics as a result these days some of the laboratories are using systems that either automate one or more non-analytic functions (task-targeted automation or TTA) or use conveyors to link several non-analytic functions to analytic testing (Total Laboratory automation -TLA) (1,4,5,6).

The three phases of laboratory work flow are Preanalytical, Analytical, Post analytical phases. Around 70% of the errors in laboratory occur during pre analytical

phase(7,8,9,10). Thus automation of these processes is helpful in error reduction. Preanalytical phase plays a chief role in maintaining the quality of the laboratory (7). Automation of pre-analytical processes includes automation of operations like specimen receiving, identification , labeling, centrifugation and specimen preparation, decapping and sorting etc. After specimens are processed, they are transported to suitable workstations in the laboratory. Specimens are transported either manually or using conveyor systems, to the analyzers where they can then be analyzed with minimal or no human intervention (1). Automation of post analytical process involves result issue, waste disposal, storage of sample etc.

Automation of Pre-analytical processes in the clinical laboratory:

Specimen identification : Proper specimen identification is necessary for appropriate analysis. Laboratory should be provided with correct request and correct specimen. Different identifiers like serial number, part number, colour, patient name, medical record number or accession number are used for specimen identification. Various new techniques like Bar coding (code 128 B symbology), Magnetic stripe, Optical character recognition, and magnetic ink character recognition, Voice identification, Radiofrequency identification (RFID),Touch screens, Light pens, Hand print tablets, Optical mark readers, Smart cards are used for Automatic specimen Identification and data collection [1].Among these methods Bar coding system is considered to be the best technology for positive specimen identification. A bar coding system includes a bar code printer and a bar code scanner or reader. There are two types of Bar coding system(a) one-dimensional or linear bar code systems (b) Two-dimensional bar coding system. One-dimensional or linear bar code contains series of black bars and intervening white spaces, the arrangement of which is defined by specific bar code symbology (1). A small spot of light is passed over the bars and spaces by the using a scanning device, to decode the information in a bar code. This bar code scanner can be hand-held or a device mounted in a lab instrument. The dark bars present in the bar code will absorb light, whereas the white spaces will reflect light. The differences in reflectivity are translated into electrical signals by a light detector inside the scanner (1). The signals are transformed into binary ones and zeros. These are used in a variety of combinations to stand for specific numbers and letters. Code 128 is the common format used in clinical laboratories since this standard can encode all 128 ASCII (American standard code for information interchange) characters and requires the smallest amount of space compared to other linear barcode standards(1,11).(CLSI published standard (AUTO02-A) in 2000 and updated it (AUTO02-A2) in 2003) .Two-dimensional (2D) barcodes gives more information

compared to a linear barcode (1). In Two-dimensional (2D) barcodes a grid pattern of data elements are used to encode information in both the horizontal and vertical directions. By the using of barcode system we can avoid the human errors during loading of the samples in the analyzer and decrease identification errors (1) and we can also trace the samples during processing. At the same time errors are possible due to the minor defects in printed bar codes, inappropriate bar code scanner resolution or skewed orientation of bar code labels on the containers can result in read errors. [1]

Specimen Preparation and delivery : Once the specimen is identified ,itshould be routed to the correct part of the laboratoty. During specimen preparation enough time is required for the processes like clotting of the sample , centrifugation etc. Some of the instruments are accommodated with some automated processes to cut short the delay made by the manual processes. Hospital Pneumatic tube systems (HPTS), mobile robots and Track Vehicle System (TVS) are used to transport specimens and other laboratory supplies. Pneumatictube systems are reliable when installed as point-to-point services. They provide rapid specimen

transport but proper designing , monitoring and proper packing is required to avoid mechanical problems and hemolysis.(1,2). Automated guided vehicles (AGVs) or Mobile Robots have been used successfully to transport laboratory specimens both within a laboratory and outside a central laboratory (1) but they are cost effective ,especially for small laboratories and laboratory personnel required to place specimens onto or remove specimens from the mobile robot at each stopping place. In addition automation also replaced many manual processes like specimens sorting, loading, centrifugation, decapping, aliquoting, sealing etc (12).

Autoanalyzers

Auto analyzers play crucial role in the test analysis. There are different types of autoanalyzers. Among them random-access analyzers are the most common analyzers. In random-access analysis, testing can be performed either sequentially or prioritized (ie, STAT) on a set of specimens, with each specimen tested for a different tests based on its respective clinical orders. The different vials, packs, or kits of reagents which are required for processing the tests are stored onboard the analyzer.

Types of autoanalyzers : There are different types of analyzers -Continuous flow analyzers, Centrifugal analyzers, Discrete auto analyzers, Dry chemical analyzers

Single or multi channel continuous-flow analyzers: Continuous-flow analyzers were the first automated analyzers (invented in 1957 by Leonard Skeggs) used in clinical laboratories . There are single channel or multi channel continuous flow analyzers. The single channel continuous flow analyzer can estimate single parameter on a large number of specimens simultaneously . In this the specimens and reagents are passed through a single hydraulic line where the reaction takes place, and the samples are separated by series of air bubbles. The air bubble form a discrete sample packets and prevent cross contamination, creates turbulent flow and helps in the easy check of the flow characteristics of the liquid. The extent of reaction is finally read using a colorimeter, spectrophotometer, nephelometer or fluorimeter and then displayed on the screen or printed (1,13). The multi-channel continuous flow analyzers work based on the same principle like single channel analyzers but analyzes two or more parameters at the same time. In these analyzers sample and reagent are transferred to cuvette, then mixed ,incubated and analyzed at specific wavelength according to the programming of the test parameter (1,13).

Centrifugal analyzers : In Centrifugal analyzers specimens and reagents were loaded into discrete chambers in a rotor by discrete pipetting (1, 13). Then the samples were analyzed sequential manner in parallel by spinning the rotor. Spinning exert centrifugal force to mix the specimens and reagents and also moves the mixtures into cuvettes located on the periphery of the rotor(1,13). Such analyzers could be operated in a multiple specimen/single chemistry or a single-specimen/multiple-chemistry mode (1, 13).

Discrete analyzers: Discrete auto analyzers are the most popular and versatile analyzers. They contain separate testing cuvettes for each test and sample (random or irregular access). They have the capability of running multiple tests-one sample at a time or multiple samples-one test at a time. And each sample is treated differently according to the tests requested and programmed by the operator (1,13). Discrete analyzers are provided with a robotic sampling arm which aspirate and dispense accurate quantities of sample and reagents in discrete reaction wells. The reaction occurs in these reaction wells during pre-programmed incubation period and then absorbency is read by a spectrophotometer (1,13).

Dry chemical analyzers: Dry chemical analyzers utilize reagent slides that are composed of several layers. In this dry reagents are spread in extremely thin layers on a plastic chip to which the serum sample is added. The coloured end products are confined to a fixed area on the slide read by a reflectance spectrophotometer (1,13). Dry chemistry analyzers are discrete analyzers.

Automation of post analytical process: After test analysis the result obtained should be transcripted in to report forms and issued without delay. computer assisted reporting of results to linked monitors and printers is helpful in rapid issue of results (14). The integrated systems comprises of automated storage and retrieval options and additionally have options for LIS modules and PC-based software systems, which permit laboratories to track sample trays in their own freezers or refrigerators.

Standalone devices and Total Laboratory Automation Systems (TLA):

Laboratory automation ranges from standalone devices to Total Laboratory Automation Systems (TLA) where different analyzers analyzing different parameters (i.e. clinical chemistry, immunochemistry, hematologywtc) using different sample types (e.g. serum,whole blood, heparinized or citrated plasma) are integrated as modular systems or physically connected by tracking systems (e.g. tracks, belts and other types of conveyers) from begin to end for transferring samples(15). . The stand alone systems perform their task without the cost of a track (15). So, sample transport can be done manually , called 'sneaker network'. As stand-alone systems offer a smaller footprint and comparatively of low cost, may be good choice for laboratories with limited floor space (15). Total Laboratory Automation Systems (TLA) may be of good choice for laboratories (a) with daily workloads of 500 to 1500 specimens, (b) with space limitations, or (c) that desire ease of use with different analyzers from different vendors [1]. TLA is described as laboratory automation where pre-analytical, analytical, and post-analytical operations are automated (15). Automated systems that lack one of these components are considered as subtotal (17). The pre and post analytical systems can be of closed and/or open type. Closed solutions connect the systems of the same manufacturers and the open solution can interface systems from different companies. Among these closed type is common

Single-Function Workstations: These are the Pre analytical auto-mated system that performs a single task, also referred to as task-targeted automation (TTA). Examples of such automation include automated labeling, automated centrifuges, decappers, recappers, aliquotters, and sorters.
Multifunction Workstations (Automated Specimen Processing): These are the Pre analytical auto-mated systems that perform several tasks. These systems will typically (1) receive incoming specimens, (2) sort, (3) decap,(4) aliquot, and (5) label aliquot specimen containers with bar codes.A track system (conveyor) is vital to TLA however this requires more floor space. The conveyor track may either be a 'loop /dual line circular conveyor' or a linear, or 'unidirectional' conveyor. Circular conveyor has a single module for both input of new specimens and removal

of completed specimens. While passing through the loop the specimens will be taken to the processing and analytical modules. Specimens may be sampled directly by the analytical instrument while on the conveyor, or a robot attached to the workstation may remove selected specimens from the conveyor for analysis. (1,15,18). As different diagnostic disciplines can be integrated through one single track this type of system can be more efficient and organized ,can improve quality and lab safety .However ,the chief disadvantages of TLA are high cost ,space and infrastructure, enhanced expenditure for materials etc (11).

laboratory information system (LIS): Laboratory instrumentation is equipped with advanced software system (16). Laboratory information system (LIS) is a software system that manages different tasks like receiving test request, sending laboratory test orders to lab instruments, processing the test and tracking the orders, result entry, Storage of information and data in a well-organized, manner with in the clinical laboratories. In addition to improving all the steps in total testing process, implementation of LIS has a positive impact on quality of issued laboratory results(19). For efficient functioning a multidirectional, coordinated communication between LIS, the preanalytical processing components, the specimen transportation system, the analyzers, and the post analytical archiving system is required (20).

CONCLUSION : laboratory play vital role in the diagnosis of a disease. Laboratory automation decreases turnaround time (TAT), increases work efficiency, on the other hand the extent of automation required depends on individual lab's budget, space & size and work load. Proper work flow analysis and understanding the current status and processing are the important factors for selecting the Laboratory automation. TLA is a complicated and expensive process.TLA can be adapted to handle ever-increasing workload of the laboratory for quicker TATs and for standardization of laboratory operations.

Conflict of interest

There are no conflicts of interest

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