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Pregledni članak

PRE-ANALYTICAL WORKSTATIONS AS A TOOL FOR REDUCING LABORATORY ERRORS

PREANALITIČKE RADNE STANICE KAO SREDSTVO ZA REDUKCIJU LABORATORIJSKIH GREŠAKA

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Summary: Reducing errors and improving quality are an integral part of Laboratory Medicine. Laboratory testing, a highly complex process commonly called the total testing process (TTP), is usually subdivided into three traditional (pre-, intra-, and post-) analytical phases. A series of papers published from 1989 drew the attention of laboratory professionals to the pre-analytical phase, which currently appears to be more vulnerable to errors than the other phases. Consequently, the preanalytical phase should be the main target for further quality improvement. Therefore, identifying the critical steps in the pre-analytical phase is a prerequisite for continuous quality improvement, further error reduction and thus for improving patient safety. Use of automated systems where feasible, and use of error reduction/improved quality as a factor when selecting instrumentation are the main tools we have to insure high quality and minimize errors in the pre-analytical phase. The reasons for automation of the pre-analytical phase have become so compelling that it is no longer simply a competitive advantage for laboratories, but rather a competitive necessity. These systems can impact on the clinical/laboratory interface and affect the efficiency, effectiveness and quality of care.

Keywords: laboratory errors, total testing process, information technology, pre-analytical phase, robotics, patient identification, patient safety

Kratak sadržaj: Redukcija grešaka i poboljšanje kvaliteta su integralni deo laboratorijske medicine. Laboratorijsko testiranje, vrlo složen postupak koji se često naziva procesom totalnog testiranja (TTP), obično se deli na tri tradicionalne faze: pre-analitičku, intra-analitičku i post-analitičku. Niz radova objavljenih počev od 1989. skrenuo je pažnju laboratorijskih stručnjaka na pre-analitičku fazu, koja se trenutno čini najpodložnijom greškama. Stoga bi pre-analitička faza trebalo da bude glavna meta za dalje poboljšanje kvaliteta. Prepoznavanje kritičnih koraka u pre-analitičkoj fazi preduslov je za stalno unapređenje kvaliteta, dalju redukciju grešaka, kao i za unapređenje bezbednosti pacijenta. Korišćenje automatizovanih sistema kad god je to moguće i uvid u redukciju grešaka/poboljšanje kvaliteta kao faktor pri izboru instrumenata jesu glavna sredstva kojima raspolažemo u nastojanju da osiguramo visok kvalitet i smanjimo broj grešaka u pre-analitičkoj fazi. Razlozi za automatizaciju pre-analitičke faze postali su toliko jaki da je ona sada neophodna, a ne više samo prednost u odnosu na konkurenciju. Takvi sistemi mogu uticati na klinički/ laboratorijski interfejs i odraziti se na delotvornost, efikasnost i kvalitet nege.

Ključne reči: laboratorijske greške, proces totalnog testiranja, informaciona tehnologija, pre-analitička faza, robotika, identifikacija pacijenata, bezbednost pacijenata

Introduction

Errors related to laboratory medicine may be defined as »any failure to meet the required output quality necessary for optimum patient care anywhere in the pathway from test selection to the return of an appropriately interpreted report to requesting clinician« (1).

Laboratory errors have been shown to impact patient safety (2–3). They can result in misdiagnosis, inappropriate treatment/therapy, and delays in treatment/therapy, or can cause unnecessary pain and discomfort, such as that associated with unnecessary diagnostic procedures. Some of them are known to result in serious adverse events. Others are much more benign and result only in the re-collection of the specimen. Between these two extremes there is a large variety of possible outcomes

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with different impact on the patient, such as prolonged or unnecessary hospital stays or inappropriate diagnostic procedures and testing. The risk of adverse events and inappropriate care due to laboratory errors ranges from 2.7% to 12%, while in a larger percentage of cases (24.4% to 30%), the laboratory error translates into a patient care problem (4–7).

Traditionally, the total testing process (TTP) has been divided into a pre-analytical phase, an analytical phase, and a post-analytical phase. The pre-analytical phase can be further subdivided into the »conventional« pre-analytical phase, which occurs under the control of the laboratory, and the pre-pre-analytical phase which occurs outside the laboratory and consists of the selection of appropriate tests on the basis of clinical question, ordering, collecting and handling, transportation and reception of samples prior to testing. The »conventional« pre-analytical step involves the processes required to make a sample suitable for analysis: centrifugation, aliquoting, diluting and sorting the specimens into batches for their introduction into automated analyzers (8).

A series of papers published from 1989 drew the attention of the laboratory professionals to the pre- and post-analytical phases, which currently appear to be more vulnerable to errors than the analytical phase. Summarizing the error frequencies found in published studies, the pre-preanalytical phase was affected by 46–68.2%, the pre-analytical phase by 3.0–5.3%, the analytical phase by 7–13%, the post-analytical phase by 12.5–20%, and the post-post-analytical phase by 25–45.5% of all of the errors (9, 10).

Consequently, the preanalytical phase should be the main target for further quality improvement. Therefore, identifying the critical steps in the pre-analytical phase is a prerequisite for further error reduction, and thus for improving patient safety.

Pre-pre-analytical procedures performed outside the laboratory and strategies to prevent errors

The pre-pre-analytical phases performed outside the laboratory are: formulating a clinical question and selecting appropriate examinations, ordering, collecting, handling, and transporting samples. Newer models for the preanalytical phase also include patient satisfaction with the collection process (demeanor and knowledge of the staff), professional staff satisfaction with this phase (request forms easy to understand, availability of satellite drawing stations, adequate specimen transport) and general customer service satisfaction with the menu of testing offered (11).

Errors can occur in each of these steps, the most common being inappropriate test requests, incorrect or incomplete information on the test request, patient or specimen identification errors, use of inappropriate container and excessive waiting time in transporting sample in the laboratory. Paper-based test requests in themselves pose a risk because they may be completed only partially, placed in the wrong collection box, or simply lost. Laboratory order entry systems (LOES) replace the paper-based test request by allowing the ordering information to be directly fed into a computer. This type of system is often combined with the electronic delivery of the test result, sometimes accompanied by a digital signature.

LOES eliminates many sources of error, above all those connected with paper-based information, such as transcription error and loss of requests or results. LOES reduces physician time spent in finding nurses to communicate orders, time spent discussing underspecified or erroneous lab orders with unit clerks, and reduces moreover lab turnaround time (12, 13).

Proper patient identification is a crucial aspect of patient safety in any healthcare organization, being a necessary component for providing safe (effective) clinical and diagnostic services. Patient identification errors are associated with harm, or the potential for harm, when incorrect information is used to link a particular individual to an action or activity. Therefore, the patient safety risk associated with patient identification can be considered as a mismatching between a given patient and their care. These errors can occur in all types of clinical activities, whether they are diagnostic (such as radiology or pathology testing), therapeutic (medication administration, surgery) or supportive (such as patient admission processes) (14).

Patient misidentification in clinical laboratories occurs in several stages: in requesting the sample, in taking the sample, in carrying out the investigation, and in reporting the results. Errors in the process of requesting pathology investigations include, for example, ordering a test for a patient and accidentally putting the details of another patient on the form. Errors in the process of taking the sample include placing the wrong label or tag on the specimen. Errors in the process of carrying out the investigation include mixing up the request and the type of investigation required.

The prevalence of patient misidentification in clinical laboratories has not been extensively investigated. The College of American Pathologists (CAP) published in 2007 a report that reviewed 3.4 million blood specimens collected at 147 institutions, concluding that the median specimen error rate of U.S. laboratories was 1.31 per 1000 labels (15).

To prevent this type of error, it is necessary to positively confirm the identity of the patient before venipuncture. There are three ways to achieve this: (1) non-technological solutions: the query system, or visual or verbal confirmation of patient identity by the health care provider performing phlebotomy, (2)

information technology solutions: use of wireless bar code technology to match the identification of patient and specimen at the episode of specimen collection, after having the labels, generated at the point of care, affixed to the specimens, (3) technological solutions: patient identification reported on a small box containing labeled blood collection tubes automatically prepared in advance, based on the physician's test order, is matched with patient data reported on a bar-coded or RFID wristband at the time of venipuncture using a bar-code or RFID reader handheld device. This transaction must be automatically recorded.

Most agree that automation of the specimen processes will enhance patient safety, quoting the aphorism that »humans do poorly at routine repetitive tasks… [m]achines on the other hand are best for these tasks« (16).

Correct patient wristband identification is also necessary to prevent patient misidentification during specimen collection. Process improvements should be implemented to minimize the number of wristband errors (17).

Diligent execution of appropriate process/workflow remains the key aspect of patient identification. Technology is an enabler, not the sole solution.

Positive patient ID systems

Beginning in the late 1980s, many LISs implemented the ability to print bar code labels for specimens that were newly accessioned upon receipt by the laboratory and for specimens drawn by the phlebotomy team. However, most of these systems did not provide positive identification of the patient sample by comparison with a bar code wristband on the patient at the time of collection.

At the AHA's annual meeting in 1988, Karen Longe presented an integrated system for applying a bar-coded wristband, and using it to follow a patient through the entire admission/treatment/discharge process, including laboratory, radiology, and pharmacy tests and interventions.

Subsequently, several laboratory information systems vendors have introduced positive patient ID systems for phlebotomy, but the vendors were soon to realize that laboratories were not interested in such products (18). In the U.S. perhaps the most powerful influence on the direction and acceptance of PPID systems is the Federal Government; providers will have to implement patient safety strategies to be eligible for incentives. In the past, these solutions were »nice to have«; today, every health care organization recognizes the need for these solutions (19).

Automated test tube labelling systems

The tube labeler is a device that:

- Based on the test order from the LIS/HIS, automatically selects appropriate tubes from several hoppers,
- Prints separate bar-coded labels for each tube,
- Precisely applies the label to avoid difficulty in reading the bar code,
- Places patient tubes into an appropriate container for each patient.

The drudgery and danger involved in the manual blood tube preparation are thus being obviated.

The following three vendors supply different systems:

Techno Medica: BC Robo 585 – Multi-tray system; throughput, up to 300 patients/hour; BC Robo 888 – Multi-tray system; throughput, up to 360 patients/hour.

Radim: SprintLab – Single tray system; throughput, 150 patients/hour (with 4 test tubes).

Becton Dickinson: EOS Lab.E.L.® 8 – Multi-tray system; throughput, up to 308 patients/hour;

EOS Lab.E.L.® 16 – Multi-tray system; throughput, up to 308 patients/hour).

Specimen transportation

Once the sample is collected, it must be transported to the laboratory in time to be processed; various approaches have been used for the transport of specimens to the laboratory and within the laboratory including human messengers, pneumatic-tube system, mobile robot, track vehicles.

Human messengers

Human delivery is inherently a batch process, messengers will only service a given pick up station at discrete time. The time required to call a stat messenger adds cost to the analytical process and increases turnaround time. Tube breakage or loss can occur with manual handling of specimen (20).

Hospital Pneumatic-Tube System (HPTS)

A carrier introduced into a pneumatic tube transport station is moved by vacuum to a centrally located switch where it is aligned with the destination tube and moves by a positive pressure to the destination. A computer is used to control the routing and tracking of all carriers introduced into the system. The number of carriers per unit of time that can be carried in a single zone is an important parameter that determines the overall performance of the HPTS.

Mobile robot

Programmable mobile robots have become more sophisticated, while the cost has decreased. Some mobile robots are capable of not only moving autonomously along the floor, but they have also been programmed to ride elevators, open doors and find their destinations while avoiding obstacles. Mobile robots are able to perform routine tasks in the face of unpredictable obstacles such as elderly patients, who may have limited visual acuity and hearing, and pediatric patients.

Track Vehicle System (TVS)

The system consists of a series of sending and receiving stations, interconnected by a network of electrified track, for powered vehicle. Vehicles for TVS systems are self-powered, safe, low-voltage units. A delivery vehicle consists of a vehicle and a container. The vehicle travels smoothly and quietly along the track to its destination.

Pre-analytical procedures performed within the laboratory

Pre-analytical processing is one of the most labor-intensive aspects of clinical work. It occupies up to two-thirds of the total time spent by personnel on clinical laboratory procedures, consumes a large percentage of laboratory labor budget, approximately 19% of the overall cost of analyzing a single specimen, and exposes laboratory staff to biohazards whenever the samples are splashed or test tubes broken (20).

In addition, due to the largely manual nature of pre-analytical processing, there are many opportunities for laboratory errors, e.g. mislabeling aliquot tubes, centrifugation (time and/or speed), pour-off, failure to place stat specimens in stat queues, excessive waiting time in processing the specimen that invalidates its analysis. The risk of human error in this phase is exacerbated by the fact that currently laboratories are handling ever-increasing workloads while experiencing a reduction in personnel: the consequent physical and mental fatigue also leads to errors.

The tedium of pre-analytical processing and the accompanying pressure to avoid making mistakes often lead to low satisfaction rating in this area of laboratory and to high rates of employee turnover.

Pre-analytical workstations

The automation of the pre-analytical phase is therefore a means of preventing errors. Pre-analytical workstations must be able to duplicate actions carried out by people. The system must be able to identify the patient to whom a specimen belongs and which tests have been requested on that sample.

A mechanism is necessary to determine the specimen tube type (cap color) to avoid improper container, the volume of the sample and the conditions (e.g. the presence of clots, haemolysed, lipemic or icteric specimens). The pre-analytical workstation must have an area with robotic systems for removing container caps, placing samples into centrifuges, making aliquots and sorting samples according to laboratory destination. Additional features may include recapping, specimen storage and retrieval capability and automated delivery of the specimens to analytic workstations.

In a paper on this issue, the use of automated pre-analytical robotic workstations was shown to effectively reduce the labor associated with specimen processing, and reduce the number of laboratory errors that occur in sorting, labeling, and aliquoting specimens; it was also found to improve the integrity of specimen handling throughout the steps of specimen processing (22).

The characteristics of available pre-analytical workstations are (23–25):

1. Sample specimen input area: a loading module where bar code–labeled specimens are introduced into the system. These input units often separate stat specimens from routine specimens, or specimens requiring centrifugation or decapping, into different trays or racks so the system's process control can determine the steps to be performed based on the specimen's loading location.

2. Sample identification: although all systems initially read the specimen bar code to identify the sample, there are two options for sample identification: (1) multiple linear bar code readers, and (2) radio-frequency identification (RFID) of specimen carriers combined with 1 or more bar code readers. The robustness of sample identification is critical; when specimens are identified by bar codes, the sensitivity of the system to bar code–label quality and orientation is important and, on the other hand, when specimens are identified by RFID fixed in their carriers, it is of crucial importance to prevent the manual removal of tubes from the carriers in order to maintain the link between the tube bar code and the carrier's identification. Some systems have multiple bar code readers placed at critical locations in the processing system to track specimens and provide information for their proper routing to the various stations in the processing system.

3. Tube types: systems differ with regard to the size and type of the tubes for processing. Some systems have tube carriers or racks that can handle tubes of any size, but the centrifuge, decapper, aliquoter, and/or recapper may not be so versatile. In some of these systems, larger tubes must be decapped or centrifuged manually. Some systems can perform cap color analysis to validate sample type against test ordered for error prevention.

4. Transport system: segments of conveyor belt line that move the specimens in transport carriers to the appropriate destination. Some carriers hold only one specimen, while others may hold several specimens.

5. Sorting or routing device: this separates specimens by order code, specimen type (e.g. tube height or cap color), or information derived from the input unit (see point 1), and directs or routes the specimens to either the transport system or racking system.

6. Automated centrifuge: a module in which specimens for centrifugation are removed from the conveyor and placed in a centrifuge. The capacity and functionality of each centrifuge differ, depending on the system. Centrifuge capacity, tube sizes and types accommodated (i.e. pre-spun, decapped), throughput, and temperature of spin were all evaluated metrics. The presence of the mechanism that balances different-sized tubes is important because prebalancing the tubes or placing the tubes individually in the centrifuge may delay the processing. It is also important to consider the number of centrifuges available, especially in higher-volume laboratories or in laboratories with frequent stat test requests. Moreover, multiple centrifuges may be necessary for laboratories planning to install automated coagulation testing.

7. Level detection and evaluation of specimen adequacy (specimen integrity): an area in which sensors are used to evaluate the volume of specimen in each container and to look for the presence of clots, hemolysis, lipemia, or icterus. In some systems, integrity checking is included in the main automation system and in others, the interfaced analyzers perform these functions. Most aliquoting systems can measure specimen volume, and some can check for interfering substances.

8. Decapping station: a module in the automated system by which specimen caps or stoppers are automatically removed and discarded into a waste container. While most systems contain a decapper, not all of them can decap hemogards and rubber stoppers and/or screw caps.

9. Aliquoter: a module that aspirates appropriately sized aliquots from each original specimen container, as directed by order codes and the system's process control software, placing them into bar-coded secondary specimen containers. Most aliquoters can perform clot detection and level sensing. Some systems record the volume remaining in the tube optically, notifying the technologist if enough volume is available for an add-on.

10. Interface to automated analyzer: a direct physical connection to an automated analyzer that allows the analyzer's sampling probe to aspirate directly from a decapped specimen container. In some total laboratory automation designs (TLA), the specimen container is robotically removed from the transport carrier and inserted in the analyzer.

11. Specimen Delivery/Sorting: the system may be designed to accommodate aliquots and/or primary tubes. A sorter usually sorts into different groups in racks or carriers. In some systems, the racks are specific to certain analyzers for convenience. One manufacturer routinely produces aliquots from the primary specimens, delivering them to the analyzers. Although the system records the location of the primary specimens and aliquots, the aliquots are not individually labeled.

12. Recapping station: a module in the automated system by which specimen tubes are automatically recapped with new plastic caps or heat-sealed aluminum foil, in preparation for online or off-line storage. An automated mechanism to subsequently decap the specimen for add-on testing is not always available.

13. Take-out stations: a module for temporarily holding specimens before or after analysis. The take-out station may be the same as that for the above-described specimen delivery/sorting, specimens being sorted for manual delivery to off-line laboratory sections.

Vendors supply both stand-alone, independent specimen processing systems that automate several pre-analytic activities, but do not transport tubes with conveyors (*Table I*), and pre-analytic workstations interfacing directly with the automation system that combines analytic activities (analyzers) and post-analytic functions (*Table II*).

The first type of automation may be considered »subtotal automation«, these systems sorting processed specimens and putting them into racks for manual transport to the testing areas. The second type of automation is defined as total laboratory automation (TLA).

Any laboratory can take advantage of some of the advances in automation – the questions are what to automate and to what extent? The options cover the spectrum from islands of automation, which retain some manual processes, to fully automated integrated systems (26).

The optimal degree of laboratory automation depends on the laboratory setting and considerations of cost, throughput, and flexibility. Other considerations include the time that will be required to complete the installation, the space available, the proportion of the tests that are routine, the availability of skilled technicians, safety, and reliability.

The original motivation for laboratory automation was primarily the cost (27).

While this is still a driving requirement, there are many other reasons to automate, including error reduction, productivity, safety, and labor satisfaction.

Table I Types and features of pre-analytical workstations (subtotal automation).

Company/ Name of system	Automated sorting	Centrifuge	Automated aliquoting	Decapper	Recapper or sealer	Specimen integrity monitor available
Aim Lab (formerly Ai Scientific) PathFinder 350S	yes	no	no	no	no	no
Aim Lab (formerly Ai Scientific) PathFinder 900	yes	no	yes	yes	yes	no
Aloka LabFlex 2500	yes	yes	yes	yes	no	no
Beckman Coulter AutoMate 800	yes	yes	yes	yes	no	no
Beckman Coulter AutoMate 1250/2550 (formerly OLA 2500 HSS)	yes	no	yes	yes	sealer	no
LGP Consulting m.u.t HCTS2000 MK2	yes	no	no	no	no	no
Motoman Autosorter II	yes	no	yes	yes	yes	no
Motoman Autosorter III	yes	yes	yes	yes	yes	no
PVT Workstation RSA Pro	yes	yes	yes	yes	yes	yes
Sarstedt PVS	yes	no	yes	yes	yes	in development
Tecan FE500Pro	yes	yes	yes	yes	no	no

Table II Types and features of pre-analytical workstations interfaced directly to the automation system (TLA).

Company/ Name of system	Automated sorting	Centrifuge	Automated aliquoting	Decapper	Recapper or sealer	Specimen integrity monitor available	Refrigerated storage & retrieval available
Abbott Diagnostics Accelerator APS	yes	yes	no	yes	sealer	no	yes
A&T Open LA21 Module System (CLINILOG Ver.3)	yes	yes	yes	yes	no	no	no
Beckman Coulter Power Processor	yes	yes	yes	yes	yes	yes	yes
Inpeco FlexLab	yes	yes	yes	yes	yes	yes	yes
Integrated Laboratory Automation Solutions The Efficiency Series	yes	yes	yes	yes	yes	no	no
Ortho-Clinical Diagnostics enGen Laboratory Automation System	yes	yes	yes	yes	yes	yes	in development
Roche Diagnostics Corp. Modular Pre-Analytics Plus	yes	yes	yes	yes	yes	no	in development
Siemens Healthcare Diagnostics Advia Solutions	yes	yes	no	yes	no	integrated on chemistry instrument	in development
Siemens Healthcare Diagnostics StreamLab Analytical Workcell	yes	yes	yes	yes	yes	yes	in development

In most cases, these systems will not necessarily process tests more quickly than is possible by a focused human; however, the systems can work consistently for extended periods with minimal human intervention. The resulting benefits include higher total throughput, reduced potential for human errors, limited human exposure to hazardous material, reduced labor costs, consistent performance and less need to find and train skilled technicians.

Besides the pressures to ensure patient safety, the diagnostic laboratories are being challenged by many factors – rising costs, shrinking budgets, shortages of skilled personnel. Among the many variables that can affect the efficacy of the health care environment, three in particular are prompting dramatic changes to diagnostic laboratory processes and greater demand for automation (28):

a) Medical errors and patient safety: the laboratory provides as much as 60–70% of the information used by physicians to make important medical decisions. Laboratories are obligated to provide the right test for the right patient at the right time.

b) The job shortage: laboratories must take steps to adopt new processes and systems to offset the labor shortage.

c) Length of stay: the sooner a laboratory provides physicians with valuable patient test results, the sooner physicians can diagnose and treat their patients. That, in turn, can mean a shorter patient length of stay and have an immense impact on the hospital budget. Laboratories must provide physicians with fast, accurate test results and decrease variability in test turnaround time to help shorten patient length of stay.

In reaction to these pressures, there is a trend to seek solutions through automation. Pre-analytical automation can mitigate the effect of the growing labor shortage, as well as help reduce medical errors, improve patient safety and provide a safer working environment.

Furthermore, pre-analytical automation increases labor satisfaction; skilled laboratory personnel see a modern automated laboratory as their preferred work environment; there is less dull, repetitive work, the work is safer, and they are exposed to new learning experiences on the latest equipment. Employers report that an automated laboratory has proven to be a key advantage in attracting and retaining highly qualified staff (29, 30).

The management of the pre-analytical phase at San Bassiano Hospital, Bassano del Grappa

Dr. Deming emphasized the importance of improving the process to achieve better quality/fewer errors, thus the experience gained at the San Bassiano Hospital illustrates how a series of decisive and thorough interventional measures taken effectively have reduced pre-analytical errors.

San Bassiano Hospital is a 450-bed hospital in the northwest of Italy.

The Laboratory Medicine of San Bassiano Hospital performs over 2.7 million tests/year and employees 36 full-time workers. It has a tradition of excellence, innovation technology, and evidence-based inquiry.

The following interventional strategies have been implemented:

1) Implementing a wireless network to provide fast access to medical records, images, and other clinical applications at the point of care and electronic recording of treatments at patient's bedside.

2) Introducing Tablet PC with wireless connectivity and Laboratory Order Entry System (LOES) for inpatients. The system allows physicians greater mobility in patient wards and, more importantly, instant access to patient information as laboratory results.

3) Introducing an automated samples labeling system (Lab.E.L.® Eos) for inpatients and outpatients, which automatically prepares the »Patient kit«, a paper-sealed box containing a complete set of labeled blood tubes based on the physician's test order.

4) Introducing bar-coded ID wristbands for inpatients and the Lab.E.L.® Track system, a handheld-based patient identification system. At the bedside, in addition to verbal checks, the phlebotomist scans the wristband for the medical record bar code and then reads the »Patient Kit« bar code to verify correspondence between sample and patient. This transaction is automatically recorded.

5) Standardizing the collection: a key intervention has been implemented. Standardization of phlebotomy procedures around a new process and training, coaching and monitoring nurses regarding the new procedure.

6) Utilizing the Track Vehicle System for the transport of specimens from the wards to the laboratory.

7) Utilizing a preanalytic workstation interfaced with analyzers ADVIA® LabCell® Automation Solution. The system includes two samples input-output units, two centrifuges and decappers, and seven analyzers (two ADVIA® 2400 Chemistry System, three ADVIA Centaur® XP Immunoassay System, an IMMULITE® 2500, an ADVIA® dual hematology module with two ADVIA® 2120i Hematology System and two ADVIA® Autoslide Slide Maker Stainer).

The workflow for inpatients is shown in *Figure 1*.

Improvements yielded by the system are: promotion of patient safety, enhanced specimen collection efficiency with consequent laboratory workflow efficiency.

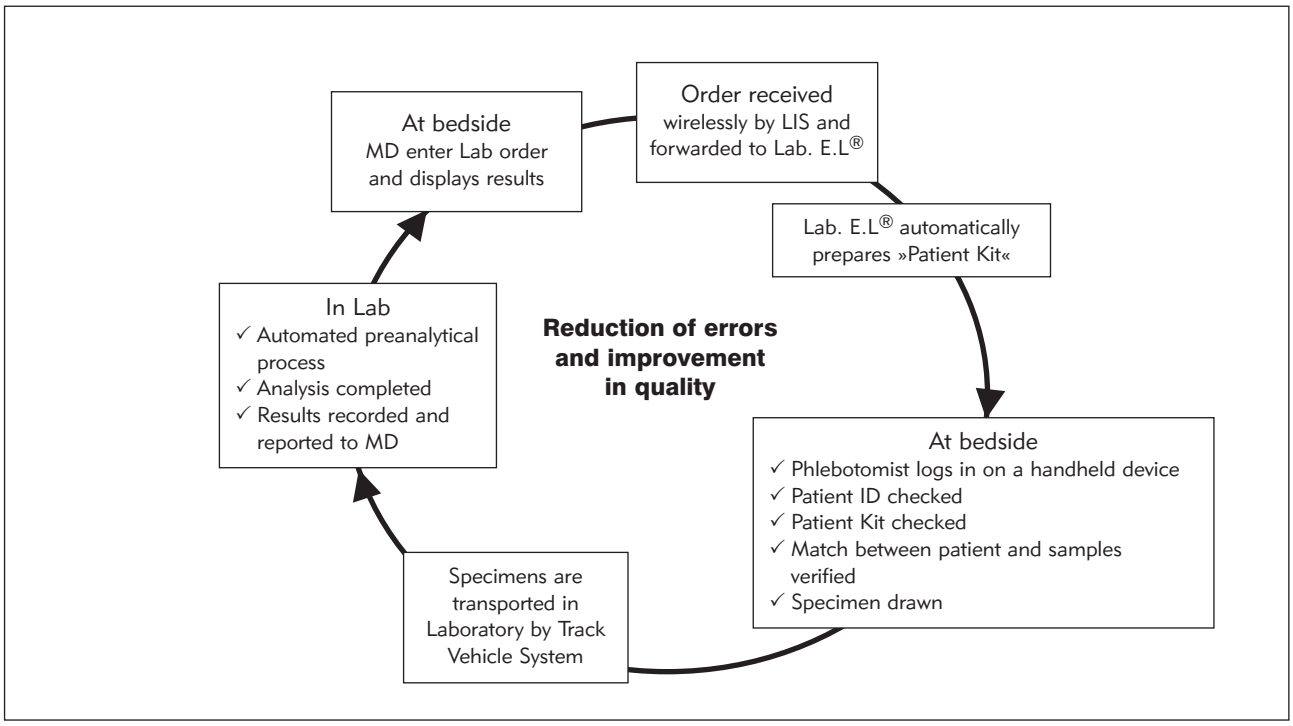

Figure 1 Workflow for inpatients at San Bassiano Hospital (modified from reference 24).

Managing the Change: risks and inhibitors

There is a large literature on what is needed to achieve success by managing change (31–34). It is beyond the scope of this paper to summarise their findings and success factors. We will however, present a synthesis of some important lessons that have emanated from our experience.

Organisational culture

Patient identification technologies operate optimally within a healthcare workplace that has established formal and widely promulgated principles and policies in relation to patient safety, including reliable patient identification. The establishment of a 'safety culture' within a health-care facility can only be implemented as a corporate endeavour. Without institutional support and commitment, isolated initiatives to improve patient safety, while commendable, usually do not extend beyond the participating business units nor survive the departure of the individuals who instigated them.

Inter-department functions

Our field experience demonstrates that Laboratory Medicine must be centrally involved in the implementation process if these systems are to bring about improvements in efficiency and effectiveness. Successful implementation should become synonymous with the building of new relationships and improved levels of collaboration across the hospital.

Process improvement

The introduction of patient identification technologies will not, of itself, solve the problem of patient misidentification. The solution lies in defining and consistently executing appropriate processes and workflows, supported by relevant technology.

Certainly, any proposed implementation must start with a recognition and understanding of the enormous challenges involved. This implies the existence of a firm organisational foundation for implementation with leadership that is open and responsive to feedback (35).

Staff resistance

The introduction of patient identification technologies and LOES can be met with resistance by clinical staff. For example, the use of the technology can be seen as time consuming. In some cases, staff resistance can stem from a lack of experience with or knowledge of information technology. It is not sufficient to merely say that the hospital will benefit by being at a better competitive advantage and that the new system will bring more to the bottom line. There clearly have to be tangible benefits to the individual clinical users.

Conclusion

The goal, laboratory medicine is to provide an error free service to physicians and their patients. The key to error reduction is continuous quality improvement of the many systems and processes. Since the majority of the errors in the total testing process originate in the pre-analytical phase, this step should, therefore, be focused upon, in the attempt to enable further reduction in total testing process errors, thereby maximizing patient safety.

The main tools we have to insure high quality and minimize errors in the pre-analytical phase are:

- have a user-friendly computer system that facilitates direct physician ordering for laboratory services,
- develop a quality wristband policy and use bar codes on the wristband and specimen labels to insure positive patient identification,
- use automated test tube labeling systems, based on the physician's test order,
- use automated systems for procedures such as specimen centrifugation, decapping, aliquoting, pipetting and sorting,
- use error reduction/improved quality as a factor when selecting instrumentation.

The reasons for automation of the pre-analytical phase have become so compelling that it is no longer simply a competitive advantage for laboratories, but rather if is now a competitive necessity. These systems can impact on the clinical/laboratory interface and affect the efficiency, effectiveness and quality of care. Error reduction and improved quality are essentially two names for the same goal.

Conflict of interest statement

The authors stated that there are no conflicts of interest regarding the publication of this article.

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