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Sandesh Oli

February 11, 2014

April Honaker, Executive Director
Shared Light Foundation
1009 Light Brigade Lane
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Dear Ms. Honaker,

Enclosed with this letter of transmittal is my technical report, which provides detailed information about my research evaluating Total Laboratory Automation to reduce errors in clinical laboratories. My research established reliability and validity of automated specimen processing over manual specimen processing. This finding provides the prospect that manual specimen processing will be replaced by automated systems in the future.

In my research, I evaluated Total Laboratory Automation based on three criteria, which represent all the three phases of specimen analysis: the pre-analytic phase, the analytic phase and the post-analytic phase. The data collected for each criterion were subjected to statistical analyses and the results were obtained. The analyses showed that automated systems are accurate in terms of results, efficient in terms of saving time and resources, and most importantly, effective in reducing errors that can possibly have an impact on patient safety.

I am thankful to the Board of Directors at the Shared Light Foundation for providing me with the opportunity to conduct research towards improving quality of laboratory services and setting a new standard in the healthcare system. If you have any questions or suggestions regarding my research, please call me at 571-245-3434 or send me an email at sundaesholi@gmail.com. Thank you for your time. I look forward to partnering with you in future research.

Sincerely,

Sandesh Oli

Enclosure (1): Technical Report

Shared Light Approved Research Project

February 11, 2014

Sandesh Oli

ENGL 303: Technical Writing

Evaluation of the Effectiveness of Total Laboratory Automation in Reducing Errors in Clinical Laboratories

Prepared By: Sandesh Oli, Independent Researcher

Prepared For: SLF Board of Directors

February 11, 2014

Abstract

Evaluation of the Effectiveness of Total Laboratory Automation in Reducing Errors in Clinical Laboratories

Prepared by: Sandesh Oli
February 11, 2014

The purpose of this technical report is to assess the role of automated systems in reducing errors in clinical laboratories. The errors that occur while processing clinical specimens have an impact on patient health. Such errors cost hospitals resources, time, and labor. Manual processing of specimens usually produces such errors. Automated systems that replace the manual processing of specimens have been found to be effective in reducing the errors. In this report, Total Laboratory Automation has been evaluated based on three criteria: colony isolation, specimen labeling error, and cell count. For each criterion, data were collected from peer-reviewed journals that have already examined the functionalities of laboratory automation. The results showed that automated systems are effective in reducing the errors by replacing the error sensitive manual processing of specimens. The research findings recommend clinical laboratories to install automated systems and clinical scientists to improve the existing laboratory automation to reduce the errors that still occur.

Key words: Total Laboratory Automation, colony isolation, specimen labeling error, cell count, manual processing

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List of Abbreviations and Acronyms

ASCP: American Society for Clinical Pathology

CPOE: Computerized Physician Order Entry

CSF: Cerebrospinal Fluid

EUR: Euro currency

MLO: Medical Laboratory Observer

MN: Minnesota

PA: Pennsylvania

RFID: Radiofrequency Identification

SC: South Carolina

TAT: Turnaround Time

TLA: Total Laboratory Automation

Executive Summary

In clinical laboratories, the process of analyzing specimens produces errors. Numerous studies have shown that such errors jeopardize patient health. At the least, such errors cost laboratories time, resources, and labor. A number of process and risk analysis studies have shown that manual processing of specimens accounts for the majority of errors. Automated systems have become an increasingly popular replacement of manual specimen processing. Yet, only a few studies have tested their validity and reliability in clinical settings. This research aims to evaluate their role in reduction of the errors.

In order to evaluate the Total Laboratory Automation, two types of analyses have been chosen among various types of tests performed on a day-to-day basis in clinical laboratories. Similarly, one of the frequently encountered errors has been chosen from the pre-analytic phase of the specimen processing. These three benchmarks form the criteria based on which the Total Laboratory Automation has been evaluated. They are:

- Colony isolation
- Specimen labeling error
- Cell count

This research focuses on three studies that have each compared the manual processing with the automated processing based on each of the aforementioned criteria. The data values from those studies were subjected to three statistical analyses: a t-Test, an F-Test, and a correlational analysis. The results showed that the automated system, PREVI™ Isola, showed an increase in the total number of isolated colonies compared to the manual isolation ($P<0.05$). Similarly, the Radiofrequency Identification system showed a decrease in the number of specimen labeling errors compared to manual specimen labeling ($P<0.05$). Lastly, the Coulter LH 750 hemogram counted the same number of cells in peritoneal fluid specimens as expert performed manual count, establishing its validity ($P>0.05$).

Thus, it is evident that automated systems can reduce errors in specimen processing. They can reduce the workload of medical technologists and provide them more time to carry out research on further improving laboratory services. They can also save laboratories time and resources. Future research in this field can be based on different criteria, such as turnaround time, cost, and space to evaluate the Total Laboratory Automation. Clinical scientists can enhance automated systems to further reduce the errors that still occur with their use. As a whole, managers should install automated systems in their laboratories to improve the existing standard of laboratory services.

Introduction

Clinical laboratories are indispensable parts of the healthcare system. Everyday hundreds of specimens collected from patients are analyzed in clinical laboratories. The results of such analyses are vital in diagnosing patients. The most commonly collected patient specimens are whole blood samples (serum, plasma, and blood cells), arterial blood samples (partial pressure of oxygen and carbon dioxide), urine, cerebrospinal fluid, paracentesis fluid (pleural, pericardial, and peritoneal), and amniotic fluid (Bishop, Fody & Schoeff, 2005, p. 27). Figure 1 shows an example of whole blood samples collected for analysis.

Figure 1: Whole blood sample

Source: Liquichek™ Hematology Control (S) [Online Image]. Retrieved Feb 1, 2014 from http://www.bio-rad.com/en-us/product/liquichek-hematology-control-s

The entire process of specimen analysis can be broken down into three distinct phases: the pre-analytic phase, the analytic phase, and the post-analytic phase. Proper patient identification, proper order of collection tubes, proper labeling of collection tubes, and matching labels on blood collection tubes with the test requests are some of the measures adopted to reduce the errors in the pre-analytic phase (Bishop et al., 2005, p. 29).

Similarly, appropriate quantity of specimens, use of proper anticoagulation and preservatives, indication of time and date of specimen collection, and proper transportation of the specimens reduce specimen rejection rate (Bishop et al., 2005, p. 29). Proper specimen storage is also equally important in maintaining the integrity of the collected samples. Evaporation, refrigeration, and the amount of light present can reduce the quality of the collected specimens (Bishop et al., 2005, p. 69). Patient preparation is another vital step in ensuring accurate diagnosis. Alcohol, drugs, stress, exercise, and sleep can result in variations of the results (Bishop et al., 2005, p. 69).

In the analytic phase, timed maintenance, calibration, and reagent quality impact the result of specimen analysis (Bishop et al., 2005, p. 70). Finally, in the post-analytic phase, the quality of communication systems, laboratory interfaces, and databases determine appropriate result reporting and storage for future references (Bishop et al., 2005, p. 70).

Literature Review

A number of studies have shown widespread prevalence of errors in clinical laboratories. Salvango, Lippi, Bassi, Poli and Guidi (2008) conducted a study at the University Hospital of Verona to determine all the possible pre-analytic problems that appear in coagulation tests of the routine and stat inpatient samples (p. 352). Over a period of two years, 3,617 pre-analytic errors were identified (Salvango et al., 2008, p. 352).

Similarly, a study by Carraro and Plebani (2007) showed a total of 393 suspicious test results with 160 errors out of 7615 test requests (p. 1339). The pre-analytic phase contributed to 61.9% of the total errors. The errors included improper blood:anticoagulant ratio (coagulation test), quantity of specimens not sufficient, patient misidentification, incorrect tube selection for specimen collection, test request errors, empty test tubes, missing test tubes, sample dilution with intravenous infusion solution, ordered test not received, and errors in demographic data that caused delay in result reporting (Carraro & Plebani, 2007, p. 1339). Of the errors observed, 24.4% of the errors had a negative impact on the patient health (Carraro & Plebani, 2007, p. 1340). The study also revealed that 24.6% of the errors caused unnecessary test repetition and 73% of the errors were considered preventable (Carraro & Plebani, 2007, p. 1342).

A study by Jacobsz, Zemlin, Roos and Erasmus (2011) showed a total of 481 rejected specimens out of 32,910 blood specimens. (p. 2048). They also calculated the average time required for the re-analysis of rejected specimen to be about five days (121 hrs) (Jacobsz et al., 2011, p. 2048). Overall, 40% of the specimen rejection cases jeopardized patient health (Jacobsz et al., 2011, p. 2048).

Laboratory Automation

In order to reduce the errors, produce faster and accurate results, and save laboratory resources, clinical scientists have developed Total Laboratory Automation. Similar to the process of specimen analysis, the functionality of laboratory automation is divided into the pre-analytic, the analytic, and the post-analytic components. The specimen preparation step of the pre-analytic phase involves clotting, centrifugation, and transportation of specimens to the analyzer. Automated systems, such as the Abbott Vision analyzer, can reduce the delay in this step by using whole blood samples (Bishop et al., 2005, p. 127).

Similarly, automated systems, such as the ADVIA® Total Laboratory Automation (Figure 2), allow accurate specimen identification through the use of bar code labels that match the electronic worksheets of the test requests (Bishop et al., 2005, p. 127). The rejection of specimens due to degradation of their quality is not an issue with the automated system because of the internal control of temperature, light, humidity, and carbon dioxide levels in the test chambers (Bishop et al., 2005, p. 130).

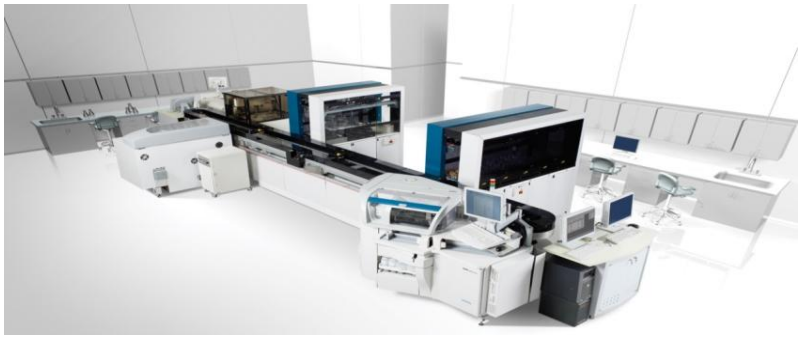

Figure 2: ADVIA® Total Laboratory Automation

Source: ADVIA® Automation Solutions [Online Image]. Retrieved Feb 1, 2014 from http://www.healthcare.siemens.com/laboratory-automation/systems/advia-automation-solutions

In the analytic phase, an automated system, such as the BD Kiestra™ Total Laboratory Automation (Figure 3), mixes the specimens with the reagents, removes unwanted constituents such as protein, incubates inoculated agar plates, and finally measures the test parameters (Bishop et al., 2005, p. 136).

Figure 3: BD Kiestra™ Total Laboratory Automation

Source: BD Kiestra™ WCA [Online Image]. Retrieved Feb 2, 2014 from http://www.bd.com/europe/labautomation

The final measurement phase employs visible and ultraviolet light spectrophotometry, ion-specific electrodes, gamma counters, luminometers, ultraviolet, fluorescent, and flame photometry (Bishop et al., 2005, p. 136). Lastly, in the post-analytic phase, the automated systems facilitate signal processing and data handling to report the results (Bishop et al., 2005, p. 139). In this phase, computerized monitoring systems flag abnormal results, display reagent inventories, environmental conditions of the test chambers, and quality control data (Bishop et al., 2005, p. 139).

Evaluation of laboratory automation in the past studies

Numerous studies have shown the effectiveness of the laboratory automation in reducing errors and producing faster results. Koenders et al. (2012) performed a study to compare post centrifugation analyte concentration of serum and chemistry and immunochemistry assays in plasma between a manual centrifugation carried out for 10 minutes at 1885×g and an automatic centrifugation carried out for 5 minutes at 1885×g (p. 469). They observed no significant difference in the analyte concentration of the serum between the manual and the automatic centrifugations ($P>0.05$), implying reduction of the centrifugation time by 50% (from manual 10 min to automatic 5 min) with the sample quality preserved (p. 473).

Similarly, Zimmermann, Ruprecht, Kainzinger, Heppner and Weimann (2011) performed a study to evaluate the effectiveness of laboratory automation by focusing on automated vs. manual Cerebrospinal Fluid (CSF) cell count using the Sysmex XE-5000 hematology analyzer (p. 630). The study was performed on 116 routine CSF samples (59 female and 57 male) obtained through lumbar puncture (Zimmermann et al., 2011, p. 630). The turnaround time (TAT) for the manual count was 635 seconds while that for the XE-5000 analyzer was 85 seconds (Zimmermann et al., 2011, p. 632). Without considering mixing, preparing, and cleaning steps, the counting process for cells less than 20 counts per µl took 103 seconds for the manual count while it took 62.1 seconds for the automated count (Zimmermann et al., 2011, p. 632). The manual count showed the cost of 6.74 EUR per CSF count including personnel expenses and equipment costs compared to 1.22 EUR for the automated count with the XE-5000 analyzer (Zimmermann et al., 2011, p. 632).

Preview of the report

This report includes a methodology section, where the steps taken to execute the research are described. It is followed by a results and discussion section, where the findings and their meanings are discussed. Finally, a conclusion and a recommendation section are presented.

Methodology

The methodology section discusses the steps that were taken to study the problem, identify its solution, establish criteria to evaluate the solution, collect and analyze data, draw conclusions, and finally make a recommendation. The project plan was followed strictly and the project schedule was adhered to during the process of research, evaluation, and analysis to complete the project. The following steps were executed in the process of writing the final report:

Identified the types of errors that occur in various phases of specimen analysis:

I broadened the extent of my knowledge about the different types of errors that occur in clinical laboratories by studying peer-reviewed journals and online magazines. EBSCOhost, JSTOR, PubMed, and the database of the American Society for Clinical Pathology (ASCP) were the chief sources for the peer-reviewed journals. Online magazines were made available by the Medical Laboratory Observer (MLO). All these sources of information were accessed via the resources provided by the Prescott Memorial Library at Louisiana Tech University.

Selected the best available solution to reduce errors in clinical laboratories:

With the help of the online databases mentioned above, I was able to identify three possible solutions to address the issue. They were Computerized Physician Order Entry (CPOE) system, Total Laboratory Automation (TLA), and the process and risk analysis method. After studying about the available solutions, I decided to select TLA for the evaluation because it was the only solution that could address all the three phases of specimen analysis. The CPOE only helped in bi-directional communication between physicians and laboratories. It did not have any role in the specimen analysis. I found the process and risk analysis method to be labor intensive and unsuitable as a long term solution. The reason was that it depended on enhanced training of laboratory technicians and still relied on the manual processing. TLA replaces manual processing, helps in conserving resources, and produces faster and accurate results. Hence, TLA was chosen for the evaluation.

Determined criteria to evaluate the effectiveness of TLA:

In order to evaluate the effectiveness of TLA, three criteria were determined. The criteria were selected such that all the three phases of specimen analysis were encompassed. They are as follows:

- **Colony Isolation**: In order to identify the type of pathogen present in any clinical specimen, it should first be plated on a nutrient plate. The goal of inoculation of clinical specimens on plates is to isolate pure colonies. Only the pure isolated colonies can be used to perform biochemical tests to identify the types of pathogens

present. This criterion compared the automated colony isolation vs. manual inoculation method. It addresses the analytic and the post-analytic phases of the specimen processing.

- **Specimen labeling errors**: This criterion compared the frequency of specimen labeling errors in automated systems vs. manual specimen labeling. It addresses the pre-analytic phase of specimen processing.
- **Cell count**: The number of cells present in a given volume of a specimen is one of the most frequently performed assays in clinical laboratories. An automated system that counts the same number of cells in a specified volume of a specimen as an expert performed manual count is reliable and valid. It addresses the analytic and the post-analytic phases of the specimen processing.

Performed further research and collected data:

By referring to the peer-reviewed journals that have already evaluated the effectiveness of TLA through its comparison with manual processing, data values were collected for each criterion. The three laboratories mentioned in the peer-reviewed journals were the Spartanburg Regional Healthcare, Spartanburg, SC, the Gastroenterology and Colorectal Surgery outpatient endoscopy unit at the Mayo Clinic, Rochester, MN, and the Yuzuncu Yil University's medical facility in Van, Turkey. Each of these three laboratories had evaluated TLA for each of the aforementioned criteria.

Evaluated criteria and analyzed data:

All three criteria are important, but I consider specimen labeling error and cell count to be the most important of the three criteria. Specimen labeling error addresses the pre-analytic phase of specimen processing while cell count and colony isolation both address the analytic and the post-analytic phases. However, of the latter two, cell count is important because it is one of the most frequently performed assays. The quantitative data collected were subjected to statistical analyses. For each criterion, the automated systems were compared with the manual systems. To determine the difference between the data values of each system, a t-Test and an F-Test were used. An F-Test was used for larger sample sizes and a t-Test was used for smaller sample sizes. To determine the similarity between the two data values, correlational analyses were used. The data values for the first two criteria, colony isolation and specimen labeling error, require differentiation to determine which system is more effective in reducing the errors. The data values for the last criteria, cell count, require correlational analysis to determine the reliability and validity of the automated systems.

Drew conclusions from the results and made a recommendation:

The research concluded that the TLA is effective in reducing the errors in clinical laboratories. However, it cannot completely eliminate all the errors. It is the best available solution that requires further development to ensure that no errors occur in the process of specimen analysis. I recommend the Shared Light Foundation share this research project with the American Society for Clinical Pathology and the Medical Laboratory Observer so that appropriate steps can be taken to further develop TLA to set a new standard in the healthcare system.

Results and Discussion

The results of this study have been integrated with discussion for better understanding. The outcomes of this research have been categorized based on the pre-defined criteria, which are as follows:

Colony Isolation

Rice and Baruch (2009), from the microbiology department of Spartanburg Regional Healthcare, Spartanburg, SC, evaluated the effectiveness of bioMérieux's PREVI™ Isola in processing specimens in microbiology laboratories. The PREVI™ Isola is an automated system that inoculates a specified volume of stimulated specimen on nutritional plates in order to isolate pure colonies. In addition to that, it is capable of labeling plates and sorting them with respect to specified environmental conditions, such as temperature, carbon dioxide requirements, and humidity (Rice & Baruch, 2009). It was evaluated by comparing it against manual inoculation based on two criteria: number of colonies isolated and time saved. Over a period of two weeks, three types of routine specimens were inoculated: urine, swabs, and stool. A total of 756 specimens were tested (Rice & Baruch, 2009). Table 1 presents the data collected.

Table 1: Number of colonies isolated and time saved

Culture Type	Number of specimens tested	Time (sec)	Equal number of isolated colonies	Greater number of isolated colonies
Urine	531			
Manual		157.2	71%	
Isola		127.2		26%
Savings (sec)	15930	30		
Swabs	174			
Manual		230.4	82%	
Isola		188.4		18%
Savings (sec)	7308	42		
Stools	51			
Manual		264	82%	
Isola		130.2		18%
Savings (sec)	6823.8	133.8		
Seconds saved/week	30061.8			
Hours saved/week	8.3505			
Total % savings	Total savings per 40hr week = 21%		Average increase in isolated colonies = 21%	

Source: Rice, F. & Baruch, A. (2009, May). *Evaluation of bioMérieux's PREVI™ Isola, an Automated Microbiology Specimen Processor: Improving Efficiency and Quality of Result.* Poster presented at the 109th general meeting of The American Society for Microbiology, Philadelphia, PA.

Table 1 shows an increase in the number of isolated colonies for the Isola compared to the manual inoculation for all three culture types. The average increase in the number of isolated colonies was determined to be 21%. Ttable 1 also shows a decrease in the time required for inoculation of all the three culture types while using the Isola. The total time savings per week was calculated to be 21%. Figure 4 shows an example of a nutrient plate used to isolate colonies.

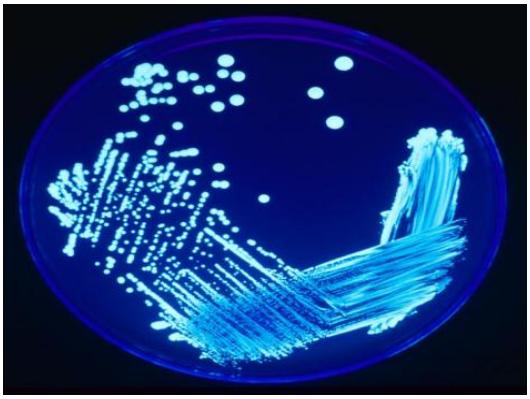

Figure 4: Colony Isolation on a nutrient plate

Source: AquaSept™ Legionella plate [Online Image]. Retrieved Feb 1, 2014 from http://www.aquasept.com/biofilm/who-is-at-risk

The scientific significance of the results can be verified with the help of statistical analyses. A Two-tailed t-Test can be employed because the sample size is small. A P value less than 0.05 is considered scientifically significant, which means if the P value is less than 0.05, there is significant difference between the data values obtained for the Isola assisted automated processing and the manual processing. Table 2 provides the result of the t-Test for the number of isolated colonies.

Table 2: t-Test result for number of isolated colonies

	Greater number of isolated colonies	
	Manual	Isola
Urine	0	26
Swabs	0	18
Stool	0	18
P(T<=t) two-tail	0.0162 (P<0.05)	

Source: Based on Rice, F., & Baruch, A. (2009, May). *Evaluation of bioMérieux's PREVI™ Isola, an Automated Microbiology Specimen Processor: Improving Efficiency and Quality of Result.* Poster presented at the 109th general meeting of The American Society for Microbiology, Philadelphia, PA.

This result shows that Isola, an automated system, can increase the number of isolated colonies compared to the manual inoculation because the P value is less than 0.05. The t-Test result for the other criteria of the study, time savings, is presented in Table 3:

Table 3: t-Test result for the time saved in inoculation

	Time required for isolation (sec)	
	Manual	Isola
Urine	157.2	127.2
Swabs	230.4	188.4
Stool	264	130.2
P(T<=t) two-tail	0.163 (P>0.05)	

Source: Based on Rice, F., & Baruch, A. (2009, May). *Evaluation of bioMérieux's PREVI™ Isola, an Automated Microbiology Specimen Processor: Improving Efficiency and Quality of Result.* Poster presented at the 109th general meeting of The American Society for Microbiology, Philadelphia, PA.

The result shows that there is no significant difference in the amount of time required for inoculation between the Isola and the manual processing because the P value is greater than 0.05.

This result from Table 3 is presented in Figure 5 in the form of a graph:

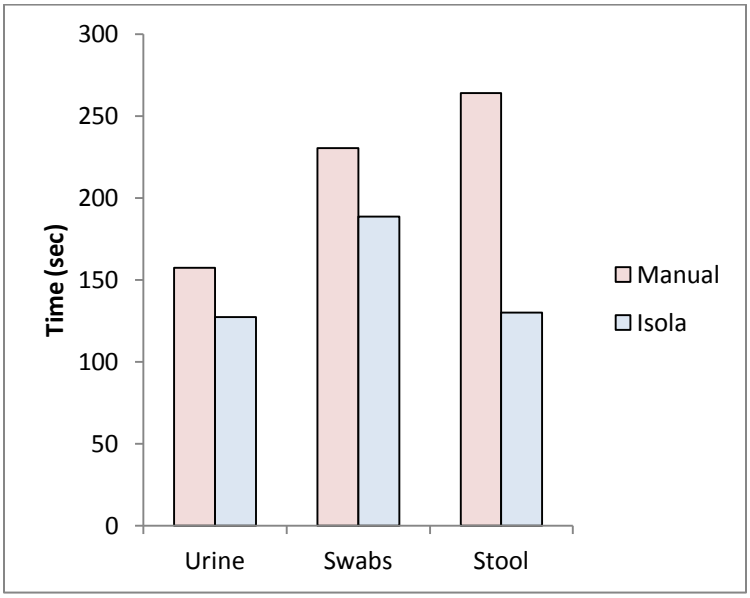

Figure 5: Difference in time required for processing

Figure 5 shows that there is a difference in the time required for specimen inoculation. The manual processing is slower than the Isola assisted automated processing. However, the difference is not scientifically significant as shown in Table 3.

These results show that automated processing can produce a greater number of colonies than manual processing. A single isolated colony contains pure strains of a pathogen. A greater number of isolated colonies mean a lower probability of contamination with other strains or impurities. Thus, automated systems can effectively reduce errors in clinical laboratories by producing nutrient plates with a greater number of pure isolated colonies. Although the time required for inoculation is not significantly different between the automated processing and the manual processing, it can be overlooked because the scope of this research is limited to the reduction of errors in the specimen processing.

Specimen labeling error

Francis, Prabhakar and Sanderson (2009) studied the role of the Radiofrequency Identification system in reduction of specimen labeling errors at the Gastroenterology and Colorectal Surgery outpatient endoscopy unit at the Mayo Clinic, Rochester, MN. (p. 973). The Radiofrequency Identification system (RFID) is an automated identification system that uses radio waves to identify the RFID tagged specimen slides and containers (Francis et al., 2009, p. 973). The study was carried out because the facility faced serious specimen labeling errors. One such event led to a surgery of a patient on the wrong site (Francis et al., 2009, p. 973). The RFID tag labeled onto the specimen slide and/or container contained the patient information such as a patient's name, medical record number, and the site of specimen collection (Francis et al., 2009, p. 973). Figure 6 shows an example of a labeled specimen tube.

Figure 6: Barcoded specimen label

Source: Trask, L. & McKibbin, A. (2013). Specimen labeling errors put patients and hospitals at risk [Online Image]. Retrieved Feb 1, 2014 from http://laboratory-manager.advanceweb.com/Features/Articles/Specimen-Labeling.aspx

The specimen labeling errors included wrong label, absence of label, and wrong site of specimen collection (Francis et al., 2009, p. 974). The errors were further classified into three classes based on the level of impact on patient safety. The errors with no impact on patient safety were classified as Class 1 errors. The errors with improbable impact on patient safety were classified as Class 2 errors. Finally, the errors with serious impact on patient safety were classified as Class 3 errors (Francis et al., 2009, p. 974).

The tests were classified into two stages: the pre-implementation stage (first 3 months of 2007) and the post-implementation stage (first 3 months of 2008). A total of 8,231 specimens were tested in the pre-implementation phase while a total of 8,539 specimens were tested in the post-implementation phase (Francis et al., 2009, p. 974).

In order to determine whether or not there is a scientifically significant decrease in the number of specimen labeling errors in the post-implementation phase, an F-Test can be employed. A t-Test is not suitable for this study because of the large sample size. Like the t-Test, a P value less than 0.05 is considered scientifically significant. The results of the study are presented in Table 4:

Table 4: Frequency of errors

Types of errors	Pre-implementation stage	Post-implementation stage
Class 1	646	35
Class 2	112	10
Class 3	7	2
Total errors	765	47
P(F<=f) one-tail	0.003 (P<0.05)	

Source: Based on Francis, D., Prabhakar, S., & Sanderson, S. (2009). A quality initiative to decrease pathology specimen-labeling errors using radiofrequency identification in a high-volume endoscopy center. *The American Journal Of Gastroenterology*, *104*(4), 972-975. doi:10.1038/ajg.2008.170

Table 4 shows a decrease in the number of specimen labeling errors in all three error classes after the implementation of the RFID system. The Class 1 errors occurred at the highest frequency followed by the Class 2 errors and then the Class 3 errors. The P value is less than 0.05, which means that there is a scientifically significant decrease in the number of errors after the implementation of the RFID system.

A graphical representation of the result in Table 4 also helps to illustrate this trend.

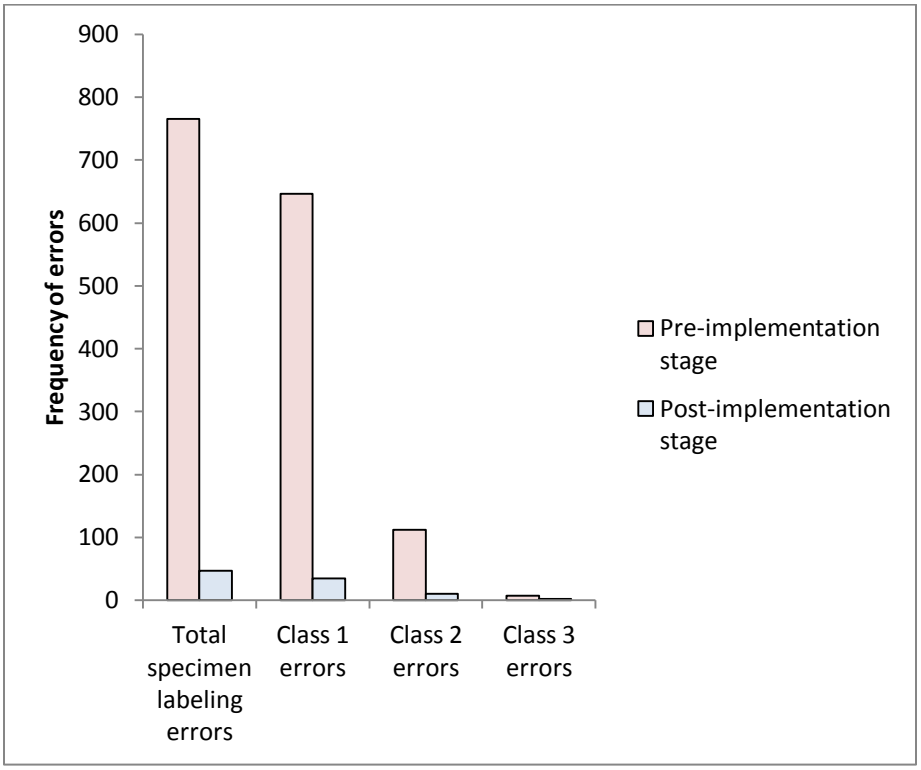

Figure 7: Reduction in specimen labeling errors

It should be noted that the Class 3 errors have still occurred in the post-implementation phase suggesting that the automated system is not flawless. Although the Class 1 errors do not impact patient safety, they are still significant because they cost laboratories time, resources, and labor. It is also worth noting that the RFID system employs radio waves that are sensitive to electromagnetic radiation (Francis et al., 2009, p. 975). Hence, it is very important to identify the sources of electromagnetic radiation that can interfere with radio waves before employing the RFID system. Overall, it is evident that laboratory automation can help in reduction of the specimen labeling errors in clinical facilities.

Cell count

Rerksuppaphol et al. (2011) evaluated the accuracy of the Coulter LH 750 hemogram in counting white blood cells (leukocytes) of routine hematology specimens (p. 1891). The evaluation was carried out at the Yuzuncu Yil University's medical facility in Van, Turkey (Rerksuppaphol et al., 2011, p. 1891). A total of 72 peritoneal fluid specimens were obtained from 27 patients (15 female and 12 male) with peritoneal dialysis (Rerksuppaphol et al., 2011, p. 1891). The purpose of the study was to correlate the number of white blood cells counted by the hemogram to the manual method (Rerksuppaphol et al., 2011, p. 1891). The manual cell

counting was carried out under a microscope. To validate the results, the same samples were used for the automated and the manual counts (Rerksuppaphol et al., 2011, p. 1891). Figure 8 shows an example of microscopy of a blood smear in order to count leukocytes.

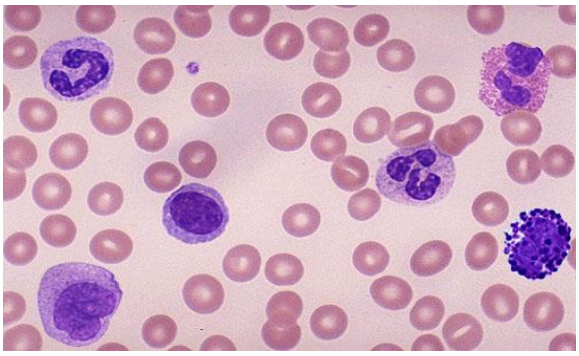

Figure 8: White blood cells

Source: Greg. (2008). Circulatory Blood WBC. [Online Image]. Retrieved Feb 1, 2014 from http://www.newagetouch.com/blog/?p=109

For this criterion, two different statistical analyses can be performed. A t-Test can be used to determine significant difference between the number of cells counted by the hemogram and the manual method. A P value less than 0.05 means there is a scientifically significant difference. Similarly, a correlational analysis can be performed to determine if the numbers of cells counted by the two systems are similar. It is important to note that correlation does not imply causation because both the data values are independent variables. In correlational analysis, the value of r (also called correlational coefficient) close to +1 or exactly +1 implies positive correlation. The value of r = 0 implies no correlation and the value of r close to -1 or exactly -1 implies negative correlation. The results of the two analyses are presented in Table 5:

Table 5: Results of statistical analyses.

Tests	Results
P(T<=t) two-tail	P = 0.13 (P>0.05)
Correlational analysis	r = 0.89

Source: Based on Rerksuppaphol, S., Soyorali, Y., Begeniki, H., Aldemir, M., Baran, A., Emre, H., . . . Erkoc, R. (2011). Comparison of the Automated Cell Counter and Manual Method for the Assessment of Dialysis Fluids in Peritoneal Dialysis Patients. *Healthmed*, *5*(6), *5*1891-1894. Retrieved from http://ezproxy.latech.edu:2052/ehost/pdfviewer/pdfviewer?sid=81700456-fcec-41f8-99f6-09b76236f25a%40sessionmgr4004&vid=11&hid=4112

The results of the two tests establish the accuracy of the Coulter LH 750 hemogram in counting cells. The result of the t-Test shows the P value of 0.13, which is greater than 0.05. It means that there is no significant difference in the number of cells counted by the two systems. From the correlational analysis, it is evident that the data values obtained from the two systems are similar because the value of r is close to +1. Thus, by comparing the number of cells counted by the automated system to the manual cell counting, the accuracy of the automated system has been determined. Hence, it can be concluded that the automated systems are equally accurate as expert medical technologists in performing hematological assays.

Conclusions

The results show that the automated processing of clinical specimens causes a reduction in the number of errors compared to manual processing. For the first criterion, colony isolation, the automated system generated a significantly greater number of colonies compared to manual inoculation. In clinical laboratories, samples can only be tested for the presence of pathogens once they are plated on the nutrition plates and single colonies are isolated. Colonies that are connected to each other cannot be used for the analysis because of contamination by other strains of pathogens. To distinguish each type of pathogen present, isolation of single colonies is important. An increased number of isolated colonies means a reduced possibility of contamination and effective identification of multiple strains of pathogens. Although there was no significant difference in the amount of time required to inoculate cultures between automated and manual inoculation, it can be disregarded because this research focuses on reduction of errors, not on time savings.

For the second criterion, specimen labeling error, the results show a significant decrease in the number of specimen labeling errors after the implementation of the automated system. It is important to note that even after the implementation of the automated system, the specimen labeling errors have still occurred. This finding implies that automated systems are still prone to errors, but they are effective in reducing the number of errors, specifically compared to manual labeling process.

For the third criterion, cell count, no significant difference was observed between the manual counting and the automated counting. This result implies that automated systems are reliable because the number of cells counted by the automated system correlated to the number of cells counted by expert medical technologists in a controlled environment. Thus, it can be concluded that laboratory automation can significantly reduce errors in clinical laboratories.

Recommendations

The outcomes of this research provide different suggestions depending upon the type of the audience. The recommendations are thus broken down as follows:

Shared Light Foundation

The research shows that laboratory automation is effective in reducing errors in clinical laboratories. Automation also shows precedence over the manual processing of clinical specimens. This finding implies that the use of automated systems can definitely improve the quality of laboratory services. Similar findings by other researchers on this topic will further corroborate the effectiveness of the automated systems in reducing the errors in clinical laboratories. The next step in setting a new standard in the healthcare system is to determine how automated systems can be installed economically in laboratories across the world.

Researchers

The research only evaluates the effectiveness of automated systems in reducing errors in clinical laboratories based on three criteria. Many other criteria, such as cost and size of equipment, turnaround time, availability of automated systems, maintenance, calibration, and specimen rejection rate have been disregarded in this project. In the future, researchers can evaluate the effectiveness of the automated systems based on these criteria.

Clinical Scientists

This research has shown that automated systems are still prone to errors. Obviously, they are superior to manual systems, but flaws are still present. Clinical scientists can focus their future research to further minimize this window of error. Their research can also focus on portability of the automated systems, economic manufacturing, and easy-to-use interface.

Managers

Automated systems are worth the investment. They also allow medical technologists to focus on performing research once they do not have to spend their time in the manual processing of specimens. Automated systems can also reduce the burnout and stress laboratory professionals have to face.

I would like to thank the Shared Light Foundation for approving my research proposal and providing me with the resources to carry out this project. I believe this research project will help in improving the quality of healthcare services and will ensure patient safety. If you have any comments or suggestions for future research, please call me at 571-245-3434 or email me at sundaesholi@gmail.com.

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Appendix A: Gantt Chart

	Dates					
Tasks	Jan 15	Jan 19	Jan 23	Jan 24	Jan 26	Feb 5
Task 1: Identify types of errors						
Task 2: Select the best available solution						
Task 3: Determine criteria						
Task 4: Collect data						
Task 5: Analyze data						
Task 6: Draw conclusions						
Task 7: Complete, review and submit						

Figure 9: Project schedule

Appendix B: Budget

Table 6: Estimated Budget

	Items						
	Labor		Laptop	Printer	Ink cartridges	Printer paper	Report cover
	Hourly wage	No. of hours					
	$11.00	60					
Quantity	-		1	1	2	2	1
Cost	$660.00		$249.00	$89.00	$44.99	$14.99	$9.99
Total Cost	$1127.95						