Establishment and implementation of an improvement plan using Lean Six Sigma methodology to minimize variation in ordering laboratory tests

Salwa H. Gomaa[a], Mona M. Abaza[a], Reham M. Rashwan[a], Nabil L. Dowidar[b], Ola H. Elgaddar[a]

Departments of [a]Chemical Pathology, [b]Clinical and Experimental Surgery, Medical Research Institute, Alexandria University, Alexandria, Egypt

Correspondence to Dr. Salwa Hamdi Gomaa, PhD, Department of Chemical Pathology, Medical Research Institute, Alexandria University, 165 El-Horreya Avenue, El-Hadra, PO Box 21561, Alexandria, Egypt.
Tel: +20 111 676 3803; Fax: +203 4283719
e-mail: salwa.hamdi74@yahoo.com

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Background/aim
Ordering laboratory (laboratory) tests by physicians is a part of the pre-preanalytical laboratory phase, which is a high error-prone process. Many of the laboratory tests ordered are unnecessary, where excess ordering represents as much as 25–40% of all ordered tests. The present study aimed at establishing and implementing a quality improvement project to avoid misutilization of laboratory tests using the Lean Six Sigma (LSS) methodology that could help to minimize variation in the laboratory requests ordered by clinicians.
Materials and methods
LSS approach methodology with its five phases, namely, define, measure, analyze, improve, and control (DMAIC), was applied to define and solve the problem of ordering of inappropriate laboratory tests. Sigma levels of the ordering process of selected laboratory tests were measured before and after implementation of the selected solutions. The stability and capability of the ordering process were retested after implementing the project.
Results
The sigma level of alanine aminotransferase/aspartate aminotransferase tests ordering process has been improved to 1.2 sigma, which represented 45% improvement. The sigma level of urea and creatinine ordering has been improved to 2.16 sigma, which represented 43.1% improvement, saving about 14 520 LE per year.
Conclusion
Successful implementation of LSS significantly improved laboratory test ordering. Simple modification in the laboratory request form could be an important source of improvement and a cost reduction tool in the pre-preanalytical laboratory phase. LSS is an evidence-based powerful tool that could improve the health care sector in general and the clinical laboratories in particular.

Keywords:
laboratory request, Lean Six Sigma, misutilization of laboratory tests, quality improvement

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Introduction

Laboratory medicine (lab) is a critical component of patient care, public health, and biomedical research. An estimated 70% of medical decisions are based on laboratory test results [1].

The total testing process (TTP) was traditionally divided into three stages: preanalytical, analytical, and postanalytical. Later on, according to the proposed definition by the ISO 15189: 2012 standard for medical laboratory accreditation (the International Organization for Standardization), the preanalytical phase was further subdivided into the conventional preanalytical phase, which occurs under the control of the laboratory, and the pre-preanalytical phase, which ends before reaching the laboratory including test request, patient identification, sample collection, handling, and transportation to the laboratory [2].

The 20th century witnessed a lot of technological innovations in laboratory medicine with constant addition of new information. Currently, more economic pressure is faced by diagnostic laboratories to provide reliable and accurate test results with reasonable costs [3].

However, this era is accompanied by very busy health care personnel who have limited time available to spend

with their patients and who may have a decline in their up-to-date knowledge that created variation in patient assessment and diagnosis. Such variation could lead to low reliability of test results, misutilization of laboratory resources, and eventually poor outcome [3].

It was found that most laboratory errors are due to preanalytical factors (46–68.2% of total errors), whereas a lesser error rate (18.5–47% of total errors) has been found in the postanalytical phase. Errors owing to analytical problems have been significantly reduced over time owing to better control on the analytical phase [4].

Many of the tests ordered in the pre-preanalytical phase are superfluous, where excess test ordering represents as much as 25–40% of all tests. Excessive testing not only leads to increased direct and indirect costs but also causes unnecessary patient discomfort and increases the risk of generating false-positive test results, which may in turn cause unnecessary worry, further investigations, and may be harmful to patients [5].

The laboratory test request as a standalone item shows high variation in its content for the same clinical diagnosis owing to poor communication between clinicians and laboratorians and variable knowledge about the laboratory guidelines [5].

Quality management plays a major role in improving laboratory processes, especially when using its powerful Lean and Six Sigma tools. Sigma methodology can be applied wherever an outcome of a process can be measured. A poor outcome is counted as an error or defect, which is expressed as defects per million. The term 'Lean' means to decrease waste and 'Sigma' is all about decreasing variations that cause defects in the process. Sigma metrics will facilitate the establishment of ideal analytical methodologies to augment process performance [6].

Ideally, in any improvement project that is based on the Lean Six Sigma (LSS) methodology, a baseline measurement for the process sigma level is done, and then different available opportunities for improvement are implemented to increase the sigma level. In the field of rational laboratory test ordering, this is mainly done using an evidence-based approach [6].

Evidence-based laboratory medicine is a more specialized term which ensures that the best evidence of testing is made available and that the clinician is assisted in making the most appropriate decisions regarding laboratory test ordering, with increasing the probability of improved health outcomes [7].

Since 2000, there have been a variety of projects applying Lean and Six Sigma strategies to health care quality improvement, yet some areas still are nonreachable and need exploration. For example, pilot programs utilizing Lean approaches at Intermountain Healthcare resulted in substantially reduced turnaround time for pathologist reports from an anatomical pathology laboratory [8]. Another example of Six Sigma application at the outpatient phlebotomy team of Kyungpook National University Hospital used Six Sigma approaches to diminish the patient waiting time [9]. These studies ensure the usefulness of LSS as a powerful tool to be applied to several health care services to improve their quality as well as patient satisfaction and safety.

Up to our knowledge, there are very few studies from Egypt reporting the use of LSS in health care sector in general and in the clinical laboratories in particular, which scarcely adopt it for improving laboratory test ordering process worldwide [10]. Therefore, the present work aimed at establishing and implementing a quality improvement plan using the LSS methodology to minimize variation in the ordered laboratory requests sent to the chemical pathology laboratory of Medical Research Institute Hospital (MRIH) from different hospital departments. This improvement plan, as it favors the patients' values and provides better quality management for them, also aims at making the service offered as a cost-effective one, in a way that reduces the unnecessary tests ordered in such a governmental-sponsored agency.

Materials and methods

Materials

Laboratory test request was the target of the study and the core for improvement of the whole research project. The laboratory tests inside the request are an important cornerstone of improvement tackled by this study.

The study setting was in the chemical pathology laboratory and the hepatology departments at the MRIH. The two departments were chosen by the help of the Six Sigma methodology. The chemical pathology performs a long list of laboratory tests, such as routine chemistry, hormones, tumor markers, and biological fluids. As for the Hepatology

Department, it covers nearly 350 to 450 patients per month, and its residents request an average of 800 laboratory tests per month. The study period started at the beginning of February 2019 till the end of December 2019.

Study design

All laboratory requests ordered during a period of 6 months were collected from all hospital departments for analysis. The total number of tests ordered per each department was calculated.

Data included in the laboratory test requests were analyzed to identify the problem. Then, after implementing the Six Sigma methodology project, the laboratory test requests newly arriving at the laboratory were collected for another two successive months for reassessment after applying the improvement project.

Ethical approval

This study received approval from the local ethics committee of Medical Research Institute, Alexandria University, with an approval number E/C S/M R2/ 2019.

Methodology

The Six Sigma methodology, one of the modern quality management tools with its five phases, define, measure, analyze, improve, and control phases (DMAIC), was applied [11]. Many tools and techniques were used in each phase of DMAIC separately including flowcharts, swimlane diagram, Pareto charts, control charts, brainstorming, affinity, and Ishikawa diagrams.

Details of data collection and analysis are mentioned in each phase separately as follows.

Define phase (D)

This includes identification of the project's purpose and scope and getting background data on the laboratory request ordering process and its possible sources of variation. In the present study, the main stakeholders identified were the hepatology and chemical pathology residents, in addition to the nurses and the laboratory technicians. The top management of the hospital, the chemical pathology laboratory, and the hepatology department were among the important stakeholders, as with their support, all suggested improvements might be easily implemented.

An analysis of stakeholders was performed and then voice of customer (VOC), describing the customers' needs and their perceptions about the process and its problems, was transferred to measurable outputs, known as critical to quality (CTQ). The CTQs were further translated into more effective and efficient terms that could be easily tackled at the measure phase. A project charter was constructed at the end of that phase using data and techniques (focused group, flowcharting, and CTQ). It describes the project vision and objectives. It also summarizes at a high level the overall project strategy, scope, organization, and implementation.

Measure phase (M)

It involved documentation of the laboratory test ordering process (flow chart and swimlane diagram), identifying possible causes for the variation problem (brainstorming, Ishikawa diagrams, and affinity), identifying controllable causes, taking stakeholder opinion via questionnaires and survey and finally having a data collection plan.

Analyze phase (A)

It included three main steps: prioritizing the root causes of the defect (using prioritization matrix and Pareto chart), measuring the stability of the laboratory test ordering process using a control chart, and measuring process capability together with sigma level calculation [12].

Improve phase (I)

This phase included providing solutions for the problem and selecting the most suitable solution to eliminate defect root causes (e.g. educational sessions and redesigning the laboratory request) [13]. Failure mode and effect analysis (FMEA) and implementing/ testing of the improvement plan were performed.

Control phase (C)

A plan for ongoing monitoring of the improved process was designed to respond to any possible emerging problem in the process performance

Statistical analysis

Data were analyzed using Minitab software package, Pennsylvania State University, version 16. It is the most common software used in quality improvement projects [14]. The ordering process before and after implementing the improvement project was compared using unpaired two sample *t* test. *P* value less than 0.05 was considered statistically significant. X–MR chart was constructed to determine if a process is stable and predictable and creates a picture of how the system changes over time, where the individual (X) chart displays individual measurements, whereas the

moving range (MR) chart shows variability between one data point and the next. Individuals and MR charts are also used to monitor the effects of process improvement theories. The capability study of a process, which is one of the Six Sigma tools, was determined by comparing the width of the process spread to the width of the specification spread, which defines the maximum amount of variation allowed based on specifications. When a process is capable, the process spread is smaller than the specification spread.

Results

Define phase

The total numbers of laboratory tests ordered by hospital departments over 6 months were 41 253 tests. The Hepatology Department was the department with the highest workload (7768 tests), representing 18.83% of the total number of test results of different departments, so it was found to be the department with high volume and high effect; hence, it was selected to be the project target.

The main stakeholders (customers) were hepatology residents, nurses, laboratory residents, technicians, head of the internal medicine department, and head of the laboratory department. All the laboratory department staff were found to be supportive toward the improvement project, whereas the rest of the stakeholders (Hepatology Department staff) were found to be neutral toward the improvement project.

The main customers (stakeholders) were interviewed and their opinions were gathered (VOC) (Table 1). This was transferred to measurable outcomes (CTQ) and then into effective and efficient tactics to be used in the coming phases (Fig. 1).

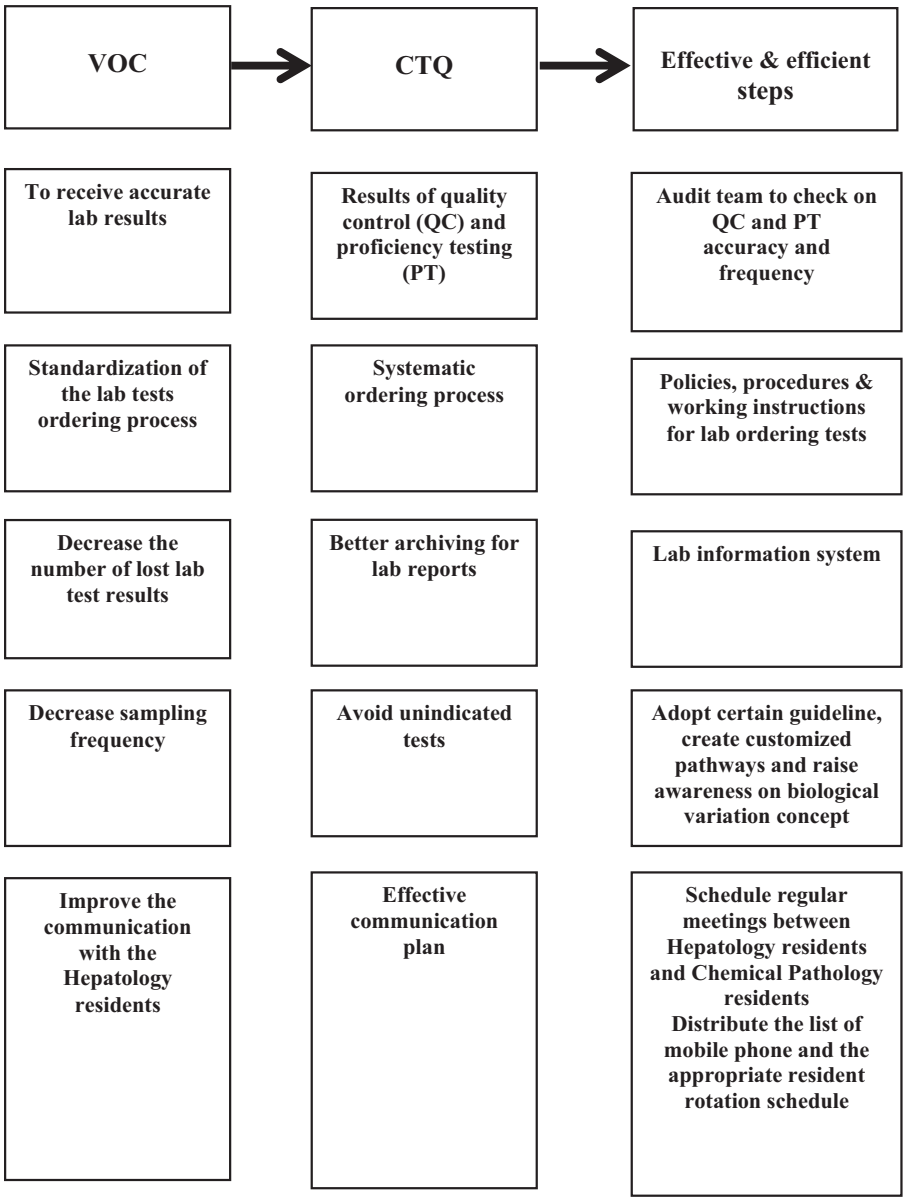
The most effective identified steps were to create an auditing team to check on quality control, set policies, procedures, and working instructions, using laboratory information system together with adopting international guideline and creating customized pathways.

The business case was the large variation in laboratory test request ordering process causing huge financial burden for the laboratory and the hospital in general. The current process of laboratory test ordering was 0.66 sigma and was seeking to reach up to 1.32 sigma. The total numbers of utilized laboratory tests were 242 tests per month. As per the annual procurement tender of the MRI, Alexandria University, the average cost per test for a single chemistry parameter was five Egyptian pounds, according to the price of each kit in the local

Table 1 The voice of customer of the process of laboratory test ordering

Hepatology residents	Nurses	Laboratory residents	Technicians	Head of the Internal Medicine department	Head of the laboratory department
To receive accurate laboratory results	To decrease the number of lost laboratory results	To decrease the number of ordered unnecessary laboratory tests	To decrease the workload	To raise the awareness of all staff regarding the efficient use of laboratory recourses	To stop the laboratory tests misutilization
To receive the results as fast as possible	To improve communication with technicians	To improve the current request form and ordering process	To decrease the number of lost reports	To reduce the turnaround time of the laboratory test results	To raise an awareness of all hepatology staff regarding the financial aspects of the laboratory test ordering process
To increase the number of available laboratory tests	To decrease workload	To improve the communication with the hepatology residents	To improve communication with nurses	To standardize the laboratory tests ordering process	To apply the MRI for better efficient utilization of resources
To improve communication with the laboratory residents		To increase the interaction between the Hepatology and the laboratory departments	To decrease frequency of sampling		
To increase the interaction between the Hepatology and the laboratory departments		To clearly justify the reason of ordering certain laboratory tests			
To set a policy for laboratory tests ordering process		To set certain protocol for ordering laboratory tests			

Figure 1



The voice of customer (VOC) transferred to critical to quality (CTQ), which was transferred to effective and efficient tactics to be used in the improvement cycle.

market of Egypt. The total saving per month was 1210 Egyptian pounds. The total saving over a year was 14 520 Egyptian pounds.

The last step in the define phase was to put the project charter, which summarizes the project, improvement target, and expected effect (Table 2).

Measure phase

The laboratory test ordering process in both Hepatology and Laboratory Departments was studied and presented as a flow chart and swimlane diagrams (not illustrated here). Identifying possible causes for the problem and selecting the controllable ones were obtained from the results of the Brainstorming sessions that were sorted out into an affinity diagram (Table 3) and then into a fish bone (Ishikawa) diagram where controllable (C) and noncontrollable causes (N) were illustrated (Fig. 2). The identified causes were confirmed by taking the stakeholders' opinion. This included analysis of the questionnaire results, which was solved by seven residents at the Hepatology Department.

Two questions in the questionnaire were testing the residents' awareness of evidence-based medicine (EBM) concept; 16.7% of the residents mentioned the correct name of the guideline adapted in their department and 33.3% knew the actual number of algorithms created in their department.

Table 2 Project charter of the improvement project

Project charter	
Business case	Problem/opportunity statement
The large variation causes huge financial burden for the laboratory with budgetary inflation of the hospital in general	Current Sigma Level is 0.66
Goal statement	Scope of the project
To decrease the number of unnecessary ordered laboratory tests, in the hepatology department by about 25%	Start point: creating the business case
Desired Sigma level is 1.32	End point: creating the control plan
Savings	
14 520 L.E/year	

Table 3 Affinity diagram constructed after grouping the brainstormed possible causes into four main categories: work policy, ordering process, people, and environment

Work policy	Ordering process	People	Environment
Absence of joint scientific events between different departments	Duplication of laboratory tests ordering in the same shift	Residents long shifts	Weak communication tools between residents of the two departments
Absence of strict sanctions for laboratory tests misutilization	Absence of reflex testing	Decreased number of residents	Absence of effective implementation of diagnostic algorithms and clinical guideline rules
Absence of policies and procedures for the ordering process	Absence of panel test ordering	Lack of motivation to improve current status	Absence of standards
Increased length of stay per patient	Absence of justification for repeated tests ordered by the hepatology residents	Lab residents lack of conjoined seminar knowledge regarding scientific updates in other departments	Absence of the role of governance
Absence of training programs for residents on laboratory medicine updates	Acceptance of unsigned requests by the laboratory (incomplete laboratory requests)	Residents are exhausted	Budget constrains
Absence of laboratory information system	Absence of unified request form	Lack of awareness of evidence-based medicine (EBM) basics	Economic instability
Absence of electronic medical records	Absence of strict criteria for tests recognized as routine	Lack of awareness of BV concept	
	Overwhelmed top management		
Absence of good archiving for laboratory reports	Duplication of laboratory tests across different shifts	Ordering certain tests in frequency that is not complying with BV	Lack of professional development programs to all medical teams
Absence of audit on laboratory tests ordering process	Ordering of unindicated laboratory tests	Inefficient handover between residents	High workload
Absence of adoption to guidelines		Absence of clear goal for the laboratory tests requested	
		Lack of awareness of average cost per test	

BV, biological variation.

Three questions in the questionnaire tested the residents' awareness of biological variation (BV) concept, where none of the residents knew the BV of creatinine for diseased patients, only 16.7% knew the correct frequency of ordering alanine aminotransferase (ALT) and aspartate aminotransferase (AST), whereas 33.3% were aware of the indications of ordering ALT and AST together.

None of the residents were aware of the average cost per test for most of the laboratory investigations ordered in their department.

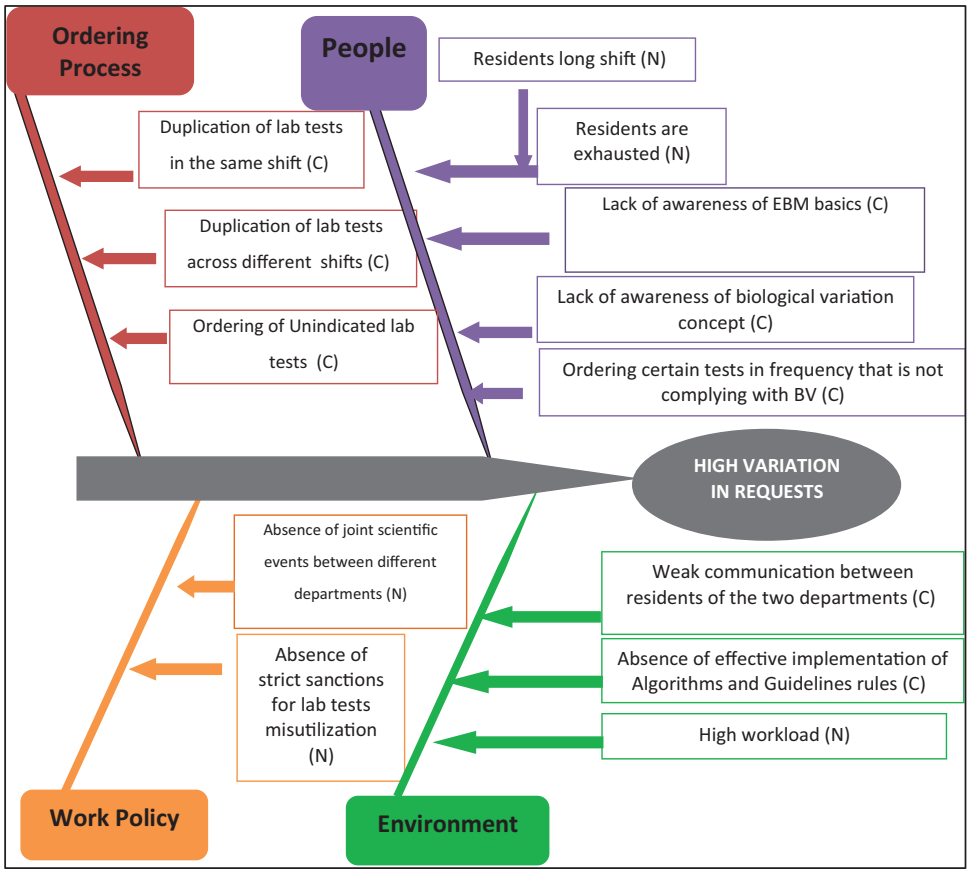
The last question was directed to detect the residents' interest in joining the current improvement project, where 83% agreed that their clinical practice need to be more evidence based.

At the end of this phase, a plan was set to collect laboratory test requests ordered by the Hepatology Department over a period of 1 month. In each request, the frequency of ordering urea and creatinine for each individual and the combined ordering of ALT and AST in the same request as well were identified and counted to measure the magnitude of the problem.

Analyze phase

The collected data through questionnaires and laboratory requests sent over 1 month were prioritized to select the most important items to be

Figure 2



Ishikawa (Fish bone) diagram for the four main categories responsible for the most root causes of the problem showing controllable (C) and noncontrollable (N) causes.

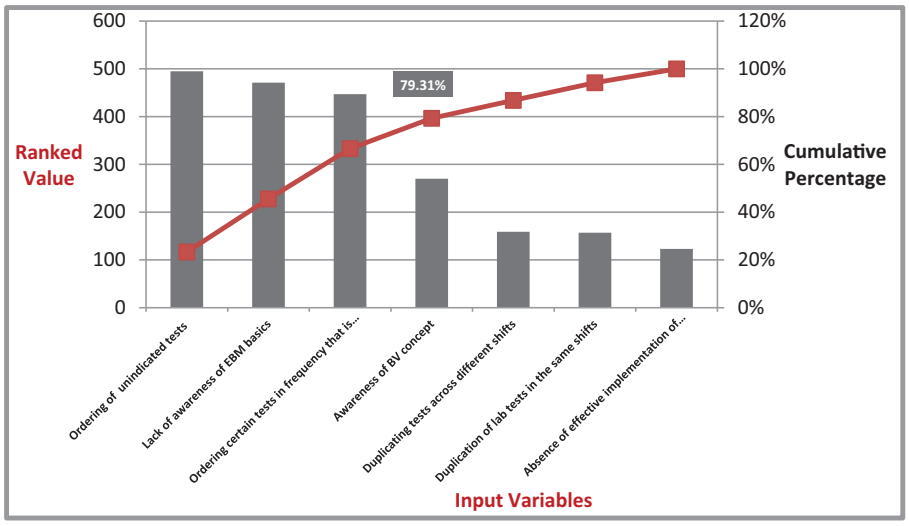
improved. Prioritization was done using two main tools: prioritization matrix and Pareto chart.

By using the prioritization matrix, the top ranked root causes identified were ordering of unindicated laboratory tests (495), which represented 23.33%; the lack of awareness of EBM basics (471), which represented 22.20%; ordering certain tests in frequency that is not complying with BV (447), which represented 21.07% (like ordering urea and creatinine on daily basis); and lack of awareness of the BV concept (270), which represented 12.72%. Then, Pareto chart was started by involving the data available from the prioritization matrix. The different root causes were ordered according to the rank and rank percentage derived from the prioritization matrix results. The ordering of unindicated laboratory tests, lack of awareness of EBM basics, ordering certain tests in frequency that is not complying with BV, and lack of awareness of BV concept together represented 79.31% of the problem (Fig. 3).

The unindicated ordered tests, in the project, were the combination of ALT and AST in the same laboratory request. Moreover, urea and creatinine were reordered on a daily basis to all patients with the problem of noncompliance with the known BV of these analytes. The stability of ALT/AST ordering process as well as urea and creatinine ordering process was measured for 30 successive days using the control charts (X–MR charts), and they showed that ALT and AST were ordered together in 100% of the cases in a stable process, which indicates a room for improvement (Fig. 4). However, the X–MR chart for urea and creatinine ordering process showed that urea and creatinine were ordered on a daily basis. It was a stable process as well with another opportunity for improvement (Fig. 5).

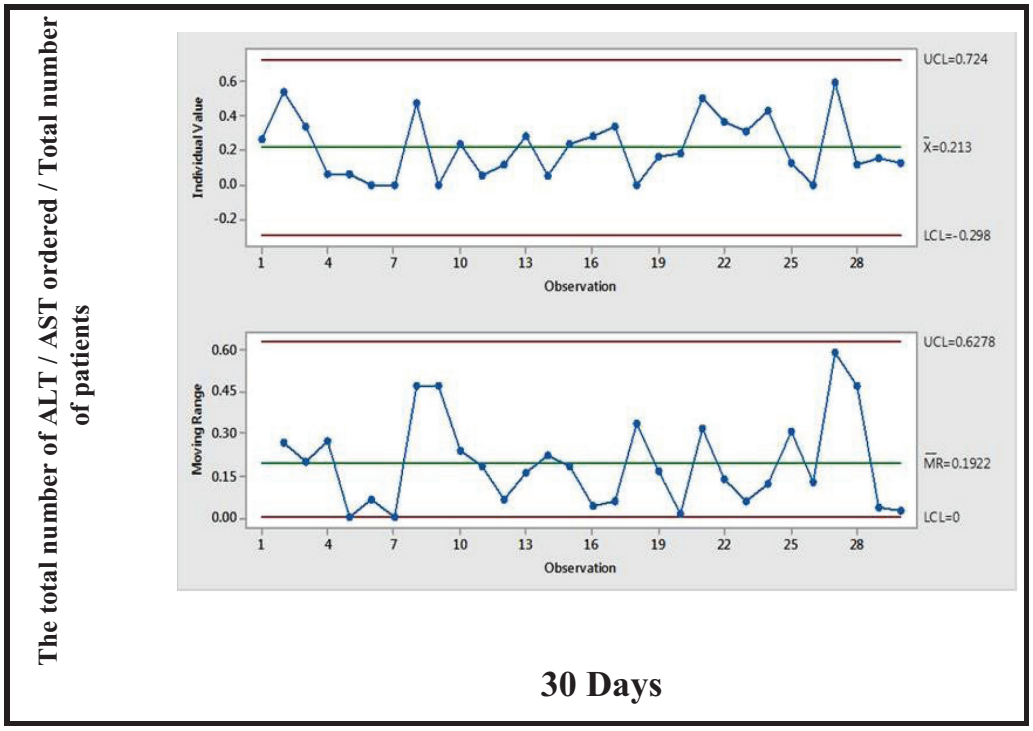
Capability study for ALT/AST ordering process showed more the 50% of the curve lies outside the specification limits, reflecting the high variation of the process and a high possibility of improvement. Sigma level of the process was 0.66. Same findings were identified after plotting the capability curve for urea and creatinine ordering process; however, the Sigma level was calculated to be 1.23 (Figures for Capability are displayed in the improve phase).

Figure 3



Pareto chart with three main axes: the horizontal axis represented the root causes arranged in a descending order (BV=biological variation, EBM=evidence-based medicine). The left vertical axis of the chart represented the ranked value of each cause. The right vertical axis represented the cumulative percentage of the root causes. Ranking system is from 1 to 9; where 9 being the highest score and 1 being the least score, depending on the stakeholders' opinion.

Figure 4



X–MR chart for ALT/AST ordering process showing its stability (X, individual points and MR, moving range control charts). ALT, alanine aminotransferase; AST, aspartate aminotransferase.

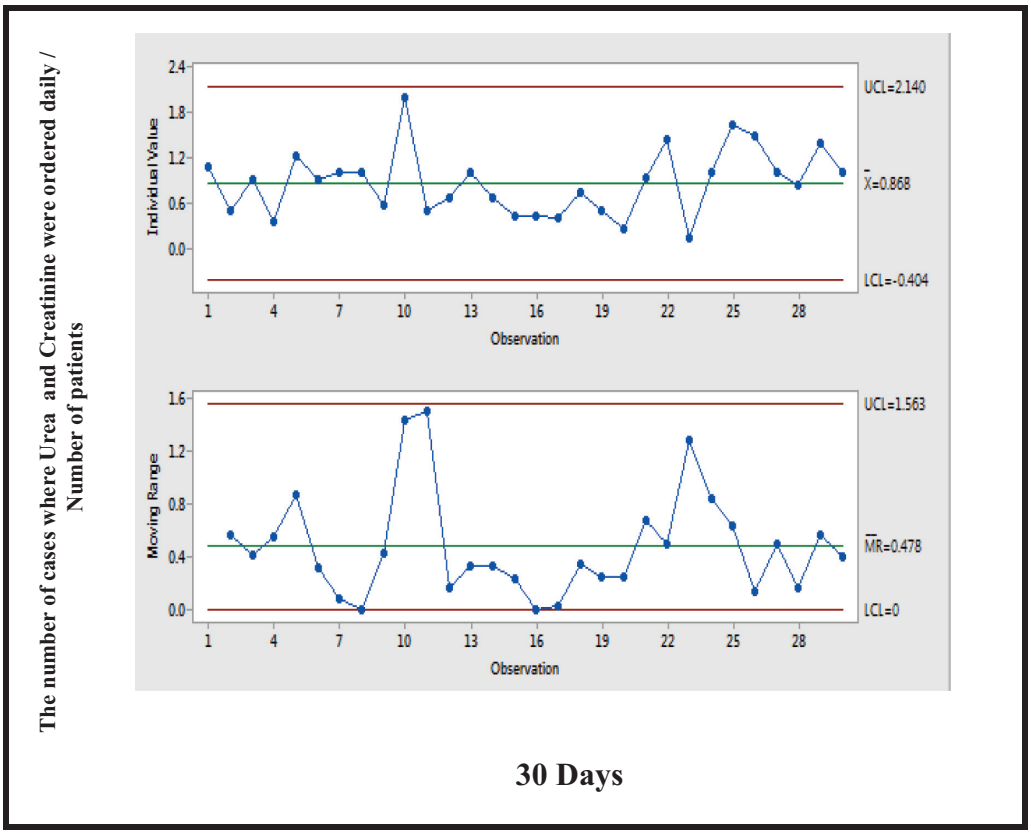
Improve phase

During this phase, several solutions for the problem and the most suitable among them were selected.

Educational sessions were conducted for the hepatology residents to raise their awareness about EBM and the concept of BV. A new laboratory request form was designed to be used by the hepatology residents.

A new laboratory request form was designed to be used by the hepatology residents, omitting some tests that

Figure 5



X–MR chart for urea and creatinine ordering process showing its stability (X, individual points and MR, moving range control charts).

were ordered frequently or irrationally. It also included the recommended frequency for ordering different laboratory tests, and it removed the 'pairing' between common laboratory tests that were usually ordered together such as ALT and AST. A field was added for the resident to write the 'reason' for ordering some laboratory tests and if they are going to order some tests with a higher frequency than the recommended; they have to mention the reason for such exceptional request as well. Those two proposed solutions were tested for their performance using FMEA. Table 4 shows that the Risk Priority Number (RPN) was 250 for the educational sessions to be conducted for hepatology residents to raise their awareness about EBM and the concept of BV. This RPN was reduced to 30 by proposing measures like top management involvement and repeating the sessions frequently. Similarly, the RPN for designing a special new laboratory request form was high (500), which could be reduced to 50 by implementing measures such as involving hepatology residents in the decision design and decision making, and also the laboratory will reject any request that is not coming on the new form.

Control phase

X–MR charts were used to measure process stability again for ALT/AST ordering process as well as for urea and creatinine ordering process. They were found to be stable as well, after applying the improvement plan (results not displayed).

In addition, the capability curve for ALT/AST ordering was plotted again after implementing the improvement project (Fig. 6), and it showed an improvement where more than 75% of the process lied within the specification limits. Moreover, the sigma level increased to reach 1.2.

Moreover, for urea and creatinine ordering, the capability study showed improvement as well after implementing the project (Fig. 7), with nearly 90% of the process lied within the specification limits and Sigma level increased to reach 2.16.

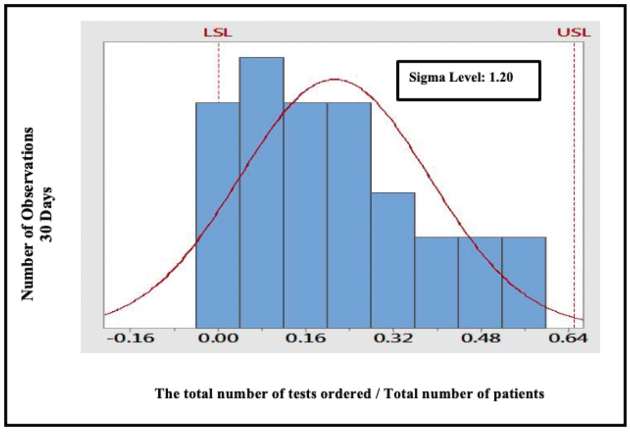
Moreover, the same questionnaire used in the measure phase before improvement was redistributed again to hepatology residents and the answers were analyzed after implementing the improvement project. There

Table 4 The failure mode and effect analysis of the proposed solutions

Solution	Failure mode	Potential effect	SEV	Potential causes	OCC	Current control	DET	RBN	Recommended actions	SEV	OCC	DET	RPN
Educational lectures to Hepatology residents about EBM and the concept of biological variation	Noncompliance With the information gained	No change in the pattern of ordering of laboratory tests	10	Too busy to attend the sessions-	5	Improve Communication with residents-	5	250	Involvement of top managers in every step-				
				Resistance from residents-		*Make the sessions simple and clear-			Repeating the sessions every week in different ways to make sure that they are well understood and applied-	10	3	1	30
				Lack of management support-		Apply the questionnaire after the sessions-							
Designing new laboratory request form to be used by the Hepatology residents	Noncompliance with the new form	No decrease in the total number of ordered laboratory tests	10	Unavailability of the printed requests-	10	Availability of the printed requests	5	500	Involving residents in decision making and design process-	10	5	1	50
				Poor compliance from residents-					Lab rejects requests that are not written on the new format-				

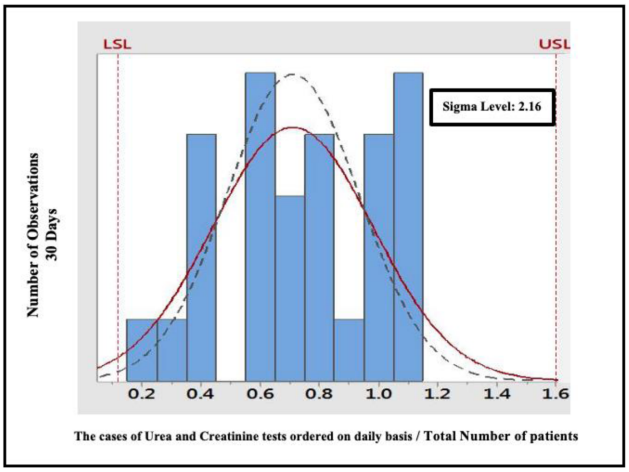
DET, how easily the failure can be detected (ranking system was from 1 to 10, where 1=low and 10=high); OCC, how frequently the failure is likely to occur; RPN, risk priority number=SEV×OCC×DET; SEV, the severity of the effect of failure.

Figure 6



The capability of ALT/AST ordering after improvement with the lower specification limit (LSL) and the upper specification limit (USL). ALT, alanine aminotransferase; AST, aspartate aminotransferase.

Figure 7



The capability of urea and creatinine ordering after improvement with the lower specification limit (LSL) and the upper specification limit (USL).

was a marked improvement in the knowledge gained, where 85.7% of the residents mentioned the correct name of the guideline adapted in their department and 71.4% recognized the actual number of algorithms created in their department. Regarding the awareness of BV concept, 85.7% of the residents knew the BV of creatinine for diseased patients and also knew the correct frequency of ordering ALT and AST. All of the residents were aware of the indications of ordering ALT and AST together. All of the residents were found to be aware of the average cost per test for the routine analyses performed in the laboratory. Moreover, all of them agreed that their clinical practice need to be more evidence based.

To sum up our results, we found that the combined ordering of ALT and AST after improvement was significantly lower when compared with ordering of ALT and AST before improvement (P=0.035); however, no significant difference was found in the frequency of ordering urea and creatinine before and after implementing the improvement project (P=0.165).

Discussion

Laboratory TTP encompasses internal and external laboratory activities that require interaction between laboratory personnel and other specialists [15].

Laboratory process is error prone at any of its phases; yet, the ability to create solutions and find better alternatives is highly possible. This is available by using modern quality management tools such as Six Sigma methodology, which represents an evolution in quality assessment and management that has been implemented widely in business and industry since the mid-1980s [6].

Owing to the scarce data worldwide concerning the application of Six Sigma in pre-preanalytical laboratory phase, and the fact that it was not applied on the tests ordering process before, it was noteworthy to work on.

The present study targeted the pre preanalytical laboratory phase aiming at establishing and implementing an improvement plan using the LSS methodology to minimize variation in the ordered laboratory requests preformed in the Chemical Pathology Department of MRIH, Alexandria University, Egypt. This study involved two departments in the MRIH, which were the chemical pathology and the hepatology departments.

LSS was the methodology used for this improvement research project as it had proven marvelous success in decreasing costs, reducing variations, and improving the quality level of the processes in different laboratory phases [6].

Six Sigma was widely used across laboratories in different phases of the TTP. In the preanalytical phase, it was used to reduce access errors and increase staff productivity at the Long Island Jewish laboratory [16], to reduce the manual laboratory requisition data entry at Uganda Makerere University labs [17], and to decrease the error rate of test registration into the laboratory information system at Tygerberg hospital laboratories [18]. It was also used

to decrease the number of phlebotomists and helping in switching to single piece workflow at DSI laboratories in Florida [19] to reduce travel time of test tubes in pneumatic system at Froedtert Memorial Lutheran Hospital in Milwaukee [20] and to reduce hemolysis occurring in blood samples at Sarasota Memorial Health Care System (SMHCS) in Florida [21]. Six Sigma was also used to identify, quantify, and monitor the nonconformities of the preanalytical process and to create quality indicators that can affect patient safety in a Romanian private clinical laboratory [22].

To the best of our knowledge, this study is the first one in Egypt to apply the LSS with (DMAIC) methodology on the pre preanalytical laboratory phase to improve laboratory test ordering process.

The define phase of the current improvement project started by selecting the department with the highest workload. The Hepatology Department represented 18.83% of the total number of laboratory tests ordered at the MRI hospital.

Stakeholder analysis was performed to better understand the identified problem; this tool was also used by McLendon labs to identify stakeholder opinion in the billing processes problem [23].

The second tool was the VOC, which intended to better understanding the customers' needs to focus on meeting their expectations. The VOC was transferred to CTQ. The CTQs were further translated into more effective and efficient terms that could be easily tackled at the next phase such as having audit teams and setting clear policies and procedures while adopting clear evidence-based guidelines that could be customized inside each department.

Both the Uganda Makerere University [17] and the McLendon laboratories [23] used the VOC and the CTQ during the define phases of their projects to establish a baseline assessment of the customers' satisfaction, then identified and prioritized the key driving characteristics of the customers' satisfaction, and turned them to CTQ.

The Project Charter was the last step in the define phase. It included the business case, the current and desired Sigma levels, and the estimated savings achieved from the current project.

In the measure phase of this study, we started constructing the flow chart of the laboratory request test ordering process and drawing the swimlane diagram for it which covers the steps occurring at each of the two departments. Likewise, Uganda Makerere University labs used flowcharting to identify the process map of the data entry problem, which was a helpful tool before any process improvement [17]. Moreover, brainstorming sessions were then held to identify the possible root causes for the problem of the variation in ordering laboratory requests. The results of these sessions were categorized in an affinity diagram that was constructed and grouped into four main categories: work policy, ordering process, people, and environment. Ishikawa (fish bone) diagram was then drawn. Similarly, the pathology laboratory of Bezmialem University held brainstorming sessions interdepartmentally and intradepartmentally to analyze the errors occurring along the laboratory testing process [21]. Furthermore, the Makerere laboratorys' Six Sigma team used brainstorming and fish bone diagram to help identify and organize potential root causes for the data entry errors [17].

In the analyze phase, prioritization matrix and Pareto chart were used to identify the vital few causes that are responsible for nearly 80% of the problem of variation in laboratory test request ordering process. The identified main causes were the ordering of unindicated tests such as ALT/AST ordered together, lack of awareness of EBM basics, ordering certain tests in frequency that is not complying with BV such as urea and creatinine, probably owing to the lack of awareness of the BV concept. Sigma level for ALT/AST ordering process was calculated to be 0.66 and that of urea and creatinine was 1.23.

In the improve phase, two proposed improvement actions were taken: conducting educational lectures for the hepatology residents to raise their awareness regarding EBM and BV basic knowledge and designing a new laboratory request form to be used by the hepatology residents, where the test menu was organized in a way rationalizing the tests ordered for each primary diagnosis and BV was included to help residents to select tests with the recommended frequency. A field was added for the residents where they have to explain the reason behind ordering any test that is not complying with the recommendations. This practice was adopted by Seppänen *et al.* [24] where they modified the laboratory request form by removing AST from it as it was considered of limited value for clinical decision making Moreover, Shalev *et al.* [13] detected an improvement in the physicians behavior in ordering laboratory tests after modifying the laboratory request form.

The two proposed solutions were then tested for their effectiveness using FMEA tool. Similarly, a Romanian private clinical laboratory used FMEA to test the feasibility of the established key performance indicators to identify and control the sources of errors occurring in their laboratory [22]. However, in our study, some more steps were included in the improvement project such as involving the top management, repeating the educational sessions, and taking the opinion of the residents in the new request format.Interestingly, the present study showed that after implementing the selected solutions for the ALT/AST being ordered together, and urea and creatinine being ordered with a very high frequency, Sigma level of ALT/AST ordering became 1.2, representing 45% improvement. The combined ordering of ALT and AST after improvement was significantly lower *(P* = 0.035). Sigma level of urea and creatinine ordering became 2.16 Sigma, representing 43.1% improvement; however, no significant difference was found in the frequency of ordering urea and creatinine between before and after the improvement.

Other laboratory studies that used the Six Sigma methodology achieved improvement of 23% at McLendon laboratories [23], 56.7% at Makerere laboratories [17], and 87% at Long Island Jewish laboratories [16], and so, the current study is considered to be a successful one among comparable studies.

To the best of our knowledge, no studies have reported on laboratory test utilization in Egypt, despite evidence that the problem of inappropriate test utilization practices occurs as addressed elsewhere. A recent study from Saudi Arabia showed that medical malpractice claims increased by 416% between 2008 and 2013. However, they reported that no single approach has been widely used to solve the problem of inappropriate laboratory test utilization [25].

The overall value of the results from this study is that it provides an evidence-based problem solving tool for an existing major malpractice problem, which is the inappropriate laboratory test ordering, and misutilization of resources faced by one of the Egyptian health care systems, and our findings could be the base for future improvement projects all over the health care systems. However, the current study was limited by the involvement of a single hospital department (although it was the one with the highest workload) and by the limited number of the selected laboratory tests ordered. Simple interventions by the help of the Six Sigma approach had a significant effect, but the attribution of success may also be influenced by variables that were not measured. Future studies could be enhanced by the inclusion of measurable patient outcomes.

Conclusion

From our results, we could conclude that educational sessions, conjoint meetings, and cooperation between physicians and laboratorians are essential for any possible improvement initiatives. Moreover, a simple change in the laboratory test request form could be an important source of improvement and a cost reduction tool in the pre-preanalytical laboratory phase. The LSS methodology and DMAIC improvement approach need to be repeated in different departments of the hospital. This replication will lead to sustained behavioral and cultural changes with better utilization of resources. Future studies must adopt specific guidelines that can bring all of the medical teams in different departments along with the laboratory team to work together for the same target.

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Conflicts of interest

There are no conflicts of interest.

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