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DESIGN NEW WORK PROCESSES AND OPERATING PROCEDURES FOR A PATHOLOGY AND LABORATORY FACILITY AT A MEDICAL CENTER USING DMADV METHODOLOGY

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ABSTRACT
Patients of a pathology and laboratory department at a Medical Center in Orlando, FL were dissatisfied with the service due to the long waiting time. In preparing for moving to new facility, the medical center aimed to improve the service using quality tools to reduce current total service time (30 minutes) and improve the efficiency of existing resources, then standardize the operating procedures. In order to accomplish these requirements in the new facility, a Design for Six Sigma framework DMADV (Define, Measure, Analyze, Design and Verify) was used to design the new work processes and operating procedures, implement and test them in the existing location before moving to the new facility. Six Sigma DMADV is an effective framework to identify the root cause of the problem, design/ redesign the work procedure, and verify the proposed solution. After analyzing the data and requirements from customers (including providers, patients and lab staff), system defects were addressed. Then, simulation models were used during the design phase to test different alternatives to find the optimal work procedure that meets customer expectation.
The team found out that a walk-in approach with no appointment for the service is the best procedure that gives patients the flexibility to decide the time of doing their lab work. It also off loads the work of the appointment team as they are no longer need to schedule appointments. There is cost saving on sending the appointment by mail as well as mileages reimbursement. The new procedures reduce the patients waiting time in the laboratory to 5 minutes with no lead-time.

Keywords:
Six Sigma, pathology and laboratory, DMADV, Design New Work

INTRODUCTION
A Medical Center Pathology and Laboratory located in Orlando, FL provides outpatient laboratory services. Reporting over 3.5 million laboratories results each year and handles over 5,500 specimens each week. The management aims to transfer to a full service laboratory in anticipation for the expansion of the new Medical Center Facility at another location. This transition includes the addition of a microbiology laboratory, a blood bank laboratory, inpatient laboratory services, and many other services not offered at the current facility. In its current operating environment as an outpatient facility, the laboratory performs between 500 and 600 phlebotomies each day with an operating schedule from 7am to 4:30pm, Monday through Friday. As a full service laboratory the working hours will be 24 hours a day, 7 days a week. The flow of patients is currently controlled by an appointment-based system. Whilst the actual workload is captured by the laboratory orders that are placed by physicians providing the facility no way to accurately measure progress.
This facility offers a variety of services for patients, all of which are in high demand within a specified time period, specifically during the early morning hours. Patients arrival and service times vary greatly; in attempt to organize the patient flow within the facility, management has implemented an appointment-based system. The medical center has received overwhelming complaints from patients claiming they wait too long and deem this as a negative factor when evaluating the quality of their patient care.
In addition to the appointment system in place, the facility also uses many manual paperwork processes and limiting computer systems to complete the review of patient orders, which sometimes lead to extended wait periods, double orders, etc. The approximate waiting time for a patient is 30 minutes. The team has been informed that the Medical Center would like to provide top of the line quality to their patients with lowered waiting time in order to accommodate more patients in less time. The organization would also like to

standardize their operating procedures in order to adopt them in the upcoming facility. The goal for this project is to revise the current operating procedures to accommodate the new designed process that is developed by the Six Sigma Engineers (SSE) team. This will improve the overall efficiency of the workflow. Hence, improves patients' satisfaction. The team focuses its efforts to reduce patient waiting time by 30%.

LEAN SIX SIGMA IN HEALTHCARE

Six Sigma methodology can significantly improve operational performance of any health care facility. As, Six Sigma has a systematic methodology to help identify and solve problems (Revere, Lee, - Black and Huq, 2004). Six Sigma may be applied to the triage process in emergency rooms. Patients may be interviewed when they arrive at the emergency room to determine the extent of their illness and their priority to see a doctor. This process could be streamlined by the use of Six Sigma so that critically ill patients can quickly see a doctor and not getting stuck in the triage process. Six Sigma can be used to decrease the time patients spend in the emergency room by getting patients admitted to hospital rooms or discharged quicker. Patient rooms are more comfortable than the emergency room and there is a higher cost to stay at the emergency room than regular rooms. Also, this could allow emergency rooms to treat more patients (Sehwail &DeYoung,2003). Six Sigma can also be used to optimize the scheduling of time for the testing equipment such as MRI machines and the resources to operate this equipment. (Torres & Kristina, 2004) Also, scheduling can be done in such a way that patients most in need of the services can be scheduled giving higher priority (Lasarus, Ian, and Neely, 2003). The rest of the paper shows the different phases of the methodology DMADV. Then, the proposed solution is verified.

DEFINE PHASE

In the define phase the team creates the project charter. Additionally, SSE has worked diligently to devise a work plan in order to track all project functions. A communications plan is created to reveal the modes of sharing information among the project team members as well as all previously identified parties in the stakeholder analysis. A risk management plan is created to identify potential events that may create a negative impact on the project as well as a mitigation strategy. A responsibility matrix recognizes all members with accompanied by the tasks they are held accountable. In this phase the team captures the current processes as well as define the problem.

Current State of Process

The current appointment-based system is labor intensive and fraught with many loopholes. Over 70% of the patients desire to be seen during morning hours, which causing low volume of patients during the afternoon. In addition, more than 50% of the patients arrive before their appointment time, affecting the overall waiting time. Current estimate wait-time is 30 minutes.

Problem Statement

The laboratory receives many complaints about the long wait-time (30 minutes). Many factors combined together creating this problem. The current appointment-based system is labor intensive to manage and fraught with many loopholes. Patients arrival and service times vary greatly; some patients arrive hours late than their appointment but and get seen before scheduled appointments. While others come before their appoint time. The creates a longer wait times for all in both cases. Most patients desire to be seen during morning hours, which result in high volume of patients in the morning and low volume of during the afternoons. In addition to the appointment system in place, the facility also uses many manual paperwork processes and limiting computer systems to complete the review of patient orders, which sometimes lead to extended wait periods, double orders, etc.

MEASURE PHASE

In this phase the team defines the detailed process-map in order to determine the root cause of the problem(s) and non-value added processes. Then, the team established data collection plan to determine what to measure, how to collect and when to measure the data. In addition, several tools are used in this phase including: process flow diagram, data collection plan, data transformation, process capability, Suppler-Inputs-Process-Outputs-Customers (SIPOC), and Voice of the Customer (VOC) and Brainstorming. The team gathers key data quantifying the existing process defects and pinpoint problem areas in the process. The goal is to establish a baseline for the current process in the department in order to compare the newly proposed process that will be developed during the design phase.

Vol (02) _Issue (01)

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Process Flow Chart
The process flow diagrams for the Lab are depicted in Figures 1 and 2. It show the high-level process map for the lab request and the high-level process map for the lab facility respectively.

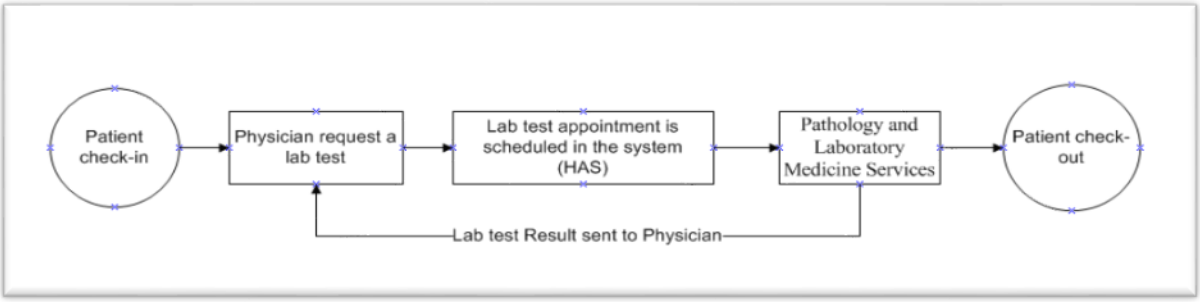

Figure 1 High-level process map for Laboratory facility

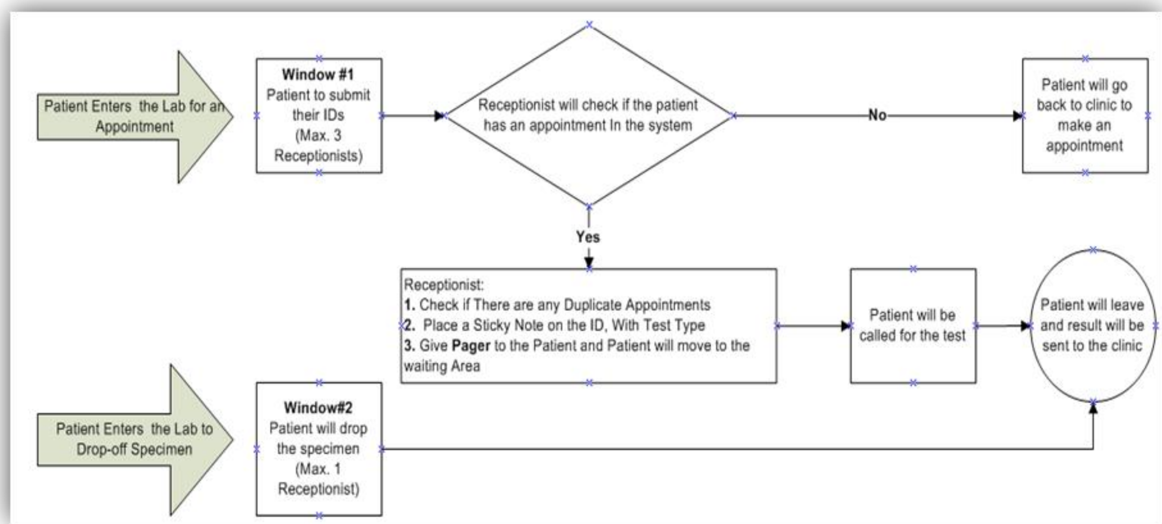

Figure 2 High-level detailed process map

Data Collection Plan
The data collection plan has been developed to know exactly what information needed to reduce the patient waiting time in the laboratory and to provide a convenient reference of forms to collect these data in a professional manner. The team has decided to collect three types of data: patients waiting time, patient requirements and satisfaction level, and laboratory process defects. Therefore, the SSE team has implemented three data collection plans for each type of these data as illustrated below:

Patient waiting time
Patients waiting time is the time period between the arrival time to the lab reception window until entering the lab. This equals to three check points. Record the arrival time at the reception where a pager is handed to the patient plus waiting time until the pager rings and handed back to the reception. Then the team compare the patient's order number with appointment in the system.

Process Defects
From a process standpoint, there are key items that are crucial for the process to succeed. These items are external factors to the lab but it is causing longer wait to patients and wasting the time of the staff. Therefore preventing process defects would improve the customer satisfaction and reduce the duplicate efforts. The study shows two major defects that happen outside the lab. If the clinic does not enter the lab order in the system and appointment clerk does not schedule an appointment, the patient has to go back to the clinic to correct it.

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Base line

To establish a waiting time base line, the team collects more than 140 observations in multiple periods over different days. The data were also used to test the provided customer waiting time information (30 minutes). Based on below mini-tab output figure3, the mean waiting time is over 30 minutes.

Test of H0: mu = 30 vs H1 mu > 30
The assumed standard deviation = 25.23

Variable	N	Mean	StDev	SE Mean	95% Lower Bound	Z	P
waiting time min	140	37.29	25.23	2.13	33.79	3.42	0.000

Since P-value < 0.05 ➔ Waiting time is more than 30 minutes.

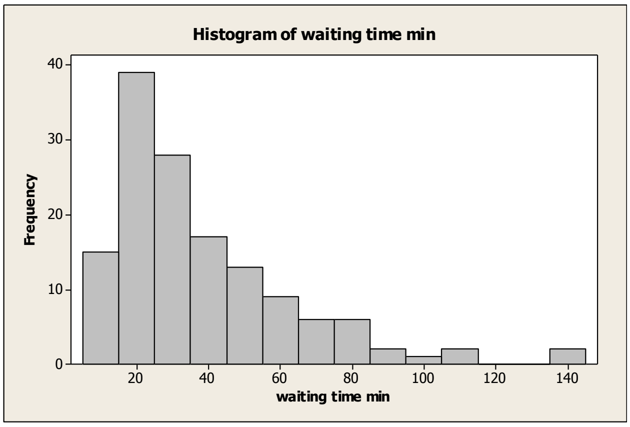

Figure 3 Waiting time Distribution fit

Data distribution for waiting time:

Descriptive Statistics

N	N*	Mean	StDev	Median	Minimum	Maximum	Skewness	Kurtosis
140	0	37.2929	25.2269	31	7	143	1.64393	3.42699

Goodness of Fit Test

Distribution	AD	P
Normal	4.875	<0.005
Lognormal	0.181	0.912
Exponential	9.774	<0.003
Weibull	1.329	<0.010

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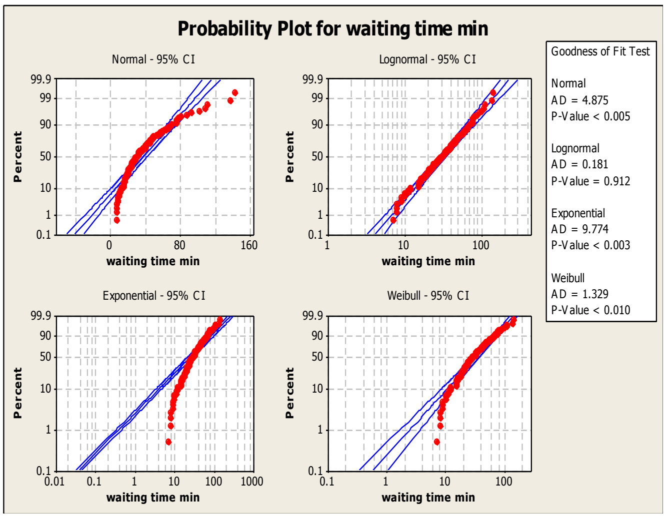

Figure 4, The waiting time is following a Lognormal distribution.

Data Transformation:
In order to test the stability of the waiting time we need to transform the waiting time lognormal distribution to a normal distribution using Johnson figure 5 Transformation as follow:

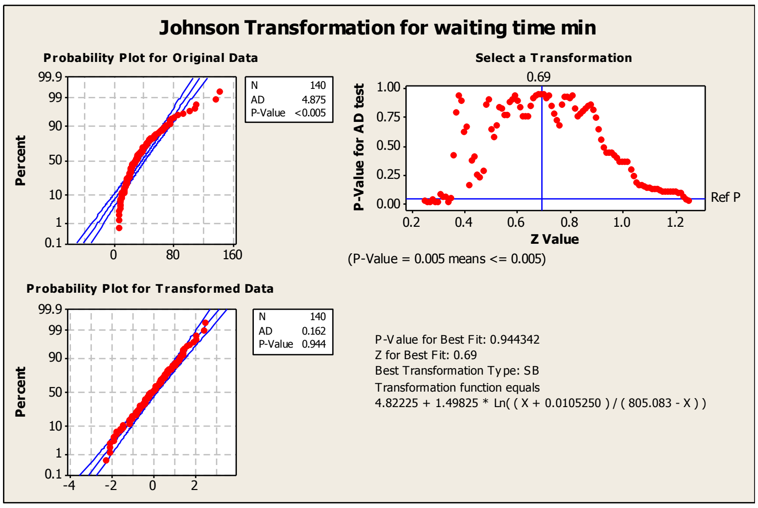

Figure 5, The waiting time lognormal distribution to a normal distribution using Johnson

Process Stability:
Twenty one points (n = 5) a total of 105 observations were recorded to establish the control limits. (Fig. 6) below shows the first control limits run. Based on the plotted points, point 8 and 10 are out of control, which is an indication of special causes in the process.

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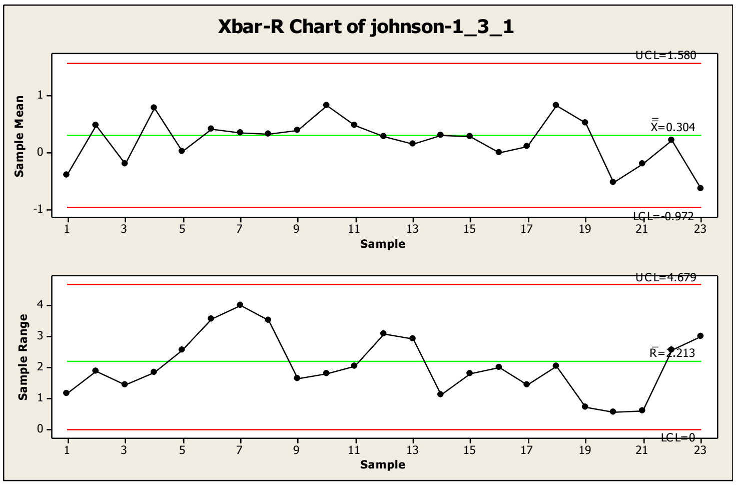

Figure 6, Control chart

The new plotted points are under control, this indicate that the process is under control now after removing the special causes. The process control limits are as follow:

- Process mean = $\bar{\bar{X}}$ = 0.304 = 37 minutes
- Upper control limits (UCL) = 1.58 = 83 minutes
- Lower control limits (LCL) = - 0.972 = 17.5 minutes

Even though the process is under control, however the process is shifted much higher that the required goal which requires no more than 20 minutes waiting time (UCL = 20 minutes).

Process Capability:

Based on above analysis and after putting the process under control, now the process capability can be measured

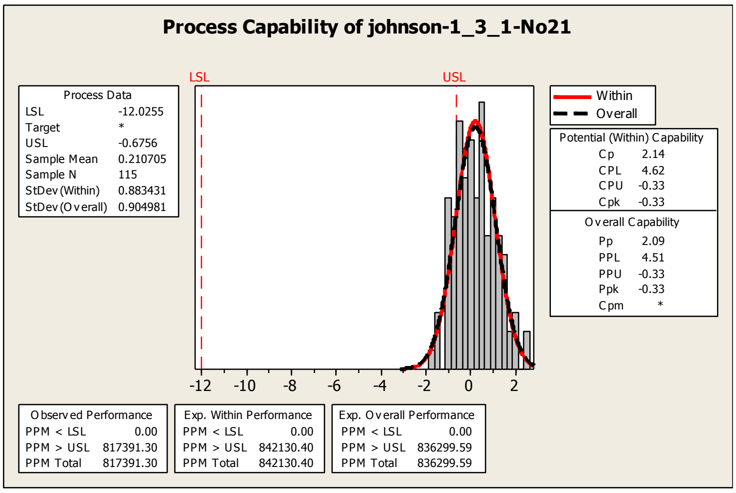

Figure 7 Process Capability

The process is clearly not capable based on above process capability analysis figure 7, and again it shows that the process needs to be shifted down to less than 20 minutes in order to have a capable process.

Voice of Customer

The customer requirements and needs in this project are extracted from three primary stakeholders; Patients, Test lab management, and physicians. The SSE team uses SIFOC to collect the customer requirements. The following table 1 represent each stakeholder needs and requirements:

Table 1 Stakeholders needs

Group	#	Requirements
Patients	1	Less waiting time (=<20 minutes)
	2	Preferred Appointment time availability
	3	Knowledgeable staff
Providers	4	Same day test and results
Lab management	5	Manage flow of patients
	6	Improve process efficiency
	7	Phlebotomist performance measures
	8	reduce missing appointments defects
	9	reduce missing orders defects

ANALYZE PHASE

The team has analyzes the collected data from the previous phase to measure the current state and find opportunities for improvement. The team has measured the sigma level in addition to the statistical analysis for the data using Minitab. A hypothesis test is conducted to verify the claim of the customer of having more than 30 minutes waiting time in the lab waiting area. Control charts and process capability indices were used to evaluate the behavior of the process in the lab. Few graphical charts are developed to demonstrate facts in the current state. Since implementing lean is part of the scope of the project, a value stream map for the current and future design is developed. The analysis of the value stream map will illustrate the difference between the two designs in terms of waste time.

Quality Function Deployment (QFD)

QFD framework is used to translate the customer needs (Table 1) the "what" into appropriate technical response (the "How"), to determine and prioritize key requirements for improve solution, including offering trade-off considerations. The following solutions address these needs and requirements (Table 2):

Table 2 Recommended solutions

#	Solutions	Note
1	No appointment system	This will reduce the big lead time of lab test appointment.
2	Qmatic system	The system will organize the queue of patients at the lab.
3	PC & Printer per station	Each phlebotomist will have a pc & printer to print and merge patients lab orders instead of making at check in window.
4	Flag reminder in the system	This will help in reducing the missing lab orders
5	Staff training	Will increase staff knowledge and improve performance.

The following House of Quality (Fig. 8) shows the customer needs and the response solution for each need and the relationship between these solutions.

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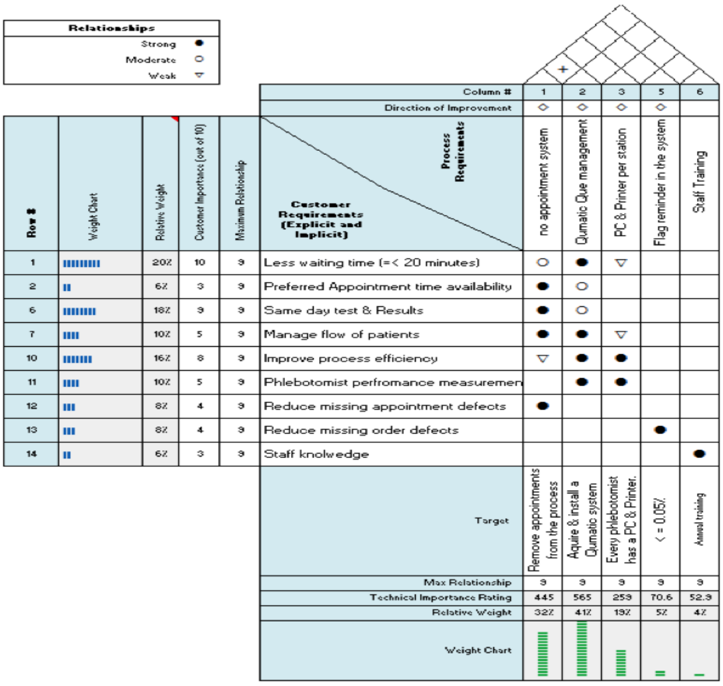

Figure 8 House of Quality

Six Sigma Score

Sigma score calculator is a measuring tool that served to model the system under study and it determines the defects per million opportunities (DPMO) in the system, which is used to determine the sigma level at which the process is operating.

The calculation of a Sigma level is based on the number of defects per million opportunities (DPMO). In order to calculate the DPMO, three distinct pieces of information are required:

a) The number of units produced

b) The number of defect opportunities per unit

c) The number of defects

The actual formula is:

DPMO = (Number of Defects X 1,000,000)

((Number of Defect Opportunities/Unit) x Number of Units)

For the sigma calculation, the SSE team first identifies the type of item being studied for the life cycle of the process from start to end. The sample size is determined based on the number of visits for three months.

The SSE identifies the key items that are causing nonconference to the process. For the check-in process, the opportunities for defects are:

- No Lab Orders that is caused at Providers level
- No Appointment that is caused at HAS team
- Waiting Time at Lab > 20 Minutes
- Number of Overbooked Appointment – happens at HAS team
- Duplicate Orders – Cause by Providers
- Patients come later than their appointment time slot

Percentages of occurrences were assigned to each of these categories to rate the process.

From the sigma calculator it can be determined that the process is currently operating at 2.31 sigma (table 3).

To improve this sigma score, the SST team studied each of the criteria in which can fail and worked to provide a new process that addresses each of the defect opportunities to lower the percentage of occurrences or eliminating it. The new process with no appointment eliminated several defects and improved one of the nonconference items by 50%. It shows an increase of the sigma score to 3.8 as shown in table 4

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Table 3 Current Process Sigma Level

Current – Current Process Sigma level		
Defects	Count	Total
Check-ins	17522	17,522
Total units:	17,522	
Defect opportunities:	6	
Total opportunities:	105,132	
Defect W-X-Y-Z actuals:		
No Lab Orders – Providers	526	3%
No Appointment – HAS	263	2%
Waiting Time at Lab > 20 Minutes	12,616	72%
Number of Overbooked Appointment – HAS	876	5%
Duplicate Orders - Providers	876	5%
patients come later than their appointment time slot	6,834	39%
Total defects:	21,990	
DPU:	1.26	
DPMO:	209,167	
Sigma Score:	2.31	

Table 4 Proposed Process Sigma Level

Proposed Process Sigma level		
Defects	Count	Total
Check-ins	17522	17,522
Total units:	17,522	
Defect opportunities:	6	
Total opportunities:	105,132	
Defect W-X-Y-Z actuals:		
No Lab Orders - Providers (50% Improvement)	263	2%
No Appointment - HAS	0	0%
Waiting Time at Lab > 20 Minutes	0	0%
Number of Overbooked Appointment – HAS	0	0%
Duplicate Orders - Providers	876	5%
patients come later than their appointment time slot	0	0%
Total defects:	1,139	
DPU:	0.07	
DPMO:	10,833	
Sigma Score:	3.80	

Vol (02) _Issue (01)
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Data Analysis

To understand the work load coming to the lab through service providers, the team find number of patients needs lab work per month as seen in the chart below (figure 9):

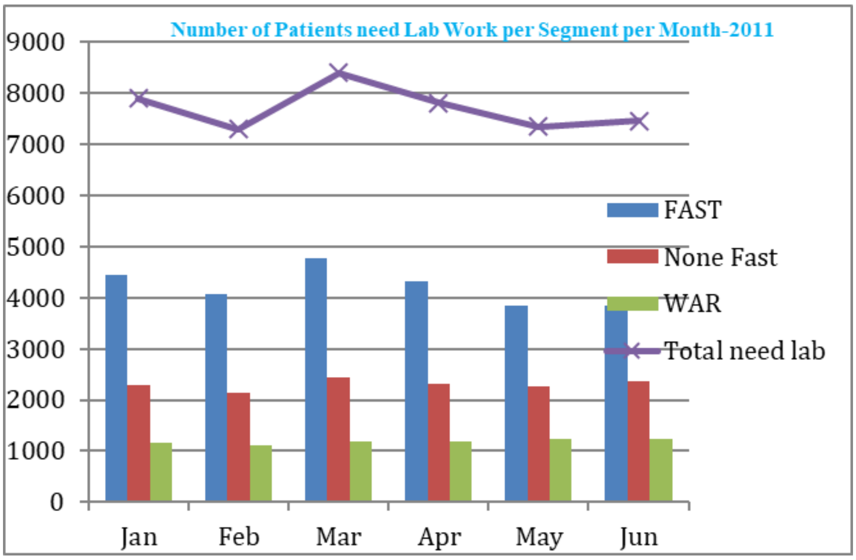

Figure 9 Number of patients

Table 5 show numbers of Patients need Lab Work per Segment per Month-2011

Table 5 number of patients need lab work per month

Month 2011	FAST	None Fast	WAR	Total need lab
Jan	4452	2291	1150	7893
Feb	4058	2131	1105	7294
Mar	4776	2443	1180	8399
Apr	4317	2303	1182	7802
May	3839	2257	1241	7337
Jun	3848	2366	1241	7455

Then, defected orders have been tracked to reach a conclusion about who are the most contributors to the defect. It is clear from the chart below that the purple team is contributing the most to defect orders (send patient to lab without requesting an order in the system). However, the team interviewed the purple team and the reason was that physicians forgot to request an order for each patient needs a lab work as shown in figure 10.

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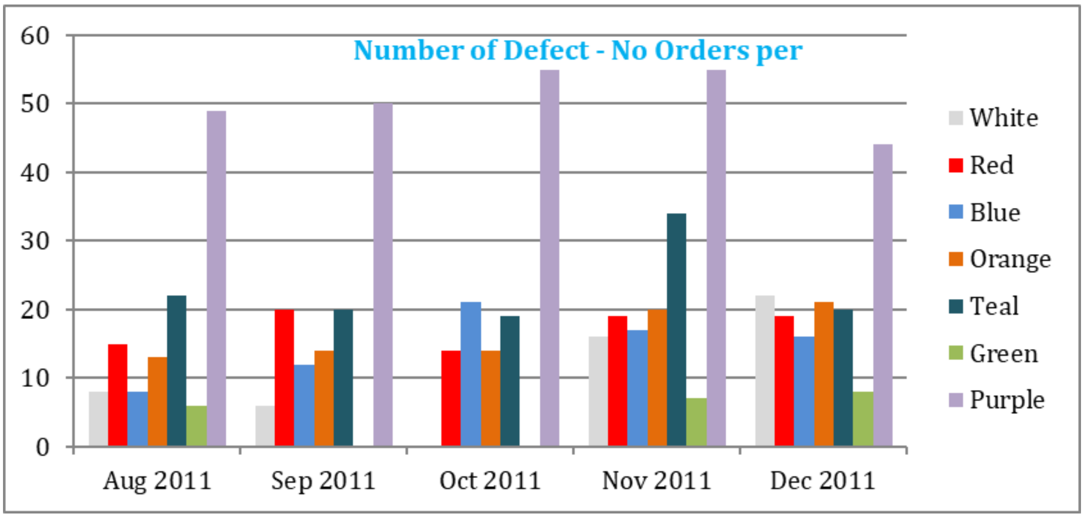

Figure 10 Number of defect orders per Team

In addition, the team found that one of the vulnerabilities in the current system is unscheduled appointment. Blue team contributes the most to defect appointments as shown in figure 11.

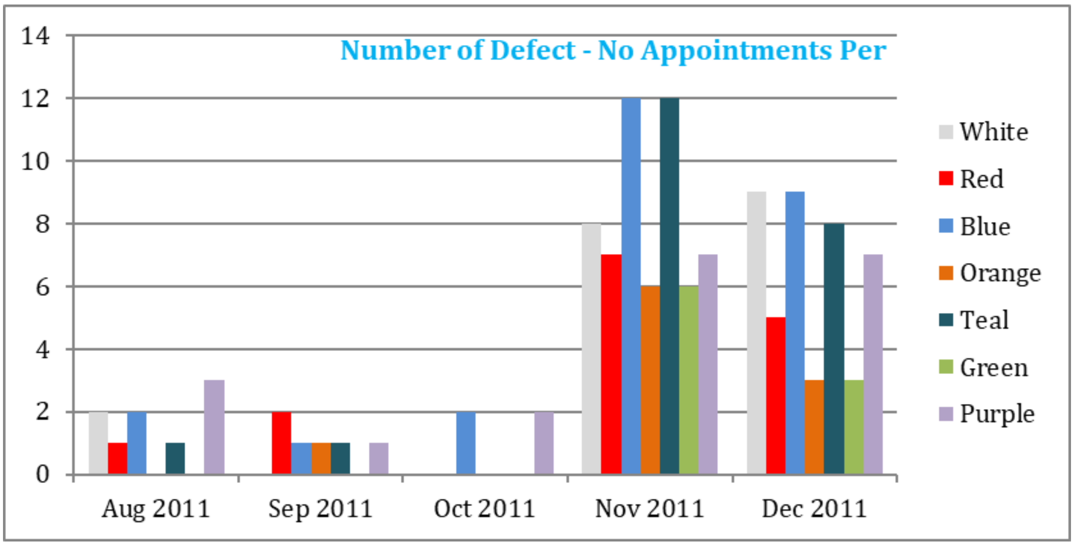

Figure 11 Number of defect appointment per team

Number of overbooked patients as shown in figure 12 and table 6 comes mostly from the non-fasting segment. High rate of overbooking is a major issue in the lab. As its leading to dissatisfy patients and increase waiting time.

This means that we can give the non-fasting patients an advice to come late morning or maybe afternoon to have less waiting time and give those whom are fasting better chance to be served in early morning.

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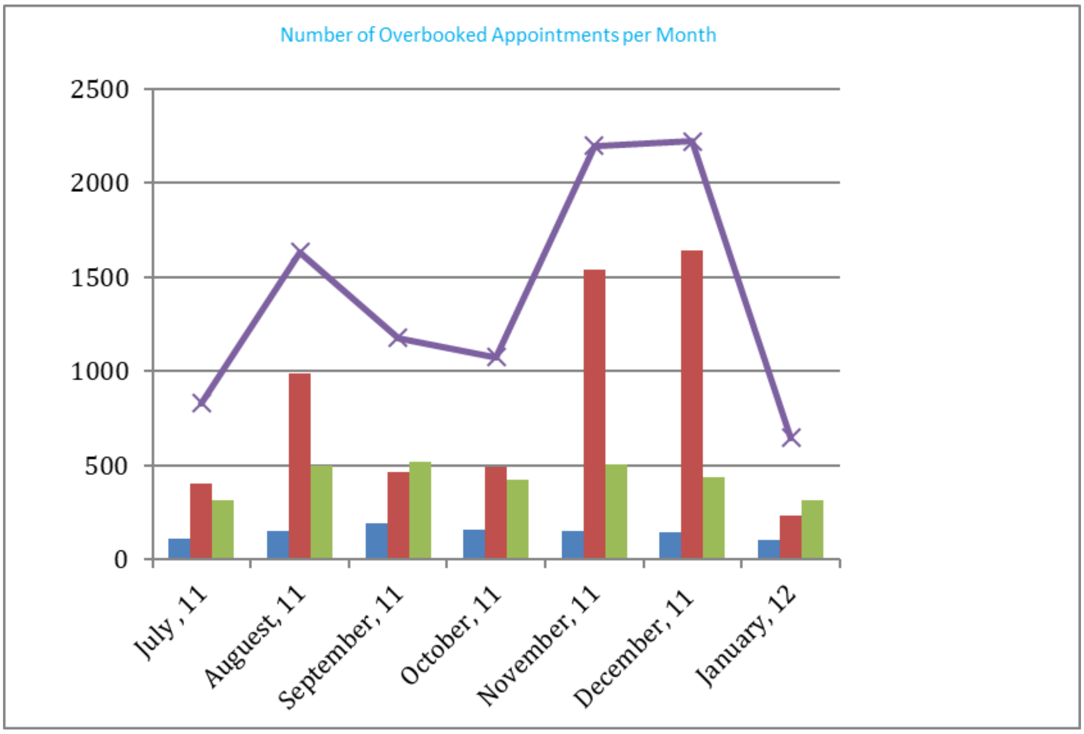

Figure 12 Number of overbooked appointments per month

Table 6 number of overbooked appointments per month

	Month	Fasting	Non-Fasting	Warfarin	Total
1	Jul 11	110	405	315	830
2	Aug 11	150	989	495	1634
3	Sep 11	193	465	518	1176
4	Oct 11	158	493	423	1074
5	Nov 11	152	1537	507	2196
6	Dec 12	103	231	312	646

DESIGN PHASE

After analyzing all the data and developing the house of quality to layout the required solution, The SSE works on design a new process that is capable to achieve the required customer's requirements. A new process map is developed after eliminating the Healthcare Administration Service (HAS) from the process. A procedure chart is also developed to specify the steps in details of the new process. The process is simulated before and after the new design to reflect the current status and the expected improved results.

New Process Flow Chart

The new process flow chart can serve as an instruction manual or a tool for facilitating workflow and service delivery. The new laboratory processes starts with the arrival of the patient to the check in counter, the clerk then should scan the patient ID card and from the Systems, the clerk will be able to determine if the patient has a test order, if there is no assigned order, the clerk should call the HAS team and ask them to place an order. On the other hand if patient has already an order, the clerk should give the patient a waiting number from Qmetic system. Then, the patient waits in the waiting area until the number appear in the Qmetic screen.

After that, the Phlebotomist should call the next patient and ensure that there is no duplicate order. Then The Phlebotomist makes the blood test and the patient leave the lab. The flow chart for the new process is illustrated in figure 13.

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Vol (02) _Issue (01) Impact Factor: 4.520

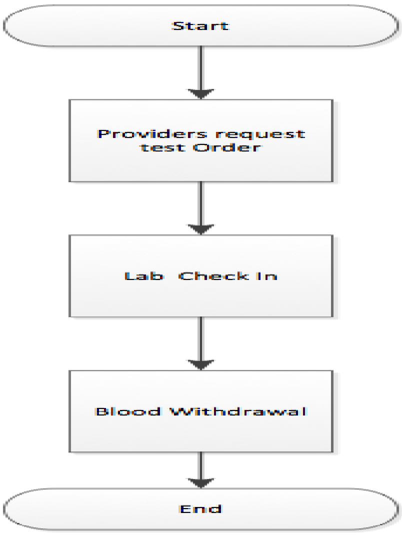

Figure 13 New Process Map

The new processes recommend some improvements to avoid the missing order by modify the system to make flag reminder for providers to place test order. This reminder is part of Poke-Yoke technique that prevents defects to occur in the process. In addition, the new process requested each Phlebotomist to have the required equipment.

Proposed Procedure Chart

The lab process life cycle starts when the provider prescribes a lab order and it finishes when the provider receives the lab results back. The lead time for patients to have an appointment with the lab and the waiting time for patients to be served are causing to have a 5% efficiency of the total life cycle of the process. With the new procedure chart as shown in figure, the expected efficiency is 69% by eliminating the lead time for getting appointments as shown in figure 14.

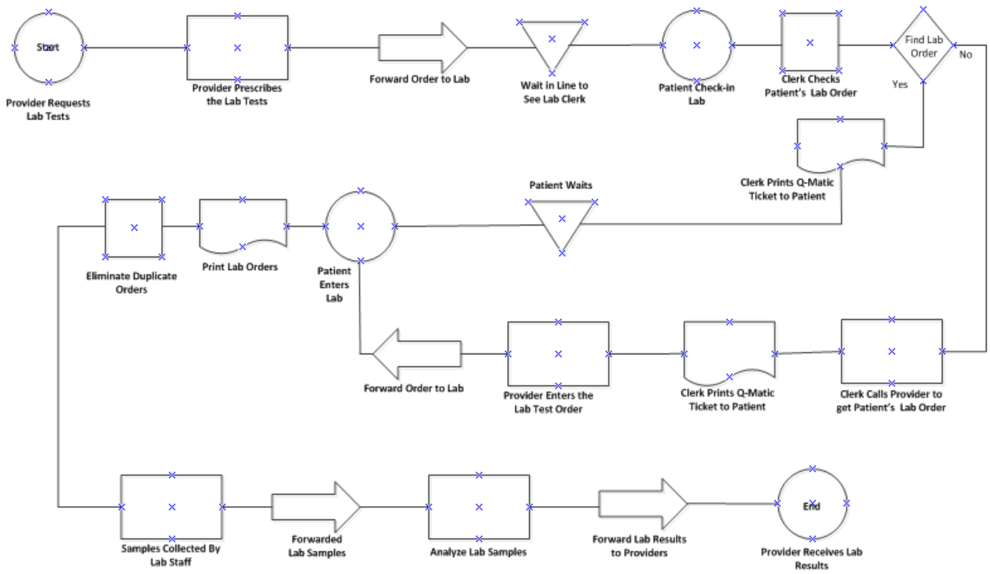

Figure 14 Proposed Procedure Chart

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Simulation Model
SSE picks ARENA software to simulate the current system and make some analysis about the system. procedures in order to get the desire performance.

Current System
SSE team started by building the current system that has two clerks in the check in counter, ten Phlebotomist in the blood withdrawal with 10 stations. Also, the lab has seven restrooms for urine specimens.
The lab flow chart indicates that, patient arrive at check in counter depending on their appointments. Then, Clerk check his/here test order in the system. If the patient has a urine test order, which usually represent only 8% from all the patients, the clerk will ask the patient to submit the specimen to window 2 after finish from restrooms. If the patient has a blood test order, which usually represent 92%, the clerk will handle the patient a pager and direct him/here to the waiting area. After that, the patients will be called in batch of ten to get in the ten stations of blood tests. If one Phlebotomist completes the test early, he/she will wait idle until next batch enter to station. Finally, the patients exist the system.

New Proposed System
As explained in the new value stream map, the Qmatic introduced to replace the appointment system. Also, there will be no batching in the blood test stations. Therefore, each Phlebotomist will call the patient independently, which will increase their efficiency. In the new proposed system, patient arrives at check in counter and test order will be checked. If patient has urine test, the clerk will ask the patient to submit the specimen to window 2 after finish from restrooms. If the patient test order is blood test, the clerk will give the patient a number from Qmatic according to his status as shown in figure 15 Then, the Phlebotomist will call the patient when station is ready.

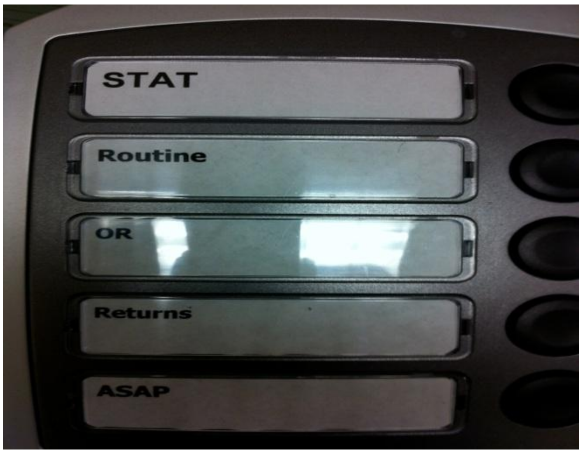

Figure 15 check-in card

VERIFICATION PHASE

The team has to ensure meeting customer expectation with the new process design. In this phase the team built a simulation model using Arena to mimic the current design and verify the future results by modeling the new design. Also, control plans established to regulate the new design. Finally, a staff motivation plan developed to enhance the performance in the lab in order to provide patients with better services in the future.

Verification using Simulation
Verification is the procedure of ensuring that the model behaves in the approach it was planned based on to the modeling assumptions. For performing the verification, the SSE allow a single patient to enter the system, by using the step feature in Arena to control the model execution and trace the patient through the system, and verifying that the model logic and data are correct.

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Control Plans (Qmatic)

Qmatic system is all about managing the flow of the patients and their experiences from their initial contact with the medical center, through to service delivery. The system also includes capturing their opinion after they have received the service. Qmatic provides the following features that are essential to the solution in the laboratory:

- Increase productivity, and reducing costs.
- Increasing customer and staff satisfaction by reducing the actual as well as the perceived waiting time.
- Establish a controlled and fair waiting process for the patients.
- Generate data and insights about how patients behave and how staff serves them throughout the day. Data which can help you improve the business processes and raise customer service standards
- Meet improvement targets and Key Performance Indicators (KPIs).

Patients Waiting Time

With virtual queuing, patients can sit down in a comfortable waiting area, or move around freely while waiting their turn. Their place in the virtual queue is secured with some kind of identifier like a number that has been printed on a ticket. The identifier is often given upon arrival.

Qmatic system will remove the patching defect in the current patient check in process. Each phlebotomist will have his own station that includes a computer and printer to process each patient's test order. As soon patient is done, the phlebotomist will call the next patient, this will create a smooth flow of patients test order and eliminate the current patching process as shown in figure 16.

Figure 16 Qmatic steps

Arrival – at check in windows

The patient comes at test lab check in window and hand the clerk his identification card to check and confirm his test order. Once the clerk confirms the patient test order in the system, he hands the patient a ticket with queuing number.

Queuing & waiting – at waiting area

Once the patient receive a ticket number, the patient can wait in the waiting area till his number is called. The patient is information on when and where to go is displayed on the ticket, LED signage, TV monitors or pre-recorded announcements.

Serving – at the phlebotomist

The patient is called and receives service or treatment based on needs. The phlebotomist will manage the patient's treatment from printing, merging, orders till blood withdrawal.

Post serving

Once the patient is done with the required treatment, the patient provides feedback on their service experience.
Information management and analysis
The system will help the test lab supervisor to actively manage staff and patients based on alerts and alarms. And will help him management, control and improvements the lab operation.

Staff Motivation Plan

As part of the improvement process, the SSE introduced a "Motivation Improvement Program" which will be a monthly reword and recognition for the best performance among the staff with the main focus on improving on

pre-determined criteria. This program is designed to motivate staff to hard that will increase patients satisfactory and will provide rewards to the best employee.
A successful program will get lab staff involved and conscious of their performance, enforcing a continuous improvement mentality.
The way this will work is by comparing number of patients served by each Phlebotomist in a monthly basis to see which one has the best performance. Lab management indicated that each phlebotomist usually serve 40 patients according to history data.
The result can be computed easily from the Q-Matric system by lab supervisor and display in the performance board. The final results should be reported to the director for tracking performance as well as to pick the month’s winner. This will serve as a dashboard to grade the performance of every employee for check in and blood test. Supervisor will be responsible for updating it every month with monthly operating percentages.

CONCLUSION AND RECOMMENDATIONS

In conclusion, the SSE team discovers that the cause of this long wait happens outside the lab. The scope of work is expanded to include the total life cycle of the process from the time the provider requests a lab work to the time the provider receives the result back. The SSE team find variation in the process between high volume and low volume periods. These results were all deduced through job shadowing and interviewing lab technicians about basic operations. The SSE discovered that the high volume is due to overbooking that HAS clerks are introducing because of the rule that all patients must be seen by the lab regardless if they have an appointment or not. After visiting similar facility that adopts no appointment approach with less than 5 minutes waiting time, the team has designed the new process based in the same method. The no appointment approach provides patients the flexibility to decide the time of doing their lab works. It will also off load the work of the HAS team as they are no longer need to schedule appointment. There is cost saving on sending the appointment by mail as well as mileages reimbursement. Stream line the process is achieved by allowing patients to be served by the first available lab technician instead of being served at 10 patients on a time. The SSE team also identified 2 sources of nonconformance that are happening by the providers and are causing delay on serving patients. The SSE team suggested a change to the system to prevent providers from closing the case before entering the lab work orders. The major finding from the collected data indicates that the average waiting time is 37 minutes and the lead time to schedule an appointment with the lab could be up to 4 weeks with cycle time efficiency of 5%. The new process could help reducing the waiting time to 5 minutes with no lead time.

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