

Recommendations for Handling Errors in the Pre-examination Phase in the Clinical Laboratory

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Abstract

The objective of the work is to introduce the necessary elements for a laboratory for the continuous improvement of the pre analytical phase, starting with a leadership of the headquarters to perform the necessary changes and therefore get the improvement, to know about the statistic data obtained and analyze its objectivity. As well as looking for the best tool for the information collecting with its redesign to achieve a better effectiveness. The work introduces that is possible to statically demonstrate the impact of the sample taking use, over the sample rejection rate, although it also identifies that is not the only reason of the sample rejection. Finally, the information objectivity search is introduced and allows having the possibility to measure the contribution of the laboratory focused on the patient's care.

Keywords: Errors; Laboratory; Samples; Pre-analytical; Improvement; Indicator; Variables; CMI; Scoreboard

Introduction

The work carried out in Clinic Davila of Chile, in the continuous improvement of the pre-analytical phase, allowed to develop a work system that may be implemented to any reality from a large or medium laboratory having tools of its own in a management system.

The experience acquired from the improvement stages, delivered the alignments to determine the cause of the pre-analytical errors and establish the strategic changes which allow implementing the improvement.

These alignments are determined by:

1. Establishing a leadership for a fluid communication with the Clinical services and the laboratory staff.
2. Understand that the objectivity of the data is a vital tool for the process improvement.
3. Look for the best system of data gathering
4. Redesign the improvement plan, focusing on effectiveness.

These elements, altogether with the knowledge of the error frequency in the pre-examination stage, constitute a continuous improvement system that is efficient and sustainable over time.

Improvement and Application Field

The objective of this document is to demonstrate the elements to be used to establish a decrease of the pre-analytic errors, in the management of the sample condition, used for the laboratory exams processing.

Definitions

a) Blood punctures: Correspond to samples of patients to which some exams are required by blood puncture leaving other samples aside such as urine, microbiological, etc.

b) Rejection per puncture: Corresponds to the sample rejection obtained by blood puncture; for these only the rejections are filtrated corresponding to coagulated samples, scarce samples and haemolysed samples.

c) Use rate of the sample taking by closed system: This is a percentage relationship between the quantities of closed system devices used concerning the total of blood punctures taken.

d) Rate of use in the sample taking by open system: This is a rate relationship between the quantities of devices of the open system used concerning the total of blood punctures taken.

e) Pre-analytical variables (pre-analytical error): Are those variables contributing to situations of an inadequate sample.

f) Indicator of samples rejection: For the specific situation of the laboratory of Clinical Davila, corresponds to the relationship between the quantities of samples rejected in a period, concerning the total of samples received during the same period, showed on the percentage.

g) Open system of sample taking: It is the system in which a sample is extracted with syringe and subsequently is transferred to the vacuum collection tubes.

This system is used in most of the regional care centres, but its use implies risks for the operator (handling of the blood) as for the sample (haemolysis when transferring, inadequate volume).

h) Closed system of blood sample taking: Is the recommended system by the CLSI, which allows obtaining samples using a closed circuit (the blood flows directly to the tube). Is a bio secure system delivering samples with adequate volumes and without deterioration risks.

i) SAP: The SAP system is an informatics system integrated of business management designed to model and automatizes the different business areas and the administration of its resources. The name of the SAP system represents the German acronyms System applications and Products meaning in Spanish “systems, applications and products”.

j) SAP Business Objects Web Intelligence (BI): Is a system which allows to obtain the knowledge from the business in a fast way and also to understand the trends and its causes.

k) Medisyn System: Corresponds to the informatics system which interacting with all the processes from the institution (LIS).

Leadership

When an improvement work is decided to be initiated in the pre-analytical phase, we cannot forget that they make this not being easy. We must consider that in this phase, the actors involved is multiple, starting by the treating physician requesting the exam, the administrative secretary entering the aforementioned request (as for the outpatients) or the nurse requesting the examination by hospital system. The phlebotomist staff (professional and nonprofessional), the transport staff, the professional staff, and nonprofessional staff from the laboratory, the managerial or liable of the devices purchase and lastly the patient.

This condition forces the management of the laboratory to take a leadership attitude to continue the improvement process.

To achieve this empowerment it is enough to review the different standards that indicate the final accountable of the improvement and monitoring of the pre-analytical processes is the laboratory. This can be observed in the requirement 4.12 of Continuous Improvement, of the NCh-ISO standard 15189, indicating “The laboratory must continuously improve the effectiveness of the quality management system including the pre-analytical processes, examination and post examination establishing indicators of the quality to make the follow up and evaluate the performance all the critical aspects of the pre-analytical processes, examination and post- examination as it is stated in the requirement 4.14.7 of the quality indicators, of the same standard. Together with this, there are other national standards, establishing that the laboratory must regulate and periodically evaluate the pre-analytical phase processes.

Initially a leadership inside the laboratory must be established, with the purpose to align all the professional and non-professional staff, involved with the sample management, so the culture of the record must be incorporated.

Therefore, the data can be gathered to determine the service having the high quantity of pre-analytical errors and which is the error type having the highest frequency.

This information determines the Clinical services with highest quantity of errors or re-processes and this permits to establish an intervention plan. In this intervention plan an effective leadership is needed because all the Clinical areas involved must be improved, using a training program that is theoretical and practical whose purpose is to deliver tools for the management of the pre-analytical variables to decrease the error. It must also be considered with the mailroom staffs that are the accountable to bring the samples to the laboratory [1]. Given that this is a nonprofessional staff and their awareness can take a longer time, for the same reason the leader must be maintained unalterable. This work must be also made extensive to the

administrative staff, that is accountable to enter the patient correctly, but that is not free from errors.

The leader must be able to create different types of tools to motivate the staff of the different Clinical services to achieve the improvement. An example of this was the manufacture of an interactive CD, mentioning the importance to make a good sample taking. It was also designed a manual of pocket sample taking, brochures with the correct order of the tubes for the sample taking trolleys, publications in the institutional journal, etc. the trainings must be constant and in all the Clinical services with a frequency allowing to encompass all the professionals.

Finally there is a work needed to be done with the managers determining the device types used for the sample taking. Is the laboratory, using the managers which must lead the incorporation of new devices, if these were necessary to correct a bad sample taking. It can be summarized that the leader must make all parties to make a switch allowing the system to reach the improvement. (Figure 1) shows the quantity of Clinical staff trained.

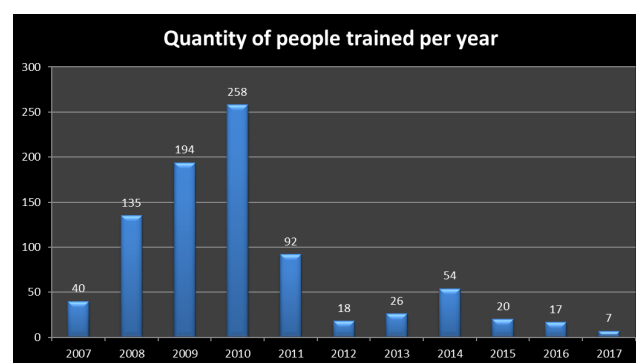


Figure 1: Quantity of people trained per year.

Objectivity of the Data

The ten year journey, allowed to visualize the effectiveness of the information collected concerning the indicator of sample rejection. This forced the search of objectivity of the data obtained.

In a first stage, the manual records were obtained; they were user dependant always, holding the characteristic of incomplete. This added to the lack of information concerning quantity of samples received in the laboratory for each service, made impossible to establish the rates indicating where the problem was. This situation motivated the search of a different system of data storage, more simple to fill, in and the data basis management allowed to know in detail the reality of the Clinical services.

For that, there was a matrix generated in Access where the data was exported to excel spread sheet, for its later analysis. When the information was obtained separated for each Clinical service, the first interventions were carried out and these consisted in visits the nursing staff to the laboratory to analyse the problem and know the sample processing system [2].

Also, it was also possible to determine that the main causes of the pre-analytical errors were the scarce samples and the haemolysed samples.

After working for two years with this system, the data base was analysed and was detected that these were incomplete, given that most of the records were generated in the day shift and there were not having records in the night shift. This would mean that the information administered was not representative of the reality and had a high rate of underreporting, an IT department request was executed to create in the reception a module some samples from a system to permit rejecting the samples more expeditiously also feed the basis of data for the posterior analysis. The development took some months and was started in January 2009.

The system allowed that, once it was visually possible to check the condition of the sample and if this did not respect the entrance requirements, the technical staff selected the reason for the rejection and this generated a status change in the system and an automatic dispatch of an electronic email to the nurse in charge of the service from where the sample came informing there was a rejection in the laboratory. All this took place in real time allowing the data base to obtain important information of the exact quantity of rejected samples and the causes of the rejection.

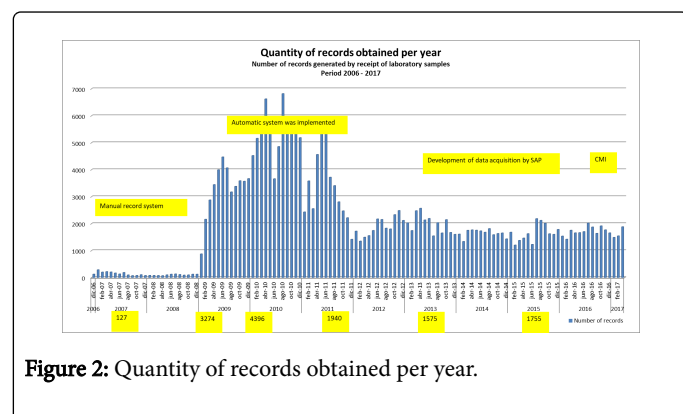


Figure 2: Quantity of records obtained per year.

With the incorporation of the automatized system sample rejection, it was possible to determine that the real information was raised concerning the pre-analytical error quantity (sample rejection) which was translated in knowing the local reality of the Clinical services and plan objective improvements.

When checking the record quantity obtained in each period it can be observed the degree of underreporting existing in the first stages and the quantity reduction of pre-analytical errors represented by the rejected record quantity of samples decreased over time (Figure 2).

With this rejection system of samples, there is a significant gap in the behaviour of the rejection rate between the outpatient area and the hospitalized service rate according to the (Figure 3).

With the objective data and knowing the reality of each service, there was a process of intervention and training out from which we obtained the following deductions:

The highest frequency of samples with haemolysis is produced for puncturing the tubes with a syringe.

The paediatric samples from neonatology showed clots due to the bad homogenization of the small containers.

The biosafety of the process must be improved with the incorporation of bio-secure devices.

We could therefore deduce that the existing gap between the outpatient rates of patient area rejection concerning the hospitalized area was determined by the use of the close system. With this information, there is a stored device uprising in each first aid kit of all the Clinical Davila Clinical services, to determine the level of use of these devices already acquired by the department of Pharmacy thanks to an action of the Laboratory [1].

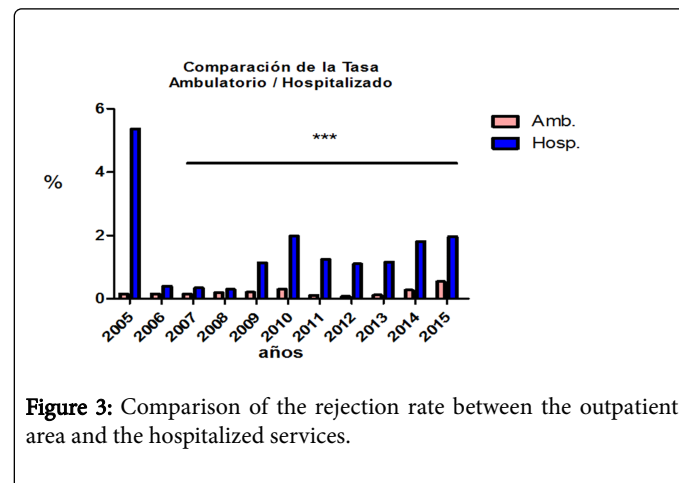


Figure 3: Comparison of the rejection rate between the outpatient area and the hospitalized services.

This uprising showed that not all the services had the devices of the closed systems of sample taking and confirms the hypothesis that most of the Clinical services still take samples with syringes puncturing the vacuum tubes.

This made us execute a research concerning the impact of the closed system use of blood sample taking over the rejection rate and statistically establish if the system use of closed sample taking is a determining factor in the decrease of the rejection rate of blood samples [3].

A collection and analysis of information was carried out in nine Clinical areas, during the first semester of the 2015 year, considering the following statistical data:

- Monthly quantity of blood punctures.
- Monthly quantity of devices of the closed system.
- Quantity of rejections per puncture
- Rate of rejection per puncture

The Clinical selected areas represent the different types of patients assisted in Clinical Davila, belonging to Clinical units (adults and paediatric) not critical, paediatric, ER and outpatient.

The data obtained for this work, come from a data base extracted from the IT system Medisyn and collected in a spread sheet Excel, containing a great part of the Laboratory activities statistical information.

To obtain the data used in the spread sheet calculation is administered executing different filters.

- blood punctures
- blood samples
- puncture rejection

To obtain the rate of sample taking system use (closed or open) it was considered the quantity of devices used per month of one or the other system, concerning the quantity of blood punctures executed.

Based on the quantity of effective blood punctures, the rate of use was calculated in the closed and open system, being this last data, currently, very difficult to obtain, given that is not possible to calculate it directly from the syringe consumption, given that this device can be used for the sample extraction as well as the administration of injectable and there is no way to detail the purpose given to this input. The calculation presented for the open system use rate comes from the two devices consumption of the closed system.

Insumos toma de muestra ambulatoria	
AGUJA VENOJECT 22X1 MULTIPLE 360210 UNI 1 UNI	
MARIPOSA C/ADAPT.23GX3/4*12PG.367283 UNIDAD 1 UNI	
MARIPOSA 21G 3/4 X7 PULG. COD.367287 UNIDAD 1 UNI	
MARIPOSA 23G 3/4 X7 PULG. COD.367292 UNIDAD 1 UNI	
Insumos toma de muestras hospitalizados y urgencias	
Adaptadores luer 21 G 1 1/2	
Agujas multiple 22 G x1	
AGUJA MULTIPLE FLASHBACK	
Mariposa 21 G con adaptador 12 PG	
Mariposa 21 G con adaptador 7 PG	
Mariposa 23 G con adaptador 7 PG	
Mariposa 23 G con adaptador 12 PG	
Alargador via venosa	
Catheter Intravenoso 20X11/4 Rosado	

Figure 4: Devices used in the studied areas.

115.239 blood punctures were analysed generating 264.712 blood samples which meant 3.144 rejections per function. Also, there were accounted for 86.046 sample taking devices from the closed system in the open system. The devices considered in the study, are detailed in the devices used in the studied areas. With this statistical information, the rejection rates were obtained per blood punctures of each studied service comparing the rate of use from the closed system and open in each area, according to our (Table 1).

Indicadores	UTI	MQ	Pediatría	UTI	U. Coronaria	UCI Adulto	Urg. Adulto	Urg. Pediatría	Ambulatorio
Punciones sanguíneas	12597	12245	1686	2052	4579	11491	21438	7158	41993
Cantidad de dispositivos sistema cerrado	7537	10036	438	838	3279	9134	14854	1030	38900
Cantidad de dispositivos sistema abierto	5060	2209	1248	1214	1300	2357	6584	6128	3093
% utilización sistema cerrado	59,8	82,0	26,0	40,8	71,6	79,5	69,3	14,4	92,6
% utilización sistema abierto	40,2	18,0	74,0	59,2	28,4	20,5	30,7	85,6	7,4
Cantidad rechazo sistema cerrado	208	284	33	60	132	233	551	57	469
Cantidad rechazo sistema abierto	140	62	93	87	53	60	244	341	37
Muestras sanguíneas	26426	22453	2848	4246	9174	28638	47134	15431	106362
Rechazo x error punción	348	346	126	147	185	293	785	398	566
Tasa Rechazo x punción	1,3	1,5	4,4	3,6	2,0	1,0	1,7	2,6	0,5

Table 1: Behaviour of the rejection rate per blood samples versus the rate of blood sample taking system use (closed and open) for each Clinical service.

When comparing the behaviour of the rejection rate v/s the use of the closed system for the sample taking in the hospitalized patients area and ER against the area of outpatients, it was observed that the outpatient area showed a rate three times lower to the hospitalized and ER patients area with a rate of use five times higher as it is observed in the behaviour of the rejection rate per blood samples versus the rate of blood sample taking system use (closed and open) for each Clinical service.

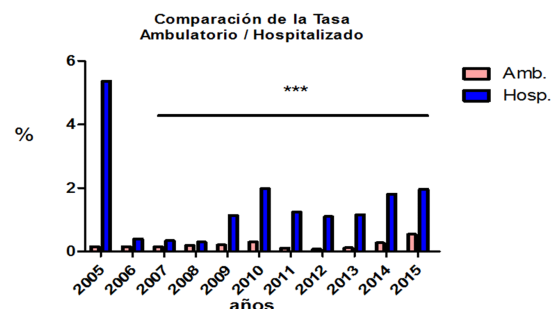


Figure 5: The gap between the rates of rejection of the outpatient area v/s the rate of hospitalized area is determined by the use of the closed system of the sample taking.

One of the arguments commonly used, to explain the low rate of use in the closed system in the critical patients area, is the Clinical condition or difficulty of venous access of those patients, but this study shows that the critical unit that has the highest rate of use of the closed system (ICU Adult) has the lowest rate of sample rejection and the critical unit having the lowest rate of use of the closed system (Paediatric UPC) has the highest rate of rejection as it is shown in the comparison of the rejection rate v/s the rate (%) of use of the closed system by service. There are lower rates of rejection in the services used in the closed system. Probably the correct input for the vein was not selected.

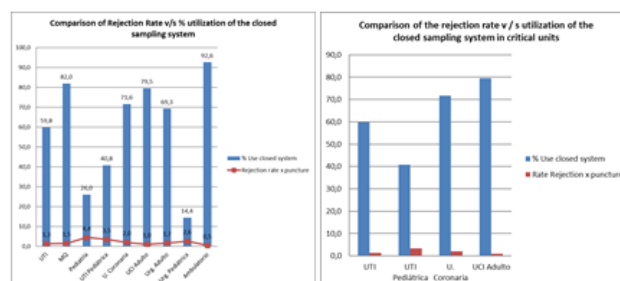


Figure 6: Comparison of the rejection rate v/s the rate (%) of use of the closed system by service. There are lower rates of rejection in the services used in the closed system.

If both critical units are compared, where the use of the closed system can be complex product of the condition of the patients with this statistical analysis, it can be shown that the closed system use, for blood sample taking is a determining factor in the decrease of the rejection rate, in the hospitalized patient area, of ER and outpatient (Figure 7).

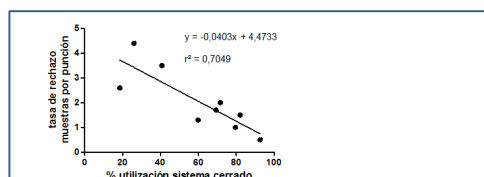


Figura 8: Correlación entre el uso del sistema cerrado de muestras y la tasa de rechazos de muestra por punción. Se observa una correlación negativa entre el uso de sistema cerrado y la tasa de rechazo. Coeficiente de correlación de Pearson (r) = -0,8396, valor p = 0,0046.

Figure 7: Correlation between the use of the closed system of samples and the rejection rate of samples per puncture. It was observed a negative correlation between the use of the closed system and the rejection rate. Coefficient of correlation of Pearson (r) = -0.8396, value p = 0.0046.

The analysis shows a correlation between a low rate of rejection and the use of a closed system of puncture, which was statistically significant.

The results show that the use of the sample taking by the closed system in the critical units allow to decrease the sample rejection rate even considering the difficult condition of the patients.

The impact of use of the closed system in the rejection rate is mainly determined by the reduction in the haemolysed, coagulated and with low volume blood samples. These causals of rejection are associated to the use of an open extraction system given that with this system the blood is not directly collected over the additive but there is a previous step implying to take the sample with a syringe and transfer the blood to the tubes. This step may favours the clot formation given the activation of the clotting during the time of permanence of the blood in the syringe and in difficult punctures where the sample takes a time in making contact with the anticoagulant. On the other side favours the haemolysis, given that during the transfer some foam can be created inside the syringe due to air intake and also because the sample is normally transferred puncturing the tube cap with the syringe, and making pressure over the plunger making the blood go through a small lumen which makes the sample to haemolyse [4].

Using these statistic calculations there was a follow up during these years, to intervene in those Clinical services with a low use of the closed system of sample taking as it is shown in the (Figures 8-12).

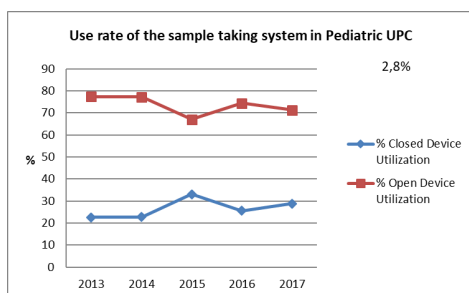


Figure 8: Comparison of the use rate of the sample taking system in Paediatric UPC v/s the rejection rate of 2.9%.

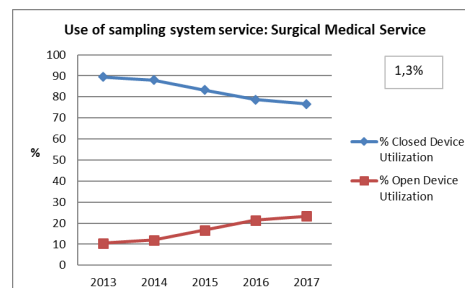


Figure 9: Comparison of the use rate, the systems of the sample taking in medical unit v/s the rejection rate of 1.3%.

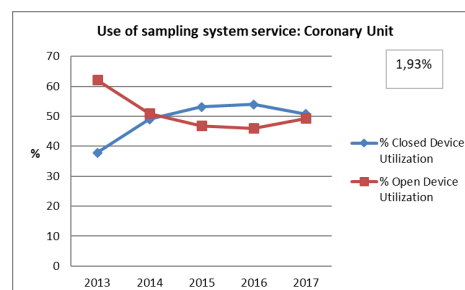


Figure 10: Comparison of the sample taking system use rate in Coronary Unit v/s the rejection rate of 1.93%.

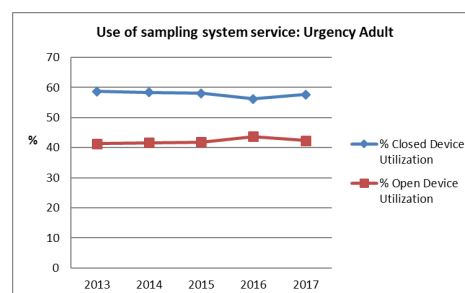


Figure 11: Comparison of the use rate of the system of sample taking in Adult ER v/s the rejection rate of 1.4%.

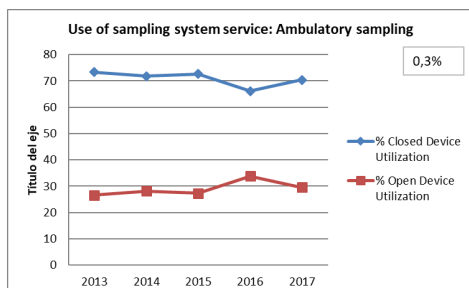


Figure 12: Comparison of the use rate of the sample taking system in the Outpatient sample taking v/s the rate of rejection of 0.3%.

When analysing this statistic data after some years of its implementation, we observe that the medical unit has the close system highest rates of use but does not show the highest rate of sample rejection, being these four times lower in the area of outpatient sample taking. The aforementioned indicates that the problem is not only the use of the close system, but it also needs to be considered the specific characteristics of the patients and above all work in the adequate management of the pre-analytical variables, such as:

- Identity of the patient
- Preparation of the Patient
- Selection of the venepuncture location
- Time and application of the tourniquet
- Adequate venepuncture technique
- Collection order
- Adequate mixture with the additive
- Correct volume of the specimen
- Adequate management of the tube and processing of the specimen
- Serum samples
- Plasma samples
- Centrifugation
- Stability of the total blood, the serum and the plasma

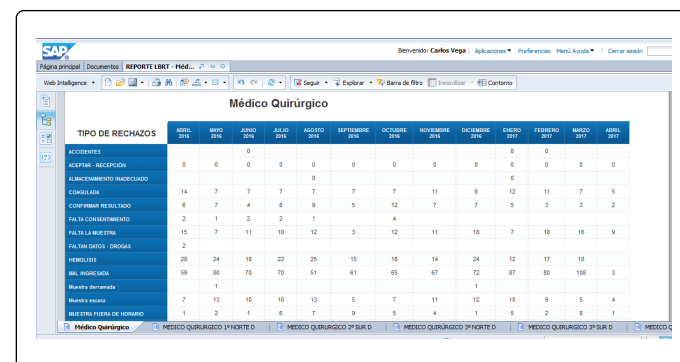
Look for the Best System of Data Collection

The experience at work of the improvement in the stage of pre-analytical phase and the interest to raise information as timely as possible, led us to examine the Web Intelligence SAP tool.

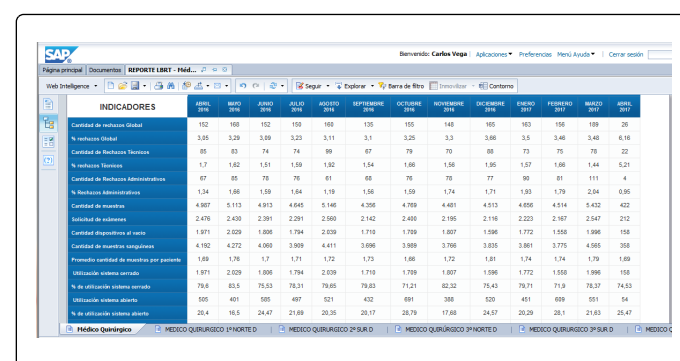


The development of the data monitoring and the report collection in real time, took a year to be constructed but it currently permits to raise the following information with a gap of hours:

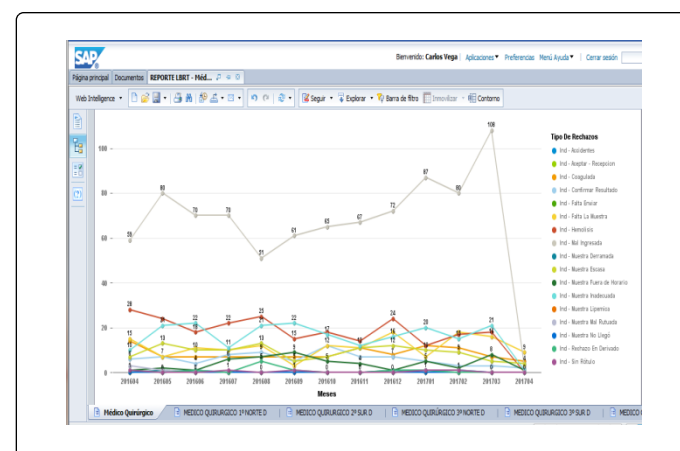
The daily rejection types, for each hospitalized service, ER and ambulatory. The information is shown per month but the last data rises what is accumulated until the date of the medical consultation.



The different indicators such as quantity of global rejections, % of global rejections, quantity of technical rejections, % of technical rejections, quantity of administrative rejections, % of administrative rejections, quantity of sample, request of examinations, quantity of vacuum devices, quantity of blood samples, average quantity of samples per patient, % of closed system use, % of open system use, index of haemolysis, etc., for each hospitalized service, ER and outpatient.



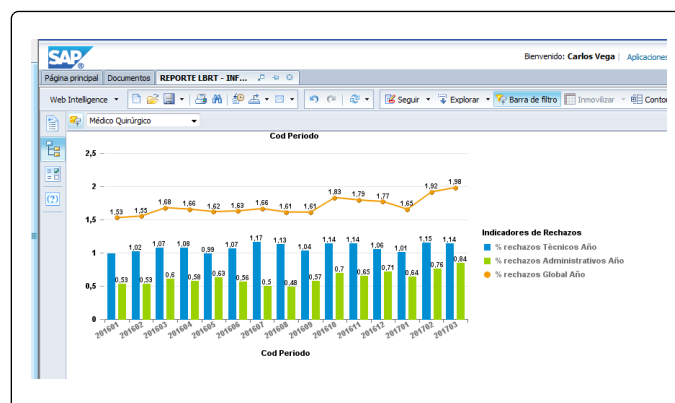
The historical behaviour of the rejection types for each hospitalized service, ER and outpatient.



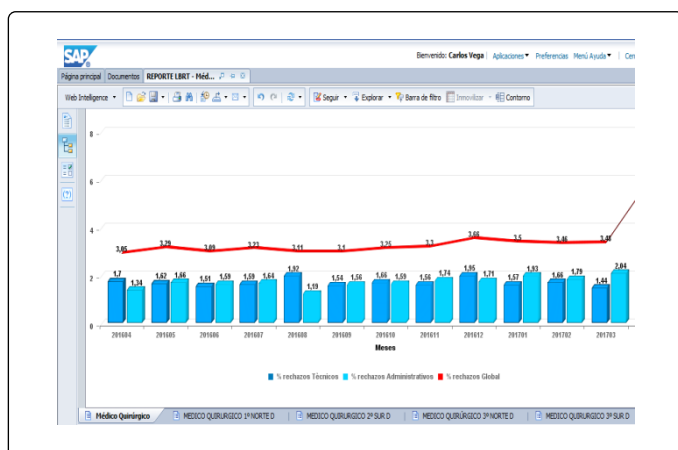
The historical behaviour of the closed and open system use % for each hospitalized service of ER and outpatient.



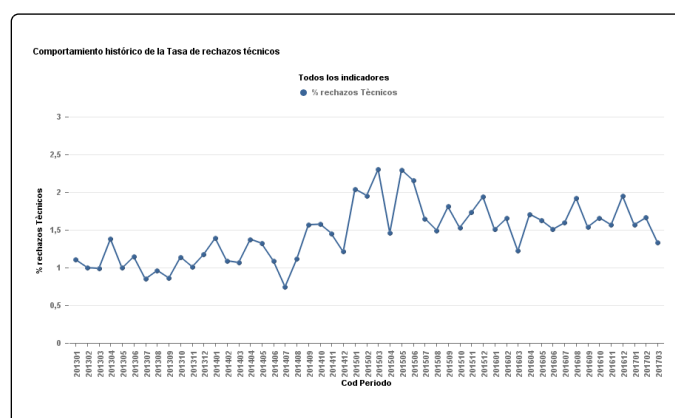
A global graph with the historical behavior of the technical rejections, administrative rejections as well as global, for each hospitalized, ER and outpatient service.



A historical graph can be raised with the % of institutional rejection.



Once per week and every month end, an automatic report is raised for each Clinical service, with the information of the local rate and the institutional rate with the data of the previous month and the “n” used.



A historical graph can be raised with the types of institutional rejection.

SAP screenshot showing a table with columns: Anterior, N, %, Formula Matematica, Actual, N, %.

Anterior	N	%	Formula Matematica	Actual	N	%
FEBRERO 2017	32.118	1,7	644*100/39.429	MARZO 2017	39.429	1,63

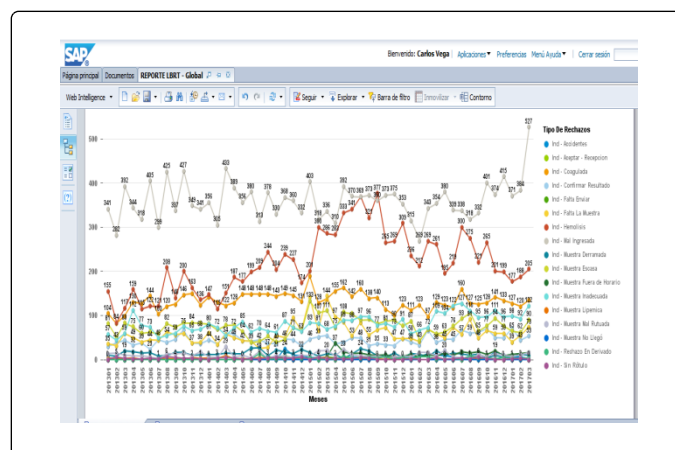
Resultados por Servicio

Servicio Evaluado : Médico Quirúrgico

Periodo Evaluado : MARZO 2017

Anterior	N	%	Formula Matematica	Actual	N	%
FEBRERO 2017	4.514	1,66	78*100/5.433	MARZO 2017	5.433	1,44

With a historical graph of the rejection % per each hospitalized service, of ER and outpatient.



Redesign the Improvement Plan, Pointing towards Effectiveness

After they able to have real-time information and a robust data collection system, being able to collect data and therefore using efficiently that information, with the purpose to achieve the control of the pre-analytical errors in the Institutional System. With this objective in mind we design an integral scorecard (CMI) delivering the daily warning of what is going on in each Clinical service. The system is visible in the corridors of the laboratory and in the laboratory head office. In a complementary manner, it was drafted an e-learning course

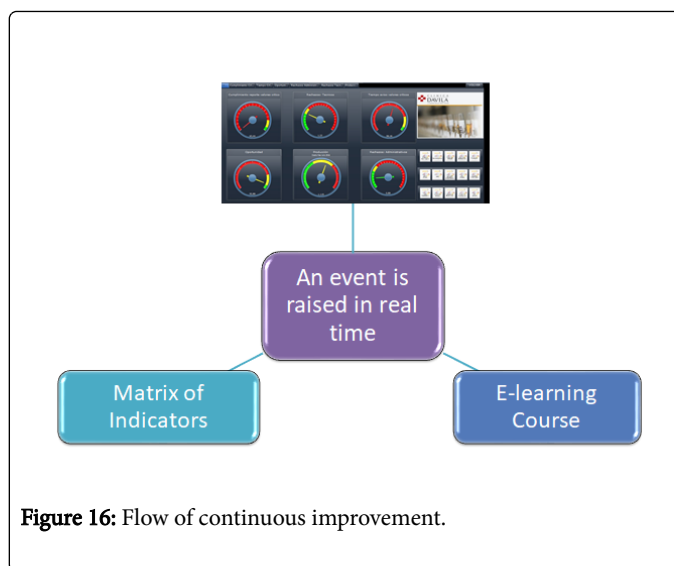
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Figure 16: Flow of continuous improvement.

Clases	Temática
Clase 0	Uso de la plataforma
Clase 1	Gestión de la información
Clase 2	Manual de Toma de muestras
Clase 3	Traslado y recepción de las muestras
Clase 4	Criterios de rechazos de muestras I
Clase 5	Criterios de rechazos de muestras II
Clase 6	Evaluación final

Figura 18: Temática del curso e-learning

Figure 17: E-learning course items.

Acción evaluada		Meta	Indicador		Unidad	Meta	% Ponderación	Resultado	Indice de logro	Nota
Política de calidad	Objetivo de la calidad	Aporte al contenido del paciente	Indicador	Indicador	Unidad	Meta	% Ponderación	Resultado	Indice de logro	Nota
La Dirección del Laboratorio Clínico de Clínica CIE, reconoce la importancia de esta política, su compromiso de adherirse con el cumplimiento de las necesidades de los pacientes, optimizar costos y de cumplir con las normas para el diagnóstico puntual y seguro de los pacientes.	Disponibilidad	Existencia de las acciones que genera el Laboratorio Clínico de Clínica CIE para cumplir con las necesidades de los pacientes.	Tasa de muestras recibidas Antidoping	1,50	5,26	4	5,75			
			Tasa de muestras recibidas Hospitalizada	2,00	3,27	3	1,50			
			Tasa de muestras recibidas Urgencia General	1,50	5,26	3	2,15			
			Tiempo de respuesta de exámenes gástricos	90	81,9	15	12,29			
			Tiempo de respuesta de exámenes de laboratorio de urgencia	90	75,4	15	7,24			
	Confidencialidad	Existencia de las acciones que genera el Laboratorio Clínico de Clínica CIE para cumplir con las necesidades de los pacientes.	Tiempo de respuesta de exámenes de laboratorio de urgencia	90	85,5	10	6,33			
			Tiempo de respuesta de exámenes de laboratorio de urgencia	90	85,5	10	7,32			
			Tasa de reporte de errores de resultados	90	99,9	12	14,36			
			Tiempo de respuesta de exámenes de laboratorio de urgencia	90	75,4	12	7,26			
			Indicador de cumplimiento de Política Signos + 4	90	81,9	10	8,41			
Seguridad	Existencia de las acciones que genera el Laboratorio Clínico de Clínica CIE para cumplir con las necesidades de los pacientes.	Resultados de la auditoría en el Programa de Gestión de Riesgos de Clínica	90	95,4	12	9,94				

Weighted Result: (Indicator Result * Weighting) / 100

Weighted Result: (81,9*15)/100= 12,29

% Weight = weight given by history

INDICE DE MEJORA:

CATEGORIZACION

100%
EXTRAORDINARIO

75- 90%
ACEPTABLE

60%
INSUFICIENTE

50%
INSUFICIENTE

Improvement Index: Sum of weighted results

Figure 18: Indicators matrix.

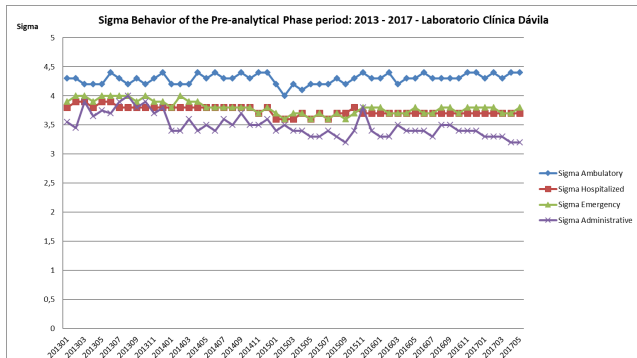


Figure 19: Behaviour Sigma of the data for each analysed area.

Finally it is important to underline that the information collected, must be expressed in a standardized manner in Sigma value, so it can be compared with the behavior in other care centers (Table 2).

Service	Sigma	DPMO
Ambulatory	4,3	2.555
Hospitalized	3,7	13.903
Emergency service	3,8	10.724
Administrative area	3,5	22.750

Table 2: Sigma values of each analysed area.

Conclusions

The work in the improvement of processes in the pre-analytical requires a lot of effort and needs an empowered leadership able to motivate the laboratory team, the staff of the Clinical services and the management. Also we should get around obstacles which should be solved with a high level of creativity taking profit of all the resources economic as well as computing.

The application of these recommendations, should deliver the first alignments to start raising objective information, creating a training system and selecting a type of IT tool allowing to monitor the indicator achievements. It is important to take as a guide some laboratory standards, useful as an argument to generate the change of behaviour of the entire environment with which the laboratory is related.

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