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Review Article

Pre Analytical Errors as Quality Indicators in Clinical Laboratory

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Abstract

The ISO 15189: 2012 standard for laboratory accreditation defines the pre-analytical phase and recognizes the need to evaluate, monitor and improve all the procedures and processes in the initial phase of the Total Testing Process, including those performed in the phase of requesting tests and collecting samples, the so-called "pre pre-analytical phase". Pre analytical phase is the most vulnerable part of the Total Testing Process. Errors in this stage can lead to a misdiagnosis and mismanagement and represent a serious harm for patients. Clinical Laboratories use many different methods to reduce errors and improve quality, including the assessment and monitoring of all steps of the Total Testing Process using Quality Indicators (QIs) and accreditation of laboratories. A prospective observational study was done in the Medical Biopathology Laboratories of a public secondary hospital, "Sismanoglio" General Hospital of Athens, Greece for a period of 7 months (June 2014 to December 2014). Of the 908.917 total tests received from the hospitalized patients and the patients treated in Emergency and Outpatient Department during the data collection period, 765 samples were found unsuitable for further processing. This accounted for 1.939% of all samples collected in the Medical Biopathology Laboratories. In order to reduce the number of errors in the pre-analytical phase of the Total Testing Process and to achieve the standards of high quality, special attention must be devoted to this process. Continuous monitoring and control will allow the decrease of pre analytical errors. The systematic reporting of these errors could be used as Quality Indicators such the model which the Working Group of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) has developed.

Keywords: Quality indicators; Pre analytical errors; ISO 15189:2012

Introduction

The increasing focus on quality and the awareness that the information provided by clinical laboratories directly affects the treatment received by patients have made it a priority for clinical laboratories to reduce errors and to adopt a Quality Control System-QCS [1]. Quality in the laboratory has a huge impact on diagnosis and patient management as about 80% of all diagnosis is made on the basis of laboratory tests [2]. The International Standard ISO 15189:2012 requires the use of Quality Indicators-QIs for assessing and monitoring the quality of all steps of the Total Testing Process (TTP) [3]. Quality indicators are statistical measures that give an indication of the quality output. However, some quality indicators can also give an indication of the quality process [4]. In 2004, The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) launched a project that promoted and developed a Model of Quality Indicators (MQI) by implementing a Working Group on Laboratory Errors and Patient safety (WG LEPS). The model was revised by a 2013 Consensus Conference, organized to establish a list of QIs that should be evidence-based, feasible, and actionable for most laboratories around the world. This model should be divided into process and outcome measures, mainly based on measures of the pre-, intra- and analytical procedures and processes [5]. Of these, 16 focused on the pre analytical phase such as request forms with errors concerning patient identification, requests with errors concerning the input of tests, haemolyzed and clotted samples, samples with inadequate sample, etc [6]. Errors of this type can lead to a delayed or wrong diagnosis, an incorrect management of treatment, blood transfusion mismatches and additional laboratory tests [7]. In addition to it, enormous cost results from such errors and further delays in the management of patients [8]. False positive or negative results can lead to repeated examinations or more costly procedures [9].

ISO 15189:2012 standard, Medical laboratories--Particular requirements for quality and competence, provides a framework for the design and improvement of process-based quality management systems by medical laboratories. The establishment of Quality Management System (QMS), the monitoring and the control of processes, the continuous education of health professionals, the interdepartmental cooperation, the automation of analysis, the Information Technology and Communication are vital factors for the reduction of errors in pre analytical phase. Consequently, the pre analytical phase must be strictly supervised so that the laboratory can achieve an adequate performance level. Quality Indicators are useful performance monitoring tools for the pre analytical phase of the testing process [10].

Diagnostic errors started declining with the increasing

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dependence on laboratory test results. The use of clinical laboratory test results in clinical decisions has become an integral part of clinical medicine. More than 60-70% of the most important decisions on admission, discharge and medication are based on laboratory test results. With this high degree of influence, the quality of laboratory testing and reporting is of utmost importance. Quality Patient Care is the ultimate goal of clinical governance, as it dictates that laboratories should be responsible for the provision of a service that positively impacts on patient care [11].

Laboratory Testing, which commonly called the Total Testing Process -TTP, is a complex process. This process includes three phases: the pre-analytical, the analytical and the post-analytical phase [12].

The Total Testing Process begins and ends with the patient, from the medical decision for testing until the announcement of the results [13]. It has been outlined that the improvement of the analytical phase by focusing in the Internal and External Quality Control (IQC-EQC) and the automation in the post analytical phase are the most error-prone and important performance factors of the laboratory. Nevertheless, a huge number of errors occur in the pre analytical phase as well [14].

The pre analytical stage is the most complex process of the TTP [15]. The effect of this process frequently appears in the analytical and the post analytical stage [16]. The number of errors mostly depends on the management of samples [17]. The handling of samples, such as sample collection, storage and transportation are managed out of the Clinical Laboratory [18]. Globally, this phase is known as "pre" pre analytical [19]. The "conventional" pre-analytical step involves the processes required to make sample suitable for analysis: centrifugation, aliquoting, diluting and sorting specimens into bathes for their introduction into automated analyzers [20]. In order for the laboratory to correspond to this key role, a lot of different information according to the sample is required [21]. Systematic daily monitoring, checks, standardization, automation, laboratory information system, quality control of the testing by health professionals of clinical laboratory contribute to accuracy and reliability of the results. For this perspective, monitoring and control for a specimen is required if properly collected, stored and transported to the Laboratory for analysis. It is understood that between the medical decision of sending and receiving samples in the Laboratory, time and other factors intervene and they contribute to the integrity of the sample. Some of these variables are: the identification and the preparation of the patient for sampling (diet, smoking), the time and the site of sampling (early morning, venous sample), the storage and the transport (serum or plasma, at room temperature and other environmental situations), the volume of sample, etc. The most usual reported types of pre-analytical error are: a) missing sample and/or test request, b) wrong or missing identification, c) contamination from infusion route, d) haemolysed, clotted, and insufficient samples, e) inappropriate containers, f) inappropriate blood to anticoagulant ratio, and g) inappropriate transport and storage conditions [22]. Most of these events appear potentially preventable. On the other hand, this period is known as "pre" pre analytical phase and it is referred to the time between the tests ordering until the receiving time from the laboratory [23].

Studies have shown that pre-analytical errors predominated in the laboratory, ranging from 46% to 68%, whereas analytical errors from 7% to 13% and post-analytical errors from 18, 5% to 47% [24]. Clinical Laboratory Errors directly lead to increased healthcare costs and to decreased patient satisfaction. For this reason the Clinical Laboratory must focus on Good Handling of samples [25].

Errors in the pre-analytical phase of the Total Testing Process have a great impact on patient outcomes. They can cause serious injury to patients or even result in their deaths. However, morbidity and mortality can sometimes be prevented by the timely and effective action of health professionals. The healthcare system is increasingly dependent on reliable clinical laboratory services which as part of the overall healthcare system are prone to errors [26].

The most relevant features of studies on laboratory errors are their scarcity and their heterogeneous nature. This means that studies performed and reported in literature have used different data collection approaches, different time spans for data collection, and have investigated different laboratory sections or activities. Data in literature clearly demonstrates that the collection method used has an important influence on error types and their prevalence [27].

In recent years, the concepts and practices of quality assessment programs, such as the implementation of ISO 15189:2012 standard in laboratory tests, are an important strategy of workshops to prevent or reduce errors. Moreover, the increasing use of Information Technology (IT) and the establishment of Laboratory Information System (LIS) in Clinical Laboratory could lead to improved quality of provided services. Errors in the Health care System are preventable if we understand the human factors causing them. The automation, standardization and technological progress significantly improve the reliability laboratory tests, errors that occur during the process sample collection, analytical review phase and the phase of release of laboratory tests [28]. To quantify performance, in the pre analytical phase and clinical laboratories can use Quality Indicators as a percentage of systematic daily reporting of received total samples. These indicators provide a means to compare the performance of the individual laboratory with that of other laboratories, as long as the same parameter (for instance number of requests, number of samples or number of samples with anticoagulant, etc.) is used as a reference [29].

Design and sample

The main scope of our retrospective study was to assess the frequency of pre analytical errors, in order to evaluate and to quantify performance in the pre analytical phase of the Total Testing Process using, partially, the Model of Quality Indicators which has been developed by the International Federation of Clinical Chemistry and Laboratory Medicine.

Also, the study's purpose was to assess

Our secondary goals were to:

1. Understand the most critical steps in the pre-analytical phase of the Total Testing Process (TTP)

2. Identify the role of continuous education of Health Professionals in order to minimize lab errors

3. Improve the quality of service provided by Medical Clinical Laboratories.

We conducted the study over a 7-month observation period (from June 2014 to December 2014) with the participation of all patients, the hospitalized ones in all clinical wards and the outpatients from the Emergency and Outpatient Departments in the Sismanoglio General Hospital of Athens in Greece.

The hospital has 420 beds and is a public secondary institution of Greek National Health Care System. The Hospital provides medical and surgical services to the community in addition to training doctors and conducting research. The hospital has a well equipped and well resourced Diagnostic Directorate parts of which are the Medical Biopathology laboratories (Microbiology/Serology) and Haematology Department. The hospital has a well equipped and well resourced Diagnostic Directorate, part of which are the laboratories of Microbiology/Serology and Haematology Department All the laboratory tests considered in the study were performed in the Microbiology/Serology and Haematology Laboratories in the same hospital. The laboratory tests were conducted by Biopathologists and technicians who have undergone mandatory training courses in laboratory science. The collection of samples for analysis is done by clinical doctors and nurses in the individual wards and in the Emergency and Outpatient Departments.

Ethical consideration

The study conformed to the principles outlined in the Declaration of Helsinki. The study protocol for the main survey was reviewed by the Science Council of Sismanoglio General Hospital of Athens-Greece (no 09/22.10.2014 sr.no 28332/06.11.2014).

Ethics approval for this research was obtained from the Administrative Council of Sismanoglio General Hospital (no 28/28.11.2014 issue 29).

Methods

All the laboratory tests considered in the study were performed in the Medical Biopathology (Microbiology/Serology) and Haematology Laboratories in the same hospital.

The laboratory process is monitored daily by internal quality controls and monitored monthly through proficiency testing by the External Independent Quality Control. After technical validation all the results are sent to several clinics of the hospital and Emergency/Outpatient Departments.

The overall work flow of the Laboratories is partially computerized i.e. physicians order tests on pre printed paper ordering slips and as orders arrive in the Laboratory, they are registered on the Computer System. Computer printed results are collected by the physicians from the laboratory area. During the study period the Laboratories started to install a Quality Management System under ISO 15189:2012 standard consulting by Head of Department of Quality Control, Research and Continuous Education in the same hospital. The Haematology Laboratory is accredited (No 1057/15.09.2016) under ELOT EN ISO 15189:2012 by Hellenic Accreditation System (ESYD). The Hellenic Accreditation System was established by the Law 3066/2002 with the purpose of the materialization, implementation and administration of the National Accreditation System as set in the provisions of the Law 2231/1994 which was subsequently modified with the Law 2642/1999. It was transformed and incorporated as an autonomous Operational Accreditation Unit in the National Quality Infrastructure System (ESYP) established by the Law 4109/2013. The Hellenic Accreditation System (ESYD) has been appointed as the National Accreditation Body of Greece according to the requirements of Article 4 of the Regulation (EC) No 765/2008 according which each Member State shall appoint a single national accreditation body.

The data derived from pre-analytical errors were obtained by means of the analysis of sample rejections and the request for new sample collection for tests in the divisions of Medical Biopathology (Microbiology/Serology) and Haematology. Data were collected from June to December 2014. The staff of each division was in charge of the criteria for sample acceptability/rejection based on the internal quality program of the clinical laboratory service.

The pre analytical variables evaluated included criteria such as incomplete or incorrect patient details as well as illegible handwriting for sample rejection. Some of these criteria were visually applied. The samples considered with insufficient volume were those presenting volume lower than the necessary for the conduction of a specific test, previously standardized and with the consent of the laboratory staff in this hospital.

The pre analytical variables evaluated included all the criteria mentioned below (Table 1) for sample rejection as well as incomplete/incorrect patient details and illegible handwriting:

Data were collected by two methods; one was by careful inspection of the samples sent to the laboratory based on the pre analytical quality indicators and the second was by checking the test requisition papers for their adequacy.

We documented the occurrence of pre-analytical errors observed at the Sismanoglio's Clinical Laboratories (Microbiology/Serology and Haematology). Samples with their accompanying request slips were received by health professionals (doctors and nurses) from various wards of the hospital. In addition, trained nurses at a collection centre collected all outpatient samples and sent them to the laboratories. Upon receiving the samples the health professionals of the laboratories examined the samples with their corresponding request slips and any errors observed were entered in the Laboratory Information System "s Lis Enterprise® Suite integrated with HIS" (created by INFOMED CS LTD, 8 Ikarias str. 121 32 Peristeri of Athens-Greece Tel: 00302107568258 Email: info@infomedcs.com).

"Bio LIS" is a state-of-the-art information system with the necessary flexibility to support any laboratory department in a user-friendly environment. Operating in an advanced, fast, powerful way and being easy to use LIS provides a unique working environment to all diagnostic departments, from Clinical Chemistry to Haematology, Immunology, Serology, Microbiology, Pathology, Cytology or Molecular Biology, using just one database and ensuring the sharing of information among all laboratory users. At the same time it is an innovative tool for Quality Control Management across the laboratory sections. The "Bio LIS" is designed and developed within a strong security system fully covering the requirements and standardization of ISO/IEC 27799-in order to be directly adapted to all the special information of the health sector and its unique operating environments.

Table 1: Main characteristics of the study.

Table 1a: Main characteristics of population of the study	
Gender	N (%)
Female	7595 (41,3)
Male	10.812 (58,7)
Age	60,6 (21,9)[a]
Patients	
Inpatients	14.478 (78,7)
Outpatients	3.929 (21,3)
Total patients in Laboratories	18.407
Table 1b: Total Number of samples and defects per Laboratory	
Haematology Laboratory samples	674.944 (74,3)
Total defects in Haematology	440 (0.065%)
Medical Biopathology (Microbiology/Serology) Laboratory samples	233.973 (25,7)
Total defects in Medical Biopathology (Microbiology/Serology)	325 (0.139%)
Total tests in Laboratories	908.917
Total defects in Laboratories	765

Data analysis

Independent student's t-test was used to investigate differences between age and gender and hospitalization while chi-square test was used in order to investigate the relationship between gender and hospitalization.

The recorded pre analytical variables were categorized into error types related to the appropriate utilization of the test requisition paper and to the quality of the sample collected for analysis.

Percentage of occurrence of defects was calculated as number of defects (n) divided by total number of tests (N).

The product of division is then multiplied by 100%: The two-sided level of significance was set equal to 0.05. All data analysis was performed using computer software IBM SPSS 21.0 (Statistical Package for Social Sciences) and summarized using percentages. Frequencies are presented using tables.

Background information on the data from the Laboratory Information System was coded and transferred manually by the researchers into IBM SPSS ver. 21.0 for all statistical analyses. All data were manually rechecked against the final data file by the researchers. In all statistical analyses the significance level was set at p<0, 05. All statistical tests and p-values were two-sided.

Results

During the study period 18.407 clinical samples were received by the Clinical Laboratories (Microbiology/Serology and Haematology). Out of these, 14.784 (78.7%) samples were collected from the patients admitted in the wards and 3.929 (21.3%) samples were collected in the emergency and outpatient departments.

Pre-analytical errors were observed in 765 out of the 18.407 samples collected and screened over a period of 7 months, which accounts for 1,939% of the total number of samples received.

The number of tests sent for analysis was greater than the number of patients because more than one tests per patient were requested on a single sample.

A total of 908.917 tests were analyzed. In this study we examined 674.944 (74.3%) tests from the Haematology Lab and 233.973 (25.7%) tests from the Medical Biopathology (Microbiology/Serology) Laboratory.

Table 2: Categories of pre-analytical errors and their frequency (%) during June to December 2016.

	Sr. No.	Errors	%
Pre-analytical Errors (Execution/Prevention)	1	Incorrect identification / improper labeling-execution prevention	0.24
	2	Samples without physician order request-execution prevention	0.24
	3	Wrong samples-execution prevention	0.2
	4	Haemolysed samples-execution prevention	0.19
	5	Clotted samples-execution prevention	0.16
	6	Insufficient quantity-execution prevention	0.09
	7	Request without sample-execution prevention	0.09
	8	Improper bleed-execution prevention	0.07
Potential pre-analytical errors (Under control)	1	Haemolysed samples	0.15
	2	Samples without registration number	0.11
	3	Lipaemic samples	0.09
	4	Insufficient quantity-results under control	0.08
	5	No clinician information	0.04
	6	Unspecified defect	0.02
	7	Jaunticed samples	0.02
	8	Delay transportation (long time between making and receiving sample)	0.02
	9	Samples without label	0.02
	10	Undefined tests samples	0.01
	11	Without clinical history	0.01

The characteristics of the study population resulting from the requisition papers examined are indicated in (Table 2).

While the pre analytical errors and the defects recorded are described in (Tables 2 and 3). A total of 18.407 patients (inpatients and outpatients) of different age groups were included in this study 7.595 (41.3%) of which were female and 10.812 (58.7%) were male. The average age of those tested was 60.6 years, the standard deviation was 21.9 years, and the median was 63 years. The lowest age was 14 years and oldest was 115 years. The average age of males was 60.5 years (standard deviation = 21.4) and of the females was 60.8 years (standard deviation = 22.5). This difference is not statistically significant (p=0.3). 82% (n = 8862) of the hospitalized patients were males while the corresponding figure for females was 73.9 (n = 5616). This difference is statistically significant (p<0.01). The average age of in house patients was 62 years (standard deviation = 21) and of outpatients was 55.3 years (standard deviation = 24); the difference being statistically significant (p < 0.01).

Discussion

The main scope of our retrospective study was to assess the frequency of pre analytical errors, in order to evaluate and to quantify performance in the pre analytical phase of the Total Testing Process using partially the Model of Quality Indicators which has been developed by the International Federation of Clinical Chemistry and Laboratory Medicine in a secondary General Hospital of Athens, Greece.

The basic principles of appropriateness in the clinical laboratory are embodied the selection of the right test at the right time for the right person. Test appropriateness is inherent to the understanding of the medical history and the value of a particular test to the respective patient. Knowledge of actual and potential adverse events related to laboratory services come from a small number of studies that have focused on the frequency of laboratory errors and the classification of the errors by cause, phase or testing, responsible party and extent of harm to the patient [30].

The pre analytical phase includes a set of processes that are difficult to define because they take place in different places and at different times. Normally, the pre analytical phase includes all processes from the time a laboratory request is made by a physician until the sample is ready for testing. The main processes that should be taken into account in the study of the pre analytical phase are: test selection; patient preparation; collection; transport; handling and preservation of the sample; and interferences. The study of the characteristics of individual patients and the biological variation for each laboratory test belong to this phase, as well. Improvement of the pre analytical process currently constitutes a challenge to be faced by clinical laboratories [31].

At Sismanoglio General Hospital of Athens, Greece the majority of the hospitalized patients' and outpatients' specimens are collected by trained doctors and nurses. However, pre analytical mistakes are a major source of error in the Total Testing Process and they have been considered as one of the most important quality indicators. Pre analytical errors may include lost physician's orders, patient identification errors, insufficient quantity of specimens, use of inappropriate containers, specimens lost in transportation, etc [32].

This study showed that error frequency was 1.939% in the pre analytical phase (Tables 1 and 2). Laboratory errors may lead to a sample recollection in order to repeat the analysis, which is inconvenient for the patient, delays treatment and increases the cost of healthcare [33]. Among a total 908.917 tests, 765 findings were confirmed as pre analytical errors/defects, with a relative frequency of 1.939%.

One of the features that should be given some attention is the volume of the sample containers required to perform a correct reading.

Out of a total number of 908.917 samples received from patients (in house and outpatients), pre analytical errors, according to above mentioned criteria (Table 2), were detected in 765 samples (1.939%). Distribution has been presented in (Table 3).

During this study, the most frequent pre analytical error occurred was that of "samples without physician order request" with an incidence of 1.26% (111 cases). Some physicians order tests to verify the results of a previous test. It may also be a mechanism to ensure that necessary tests are not missed [34]. But in many cases repeat testing is a convenience rather than a reflection of a belief that it improves patient care [35].

In the category "samples without registration number" the total number was 80. Every sample should have a unique identifier or combination of identifiers that are firmly affixed or a permanent part of the container [36]. Accuracy of patient identification is the most important goal in improving patient safety [37].

Another frequent pre analytical error encountered was that of clotted samples, with an incidence of 0.16% (162 cases).

Table 3: The defects, the number of errors/defects, the percentage of occurrence of defects and the total number of tests.

Defect	N° Defects	%	N° tests
Unknown	13	0.02	64.031
Improper blood-execution prevention	3	0,007	42.987
Unspecified samples	2	0,012	15.864
Insufficient quantity - results under control	83	0,08	103.969
Insufficient quantity-execution prevention	108	0,09	124.575
Grossly Haemolysed Samples-execution prevention	4	0.19	2.108
Haemolysed Samples-execution prevention	86	0,15	58.813
Samples without registration number	80	0,11	75.751
Samples without identification (no name)	10	0,02	59.895
Samples without physician order request-execution prevention	111	1.26	87.804
Wrong samples-execution prevention	44	0,20	21.701
Wrong label-execution prevention	58	0,24	24.527
Delay in samples transportation	2	0,02	9.907
Without clinician information	1	0,04	260
Without clinician history	1	0,01	9.850
Diluted samples	20	0,02	96.386
Lipaemic Samples	46	0,09	53.399
Clotted Samples-execution prevention	162	0,16	100.017

It, also, was observed that an occurring pre analytical error was that of haemolysed samples (86 cases, 0.15%). Haemolysis may cause certain analyzers to be increased due to lack of red cell constituents or may cause interference in the test method. The amount of interference will depend on the degree of haemolysis and on the specific test method being used. Haemolysis is a common cause of specimen rejection in laboratories, which requires the specimen to be redrawn [38]. Additionally, the monitoring of the rejected samples and the identification of factors that caused sample rejection can contribute to avoiding errors and to promoting continuous improvements of laboratory service [39].

Insufficient sample volume ["Insufficient quantity-execution prevention" (108 cases, 0.09%) and "insufficient quantity results under control" (83 cases, 0.08%)] reported as well as pre analytical errors. However, low sample volumes may occur as a result of ambient conditions reduced capillary blood flow, or insufficient depth of the lancing device penetration into the skin [40]. The need to change blood collection practice in accordance with the guidelines for collecting samples is important [41]. Additionally, the monitoring of the rejected samples and the identification of factors that caused sample rejection can contribute to avoiding errors and to promoting continuous improvements of laboratory service [42].

Laboratory medicine is a highly dynamic sector of health care. The implementation of a Quality Management System is a major issue for patient safety both inside and outside the walls of the clinical laboratory. The greatest impact on overall improvement could be achieved by focusing on the pre-analytical processes in which most "gross" errors occur, the errors that can lead into adverse events or the risk of adverse events for patients [43].

Regardless of the unpredictable consequences of medical errors, which may range from leading to little or no harm to being ultimately fatal to the patient, patient safety is increasingly acknowledged as a primary organizational goal by healthcare systems. Although most laboratory errors are likely to result in no harm to the patient, because they either remain undetected or are judged as clinically insignificant and are further ignored by the referring physician, this does not mean that the problem can be overlooked or underestimated [44].

Provided services of high-quality level and efficient laboratory performance are now adequately indispensable for a resource-constrained society. Given that patient safety approach saves lives, ensures compliance and improves the bottom line for healthcare managers, it is clear that patient safety must be fully integrated with other critical requirements and standards for clinical laboratories. With the awareness that most problems, in the total testing process, arise in the pre analytical phase, a total quality assurance system should be adjusted to this critical area and be developed around strategies based on accurate standards for error prevention (hazard analysis, traceability), detection (identification and continuous monitoring of vulnerability) and feedback (implementation of reliable countermeasures to prevent accidents from leading to harm) [45].

Conclusion

In the present retrospective study the frequency of pre analytical errors/defects (1.939%), of the Medical Biopathology (Microbiology/Serology) and Haematology Laboratories of Sismanoglio General Hospital of Athens, Greece, during 01/06/2014 until 31/12/2014, was found to be in accordance with the international scientific literature.

Our findings showed that the majority of the rejected samples were accompanied by inappropriate slips (i.e. incorrect identification and without the physician's order request), which represents 0.48% of the total number of received samples. Quality in Clinical Laboratory has been defined as the guarantee that each single step throughout the Total Testing Process is correctly performed. The pre analytical stage is the most complex process of the Total Testing Process. The number of errors mostly depends of the management of samples. Clinical Laboratory Errors directly lead to increased healthcare costs and to decreased patient satisfaction. For this reason the Clinical Laboratory must focus on Good Handling of samples. The IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) Working Group of 'Laboratory Errors and Patient Safety' (WG-LEPS) has identified several Quality Indicators (QIs) related to all stages of the TTP. Pre analytical phase quality indicators include the appropriateness of test selection, patient/sample identification; samples collected in inappropriate containers or with insufficient volumes, haemolyzed or clotted samples, improperly stored samples or samples damaged in transport [46]. Pre analytical error prevention requires excellent communication and cooperation among all health professionals [47]. The education of health care professionals involved in procedures for the collecting, handling, preparing, and transporting biological specimens is crucial in order to understand the effects of pre analytic variables on specimen quality and the reliability of results [48].

The Pre analytical phase is an area more vulnerable to uncertainties and potential harm that can determine the outcome of patient care [49]. The frequency and type of errors occurring in every laboratory must be monitored; controlled, documented and corrective measures should be taken [50]. Errors in pre analytical phase usually occur as a result of high levels of staff turnover, negligence, lack of understanding of Good Laboratory Practices-GLP and ineffective training. They include inappropriate test request, inadequate samples, delays in transport or improper storage, improper venipuncture, insufficient indication of the patient, improper identification of samples, insufficient sample volume. Such errors usually result in sample rejection, and therefore, they produce uncertainty, frustration, inconvenience and anxiety in physicians and patients; excessive costs; prolonged execution time; rework; loss of trust and laboratory loss of confidence in the Clinical Laboratory. Difficult to control pre- analytical variables are possible reasons for the prevalence of errors in this phase. Pre analytical phase processes are generally held outside the clinical laboratory; and not under the control of laboratory management. Therefore, the active monitoring and control of all possible defects that are caused by non- laboratory personnel is essential in order to incorporate actions outside the laboratory in the laboratory quality assurance plan. All QIs should be used in laboratories in order to provide evidence of compliance with the essential requirements of the ISO 15189 International Standard for assuring quality and accreditation of laboratory services, particularly as they are a tool for assuring risk management and promoting patient safety. However, the priority score should also help laboratories when difficulties encountered in practice dictate that a choice must

be made [51]. Therefore, while the entire set of QIs is essential, both for clearly understanding their usefulness and for complying with the requirements of the ISO 15189 International Standard, an individual laboratory should carefully select the most appropriate indicators to implement from the start, and over time [52]. As quality assurance is a never-ending journey, the implementation and monitoring of QIs should be considered an essential component in a continuous quality improvement program. Therefore, progressive use of QIs and monitoring should be encouraged so as to promote a valuable quality system program, based on the familiarization with the rationale of QIs and the appropriate method for data collection [53].

There are interrelated steps that can prevent pre analytical errors: a). Establish short and clear written procedures; b) Improve the health professional continuous education and training; c) Implement Standard Operating Procedures; d) Establish Quality Indicators for monitoring through automating functions; e). Improve communication and team work between health care professionals as well as promote cooperation between departments. Written standard operating procedures should clearly explain the pre analytical steps, the main source of errors in clinical laboratory, which can have a significant impact on the accuracy of the test results, on the proper diagnosis and on the patient safety. Laboratory staff that performs preliminary analytical procedures needs to understand not only what the procedures are, but also why they are important to follow. They need to know not only the consequences of non compliance with the right steps, but also what the errors are and what effect they may have on the sample and ultimately the patient. There should be ongoing training for these employees and competence should be assessed annually. The success of efforts to reduce errors is linked to the effectiveness of the measures taken. Quality Indicators should be used for the assessment as a Laboratory Management "Tool". In the test process areas involving non-laboratory personnel, interdepartmental communication and cooperation are crucial in order to avoid errors. So the whole health care system should be involved in the improvement of the overall testing process. An adequate and effective training of personnel on processes and procedures must be the priority of the whole institution.

In recent years, the concepts and practices of quality assessment programs, such as the implementation of ISO 15189:2012, in laboratory tests, are an important strategy of workshops in order to prevent or reduce errors. Moreover, the increasing use of Information Technology (IT) and the establishment of Laboratory Information System (LIS) in the clinical laboratory could lead to improved quality of care and patient safety. Errors in the Health care System are preventable if we understand the human factors causing them.

We conclude that the performance level in the pre analytical phase of the Total Testing Process, in our Medical Laboratories was good. However, according to ISO quality specifications, the performance level of the laboratory at all phases of testing requires continuous evaluation so that health care professionals can readily identify opportunities for improvement in the stat laboratory and other healthcare services departments. Quality Indicators for Laboratory Performances in the Pre analytical phase of the Total Testing Process allow the quality of services to be measured, analyzed and improved. Systematic control of the overall process of continuous analytical monitoring and management of non-conformities is obligation of all clinical laboratories. Recommendations include staff education and responsibility, implementation of objective and standardized criteria and procedures for the detection of inadequate samples and samples of inappropriate management. For effective implementation, it is essential to ensure communication and cooperation between all members of the Health Care Team. It is responsibility of the

Laboratory manager/director to instruct staff to record the pre analytical errors

Quality Improvement program addressing pre-analytical errors combined with appropriate training and tools to mitigate the errors by tracking the time points related to the sample transportation would improve patient care quality and safety. As part of a good quality management system, laboratories should track the pre analytical errors made each month and categorize them to make designing improvement efforts easier.

In summary, Quality Indicators can be used as a measure of Laboratory Performance in Pre analytical Phase of Total Testing Process. This could then be used in addition to the current accreditation system that is largely a measure of operational performance.

Study limitations

Results obtained in this study are only reflective of the Laboratories' performance in a particular period in a particular Hospital; they may not be generalized to other public Hospitals and should be considered in context with the desired outcomes of the study.

Ensuring good scientific rigor throughout the research process is imperative for the overall quality of the period and thus for the presented conclusions.

One issue specific to this thesis is possible feelings of guilt or anxiety among technicians of laboratories if the data should indicate inadequate sample receiving practices.

The staff may have also felt obligated to research the defects, since the Head of the Lab Department established a Quality Management System-QMS under ISO 15189:2012.

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