QATAR UNIVERSITY

COLLEGE OF HEALTH SCIENCES

STUDYING FREQUENCIES, TYPES AND CAUSES OF MEDICAL LABORATORY ASSOCIATED ERRORS USING THE ELECTRONIC OCCURRENCE, VARIANCE AND ACCIDENT (OVA) REPORTING SYSTEM IN DEPARTMENT OF LABORATORY MEDICINE AND PATHOLOGY AT HAMAD MEDICAL CORPORATION (HMC)

BY

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ABSTRACT

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Title:_Studying Frequencies, Types and Causes of Medical Laboratory Associated Errors Using the Electronic Occurrence, Variance and Accident (OVA) Reporting System in Department of Laboratory Medicine and Pathology at Hamad Medical Corporation (HMC)

Supervisor of Thesis: Dr. Atiyeh Abdallah.

Background:

Medical laboratory services are an integral part of healthcare systems that play significant roles in over 70% of medical decisions. Thus, unintentional errors that occur during total testing process (TTP) of laboratory may cause adverse outcomes. Therefore, implementing a system that assists healthcare professional to collect, track and analyze the frequency of incidents is essential for quality improvement. Hamad Medical Corporation (HMC) has implemented OVA system for reporting occurrences, variances and accidents (OVA).

Objectives: This study was conducted to (i) determine the types of laboratory associated errors and (ii) to analyze the frequencies and causes of these errors.

Design and Methods:

The present study, a descriptive retrospective investigation, analyzed 38,814 OVA incidents. The laboratory quality management department provided the incidents recorded by the laboratory information system (LIS) for a three years period from first of January 2017 up to thirty first of December 2019. Incident types were classified into three categories: preanalytical, analytical, post analytical. Descriptive statistical

analysis was performed by Microsoft Excel office 365, and frequencies as well as the percentages of incidents were determined.

Results:

Out of the 38,814 OVA reports, 18,679 (47.6%), 15,347 (40.0%), 4788 (12.4%) incidents occurred in 2017, 2018 and 2019 respectively. The events were grouped into three categories showing 95% for preanalytical, 2% for analytical and 3% for postanalytical categories. The data showed that 91.7% of sample rejection in preanalytical category were due to clotted, hemolysis, and insufficient patient sample volume. In analytical category, quality control issues and equipment errors represent about 82.8% and 17.2% respectively. Finally, most of postanalytical errors were delay in critical results 50.4% and discrepancy 49.6%.

Conclusions:

This study found that preanalytical category are the major source of reported errors in ova system which accounts for 92%. the main reason for sample rejection were due to sample collection process, which is conducted by nurses and phlebotomist.

DEDICATION

To

My father and My mother

Who always inspire me to give my best and help me be who I am,

To my passionate loving husband,

Without his support none of my success would be possible

My lovely daughters,

.

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CHAPTER 1: INTRODUCTION AND LITRETURE REVIEW

1.1 Introduction

Patient safety and quality of service are the main priorities for public health and healthcare system. Thus, conducting constant assessment program and continuous evaluation for each process in this system is essential for quality improvement. Due to healthcare complex processes, unintentional errors may occur with or without having adverse outcomes (Grober & Bohnen, 2005). Comprehending the existence of provenance of malfunction throughout the system is a basic step for prevention to avoid the repetition of incidents.

Medical laboratory services are integral part of healthcare system that play significant role in over 70% of medical decisions on medications, admission and discharge (Abdollahi, Saffar, & Saffar, 2014; Giuseppe Lippi et al., 2009; Sakyi, Laing, Ephraim, Asibey, & Sadique, 2015). Therefore, laboratory associated errors that are linked with medical diagnosis errors has critical impact on patient safety and public health. Thus, it is important to review and identify the frequency, causality and consequences of errors. Medical laboratory errors (MLEs) are defined as "any incidence, and accidental events or defects that may affect laboratory results through total testing process (TTP), which began from requesting laboratory test and ends by result interpretation and clinical decision" (Agarwal, 2014). The definition demonstrated that laboratory errors could be generated throughout TTP which had been categorized into three phases preanalytical, analytical and postanalytical phases. Every phase of (TTP) required to be precisely evaluated to eliminate laboratory associated errors. Therefore, the demand of applying a system where errors can be recorded is highly needed to collect and calculate the frequency of incidence of errors in order to minimize occurrence of incidents recurrence and other potential errors.

Consequently, Hamad Medical Corporation (HMC) which is the leading healthcare provider in Qatar, has implemented a web-based tool for reporting occurrences, variances and accidents called OVA system under HMC Electronic Incident Reporting System (EIRS).

HMC is the main provider of secondary and tertiary healthcare in Qatar. HMC subdivided the services into sixteen hospitals and centers; six community hospitals which are Hamad general hospital (HGH), Al Khor hospital (KH) that serves the North region of the country, Al Wakra hospital (AWH) that serves South region of the county, Hazem Mebaireek general hospital (HMGH), the Cuban hospital (TCH) that serves the Qatar's western part and Primary Health Care Corporation (PHCC) that provide primary healthcare all around the country. Moreover, ten specialized hospitals which are Heart hospital (HH), National Center for Cancer Care and Research (NCCCR), Non-Hamad Institute (NHI), Pediatrics Emergency Center Department (PECD), Qatar Rehabilitation Institute (QRI), Rumelia hospital (RH), Women's Wellness and Research Center (WWRC), Ambulatory Care Center (ACC), Home Healthcare Service (HHCS), Communicable Disease Center (CDC). Each hospital had its own laboratory service and all hospitals utilize OVA system for occurrence and incidents reporting.

1.2 Research Hypothesis and Objectives

The observations described above prompted us to generate a dual hypothesis: 1) that assessing, quantifying and classifying the most common laboratory associated errors in HMC OVA system for the last three years, will identify key performance indicators (origin of errors); and 2) These causes of errors would require an immediate plan of action to improve further the performance of HMC-OVA in monitoring better the incident reporting system.

Pursuant to this goal, we proposed the following specific aims:

(i) To determine the types of laboratory associated errors and

(ii) To analyze the frequencies and causes of these errors

1.3 Background

In 1999, the awareness toward patient's safety, medical errors and the consequent adverse events throughout healthcare systems increased after Institute of Medicine (IOM) published a report called "To Err Is Human" (Kohn, Corrigan, & Donaldson, 2000). Subsequently, guidelines and procedures were developed to improve the medical errors. (Agarwal, 2014; Hollensead, Lockwood, & Elin, 2004; Kohn et al., 2000; Mario Plebani, 2010). Thus, identifying the sources of medical and laboratory errors are very important to reduce and prevent reoccurrence as well as to improve the healthcare system.

Medical errors (MEs) are defined as "an act of omission or commission in planning or execution that contributes or could contribute to an unintended result". The definition explains both causation of errors and malfunctioning processes that lead to errors (Grober & Bohnen, 2005). Moreover, Agarwal classified MEs into four categories; medication (treatment) errors, prevention errors, diagnosis errors and miscellaneous (Agarwal, 2014). Despite medical diagnostic errors vary from 26% to 78%, laboratory errors represents up to 10% of medical errors (Giuseppe Lippi et al., 2009). Several studies revealed that more than 70% of medical decisions on medications, admission and discharge are relied on laboratory results (Abdollahi et al., 2014; Giuseppe Lippi et al., 2009; Sakyi et al., 2015). Although there is a massive number of tests and sample analyses performed in medical laboratories, the percentage of incidental events occurrence is low. However, these incidents in case of occurrence may have a significant impact on patient safety and public health (Grober

& Bohnen, 2005; Shcolnik & Mendes, 2013).

To understand where these incidents can occur, medical laboratory process is divided into: (i) ordering tests and clinical data entry, (ii) specimen collection, (iii) patient identification, (iv) specimen transportation which are carried out outside the laboratories' sites via nurses, physicians and phlebotomists, (v) sample separation, (vi) analysis, (vii) reporting and (viii)-evaluation the results performed within laboratories sites through laboratories personnel and the final step ends with (ix): an action which is taken by physician based on the laboratory results (Yeates, 2016). Noteworthy, all the errors during this cycle had been recognized and reported as part of laboratory incidents whether the incidents occur outside or within medical laboratories' facilities.

Total testing process (TTP) is the process that is activated by requisition of the test via clinician, collection of patient's samples either by phlebotomist, nurses or physicians, delivering samples to medical laboratory department where analysis is completed and ends with interpretation of the results that help the physicians to make informed decisions (Agarwal, 2014). Thus, understanding the potential various error sources within TTP is an essential step for omitting/decreasing the occurrence (Mario Plebani, 2015; Upreti, Upreti, Bansal, Jeelani, & Bharat, 2013). TTP is a complex process that has multifactorial and various sources of errors. International Organization for Standardization (ISO/TS 22367) defined laboratory errors as "failure of planned action to be completed as intended, or use a wrong plan to achieve an aim, occurring at any part of the laboratory cycle, from ordering examinations to reporting results and appropriately interpreting and reacting to them" (Mario Plebani, 2010). This process is traditionally categorized into three phases; preanalytical, analytical and postanalytical errors which could be assessed individually through quality

indicators. Several studies showed that preanalytical and postanalytical phases are more vulnerable to errors than analytical phase, accounting for 62% and 23% respectively (Abdollahi et al., 2014; Hawkins, 2012; Giuseppe Lippi, Guidi, Mattiuzzi, & Plebani, 2006; Mario Plebani, 2010). Restelli and his colleagues also conducted a relevant study showing that most of the reported errors occurred at pre-analytic phase, accounting for 76% of total testing process, whereas, postanalytical and analytical errors account for 18% and 9% respectively (Restelli, Taylor, Cochrane, & Noble, 2017). In addition, other study demonstrated that 89.6% of reported incidents were preanalytical errors, 2.6% and 7.7% were analytical, and postanalytical errors correspondingly. (Ambachew et al., 2018)

However, the analytical phase errors currently represent the minority of the errors in the laboratory settings due to implementing fully automated laboratory system and Laboratory Information System (LIS). This led to reduce human errors. Moreover, participating in internal and external quality assurance programs and monitoring the quality of the services is fully governed (Agarwal, 2014; Hammerling, 2012; Hawkins, 2012; Mario Plebani, 2015).

1.1.1 Sources of Errors in medical Laboratories

1.1.1.1 Preanalytical Errors

Preanalytical errors comprise the highest frequency of laboratory errors where majority of activities performed outside of laboratory quality control and standardized procedures (Mario Plebani, 2012). Moreover, the mistakes in this category are human errors occurring before the samples arrive at the laboratory (Mäkitalo & Liikanen, 2013). International Organization for Standardization (ISO 15189:2012) subdivides this phase into four steps: (i) ordering or requesting the tests that is conducted through physicians, (ii) collection of the specimen by phlebotomist, nurses or physicians(iii) patient identification or labeling of patients samples that is under responsivity of the person who collected the sample and (iv) transportation or delivering the specimen to the medical laboratory (Carraro, Zago, & Plebani, 2012; M Plebani, Sciacovelli, Aita, Padoan, & Chiozza, 2014). Several mechanisms and causes of errors fall under each step in preanalytical phase will be discussed thoroughly in this study.

1.1.1.1.1 Types of preanalytical errors

1.1.1.1.1.1 Appropriate Test Ordering

It is the initial step of preanalytical errors where physicians conducted the selection of appropriate examination to build on evidence-based decisions to answer the formulated clinical question. Errors related to test ordering are not threatening patients' lives. However, it has significant impact in cost effectiveness of the procedure through ordering unnecessary tests that not helping clinical investigation. The main reasons that attributes to inappropriate test ordering are physicians fear from uncertainty or lack knowledge on specific tests such as coagulation genetic testing. Moreover, sometime paper-based requests could be incomplete with missing important detailed. Most of the errors undergo this criterion includes; accuracy of test

ordering, duplicate order and requisition issue. There errors are improved by applying automated system for ordering and clinical data entry (Agarwal, 2014).

1.1.1.1.1.2 Sample Collection Quality and quantity Errors

Lippi et al, 2013, showed that sample collection errors represent the highest frequency and leading cause of preanalytical errors. Inappropriate sample collection procedures result in unsuitable samples for examination and therefore lead to rejection (Giuseppe Lippi, Cervellin, & Mattiuzzi, 2013). A large body of evidence suggests that providing clear guidelines and standardized procedures, training and education for nurses and phlebotomist, continuous evaluation and monitoring of collection procedure can reduce the errors and enhance the improvement of preanalytical phase. There are enormous number of incidents represented in this area. However, in this study we will focus on the most frequent errors such as hemolysis, clotted samples, contaminated samples and errors related to quantity or volume of collected blood.

1.3.1.1.1.2.1 Hemolysis

Hemolysis is the leading cause of preanalytical errors. It is defined as the presence of cell free hemoglobin and intracellular contents in the serum or plasma as a result of breakdown or rapture of red blood cells. This would interfere with laboratory measurements, such as incorrect increase in potassium level (G Lippi, Bonelli, & Cervellin, 2014; Saleem, Mani, Chadwick, Creanor, & Ayling, 2009; Yeates, 2016). This occurs due to conducting unstandardized collection procedure such as drawing blood from catheters regather than straight needle (G Lippi et al., 2014), fast drawing back of syringe plunger, prolonged truncating time and excessive mixing of drawn blood container (Garza & Becan-McBride; Saleem et al., 2009). Hemolysis is the main cause of sample rejection in emergency unit (G Lippi et al., 2014; Giuseppe Lippi et al., 2013).

1.3.1.1.1.2.2 Clotted Samples

Clot formation in samples can be developed during slow fill out the collection of blood in container which is due to prolonged tourniquet usage or following the collection of samples due to incomplete mixture with additives and anticoagulant. For instance, in coagulation testing, clot formation causes consumption and activation of several coagulation factors such as FII, FV, and FVIII VWF. This, in turn, leads to prolonged clotting time that yield to false diagnosis (Favaloro, Funk, & Lippi, 2012). In vitro clot formation in hematology studies leads to low and inaccurate complete blood count (CBC) results, such as reduced red blood cells, white blood cells and platelets counts (Ruf et al., 1997). Atay et al in 2014, showed that clotted specimen was found to be the second common cause of rejection counting for 24% of samples out of 1,035,743 collected samples (Atay et al., 2014). Harsimran Kaur et al 2016, showed that the most common error in the preanalytical stage was clotted sample which accounts for 0.28% of the total samples of 471,006 (Narang, Kaur, Selhi, Sood, & Singh, 2016). A recent study carried by Arul et al. 2018, disclosed that out of a total of 118,732 samples received, 0.12% of preanalytical errors were due to identification of clotted sample in hematological studies (Arul et al., 2018).

1.3.1.1.1.2.3 Quantity of Sample

The quantity of collected blood sample in the container contributes negatively with test results, whether overfilled or underfilled. Thus, due to the interference of different additives inside the tubes that preserve the integrity of the specimen with the reagents used in specific test. Previous studies highlighted the effect of underfilling sample volume on test results. For example, low blood volume in ‘sodium citrate’ container results falsely prolonged clotting times in prothrombin time (PT) and activated partial thromboplastin time (APTT). This due to interference of activated

‘left-over citrate’ with Ca++ that is added during test process (Gaskin & Yahaya, 2019; Peterson & Gottfried, 1982). In addition, Connell et al, 2007 verified that submission of an inadequate volume of blood interferes with blood culture and releases false negative results (Connell, Rele, Cowley, Buttery, & Curtis, 2007). Consequently, all the underloaded and overloaded blood volumes of the samples are rejected in the laboratories. Moreover, a Korean study highlighted that the rate of this error increased in stat section. (Lee, 2019).

1.3.1.1.1.2.4 Contaminated and Diluted samples

Drawing order is the sequence of sample collection procedure which is vital in maintaining integrity of samples and reducing chance of specimen contamination (carryover). The World Health Organization (WHO) and Clinical Laboratory Standards Institute (CLSI) recommendations of drawing orders are: 1- Blood culture, 2- Sodium Citrate (coagulation), 3- Plain serum, 4- Lithium Heparin, 5- EDTA, 6- Fluoride Oxalate. This will prevent contamination of specimen tube with additive from preceding tubes that may cause wrong results (Michael Cornes et al., 2017; Lima-Oliveira et al., 2012). The recommendations of WHO and CLSI were released based on a study carried out by Calam and Cooper 1982 which showed improper drawing orders using syringe i.e. non-evacuated/closed blood collection systems caused hyperkalemia and hypocalcemia, which are invitro representative markers of EDTA contamination (Calam & Cooper, 1982). In addition, Davidson et al. 2002, showed that several chemistry indices/parameters such as aspartate transaminase, calcium, potassium, magnesium, bicarbonate, alkaline phosphatase, creatine kinase, unsaturated iron-binding capacity, lactate dehydrogenase, alanine transaminase and amylase are affected by EDTA anticoagulant. (Davidson, 2002).

Later, several studies have been conducted to study whether drawing orders

errors using modern phlebotomy techniques and materials can be rectified. Fukugawa et al. and Indevuyst et al. highlighted the difference in coagulation results before or after blood sample taken from tubes containing anticoagulants using a closed-loop system. However, anticoagulants have no effect on several chemistry parameters, such as, sodium, potassium, magnesium, calcium and phosphate using the closed-loop system technique (Calam & Cooper, 1982; Fukugawa et al., 2012; Majid, Heaney, Padmanabhan, & Spooner, 1996). Other studies confirmed the same findings on wider range of chemistry parameters (zinc, iron, potassium, magnesium, calcium and ALP) from sample take prior or after collection of EDTA blood using vacutainers (MP Cornes et al., 2012; Sulaiman et al., 2011).

1.1.1.1.1.3 Patients' identification or misidentification

Overloaded systems and shortage of expert staff are the main causes of this error (Giuseppe Lippi, Salvagno, Montagnana, Franchini, & Guidi, 2006). Proper patient identification has significant impact on results accuracy and avoiding misleading diagnosis and therapeutic procedures errors. Misidentification or wrong labelling represents 1% of preanalytical errors. Lippi et al,2009, demonstrated that misidentification of patient's samples could be a life-threatening cause of errors which may be represented in blood bank when patients receiving incompatible blood products (Giuseppe Lippi et al., 2009).

Accordingly, Joint Commission Institute (JCI) and The CLSI recommend improving the accuracy of patient identification through double check of patient's identification and asking them about full name, age or date of birth (Agarwal, 2014). Currently, healthcare organizations introduced automated system for sample labeling and patient identification such as barcodes, magnetic stripes, smart cards and others. Such system improves the accuracy patient identification as well as patient safety. In

addition to the automated system, it is essential to implement policies and guidelines for proper patient identification and continues training and education for the staff, as well as, consistent evaluation for the system (Agarwal, 2014).

1.1.1.1.1.4 Transportation

Transportation of clinical specimen from patients' bedsides as well as satellite phlebotomy services to the lab performing analysis is one of the key factors contributing to both delays in results as wells as exposure to extreme or uncontrolled temperature and physical forces during transportation. This could compromise the quality of samples.

Several studies have been conducted to assess the impact of utilizing manual and automated Pneumatic Tube Systems (PTSs) for transportation. Ravinder et al 2004 showed that PTS induced hemolysis and plain serum samples are more susceptible to hemolysis than the other sample types using PTS (Sodi, Darn, & Stott, 2004). In addition, Streichert et al. 2012 showed that some of serum analytes such as potassium, phosphate, lactate dehydrogenase, and aspartate aminotransferase were affected critically by PTSs transportation (Streichert et al., 2011). Recent studies have shown that PTS has no impact on sample hemolysis, lipemia, or icterus indices compared to the manual transportation method. PTS is considered as a trustworthy and safe for specimen delivery for chemistry, hematology, coagulation and blood gas. However, some recommendations were suggested by Cakirca to minimize potential hemolysis (Cakirca & Erdal, 2017; Pupek, Matthewson, Whitman, Fullarton, & Chen, 2017).

1.1.1.2 Analytical Errors

Analytical errors are related to incidents occurring throughout the analysis of samples. Errors in the analytical phases are classified briefly either as systematic or

random. Systematic errors are concerned with alterations of laboratory equipment calibration while random errors are concerned with errors that occur haphazardly and unconnected to operator. For instance, analytical errors involve laboratory equipment breakdown, quality control failures, and samples mix up or interference.

Previous studies discussed the rate of errors in analytical phase. Koury 1996 showed that the rate of analytical errors ranged from 2 – 30% in Australian laboratories participating in out-house quality assurance program. Pelbani and Crrora 1997 showed that approximately 13% of laboratory associated incidents were due to analytical stage. Later, Bonini et al 2002 conducted a comprehensive literature reviews to study the frequencies of analytical errors and documented that analytical errors accounts for 13- 31% of lab associated incidents (Bonini, Plebani, Ceriotti, & Rubboli, 2002; Mario Plebani & Carraro, 1997). A 10-year follow-up study by Crrora and Pelbani 2007 showed that the analytical errors accounts for 15% of lab errors (Carraro & Plebani, 2007). Westgard et al, 2006 showed that there is still a need for improvement analytic quality of laboratories and set satisfactory performance standards for the Clinical Laboratory Improvement Amendments (CLIA) (Westgard & Westgard, 2006).

Moreover, immune-assays are associated with high incidence of analytical errors with clinical adverse events (Ismail, 2009; Tate & Ward, 2004). These analytical errors were seen in several branches of medical laboratories such as hematology, chemistry, immunology, coagulation and molecular biology and others. The technical errors in these studies could be attributed to that the laboratory methods were not fully automated, laboratory technology was in very early stage of development, insufficiency of assay standardization, uncertainty in rules for quality control, ineffective quality assurance schemes and lack of trained staff at that period.

1.1.1.3 Postanalytical Errors

Post analytical errors are associated with the interpretation and reporting of results such as validation of discrepant results, incorrect results interpretation, unbound to turnaround time, failure or delayed critical results. The JCI defines the critical results as "A test result that is significantly outside the normal range and may represent life-threatening values" (Bonini et al., 2002; Giuseppe Lippi & Mattiuzzi, 2016). Noteworthy, 37% of patients with critical result had not been followed up by physicians and 1% of patient with critical results were discharged without notifying the physician in-charge (Roy et al., 2005; Wahls & Cram, 2007).

A detailed review conducted by Caslaino et al 2009 also revealed that post analytical processes such as reviewing of patients results, notification of critical and significant patients' results and proper follow up were missed in around 7% of cases. A recent study showed the impact of failure to communicate efficiently a critical result as a possible cause of adverse events and complications in 70.0% and 60.4% of cases. The study also showed that communicating critical results led to change treatment plan and admitting to the hospital in 98.0% and 90.6% of patients respectively. In addition, the study also demonstrated that critical results were found to be unexpected findings in more than 40.0% of cases (Piva, Pelloso, Penello, & Plebani, 2014). Consequently, lack and delayed communication of critical results are clearly recognized as major source of errors, an issue that needs to be addressed comprehensively by both the clinical team and laboratory staff. These studies suggested that effective and timely reporting of critical results is crucial factor for ensuring patient safety and optimizing the clinical management.

1.1.2 OVA Errors Reporting System

IOM report "To Err Is Human" emphases the awareness of reducing medical

errors and their impact on the public health and safety. This repot also highlighted the importance of reporting these errors, which is a cornerstone for preventing their occurrence. Thus, HMC has implemented OVA system which is a web-based tool for reporting incidents and safety event through HMC Electronic Incident Reporting System (EIRS). OVA is stand for occurrence, variance and accidents; each term has its own definition. Occurrence is “An event that results in a loss to a third party due to bodily injury, or property damage or destruction”. Variance is defined as “A difference between what is expected and what actually occurs; an event that departs from expectations; an act contrary to a usual rule”. Accident is defined as “An unplanned, unexpected, and undesirable event, which occurs suddenly and results in damage, injury or harm ” (Grober & Bohnen, 2005).

This system is confidential and accessible for all HMC staff where errors and safety events are collected, tracked and analyzed. Such system allows the laboratory technologist, administrators and quality personals to capture and resolve incidents before delivered to patients care and causing harm. As well as preventing their recurrent through developing a corrective action plan.

In this research we studied the reported incidents available in OVA system in HMC laboratory department for the last three years, in order to investigate which category has the most common laboratory associated errors in HMC laboratory department during this period and the reasons behind their occurrence.

CHAPTER 2: MATERIALS AND METHODS

2.1 Ethical compliance and approval

This is a quality improvement project thus no ethical approval is required. This project was exempted from review by Qatar University research committee and was approved by chairpersons of Departments of Laboratory Medicine and Pathology (DLMP) and Quality Improvement (QI) *(Please refer to appendix 7.1).*

2.2 The study designs

This is a retrospective study including 38,814 OVA incidents which were collected from laboratory information system (LIS), from first of January 2017 up to thirty first of December 2019. The inclusion criteria are OVA reporting of three categories such as preanalytical, analytical and postanalytical categories. The exclusion criteria are other reports such as all health and safety.

2.3 Location of the Study

This study was conducted in DLMP of HMC specifically at the Quality Management Department. Data collection from 28 laboratory services of DLMP (Table 1) across 16 hospitals/centers were reviewed (Table 2).

Table 1. List of laboratories services

Lab service	
KOR	AL KHOR
WAK	AL WAKRAH
TRM	BLOOD BANK HGH

Lab service	
BDC	BLOOD DONOR COLLECTION BLOOD DONOR CENTER- HGH
CCS	CHEM/SEROLOGY, CCL QRI
CHE	HEMATOLOGY, CCL QRI
DCH	DUKHAN CUBAN HOSPITAL
CTL	CELLULAR THERAPY LAB
CYP	CYTOPATHOLOGY
CYT	DGD CYTOGENETICS-QRI
MOL	DGD MOLECULAR GENETICS/PRE-MARITAL SCREENING
HMH	HAZM MEBAIREEK GENERAL HOSPITAL CORE LAB
HTS	HEART/CARDIO HOSPITAL
HIS	HISTOPATHOLOGY
HLA	HISTOCOMPATIBILITY AND IMMUNOGENETICS-HBKMC
IMM	IMMUNOLOGY-HBKMC
FMM	MORTUARY-HGH
PCR	LABORATORY SERVICES/SPECIMEN CONTROL
MET	METABOLIC -RUMAILAH
MIC	MICROBIOLOGY-HGH
NCCCR	NCCCR LAB
PEC	PEDIATRIC EMERGENCY CENTER
POC	POINT OF CARE
QBB	QATAR BIO BANK LAB
RRC	RAPID RESPONSE CORE-HGH
SCH	CHEMISTRY SPECIAL -HBKMC
TBR	TB REFERENCE RUMAILAH
VIR	VIROLOGY/MOLECULAR BIOLOGY

Table 2. List of hospitals and centers

Hospitals and Centers	
Al Khor Hospital	AKH
Al Wakra Hospital	AWH
The Cuban Hospital	TCH
Heart hospital	HH
Hamad General hospital	HGH
National Center for Cancer Care and Research	NCCCR
Non-Hamad Institute	NHI
Pediatrics Emergency Center Department	PECD
Qatar Rehabilitation Institute	QRI
Primary Health Care Corporation	PHCC
Rumelia hospital	RH
Hazm Mebaireek General Hospital	HMGH
Women's Wellness and Research Center	WWRC
Ambulatory Care Center	ACC
Home Healthcare Service	HHCS
Communicable Disease Center	CDC

2.4 Data collection

OVA reports were collected from Laboratory Quality Management department at HMC. OVA were classified according to the laboratories' locations (Table 1), type of errors: preanalytical, analytical, post analytical, and specific characteristics of incidents under each category, such as, hemolyzed sample, clotted samples, discrepant results, delayed critical values and other errors. (Table 3)

Table 3. List of specific characteristics of incidents under each category

Types of Errors (Categories)	Specific Characteristics of Incidents
Pre-analytical (Pre-examination)	All aspects related to examination ordering.
	All aspects related to sample collections.
	All aspects related to sample transport.
	All aspects related to sample receiving and processing.
Analytical (Examination)	Examination method selection including validation.
	Examination performance (covering waived – non-waived testing, qualitative / quantitative testing).
	Quality control program (calibration, QC management).
	Reagent validations / linearity studies (where applicable).
	Review of examination results including QC review, error corrections.
	Result interpretations applicable on different levels throughout the DLMP (e.g. immunology, biochemistry, hematology morphology, frozen section, histology, cytopathology).
Post-analytical (Post examination)	Preliminary reports - final reports.
	Report turnaround times (TAT).
	Corrected reports.
	Sample management, including sample storage, sample retention, sample indexing (e.g. histo-cytopathology) after analysis process.

2.5 Statistical analysis

Descriptive statistical analysis was performed by Microsoft Excel office 365, and frequencies as well as the percentages of incidents were determined.

CHAPTER 3: RESULTS

3.1 OVA error reporting across HMC

A total of 38,814 OVA incidents were reported from first of January 2017 up to thirty first of December 2019. Incidents reported in 2017, 2018 and 2019 were 18,679 (47.6%), 15,347 (40.0%), 4,788 (12.4%) respectively. Overall reporting of incidents across the three years is illustrated in (Figure 1) and reveals a gradual decrease in the number of reported errors.

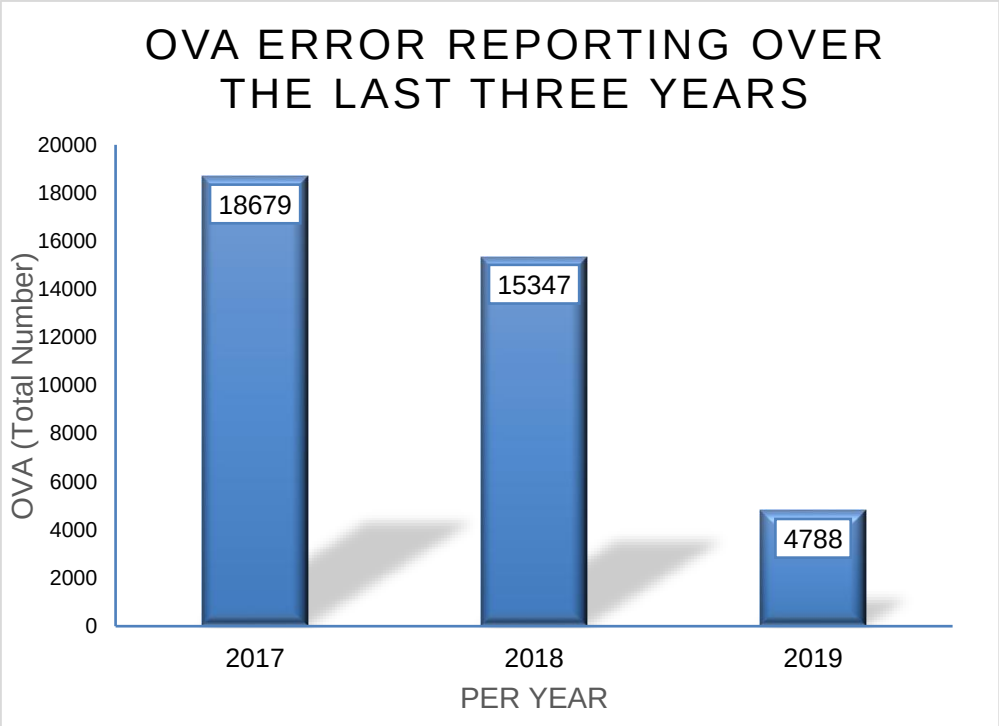

Figure 1. Decrease in OVA error reporting across HMC over the last three year

3.2 Distribution of OVA reporting errors

To study the most common category of accidental event across the three years, results obtained from OVA have been grouped into three categories including 36846 (95%) for preanalytical, 979 (2%) for analytical, 989 (3%), for postanalytical phase as demonstrated in (Figure 2).

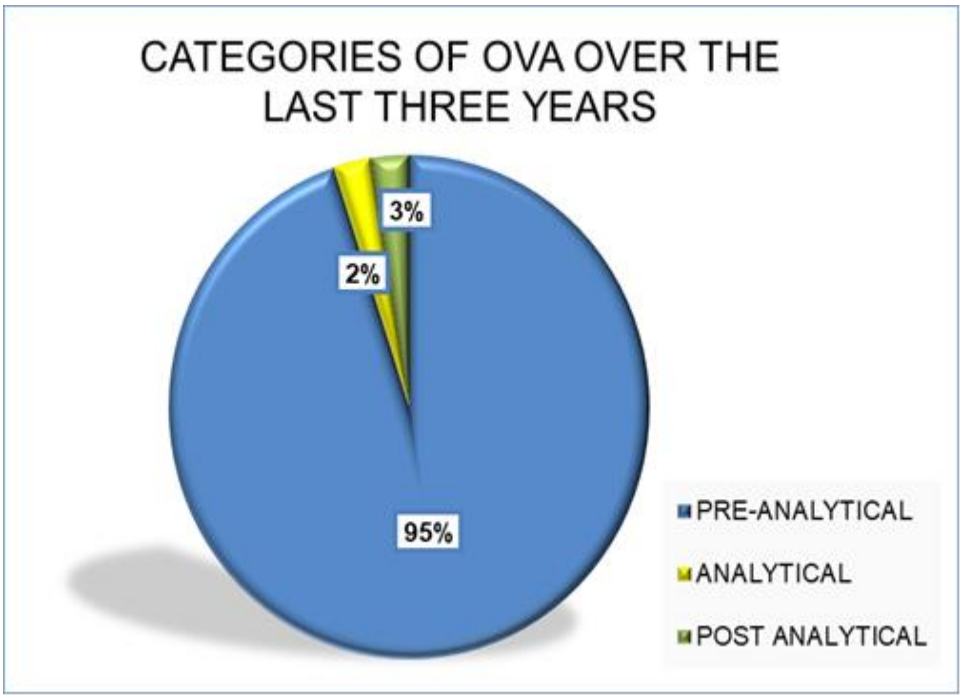

Figure 2. Categories of OVA across HMC over the last three years in general

Furthermore, we conducted in depth analysis of the three categories per year. In 2017, out of 18679 OVA errors, 18063 (96.7%) OVAs were classified as per analytical, 326 (1.7%) as analytical, 290 (1.5%) as post analytical. In 2018, out 15347 (100%) OVA reports, 14392 (93.7%) were classified as per analytical, 585 (3.8%) as analytical, 370 (2.4%) as post analytical. In 2019, out 4788 (100%) OVA errors, 4391 (91.7%) OVAs were classified as per analytical, 68 (1.4%) as analytical, 329 (6.8%) as post analytical (Figure 3).

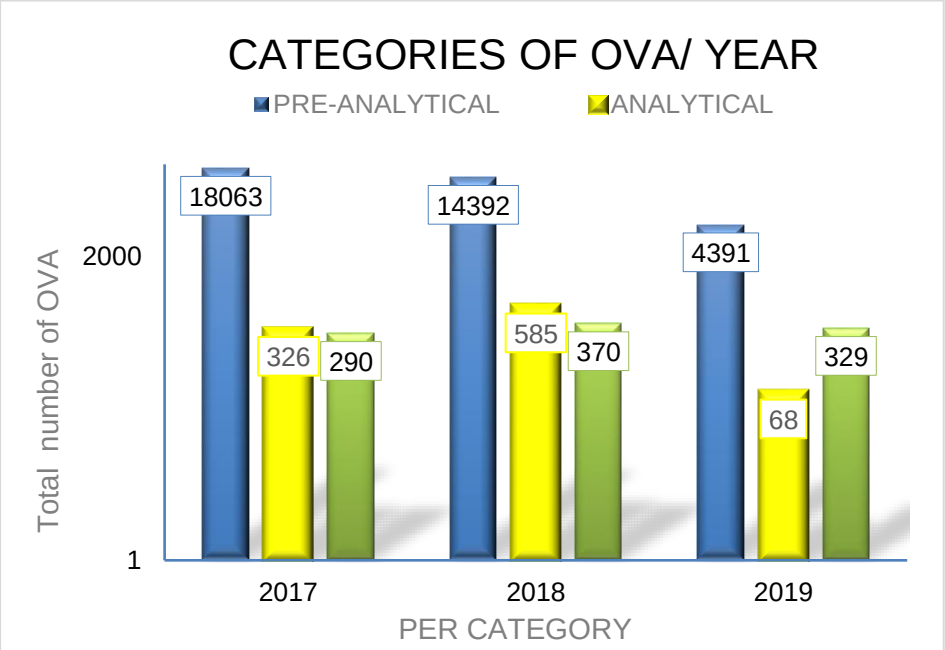

Figure 3. Categories of OVA reporting across laboratories over the last three years by year

3.3 OVA reporting errors by laboratories

In order to identify which laboratories contributed mainly to OVA reporting, we conducted further analysis by location. We found that three laboratories contributed to 24283 (62.45%) of total reporting errors. These laboratories were CHE, RRC and NCCR and contributed to 11084(28.56%), 9500 (24.48%) and 3654 (9.41%) of the reporting, respectively (Figure 4).

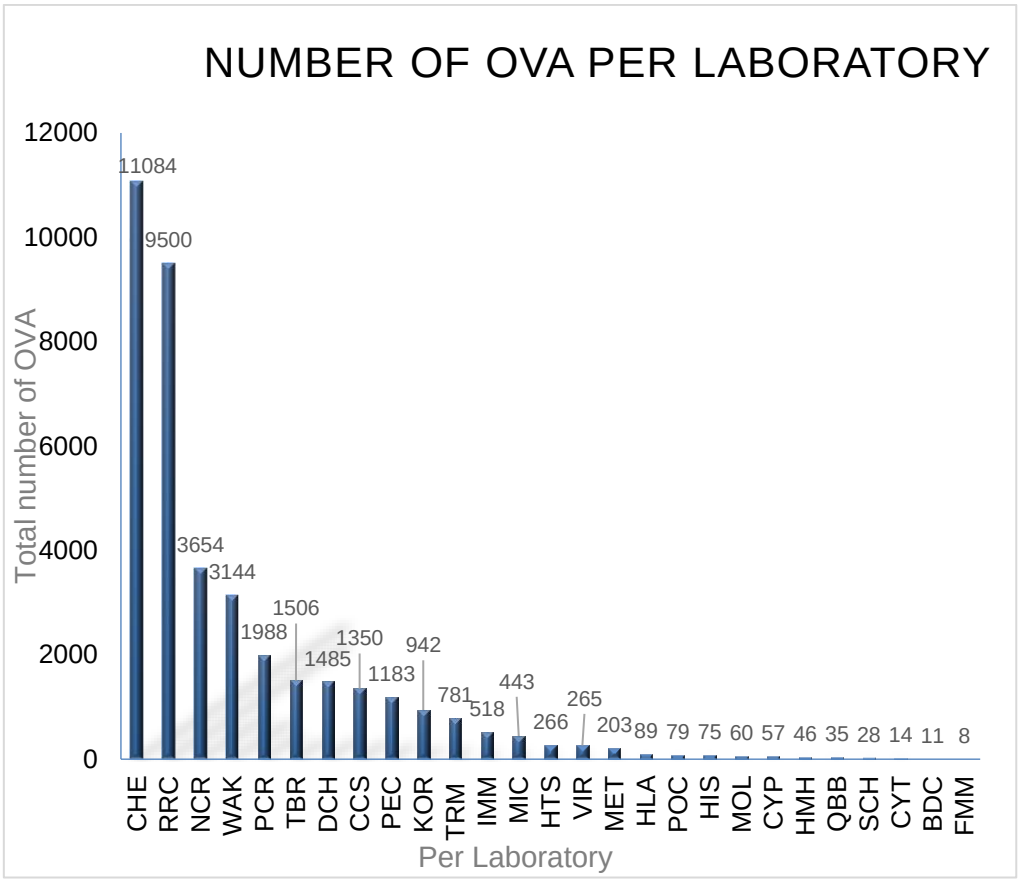

Figure 4. The status of OVA reports across HMC laboratories over the last three years

3.4 OVA categories in the three laboratories

To study the contribution of the three laboratories to OVA categories, we found that CHE laboratory enclosed 10825/11084 (97.7%) preanalytical category, 259 (3.3%) postanalytical category, and none of analytical category. On the other hand, RCC enclosed 9435 (99.3%) of preanalytical category, 61 (0.6%) and 4 (0.04%) postanalytical and analytical categories respectively. While NCCCR had 3465 (94.8%) preanalytical,166 (4.5%) postanalytical and 25 (0.7%) analytical categories (Figure 5).

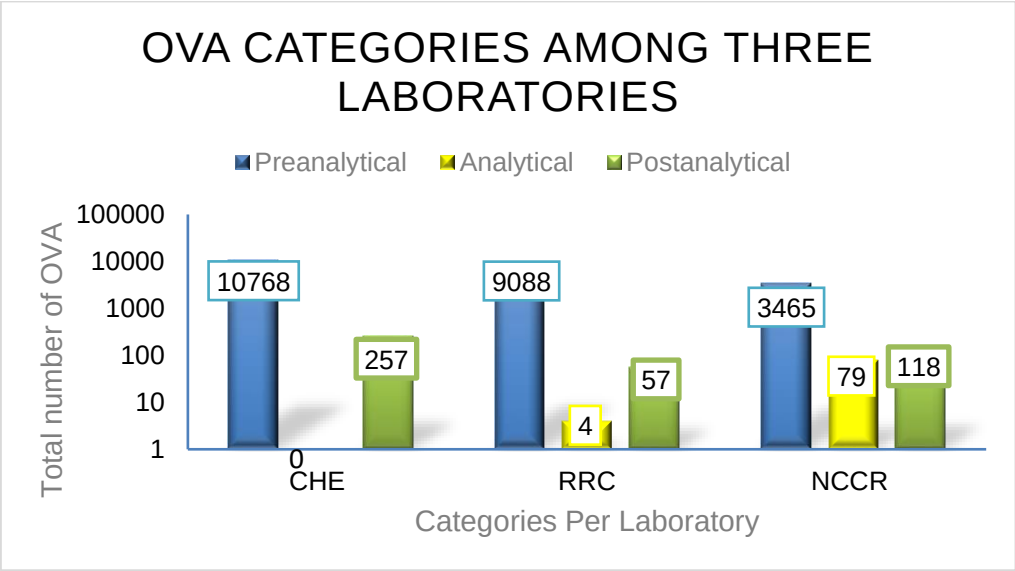

Figure 5. OVA categories among the three laboratories

3.5 OVA breakdown causes in the three laboratories

In order to understand the main causes under each category, we studied incidents main causes in detail.

3.5.1 Preanalytical category causes

We found that clotted 12070 (51.8%), hemolyzed 6359 (27.2%), and patient samples quantity not sufficient (QNS) 2971 (12.7%), were the most common causes counts for 21400/ 23321(91.7%) of total preanalytical category in the three laboratories (Figure 6).

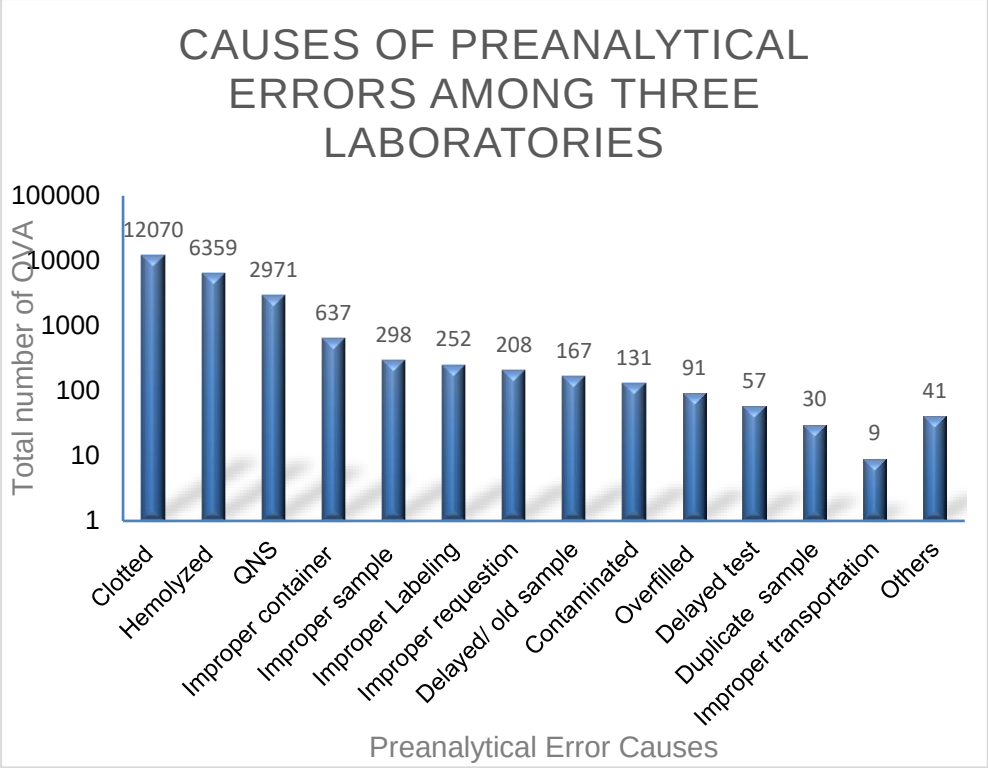

Figure 6. The preanalytical causes in three laboratories

3.5.2 Analytical category causes

Quality control problems and equipment errors were found to be 24 (82.8%) and 5 (17.2%) respectively in the analytical category (Figure 7).

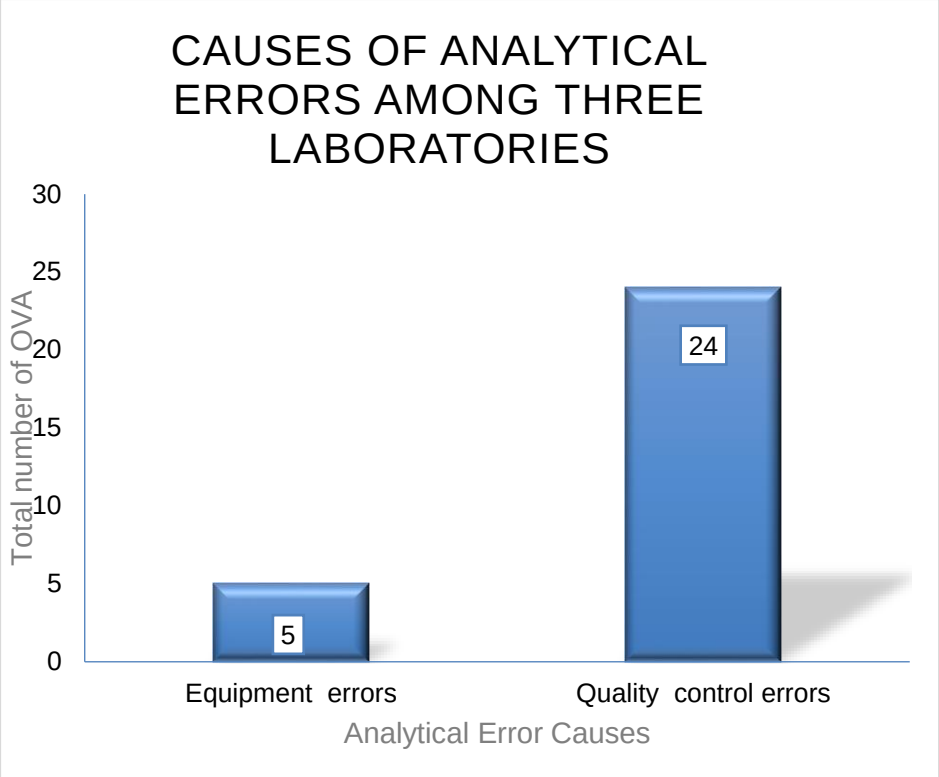

Figure 7. Analytical errors causes among the three laboratories

3.5.3 Postanalytical category causes

In addition, we found that the delay in critical results relaying counts 246 (50.4%) and Discrepant results 242 (49.6%) in the postanalytical category (Figure 8).

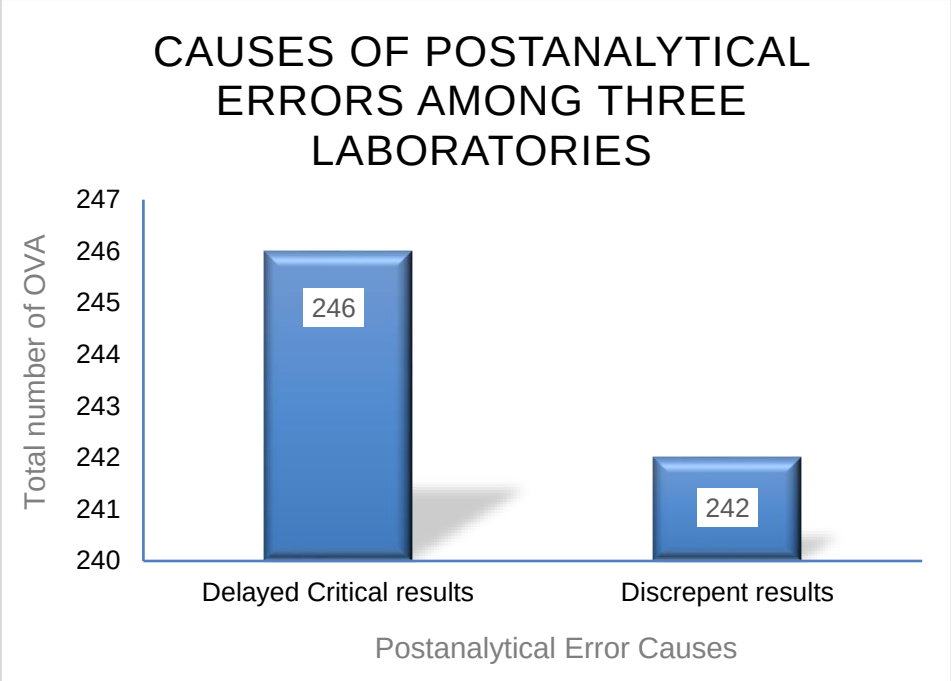

Figure 8. Postanalytical errors causes among the three laboratories

CHAPTER 4: DISCUSSION

Quality improvement is one of essential components for all healthcare systems. Thus, minimizing and reducing protentional errors in the healthcare system processes is a key factor to increase patient's safety and prevent any potential adverse events. This study was conducted to determine the different types of laboratory associated errors and analyzing the frequencies and causes of these errors retrieved from OVA reporting system. This retrospective study is considered as the first of its kind to describe the OVA reporting in the referral laboratory department in the whole country.

In this study, a total of 38,814 OVA incidents were studied from first of January 2017 up to thirty first of December 2019. The study was conducted to analyze the frequent causes of errors and classify them into three categories: preanalytical, analytical and postanalytical phases; through individual year and through location where incidents were discovered and reported.

Moreover, further investigation had been conducted to breakdown the causes of errors or accidental events via studying the three laboratories which contributed to the highest OVA reporting in the hospital that represents (62.45%) of total reporting errors.

Our results revealed a gradual decrease in reporting of errors during the three years. A total of 38,814 OVA incidents distributed through 2017, 2018 and 2019 were 47.6%, 40.0%, 12.4% respectively (Figure1). The reduction of OVA reporting in 2019 doesn't truly reflect that there is an actual decrease of incidents or errors, but it was mainly attributed to revising of OVA guidelines in which specific incidents such as single event of hemolyzed and clotted samples were not reported since October 2018.

Overall classification of reported errors showed 95% were preanalytical errors, 2% and 3% of errors were analytical and postanalytical respectively (Figure2). Our results represent higher percentages of preanalytical errors and lower percentages for analytical and postanalytical errors. However, other studies showed that preanalytical incidents are up to 76%, postanalytical incidents are up to 23% and analytical incidents are up to 15% (Hawkins, 2012; Giuseppe Lippi, Guidi, et al., 2006; Mario Plebani, 2010; Restelli et al., 2017). On the other hand, one study showed higher percentage in the analytical errors as compared to postanalytical errors, 23.2% and 11.68% respectively (Abdollahi et al., 2014). At HMC the analytical phase is fully automated which justify our data as we have the least error rate.

Moreover, this study investigates the reporting of incidents through 27 HMC laboratories according to each category i.e. preanalytical, analytical and postanalytical categories. Our results showed that only three laboratories contributed 62.45% of total reporting errors. These laboratories were CHE, RRC and NCCCR and their errors account for 28.56%, 24.48% and 9.41% respectively (Figure 4). Noteworthy, CHE provides service to all 16 HMC hospitals which explain the high incidents reports. On the other hand, NCCCR laboratory provide service to three main hospitals and RRC provides laboratory service for in and outpatient of HGH and Accident center.

The classification of the errors in each laboratory demonstrated about 94.8%-99.3% preanalytical errors, 0.6%-3.3% postanalytical errors and 0%-0.7% analytical errors (Figure 5). The absence and low number of OVA in the analytical phase could be attributed to two main reasons either due to utilizing fully automated systems or due to under reporting. The incidents details or breakdown causes of errors are varied amongst the laboratories, since, each laboratory has its unique patients' nature and service providing.

Moreover, this study demonstrated that 91.7% of sample rejection in preanalytical category in the three laboratories were due to errors in blood collection procedure such as clotted, hemolysis, and insufficient blood volume that account for 51.8%, 27.2%, and 12.7%, respectively (Figure 6). These errors occurred during blood collection process which is usually conducted by nurses or phlebotomists outside the laboratory control. Our results concord with Lippi et al,2013, findings, emphasizing that the collection process is the leading cause sample rejection in preanalytical phase (Giuseppe Lippi et al., 2013).

However, our results represent 0.04% of analytical errors. We also found that in the three laboratories most of the incidents under this category were related to systemic errors that include quality control issues and equipment errors that accounts for 82.8% and 17.2% respectively (Figure 7). Our findings were similar to study conducted by Ambachew et al., 2018, where quality control issues were the main error in this phase (Ambachew et al., 2018). However, the repetition of such errors may lead to delay in the processing of the tests, which consequently cause delayed in releasing test reports. In contrast, our analytical errors were lower than other studies as they perform manual analytical methods (Bonini et al., 2002; Ismail, 2009; Westgard & Westgard, 2006)

We found that 50.4% of the postanalytical errors were due to delay in critical results reporting and 49.6% were due to discrepant results, which is a consequence of wrong collection process (Figure 8). Despite the high percentages of causes of postanalytical errors, the total percentage of postanalytical errors among the three laboratories were 3.3% which is lower than other studies (Abdollahi et al., 2014; Hawkins, 2012; Restelli et al., 2017). However, these errors cannot be neglected due to their significant impact on patients health and safety (Piva et al., 2014).

Recommendations

In order to improve the quality of OVA system and minimize the occurrence of future incidents, the study recommends providing proper and continuous quality training program, education and personnel competency assessment for laboratory staff, phlebotomists, nurses and allied health support to reduce collection related errors. As well as increase the awareness between staff for the importance of reporting any incidents and improving communication among laboratory professionals and other departments that enhance improving the quality of the service. Moreover, provide continuous and regular assessment and evaluation of OVA system such as implementing a unified template for reporting errors to minimize intra and inter individual expressions for errors. Finally, we do recommend to have two additional OVA categories such as Pre-pre-analytical and Post-post-analytical that may have great value in influencing the laboratory's tactic to potential error management by acting as an obvious reminder of the error-prone nature of lab study assortment and interpretation activities.

Future directions

This study provides a baseline data for future investigations to study in details the root causes analysis of all errors in each category. In addition, to study the preanalytical phase errors according to the departments of patients, the sections of the laboratory, and the wards involved. Furthermore, to analyze the severity of the errors and their consequence on patient safety and healthcare properties. Thus, provide correction action to eliminate the activities that may cause the greatest risk on patient health and safety. Moreover, studying the cost effectiveness for the most frequent errors in preanalytical phase such as test ordering errors by physicians, errors related to collection process and transportation.

Limitations of the study

This is a retrospective study, where the researcher has no control on the reported incidents in OVA system. In addition, in this study we cannot account for unreported incidents.

CHAPTER 5: CONCLUSION

This study found that preanalytical category are the major source of reported errors in OVA system which accounts for 92%. Large number of OVA reported errors are from CHE, RRC and NCCCR laboratories. The main reason for sample rejection were due to errors in sample collection process which is conducted by nurses and phlebotomist. OVA error reporting system in HMC provides assistances to study the different types, causes and frequencies of laboratory associated errors in order to improve the quality of clinical laboratory services. However, further studies are still needed to investigate the impact of preanalytical errors on the cost of testing.

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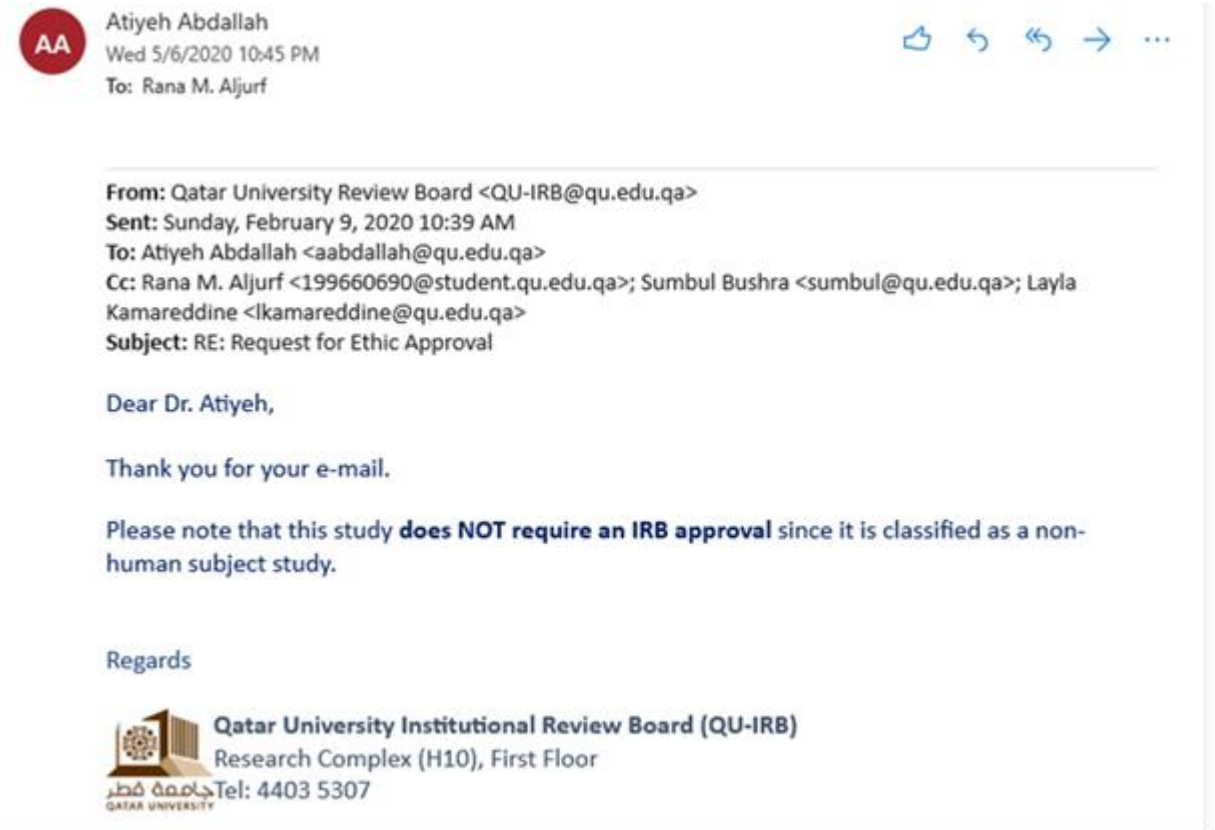
APPENDIX

7.1 Appendix 1 QU-IRB exempted letter



AA

Atiyeh Abdallah
Wed 5/6/2020 10:45 PM
To: Rana M. Aljurf

From: Qatar University Review Board <QU-IRB@qu.edu.qa>
Sent: Sunday, February 9, 2020 10:39 AM
To: Atiyeh Abdallah <aabdallah@qu.edu.qa>
Cc: Rana M. Aljurf <199660690@student.qu.edu.qa>; Sumbul Bushra <sumbul@qu.edu.qa>; Layla Kamareddine <lkamareddine@qu.edu.qa>
Subject: RE: Request for Ethic Approval

Dear Dr. Atiyeh,

Thank you for your e-mail.

Please note that this study **does NOT require an IRB approval** since it is classified as a non-human subject study.

Regards

Qatar University Institutional Review Board (QU-IRB)
Research Complex (H10), First Floor
جامعة قطر QATAR UNIVERSITY Tel: 4403 5307