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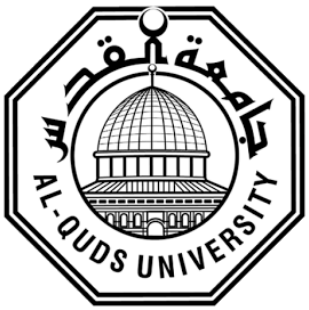

"Patient Safety during Pre- and Post-analytical phases of clinical testing in Beit Jala hospital"

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“Patient Safety during Pre- and Post-analytical phases of clinical testing in Beit Jala hospital”

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Patient Safety During Pre – and Post – Analytical Phases of Clinical Testing in Biet Jala Hospital

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DEDICATION

In thankfulness this thesis is dedicated to my wife, Haya, and family, my friends and to everyone who supported me in accomplishing this work

Michael William Lama

DECLARATION

I certify that this thesis submitted for the degree of Master in Health policy and management is the result of my own research, except where otherwise acknowledged, and that thesis or any part of it has not been submitted for a higher degree to any other university or institution.

Singed:

Michael William Ibrahim Lama

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Abstract

Background: Recent studies show that most work was done on patient safety in the laboratories in the analytical phase and the results show that the percentage of errors in that phase is not highly significant compared to the more numerous errors found in pre- and post-analytical phases. Most of the studies nowadays, concerning patient safety in clinical laboratories, focus their direction on the pre- and post-analytical phases, in which they found the majority of errors occur in the diagnosis of the patients. The aim of this study is to determine the level of patient safety during pre and post-analytical phase of laboratory testing in Beit Jala Hospital.

Methodology: An observational study was done in Beit Jala Hospital for a six month period in five acute departments, with a sample number of 450 laboratory specimens, and these observations were focused during the peak of work.

Results: The study results indicated that the pre-analytical phase have more percentage of errors that the post analytical phase after assessing certain departments in Beit Jala Hospital (Surgical, maternity, pediatric, internal medicine and oncology) in the area of patient safety in the pre- and post-analytical phases, also the study focuses on the personnel characteristics of the medical staff who did the work in the pre-analytical phase, step by step beginning with the tray or rack of the specimen collector, Clerical work, the process of venipuncture, trouble shooting and finally the specimen handling. The most noticeable errors in these steps were in the use of tourniquets and sharp disposal containers, no tourniquets were used in 350 observations, also it was found that errors increase when trainees were doing the venipuncture process, handling the samples to the right place at the right time was the best category of all other categories, and the lowest number of errors was noticed in that category, the noted points were that they handle the tubes properly, at the right place, and at the right time.

The post analytical phase focuses on the data entry, communication of results, result losses and repeated tests. The major problem that was noticed in the post-analytical phase was found in retrieving the results in the patient files with a percentage of 5% lost results. Moreover, the laboratory technicians have to reject and repeat about 4.7% of the results because the clotted samples or insufficient or other sampling problems. The good thing that was noticed in the post-analytical phase in Beit Jala Hospital is that because of sufficient number of the team working in the laboratory there was only 1% delay in the results and this happens only when they receive the samples delayed.

Conclusion and recommendations: there was found no significant relation between the results in the pre- and post-analytical phases because of the different health workers who do the job in each phase, and also the percentage of errors that were found in the pre-analytical phases are more significantly than the errors in the post-analytical phases, it can be noticed that the results of the observations were found to be the same in other studies globally, and the other researches also was found that the percentage of errors were higher in the pre-analytical phase than the post-analytical phases in their results. Some of the recommendations were to develop policies and guidelines to the pre- and post-analytical phases of laboratory, training programs should be introduced, an infection control program should be also introduced, providing adequate supplies and resources and equipment which are necessary to use such as tourniquets, syringes, test tubes, recording all errors if it happens, introducing management information system program to the hospital to eliminate the post analytical errors.

English key words

Patient Safety, Laboratory Testing, Pre-Analytical Phase, Post-analytical Phase, Lab errors, Clinical laboratory improvement, Guidelines to patient safety, Sample collection, Sample handling, Venipuncture procedure, Improve patient safety, Medical errors, Quality management, Phlebotomy, Total testing process.

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Acronyms and Abbreviations:

Abbreviations	Abbreviations Expansion
CAP	College of American Pathologists
EC	European Commission
EU	European Union
JCI	Joint Commission International
MOH	Ministry of Health
NGO	Non-Governmental Organization
NHS	National Health System
TTP	Total Testing Process
ISO	International Organization for Standardization
CLSI	Clinical Laboratory Standards Institute
Q- Probes	An external peer comparison program sponsored by the College of American Pathologists that addresses process, outcome, and structure-oriented quality assurance issues
Q-Tracks	A College of American Pathologists program of continuous laboratory monitoring and longitudinal tracking.
Error	Any procedure that is done with differences from guidelines

Chapter One: Introduction

1.1 Introduction

Nowadays, patient safety in receiving significant attention worldwide. Many patients worldwide are affected by medical errors most of which come from human error. In a report for medical laboratories in the United States of America (USA) there was a study that shows (46% - 68%) of errors occur in the pre- analytical phase, (7% - 13%) in the analytical phase and (25% - 46%) in the post-analytical phase. (Hawkins, 2012). Unfortunately, in Palestine, we have small evidence that show statistics about the number of errors that happen in the pre- analytical, analytical and post-analytical phases.

We believe that most mistakes came from the pre- and post-analytical phases of clinical laboratories and mistakes in the pre-analytical phase have a higher percentage than mistakes from the analytical phase. The high percentage of errors affects laboratory test results and therefore they have an effect on the percentage of analytical and post-analytical errors.

All physicians and patients need accurate and reliable laboratory results that occur within one standard deviation, so that they can diagnose properly. Therefore diagnoses and improved treatment depend on these results; any error in the results will be reflected directly on the patient.

It is known that all staff working in hospitals who deal with specimens has studied the procedures of pre- and post-analytical phases such as specimen collection, labeling and delivering, but most of the times they miss use the procedures. In more than one hospital it was discovered that most errors come from the pre and post analytical phases, which are dealt with as non-important issues. By not using these procedures, they increase the number

of errors and the analytical and post-analytical mistakes, which eventually decrease the patient's safety and may harm the patient more than cure the disease.

In this study, the pre- and post-analytical phases looked at to identify incidences of laboratory related errors which occur in the pre and post analytical phases of laboratory testing, and to determine incidences that may hinder the implementation of quality systems in order to increase patient safety

1.2 Study Problem

Recently, patient safety has evoked national attention on giving more care to patients and patient safety in laboratory hospitals took the headlines in the beginning of this century because all patients need to get care in a safe and secure health care organization. Worldwide reports show that most errors are human errors(Wagar, 2006). It was estimated in the USA that more than 100 million Americans where effected by medical errors which cost them about $200 billion a year (WHO, 2013). The majority of errors that affect patient safety appear to be in the pre-analytical, analytical, and post-analytical phases (Plebani, 2012).

All laboratories worldwide have introduced new methods, such as internal and external quality control and procedures that deal with both pre- and post-analytical phases in order to get more accurate results and fewer errors. They also try to assure patient safety with new procedures. Despite all these interventions, errors still occur in the laboratory phases and most reports concern errors that effect patient safety and show the same results, namely that most errors occur in the pre analytical phase and less in the other phases.

Unfortunately, in Palestine there is no obligatory consistent and systematic external quality control but these is an internal quality control monitoring and few researches were done to show the quality of patient safety and in what areas of health errors occur.

On the other hand the Palestinian Ministry of health (MOH) participated in the program of "Patient Safety Friendly Hospital Initiative (PSFHI)" of the World Health Organization. The PSFHI includes a set of standards to be practiced in health care facilities in order to ensure safe patient services, but there is still no data to show if the MOH has succeeded in its goal of improving patient safety

This study noted the presence of patient safety in the pre-and post-analytical phases in Palestinian clinical laboratories in order to find the kind of errors that have an effect on patient's health. Furthermore these errors also have a cost effect on the Ministry of Health; noted in "health care expenditures in the secondary and tertiary care" and increased occupancy rate in the hospitals.

1.3 Study Justification

The Patient Safety issue should be introduced with great emphasis into Palestinian government hospital laboratories with special focus on the pre- and post-analytical phases. The importance of a study like this is to challenge the staff that works in hospitals, to increase the quality of work by putting standards and strategies to their work, as well as challenging them to reduce patient harm and reminding them of the importance of a patient as a human being and not an object to trade with their life. New lab technicians should be aware of this situation, which they may think doesn't matter, but on the contrary most medical errors that occur during these phases in hospitals cause great harm, such as more

complications or even death, or it may increase the days of hospital stay which surely will increase costs on both sides.

Studying patient safety is not easy in West Bank hospital medical laboratories. To introduce such programs, the laboratories must work on criteria and international standards to achieve an international level of safety. There are many reasons which slow down introducing such programs in West Bank. One of the most important reasons is that few hospitals had perform a survey or a study like that, and in my opinion some hospitals may not accept these safety programs easily for their hospital. For that reason the researcher explained to the hospital administration that this research is in the area of patients' safety, and to show evidence based on the results of having such research in their hospital and the cost benefits from implementing a strategy to assure higher patient safety in the pre- and post-analytical phases of the laboratory. On the other hand Palestinian patients must be in a safe place where they get proper care. Patients will be more confident in the hospitals if they knew that these hospitals are working with good standards and procedures and will also be more comfortable in safer places and trust will be built between both sides.

1.4 Research Objectives

1.4.1 Aim & Objectives of the Study:

The aim of this study is to determine the level of patient safety during pre and post-analytical phase of laboratory testing in Beit Jala Hospital.

1.4.2 Specific Objectives:

- To identify incidence of laboratory related errors or deviations from guidelines standards that occurs in the pre-analytical phases of laboratory testing.

- To identify incidence of laboratory related errors or deviations from guidelines standards that occurs in the post-analytical of laboratory testing.

- To determine the challenges that might hinder the implementation of patient safety in laboratory testing.

1.5 Potential Difficulties & Limitations

One of the limitations is that this study was conducted in Beit Jala hospital only because this study is an observational study which takes a long time and so the researcher could not cover more than one hospital but he can cover more than one department in the one hospital. Therefor findings cannot be generalized to MOH hospitals.

Another limitation is that the study is conducted during the morning shift only and no observations are done on other duty shifts. Normally errors do not happen during a specific period of time but may happen anytime.

Chapter Two: Literature Review

2.1 Patient Safety

There are more than one definition for patient safety between the dictionaries and the different National Health system (NHS). All of them agreed on the same results. Here we have the World Health Organization's (WHO) International Classification for Patient Safety defines patient safety as, "*the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment*" (WHO, 2013).

The European commission (EC) definition for patient safety as *"freedom for a patient from unnecessary harm or potential harm associated with healthcare"*. The patient safety concerns the European Union (EU) because they notice that the errors are occurring in around 10% of the cases in the hospitals in the recent years, with all the precautions that they set in their health care including primary care, secondary care, community care, social care and private care, in acute and chronic care. In 2005, Member States of the EU put the patient safety at high position in their agenda and they began a mechanism to discuss and take forward patient safety issues as a priority. A lot of efforts are taken to improve patient safety in the EU and these efforts depend on the strong and sustained policies and programs that are put in place throughout Europe (EU, 2009).

2.2 Patient Safety in the Clinical Laboratory

In Recent years healthcare programs have increased their interest in patient safety and quality improvement. Clinical laboratories are a major part of healthcare which has an important relationship to patient safety and quality improvement. Clinical laboratories normally are concerned with the quality of the results in the analytical phase. These days they are moving beyond the analytical phase to the pre- and post-analytical phases, where most errors occur (Hawkins, 2012).

The total testing process (TTP) begins with questions in the physician's brain about the patient situation, test selection, sample collection, transporting the sample to the laboratory, processing the sample in the laboratory, and finally making the decision on the results that the physician received from the laboratory (Hawkins, 2012).

All these units in the testing cycle are included in the three major phases (pre-analytical, analytical and post analytical). Continuing research in these phases indicated that most errors occur in the pre- and post-analytical stages (Hawkins, 2012).

Lower cases of patients are concerned about healthcare in their hospital. In the United States, it was found that the estimated percentage of errors in the health care sector varies between 31% - 69% (Hawkins, 2012). It was also found out that most errors occur in institutions of health care that work under pressure to increase income, to reduce operational costs, and to work to full capacity. When the analytical phase in clinical laboratories was analyzed it was discovered that the percentage of error was very low about 0.002%, and 3000 times lower for infection control and medication errors. However the percentage of error in the laboratory changes dramatically when they add all the phases, pre- and post-analytical, to the total percentage of errors. It was discovered that the majority of errors comes from other phases than the testing phase. In an Italian study to check the error rates

between the year 1996 and 2006 they discovers that the percentage of errors is decreased but The Percentage of errors in each phase didn't change, 62% errors in the pre-analytical, 15% analytical and 23% post-analytical phase, which occur in failure to reporting, delay in reporting, improper data entry and manual transcription errors (Hawkins, 2012).

To resolve the problems in these phases, laboratories focus on controlling the analytical phase by improving quality. Some Laboratories in trying to be the leader in patient safety inside and outside the laboratory began to report errors and from where they occur. For that reason, the federal government and the organizational entities established and implemented standards for laboratories that should help in improving patient safety (ASCP, 2006).

2.3 Clinical Laboratory Improvement

Different standards and quality programs have been introduced such as International Organization for Standardization (ISO) standards, Joint Commission International (JCI) standards, Lean quality programs and others, theses where introduced to assure patient safety and decrease errors in the clinical laboratory work.

These are the implementation for the laboratories which are used to standardize the operating procedures and maximize patient safety:

1. **Personnel Standards**

   For improving personnel standards, there must be a good training to the employees. In addition to good personnel training, they add some continuing educational programs and licenses for laboratory personnel.

Moreover, personnel standards are important because the medical diagnoses depend on the laboratory results and any errors in the results will lead to negative impact on the patients. False positive and false negative results will harm the patient and costs more for both the patient and the health care organization. From not having such problems, they need to report for the errors, by reporting them they can know where the errors are. They can learn from them and improve their work, their results, and reduce the harm for the patent.

2. Proficiency Testing

It comes from quality assessment and education to help the staff in the laboratory to know what the problems are, how to solve them, how to evaluate themselves, and how to improve the test results. All of the laboratory staff needs to complete proficiency testing because of its importance to them, because the results quality are very important measure that ensure patient safety.

3. Laboratory Accreditation and Regulatory Compliance

This means continues improvement in the quality laboratory practice. It covers proficiency peer review and education compliance that plant laboratory standards.

4. Health Information Technology

The laboratory plays an important role in patient safety because there are always new technologies that enter the laboratory more than the other areas of health care

and these technologies improve standardization and validation measurements in all the tests and the results, and this will reduce the errors and increase patient safety.

2.4 Noticeable Errors

In the literature, the most errors that are noticed in the pre- and post-analytical phases are:

2.4.1 List of the Pre-analytic Errors:

1. Physician orders wrong test,
2. Requisition incorrect,
3. Specimen unlabeled, mislabeled, illegible (includes swapped labels),
4. Hemolyzed or clotted samples,
5. Failure to collect a specimen,
6. Using wrong venipuncture materials ,
7. Wrong container,
8. Incorrect fill level of sample ,
9. Insufficient sample,
10. Contaminated sample,
11. Specimen lost or delayed,
12. Other specimen transport error,
13. Data entry error during accessioning of requisition (e.g., wrong patient, wrong test), and
14. Specimen processing error (e.g. aliquot labeling error).

2.4.2 List of the Post-analytical Errors:

1. Post-analytic data entry error,
2. Oral miscommunication of results,
3. Error in reporting to downstream printer, fox, or electronic medical record (EMR),
4. Physician or other provider fails to retrieve test result,
5. Failure to communicate critical value,
6. Provider misinterprets lab result, and
7. Turnaround time.

The challenge in the hospitals nowadays is to get accurate results from an accurate specimen, because a mislabeled specimen or other type of errors in specimen. It can lead to several consequences for the patient and for the hospital (Wagar et al, 2006).

To be sure that patient safety is present in the laboratory, quality improvement system must be done in laboratories to insure that quality is being maintained. The laboratory supervisor must select a quality improvement program and address it in the laboratory with a purpose of reaching high quality or results and patient safety. A good quality improvement plan will assure that the laboratory meets defined standards of quality practice, it has compliance with applicable laws and regulations related to quality and patient safety, the laboratory is engaged in some quality improvement activities, and the interest of the plan will be used by the laboratory itself and the patients that deal with the laboratory (CAP, February 2009).

The plan elements of quality improvement are:

- A Commitment to Quality and Patient Safety,
- Risk Assessment,
- Control Activities,
- Information and Communication,
- Monitoring, and
- Continuous Improvement.

2.5 Guidelines for patient safety in Pre- and Post-analytical Phases in Laboratory Testing:

(CAP, August 2009)

Goal 1: Ensure Correct Patient and Sample Identification:-

a) at the time of specimen collection,
b) at the time of analysis,
c) at the time of result delivery.

Goal 2: Ensure the Verification and Communication of Laboratory Results Requiring Action on the Part of Treating Clinicians, Examples may include:-

a) New malignancies,
b) Infectious disease diagnosis requiring immediate treatment or patient isolation,
c) Critical laboratory values.

Goal 3: Ensure Performed Time Outs are Prior to Starting Procedures:-

a) Correct test preparation,
b) Correct patient position,
c) Safety precautions based on patient history or medication use Operationalization.

Goal 4: Ensure the Identification, Communication and Correction of Errors:-

a) Timeliness of identification of errors,
b) Revised reports.
    1. All inaccuracies in the medical record should be documented and communicated at the time the inaccuracy becomes known. The correct test result or diagnosis should be made clear in an amended or corrected report with the date of correction as soon as possible. The original inaccurate result should be reported as such in the medical record. The reason that the original result was reported incorrectly (i.e., due to error or other reason) may not be known and need not be reported in the medical record.
    2. When an incorrect result or diagnosis causes material injury to a patient, the correct result/diagnosis and the fact that the result has been changed must also be reported to the patient. For an inaccuracy caused by or directly involving a pathologist, the pathologist involved in the case should discuss the matter with the physician who ordered the pathology consultation. The two physicians should jointly determine how best to communicate the corrected result to the patient.

Goal 5: Improve Integration and Coordination of Laboratory Patient Safety Role within Healthcare Organizations and Operations among the following groups:-

a) Nursing,
b) Administration,
c) Point of care testing personnel, and
d) Providers.

Goal 6: Provide a standardized List of Acceptable Abbreviations, Acronyms, and Symbols to the following groups:-

a) Physicians,
b) Nurses, and
c) Laboratory testing personnel.

Goal 7: Improve Hand-off Communication Approaches, In High Risk Clinical Situations such as:-

a) Shift changes, and
b) Laboratory testing performed during surgical procedure.

Goal 8: Reduce the risk of health care associated infections by the following activities:

a) Reviewing WHO and CDC Hand hygiene guidelines
b) Implementing best practices,
c) Conducting periodic risk assessments,
d) Ensuring participation of laboratory staff in infection control activities in health care organization.

2.6 Joint Commission International Accreditation Standards

The Joint Commission International presents international standards for hospitals which are used to achieve goals that lead to patient safety (JCI, 2011). These goals begin with identifying patients, improving communication, ensuring correct site, correct procedure, correct patient, in order to reduce the risk of health care caused by infections as well as the risk of harm resulting from falls.

The process of identifying patients is most important because wrong patient errors occur often. The situation could occur when the patient may have had his bed changed or his room, or location within the hospital or the patient may not be fully conscious, which may lead to errors in correct identification.

This standard has two purposes. The first is to identify the patient as the person being attended to and the second is to match the service to that patient.

To identify the patient correctly in the hospital, the JCI has developed policies and procedures to improve the identification process, which is needed when the patient is given medication or giving blood or receiving blood or other samples taken for clinical testing. These procedures require at least two methods for identification, which are the patient name, room number, date of birth, bar-coded wristband. The patient's room number alone on the form or location cannot be used for identification.

2.7 The Procedure of Collecting Samples

2.7.1 Skin Preparation:

Skin cleansing has been a controversial subject as it has been acknowledged that wiping the skin with an alcohol swab disturbs the skin flora and causes increase discomfort for the patient. Normally clean skin is all that is required. Asepsis however is vital when performing venipuncture as the skin is breached and an alien device is introduced into a sterile circulatory system.

The two main sources of microbial contamination are:

a) The hands of the phlebotomist,

b) The skin of the patient.

Good hand washing and drying techniques are therefore essential on the part of the phlebotomist. If hand washing facilities are unavailable, an alcohol based hand wash solution is an acceptable substitute.

The phlebotomist must be aware of the Community Health Oxford shire PCT Infection Control.

2.7.2 Personal Safety:

Protection for all personnel is paramount when handling blood products and body fluids.

In order to avoid any risk to personal safety, the phlebotomist must, at all times adhere to the Universal Precautions:

a) Every patient should be regarded as a potential biohazard,

b) Latex or vinyl gloves must be worn,

c) Avoid needle stick injury – this is a potential source for many infections but especially dangerous are the Hepatitis B and HIV viruses transmitted in blood and body fluids,

d) Dispose of sharps and or soiled equipment appropriately and safely; keep gloves on whilst disposing of equipment, then dispose of gloves safely. All vacationers should be single use only and disposed of with the needle after use,

e) Suitably protect cuts or other skin breaks on hands,

f) Ensure you are immunized against Hepatitis B,

In order to perform a safe and successful venipuncture it is important that the phlebotomist considers carefully the choice of vein maintains good technique and applies the principles of asepsis.

2.8 The Practices

2.8.1 Equipment:

Clean surface on which to place equipment,

Gloves,

Tourniquet,

Vacuum device – needle, shell, appropriate tubes,

Cotton wool/gauze swab and tape,

Request card/bag,

Sharps container and clinical waste disposal bag.

(NHS, 2010)

2.8.2 Disposal of Used Equipment:

Phlebotomists must be responsible for the disposal of their own venipuncture equipment

Use an approved sharps container,

Keep gloves on whilst disposing of used equipment, then dispose of gloves safely turn gloves inside out when removing,

Discard shell and needle as one unit into sharps container

Any other non-disposable equipment which may have become contaminated with blood should be discarded – tourniquet needs to be washed regularly in hot soapy water or use disposable tourniquet,

Equipment Container should be regularly cleaned during phlebotomist duties (NHS, 2010).

2.8.3 Procedure, Technique and Aftercare of Puncture Site:

Check the specimen request and select the appropriate tubes – place in order of draw. Order of Draw - Bottle Color - Additive invert**.**

1 **BLUE**	Sodium Citrate 3-4 Times
2 **YELLOW**	Serum
3 **GREEN**	Lithium Heparin
4 **PURPLE**	EDTA
5 **GREY**	Fluoride/Oxalate
6 **RED**	No anticoagulant; contains clot activator; yields serum

Approach the patient in a confident manner and explain the procedure, consulting the patient on preferences and experiences related to previous venipuncture.

Gather the necessary equipment,

Position the patient in a suitable place, taking into account lighting, ventilation, privacy, phlebotomist and patient safety and comfort. Where possible, request the patient to sit upright, although in those with a history of fainting it is best to position the patient lying on a bed or couch,

Examine both arms and choose the most suitable according to the aforementioned criteria

Fully extend the chosen arm and position it downwards. The arm should be supported, comfortable and relaxed,

Wash your hands,

Assemble the devic,

Apply a tourniquet above the elbow, ensuring that it does not obstruct the arterial flow

The veins may be tapped lightly,

Select the vein,

Put gloves on,

Anchor the vein by applying manual traction to the skin just below the proposed insertion site,

Hold the assembled device, with the needle bevel upwards, between thumb and index finger, penetrate the skin and insert the needle into the vein, smoothly at an angle of approximately 15 degrees. Level off the needle after entry, so it is flush with the skin

Advance the needle approximately 1cm into the vein if possible,

Once satisfied the needle is safely anchored, swap hands and whilst supporting the device, press the tube home with the thumb of the free hand. Blood should then be drawn into the tube. Continue to hold the device until the tube fills; flow will stop automatically,

Once the blood has begun to flow release the tourniquet within one minute,

Once the tube is filled, hold the device steadily with one hand and with the other hand disengage the tube and gently agitate, but do not shake, to mix the blood and the additive, side to side shaking causes hemolysis,

Should more than one sample be required, remove the filled tube and replace with another immediately, in the following order: Blue, Yellow, Green, Purple, Grey,

Once all the samples have been obtained, remove the needle,

Place cotton wool over the puncture site and ask the patient to apply gentle pressure until the bleeding stops (approximately; longer for those on warfarin or heparin),

Inspect the puncture site and apply a clean swab, secured with tape,

Dispose of sharps and soiled equipment safely,

Check that the patient feels well and comfortable,

Label and pack tubes for transport to the laboratory. Lab requests only to use Stickers on INR bottles and hand write all others,

(NHS, 2010)

2.8.4 Care of Samples, Storage and transport:

The importance of clear and correct labeling has been identified and is the continued responsibility of the phlebotomist to ensure that this final stage in the venipuncture service is performed thoroughly,

Ensure that the tubes and the request cards are filled in correctly and that the bags are then sealed. For blood collected from patients in their own homes, the bags should then be placed ideally in a cool box, (hospital phlebotomy dept. say it is more important that they are not in direct sunlight i.e. a dashboard). Samples should not remain in the cool box for any longer than necessary and certainly not overnight. (NHS, 2010)

2.8.5 Sample Rejection:

The samples usually rejected if they have two types of problems, the first type of rejection is the identification problems which mean that the laboratory staff are unable to match the information on the test tube with the information on the requisition form, or that there are some missing information with the labeling. And the second type of rejection is the sample problems which consist of errors in sample volume, wrong collection tubes, clotted samples or incorrect sample storage and transport.

Usually the rejection increases the patient safety be reducing the errors in the results, if these samples are not rejected more percentage of error may occur and it may harm the patient.

2.9 Previous Studies

A review of experiences from Q-Probes and Q-tracks studies supplemented with other studies from the CAP (Howanitz, 2005) was done to identify performance measures in laboratory medicine to describe error rates of these measures and provide some suggestions to decrease those errors. The Q-probes study lasted from 1 to 4 months and the Q-tracks study is done yearly and conducted since 1998. The data was collected and summarized by the CAP and the data includes performance measurements, significant of errors, magnitude of error rates, tactics of error reduction. Conclusions of the study shows that eight performance measures were identified, including customer satisfaction, test turnaround times, patient identification, specimen acceptability, proficiency testing, critical value reporting, blood product wastage, and blood culture contamination, and the error rates for pre analytic and post analytic performance measures were higher than the analytic

measures. Error rate benchmarks for these performance measures were cited and recommendations for improving patient safety presented.

The experience at San Bassiano Hospital (Da Rin, 2009) illustrates how a series of decisive and thorough interventional measures taken effectively reduced pre-analytical errors, some interventional strategies were implemented over 2 years period and the implements where: Implementing wireless network to provide fast access to medical Records, Introducing laptop with wireless connectivity and computerized order entry systems for inpatients, Introducing automated samples labeling system for inpatients and outpatients, Introducing bar-coded ID wristbands for inpatients, Standardizing collection, Utilizing a pre-analytic workstation interfaced with analyzers. The results at San Bassiano hospital after implementing all the combination of strategic thinking, farsighted management planning, advanced information technology and robotics has led to more reliable specimen collection and pre analytical sample handling and enhanced clinical efficiency as an integral part of the laboratory process therefor errors in the total testing process have been almost completely eliminated.

A cross sectional survey study using a questionnaire for physicians was conducted by Laposata (2007). The results showed that a large number of test ordering errors came from physicians ordering the wrong test. For that diagnostic providing guidelines were made for test selection in specific disorders, moreover basis for the establishment of reflex protocols in the clinical laboratory were used, and the results were improvement in both the time and the accuracy of diagnosis. This survey showed that in the absence of such an interpretation, for patients being assessed for a coagulation disorder, approximately 75% of the cases would have involved in some level of test result misinterpreted.

In a study conducted by Codagnone et.al (2014) with a purpose of evaluating the frequency of pre-analytical errors in the clinical laboratory service of Naval Marcílio Dias a military hospital with 329,582 tests were performed in the clinical laboratory from August to October 2012, the study also aims at assessing the frequency of errors from different sources: outpatient and inpatient departments, and Integrated Home Care Service. Some improvements were done in the laboratory environment, but errors still persist. These errors are classified as pre-analytical, analytical and post analytical, according to the time of occurrence. A total of 329,582 exams were conducted in the period of this study, of which 806 presented some type of pre-analytical error (0.25%). The three main observed causes of pre-analytical errors were hemolysis (27.54%), material not received (25.43%) and insufficient sample volume (18.49%), The samples from the Integrated Home Care Service (SIAD) showed the highest frequency of errors (3.38%), followed by those from the inpatient (0.76%) and the outpatient departments (0.21%). Result shows that in spite of the technological improvements in laboratory medicine, the pre-analytical phase is still the main responsible for laboratory errors, and the frequency of pre-analytical errors in our laboratory routine (0.25%) is in accordance with the international scientific literature the SIAD presented the major rate of errors, falling outside the internationally accepted range and this study reinforce the laboratory team members for doing constant training.

A descriptive, cross-sectional study by Abdollahi and Saffar (2014) was conducted throughout January–December 2012 to observe the types and frequency of errors during different phases of testing at a clinical medical laboratory of a teaching hospital in Tehran, Iran. The errors were recorded by the Quality Control Committee in a specially designed record. According to official data, 60–70% of clinical decisions about hospitalization and

discharge are based on laboratory results. A total of 303,866 samples were included in the study and the results show that about 2,430,928 tests were received for analysis and the total number of errors was 153,148 (6.3%) (116,392 for inpatients and 36,756 for outpatients). And this indicates a high number of errors occur in the inpatients, which means that those samples weren't collected by the laboratory staff but they were collected by other health care givers in the hospital such as nurses or trainees, also from analyzing the total testing process results there were about 65.09% of the errors occur across pre-analytical phase, whereas 23.2% and 11.68% are related to analytical and post analytical phase, respectively. More than half of the laboratory errors are related to pre-analytical phase; therefore, proper training and knowledge of intervening factors are essential for reducing errors and optimizing the quality.

Longitudinal statistical tools by Wager et.al (2006) is used to assess patient identification and specimen labeling improvement after multiple implementation projects because Patient safety is an increasingly visible and important mission for clinical laboratories. The attention to improve processes related to patient identification and specimen labeling were been paid by accreditation and regulatory organizations because errors in these areas that jeopardize patient safety were common and avoidable through improvement in the total testing process. In this study the specimen errors were categorized by a multidisciplinary health care team. Patient identification errors were grouped into 3 categories: (1) specimen/requisition mismatch, (2) unlabeled specimens, and (3) mislabeled specimens. Specimens with these types of identification errors were compared pre-implementation and post-implementation. Results showed that from 16,632 total specimen errors, mislabeled specimens, requisition mismatches, and unlabeled specimens represented 1.0%, 6.3%, and 4.6% of errors, respectively. T-test showed a significant decrease in the most serious error,

mislabeled specimens (P < .001) when compared to before implementation of the patient safety projects. Trend analysis demonstrated decreases in all 3 error types. Applying performance-improvement strategies that focus longitudinally on specimen labeling errors can significantly reduce errors, therefore improving patient safety.

A study for Turner et.al (2013) was conducted to review the impact of electronic requesting in Primary Care on the number of pre-analytical errors seen by the laboratory, because Pre-analytical variables are common across all laboratories and can negatively impact on patient care, error in data were reviewed during 6 months pre- and 6 months post-implementation of Primary Care electronic requesting. The outcome measures related to: the correct information on the sample tube (patient name, unique patient ID number, date of collection); the correct sample received and the availability of a clinical history. The results show that there was a marked decrease in the number of pre-analytical errors following the introduction of electronic requesting (2764 pre-implementation vs. 498 post-implementation, P < 0.001). There was an improvement in the quality of information provided with each request in the forms of clinical history, date and time of sample collection. The introduction of electronic requesting in Primary Care can reduce the number of pre-analytical errors and can improve the quality of information received with each request.

A descriptive study was conducted in Children's Medical Center in 2008 by Shams et.al (2012) with the aim of evaluating the rate and causes of post-analytical errors in the clinical laboratory of Children's Medical Center, and the researcher focused on delay in reporting test results and inaccuracy of test results. The three months study was focusing on registered complaint related to accurate reporting and on time test results from inpatients and

outpatients, physicians and wards during and the research were investigated, then the data was recorded and analyzed with Chi square and Fischer's tests. The results were a total of 375 of 425 complaints were related to delay in reporting test results and they recorded 50 cases of erroneous result complaints, they checked the types of errors and they found that "Failure to input the results in computer" was the main reason (37%). "Lost results "(25%) and transcription error (22.6%), "absence of laboratory request form" (9.8%) and "wrong method of filing" (4.2%) were the other observed causes. The rate of complaints was 1:108 patients or 1:541 tests, and 4.8% of results were not reported in timely manner, they conclude that of most of the errors related to reporting test results were in post-analytical phases, therefore they decide to do continuous educational programs and improve the automation that will reduce those errors, also cooperation with the clinicians and the other personnel outside the laboratory is important for error reduction.

A cross sectional study was done by Sharaki et.al (2014) at the clinical chemistry laboratory of Alexandria Main University Hospital with the aim of evaluating the performance of the Clinical Chemistry Unit of Alexandria Main University Hospital through identifying the problems related to the total testing process by using inspection sheets that were based upon the integration of the CLSI approved guidelines for urinalysis collection, transportation and preservation, the study was conducted on 514 consecutive urine specimens that were received at the clinical chemistry during 3 months period from March to June 2013. After looking at the request forms that are being authorized by a physicians' name or signature, the study showed that almost one third (185) of the request forms of the studied samples, lacked any indication for ordering physician, which accounts for 4.41% of the TTP errors. Also a comparative study was done between the pre analytical errors in the authorized request form and the unauthorized forms, which revealed that there was a high statistical

significance difference ($P < 0.0001$) between the two forms, with errors being much lower in the authorized request forms. The analytical phase showed the least number of errors, 23 errors done in 1970 activities for 514 specimens studied and 0.55% TTP errors. The high frequency in the analytical phase was for error of analysis 0.31% (13 specimens), followed by 6 specimens lost (0.14%), and 4 specimens mixed up (0.10%) out of 514 specimens study sample. Post analytical phase ranks the second in the error frequency in the present study, 487 errors in 1461 activities done for 514 specimens, which account for 11.61% of the TTP errors. In studying the post analytical phase, no losses in results were found, but also there were no result verification procedure nor age and sex reference ranges in the results report and they conclude that in all the testing process they found errors but the minimum errors were found in the analytical phase.

A study done by Wallin (2008) consist of two parts the first one was a questionnaire survey and the second part was an experimental study with the aim of surveying pre-analytical procedures in hospitals to identify sources of error. Results showed that most errors in the venous blood testing process are pre-analytical, and they occur before the sample reaches the laboratory. Unlike the laboratory analysis, the Pre-analytical phase involves several error-prone manual tasks not easily avoided with technological solutions. The results of the questionnaire survey indicate that the desirable procedure for the collection and handling of venous blood samples were not always followed in the wards such as 2.4% of the ward staff always label the test tube immediately before sample collection. Compared to the ward staff, the laboratory staff reported significantly higher proportions of desirable practices regarding test request management, test tube labeling, test information search procedures, and the collection and handling of venous blood samples, but not regarding patient identification. The results suggest a clinically important risk of pre-analytical errors in the

surveyed wards. Computerized test request management will eliminate some, but not all, of the identified risks. The better performance reported by the laboratory staff may reflect successful quality improvement initiatives in the laboratories, also manual transport is recommended for analysis techniques.

These studies showed the researches that have been done in the pre-analytical phase and post-analytical phases in more than one country, and it showed that there a lot of similarities in the results between countries, for that we did our study to check the patient safety and to continue the studies that had been done on patient safety during laboratory testing.

2.10 Summary

This Chapter has explained what patient safety is and how do some of the world's wide organizations deal with it, besides that this chapter explained what standards, protocols and procedures should be used for reaching the highest limit of patient safety in the clinical laboratories. Also this chapter reviewed some studies that are related to the patient safety within the different steps of the total testing process.

Chapter Three: Conceptual Framework

3.1 Introduction

This chapter entails the conceptual framework of the study which is considered as a guide/blueprint form the research process. This framework which is developed after a deep study in the literature review includes different factors that affect the patient safety through and it is a part of the total testing process.

3.2 Conceptual Framework

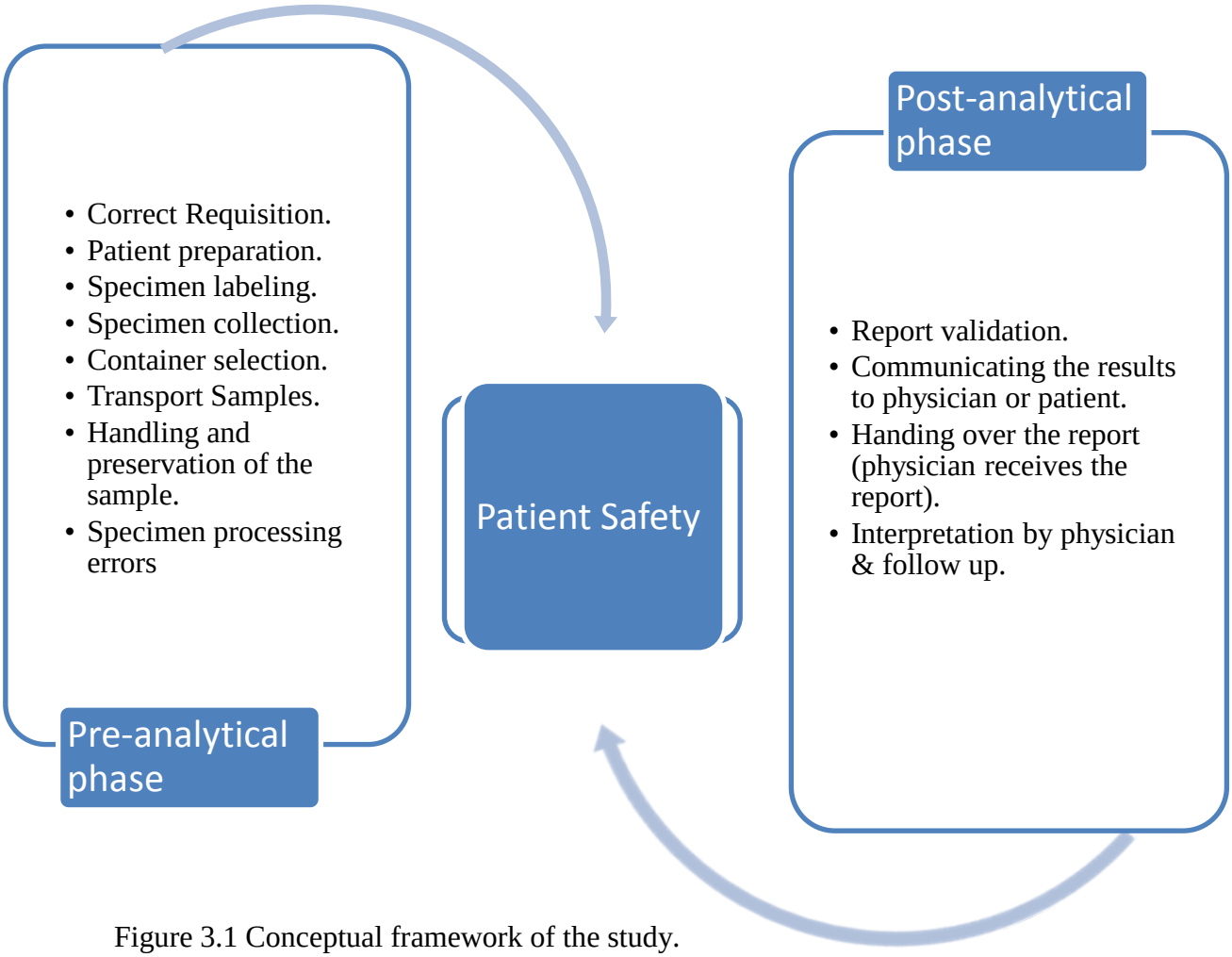

Figure 3.1 Conceptual framework of the study.

3.3 Conceptual Definitions

Patient Safety: is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment (WHO, 2013).

The Pre-analytical Phase: is the first phase in the laboratory process and it included all processes from the time a laboratory request is made by a physician until the sample is ready for testing. Errors that occur in this phase often become apparent later in the analytical and post-analytical phases. The main processes that should be taken into consideration in the study of the pre-analytical phase are: test selection, patient preparation, collection, transport, handling and preservation of the sample, and interferences as shown in figure 3.1 (LLopis, 2011).

Requisition Form: A requisition is a request for something, especially a formal written request on a pre-printed form, each health institution has its own requisition forms for the laboratory use, the physician usually request for the test by adding them correctly on the requisition form.

Patient preparation: many tests require that the patient be prepared in some specific way to ensure safety. The laboratory patient preparation is to ask the patient to open his hand, so that the tourniquet is applied, the vein is selected, alcohol applied on the area and finally phlebotomy is done.

Specimen labeling: is a process of putting the patient's information on the specimens, by asking the patient for the information and match them with the provided information on the requisition form, the information are:

a. Patient's full name (first and last).

b. Patient's number. *(Or other identification number on the label AND requisition).*

Container selection: is a process of selecting the appropriate container for each test that is requested, because there are a variety of container types. Each kind of tests needs a specific container type and the phlebotomist will select the needed containers from the test order for each patient.

Handling and preservation of the sample: maintain specimens at room temperature or on cold packs unless otherwise noted under the "Transport Temperature" or other specimen requirement in the Test Listing**.**

Post-analytical Phase: is the final phase of the laboratory process. This phase culminates in the production of a final value or result and it includes several steps as shown in Figure (3.1). Patient safety will be affected directly in this phase because it is the sum of the three phases (pre-analytical, analytical and post-analytical).

3.4 Summary

This chapter illustrated the conceptual framework of the research study for patient safety in the pre and post-analytical phases as well as the conceptual definitions of the variables.

Chapter Four: Methodology

4.1 Introduction

This study focuses on patient safety in the Pre-and Post-analytical phases on the clinical laboratory in Beit Jala Hospital. In this chapter, research methods are presented. The study population and sample size, design, tools, study period, piloting and the sampling method and data collection are described. The methods of data analysis and ethical considerations also are described. In addition to validity and reliability of the instruments that are used for the purpose of data collection are presented.

4.2 Study Design

The study design was observational, because it provides information on real use and practice. It can detect signals about the benefits and risks of using these practices. It provides real answers more than surveys and it helps researchers gain a deeper understanding of processes that surveys cannot give (Nahin, 2012). Moreover, the observation over the time describes the whole situation (Labonte, 2006).

4.3 Study Settings

The study was conducted in Beit Jala (Al-Hussein) Hospital, Beit Jala is a governmental hospital and it is the second largest hospital in the South West Bank, which has five acute departments that were included in the study. The departments are: Pediatric, Maternity,

Oncology, Surgical and Internal Medicine. Moreover Table (4.1) shows some information about Beit Jala Hospital.

Table 4.1: Information's about Beit Jala Hospital.

Governorate	Occupancy Rate	No. of Beds	No. of Technologists, Personnel Qualified	Average No. of Lab. Tests done Yearly
Bethlehem	85.1 %	113	15	312,712

4.4 Subject Population

The total number of admitted patients in Beit Jala hospital in the period of May until October, 2012 (six months) was 5474 patients.

It is estimated according to Beit Jala hospital that on average, the number of tests per patient during hospital stay is 25 tests and the average of collecting specimens is 5 for each patient,

Therefore, the average number of collected specimens during six months period was 5474 X 5 = 27370 specimens

After reviewing the data from the hospital form the previous year's most patients were admitted to these departments, it also showed that the percentage of admissions was as the following, Pediatric 10%, Maternity 26.9%, Oncology 10.3%, Surgical 30.8% and Internal Medicine 21.7%.

4.5 Sampling Method

The sample size was 244 lab specimens. The sample size was calculated by using the sample size calculator from (The Department of Statistics, University of British Columbia).

P0 is the known value worldwide for errors in laboratory tests and it is about 14%

P1 is the unknown value that we think it might be in Palestine about 20%

α is the default value of error and it is 0.05

Sample size was calculated to see the minimum sample we can take. However, it was decided to make 450 observations.

4.6 Inclusion Criteria

The entire tests that could be done in the hospital laboratory in a period of 48 hour or less, for analysis.

4.7 Study Tool

The tool consists of items selected from the guidelines of specimen sampling (WHO guidelines, JCI standards) which are then studied in areas of nursing, medicine and the laboratory. These procedures must be known and practiced (NHS, 2010).

Pre-analytical phase consists of: preparation for the tests (5 items), material preparation (9 items), venipuncture procedure (24 item), and sample handling (5 items) as shown in annex (1).

Post-analytical phase consists of: 8 items as shown in annex (1).

4.8 Data Collection

The data was collected from the five departments during the rush hour of ordering tests and specimen collection. These hours are in the morning before the medical round of the physicians to the departments, as shown in the Table 4.2:

Table 4.2: The Time that the Phases are done in the hospital.

	Order Time	Specimen collection time	Transfer and handle time	Take Results same day	Take results more than one day
Morning	7:00-7:30	7:30-8:00	8:00-8:30	After 1-3 hrs.	Depend on test type

Five departments in the hospital were observed. The data was collected in the morning after having the test request forms from the physicians and then observing the phlebotomist collecting the samples, which is the pre-analytical phase, and when the laboratory results are given, which is the post-analytical phase.

The observations were done within a six month period 3-4 days a week at the morning shift by the researcher and two other trained lab technologists not working in Beit Jala Hospital (Appendix 3) in the period from December 2013 to May 2014. Each observational day was done by two observers, the number of observers in the departments depends on the number of phlebotomists that want to collect the samples, is one phlebotomist went to collect samples, one observer was gone with him and the second observer went to the laboratory to observe the post analytical phase, if two sample collectors then two observers were gone with them to collect observations. The number of observations per person in each day varies depending on the test ordering in each day by the physicians.

4.9 Pilot Study

A pilot study for one day in Holy Family Hospital was conducted to test the logistics and data collection procedure in order to improve the quality and efficiency in data collecting procedure, and also to introduce necessary changes. However no major changes where done, some small changes were made on the checklist such as replacing the name area with case number, adding the date to the checklist, the order of two tables in the checklist were replaced.

4.10 Data Analyses

A statistical software (SPSS version 19) was used for data was entering. The frequencies, means and standard deviations were computed for continuous numerical variables, moreover using the Microsoft Office Excel 2010 in the analysis of some figures.

4.11 Permissions and Ethical Considerations

4.11.1 Formal Letters:

Before beginning the pilot study, a letter was sent from Al-Quds University to the Holy Family Hospital (Appendix 4 and 5) in which the study purpose was explained. Also before beginning the Study in Beit Jala Hospital a letter was sent from Al-Quds University (Appendix 6 and 7) in which the study purpose was explained. An official permission had been asked for the researcher to visit the hospitals and do his observations there.

4.11.2 Ethical Considerations:

For doing the observations in Beit Jala Hospital some ethical considerations were taken into account. The staff in the hospital was informed about the purpose of the study and how the observations will be done. The personnel were assured that: The data was confidential and if

a staff member or patient refused to be observed then the observations were not taken. Moreover any other issue is not in the field of the observations it was not mentioned.

4.12 Validity of the Study Tool

After developing the questionnaire, it was sent to a team of (5) experts (Appendix 2) in the field of hematology, medical laboratory, public health who have experience in research to determine whether the items in the questionnaire were relevant and suitable to the study propose and objectives. The Questionnaire was modified according to the experts' suggestions also some changes were made according to the pilot study results.

4.13 Reliability of the Study Tool

The Reliability of the study was tested by using the Cronbach's Alpha test. The questionnaire shown an excellent coefficient (α=0.94) for the 51 items excluding the post-analytical phase, the best score was shown in the sample handling and the lowest score was showed in the Clerical work.

Table 4.3: Instrument Reliability.

No.	Field	No. of items	Reliability coefficient
1	Clerical work	9	0.23
2	Venipuncture procedure checklist	24	0.90
3	Trouble-shooting	8	0.93
4	Sample handling	5	0.98
5	total degree	51	0.94

4.14 Summary

This chapter covered the study design, study setting, subject population, sampling method, inclusion criteria, exclusion criteria, study tool, data collection, and reliability of the study, pilot study, and data analysis. Moreover it covered permissions and ethical consideration for this study.

Chapter Five: The Results

5.1 Introduction

In this chapter the results of the observations done in Beit Jala hospital had been shown, including the personal characteristics of the one who did the work in the pre-analytical phase. The observations included frequencies of the preparation for the test (clerical work), the tray of venipuncture, the procedure of venipuncture, troubleshooting while processing the venipuncture, specimen handling and also those of the post-analytical phase. Furthermore the relations between the pre-analytical data and the characteristics of the health care professional that was doing the venipuncture had been presented.

5.2 Personnel Characteristics

The personal characteristics of the health care professionals who were collecting the blood samples from the patients and who agree to participate in the study, (N= 450) observations were as follows:

5.2.1 Gender of the Sample Collector:

The gender of the sample collectors were distributed into 158 male (35.2%) and 292 female (64.8%) as shown in Figure (5.1). The female percentage was about twice of the male percentage.

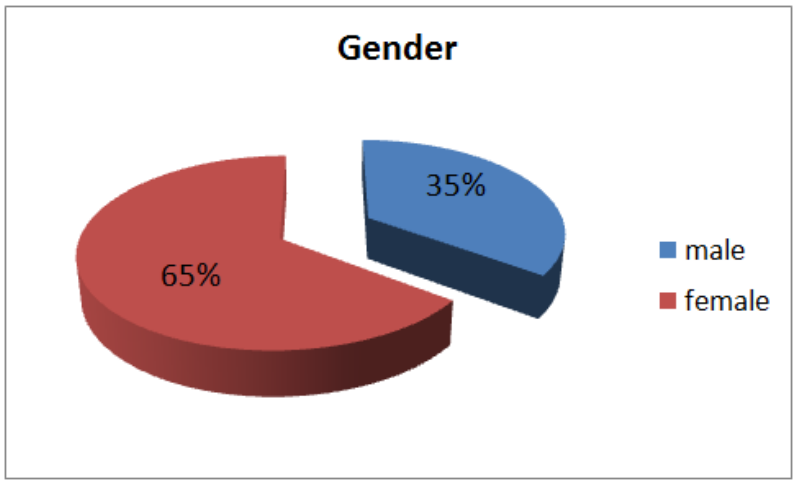

Figure 5.1: Gender of the health worker who collected the samples.

5.2.2 Job Position:

The persons that were included in the sample they were working in the hospital with different positions. Mostly, they were laboratory technicians and the others were nurses, physicians and the trainees that were divided into two parts: first part was lab trainees and the second part was nursing trainees. Both parts of trainees were from different universities in the West Bank finishing their training courses and some were training for getting experience before applying to work.

Lab technicians' observations were the highest with (51.8%), the nursing observations were (1.8%) observations while the nursing trainees' observations were (25.3%) and the lab trainees' observations were (21.1%) as shown in Figure (5.2):

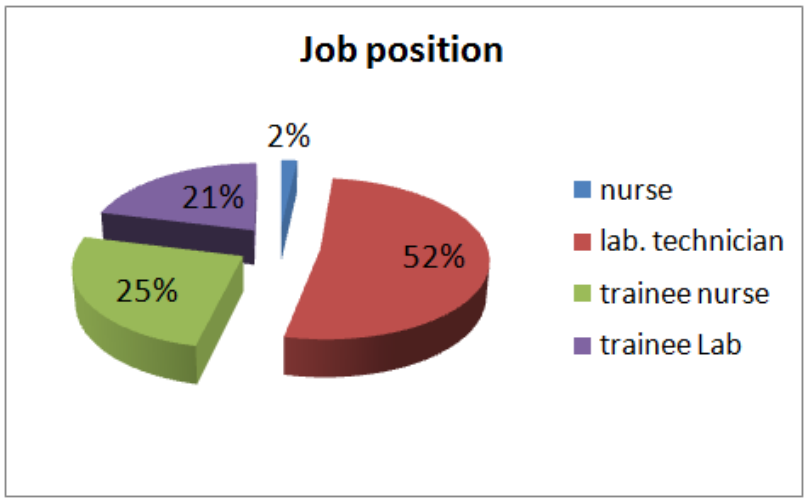

Figure 5.2: Job Position of the health worker who collected the samples.

5.2.3 Years of Experience:

The years of experience here meant to the people who were included in the observations and their experience in that work, it varies from less than one year such as a trainee or newly employed person to more than ten years or experience, the years of experience was divided into five parts and the frequencies were different to each part.

The first part it was less than one year of experience and there were 200 observation with a percentage of 44.4% of the total observations and it was the higher frequency , from 1 – 3 years of experience there were 90 observations with a percentage of 20.0%, from 4 – 6 of experience there were 39 observation with a percentage of 8.7%, from 7 -10 of experience there were 56 observation with percentage of 12.4% and finally the experience that is more than ten years there were 65 observation with a percent of 14.5% as shown in Figure (5.3):

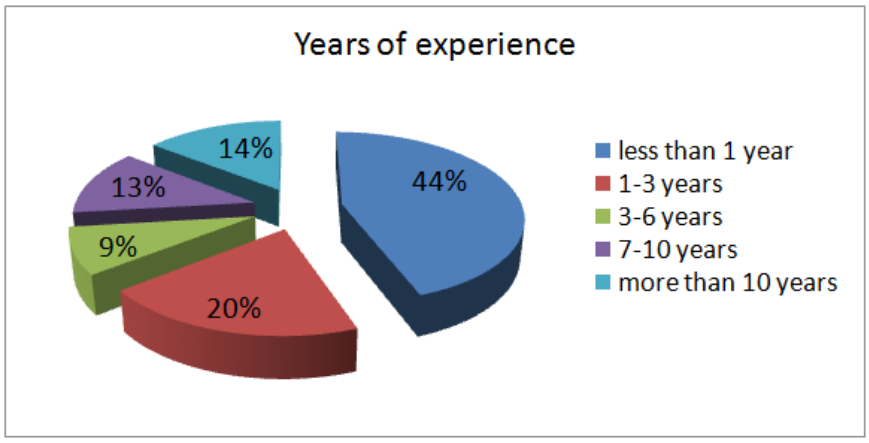

Figure 5.3: Years of experience of the health worker who collected the specimens.

5.2.4 Departments:

The observations were taken in five major departments in the hospital and in every department there were taken a different number of observations depending on the request form from the physician in each department, 37 observation where taken in the pediatric department about 8.2%, another 84 observation were taken in the maternity department with a rate of 18.7%, in the oncology department there were 90 observation in a percentage of 20%, the surgical department were observed 117 observations with a percentage of 26.0% and finally in the internal medicine department the most of observations were done with 122 observation and it is about 27.1% as shown in Figure (5.4):

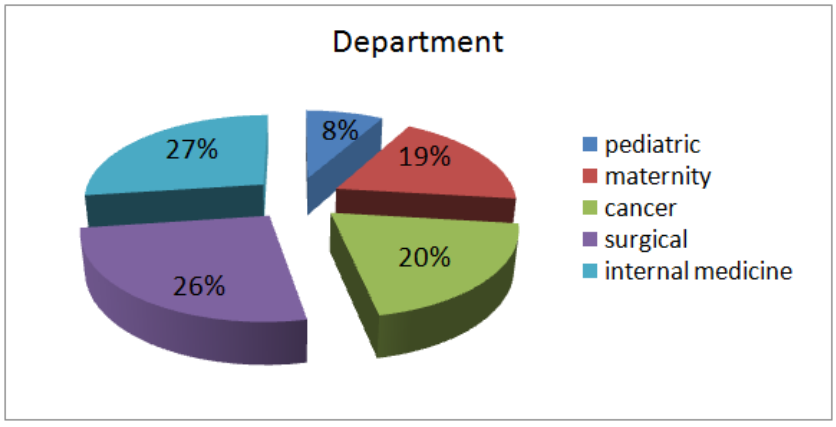

Figure 5.4: The department where the observations were done.

5.2.5 Educational Level:

In this category the educational level was checked for every person who was observed, and it was noticed that 95.8% of the persons who did the work where bachelor degree holders 431 person, and 3.1% were diploma holders (2 years assistant technicians) 14 person, and the lowest percentage was in the higher studies degree holders there were only 5 persons 1.1% of the observations on them, as shown in Figure (5.5):

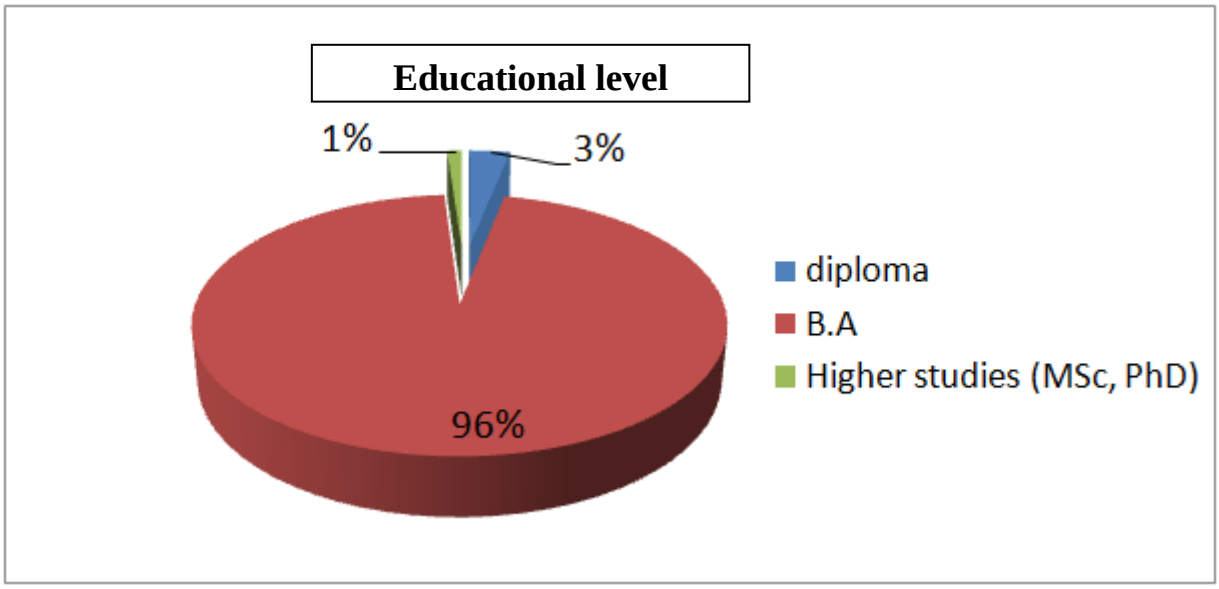

Figure 5.5: The educational level of the health worker who collected the specimens.

5.3 Pre-analytical Phase

In this phase the results of the observations were divided into different steps because the pre-analytical phase has more than one section to look at. These sections were arranged by the timing and it is impossible to skip or delay one of these steps. These steps begin with the tray of venipuncture, the clerical work, the procedure of venipuncture, troubleshooting while processing the venipuncture, and finally the proper specimen handling. From looking

to many points in each step the researcher has noted that some of these points were not applied in the proper way that were supposed to be, those steps were:

5.3.1 The Tray of Venipuncture:

This phase is the first step in the process of venipuncture and here the technician must check the trolley or rack before going to the departments and the patient's room, if they did not check for everything they went to the departments and may have needed something that is not present in the tray, so that would cost them time, and in the morning the time is running so fast because there is many patients that need blood withdraw and the results must be ready before the morning medical round. The results here showed that there were no tourniquet, tapes and no sharp box and this might reflect incompliance with infection control procedures, as shown in Table (5.1):

Table 5.1: The Trolley/Rack material availability that the person who collects blood use.

#	Needed Materials / Disposables	Observation	Frequency
1	Availability of Syringes of all volumes.	With All Syringes Volumes	240 (53.3%)
			210 (46.7%)
2	Blood Collection Tubes. With different additives.	With Different Additives	320 (71.1%)
		Missing PT or ESR Tubes	130 (28.9%)
3	Tourniquets.	Without Tourniquet	100%
4	Sharps Disposal Container. Puncture proof container marked "Biohazards".	Not Present	100%
5	Bandages or tape.	Not Present	444 (98.7%)
		Present	6 (1.3%)

5.3.2 Preparation for the Tests (Clerical Work):

Table 5.2 shows that 35.7% of patients who had special requirements for the tests were not informed and the lab forms were missing important information about the patient such as 1.3% of the forms were without room numbers, also 1.6% were with wrong or missing bed number (second identifier for the patients), 100% of them were without Patient ID number and only 0.7% where without physician signature, those identifiers were in the required to be filled in the order of blood collection, as shown in Table (5.2):

Table.5.2: The clerical work frequencies of the answers.

#	Preparation for the tests (clerical work)	Frequency of the answer	
1	Is there any special requirement for the tests (Fasting, taking a special drug).If yes, has the patient been informed or instructed about such requirements.	28 patient (6.2%) patients had tests with special Requirement	35.7% of the special test patient's were Not Informed
2	The request of lab tests is clearly filled out with all information required (type of test, the room number and the bed number of the patient, full name, ID Number).	Wrong or Missing Room Number	6 Lab Forms (1.3%)
		Wrong or Missing Bed Number	
		Without patient ID Number	450 Lab Forms (100%)
		Without Dr. Signature	3 Lab forms (0.7%)

5.3.3 The procedure of venipuncture:

This phase begins when the sample collectors meet with the patient till blood samples withdrawn and it consists of many steps as shown in Table (5.3):

Table 5.3: The venipuncture procedure observational frequencies.

#	Venipuncture Procedure Checklist	Observation	Frequency
1	Hand washing between patients.	Did Not Wash Hands	442 (98.2%)
		Wash Their Hands	8 (1.8%)
2	Put on gloves.	Used Gloves	224 (about 50%) & 28.1% Of The Gloves Were Torn
		Did Not Use Gloves	226 (50.3%)
3	Ask the patient for their full name and date of birth (this information must match the requisition form and their arm band).	Full Name	312 (69.3%)
		First Name Only	134 (29.8%)
		Not Asked	4 (0.9%)
4	Labeling the tube before blood withdraws.	Before Venipuncture	394 (87.6%)
		After Venipuncture	54 (12.0%)
		Not Labeled	2 (0.4%)
5	Appropriate selection of needle size.	Appropriate Size	440 (97.8%)
		Could Use Scalp Vein Instead	10 (2.2%)
6	Position the patient with the arm extended to form a straight-line from shoulder to wrist.	Good Position	448 (99.6%)
		Not Good Positioned	2 (0.4%)
7	Tourniquet applied above the site.	446 Uses Glove Instead	448 (99.6%)
		6 Used Folys Instead	
		Not Tourniquet Applied	2 (0.4%)
8	Select the appropriate vein for venipuncture	Appropriate Arm	448 (99.6%)

	from the appropriate arm (not with IV line hand).	The Arm With IV Line	2 (0.4%)
9	Puncture site prepared in sterile fashion, (Clean the puncture site by making a smooth circular pass over the site with the 70% alcohol pad, moving in an outward spiral from the zone of penetration. Allow the skin to dry before proceeding).	No Circular Pass	422 (93.7%)
		Circular Pass	28 (6.3%)
10	Proper technique of venipuncture?	Proper Technique	399 (88.6%)
		No Sample Taken	51 (11.4%)
11	Verification placement in vein that are connected in catheter or at hub.	No Verification	262 (58.2%)
		Verification Done	188 (41.8%)
12	Blood draw back into syringe correctly (the velocity).	Correctly	366 (91.7%)
		Fast Withdraw	18 (4.5%)
		Slow Withdraw	15 (3.8%)
13	After blood starts to flow, release the tourniquet and ask the patient to open his or her hand.	Patient Is Asked	445 (98.9%)
		Patient not asked	5 (0.1%)
14	Gauze/ cotton placed over puncture site.	Cotton Was Placed	447 (99.3%)
		No Cotton was Placed	3 (0.7%)
15	Ask the patient to apply pressure for at least 2 minutes then apply band aid.	Patient Is Asked	297 (66.0%)
		Patient not asked	71 (15.7%)
		Bending the Patient Arm	82 (18.3)
16	Blood transferred from syringe to test tube with aseptic technique.	In Aseptic Technique	217 (54.4%)
		Tubes were open to put blood	182 (45.6%)
17	Blood collection tubes must be drawn in a specific order to avoid cross-contamination of additives between tubes.	The Right Order	392 (98.2%)
		Not The Right Order	7 (0.8%)
18	Invert the tube 6 – 8 times to avoid clotting formation.	90.3% Of the inverted tubes are inverted 2-3 Times	321 (80.4%)
		Not Inverted	78 (19.6%)

19	Place needle in sharps container.	Placed	56 (12.4%)
		No Sharp Box (Recap The Needle)	394 (87.6%)

Table (5.3) indicated that 98% of the phlebotomists did not wash hands between patients, moreover 50% of them used gloves while doing the procedure, and 28% of the 50% who put on gloves were having torn gloves and not eligible.

The procedure of venipuncture include asking the patient for their full name, and labeling the tubes with full names, in the observations it was found that 30% of the samples were tagged with the first name only and this was a disconcerting situation.

Beside that, 11% of the venipuncture technique were not perfect, after doing the venipuncture to the vein no sample was taken, and if there was no sample phlebotomizes need to verify the angle of the needle with 42% of patients to have a good blood withdraw, after finishing the procedure of venipuncture and the needle is withdrawal from the venin only 66% of the patients were asked to put pressure on the puncture site so not to have bleeding in the venipuncture site or hematoma.

Furthermore, 45% of the specimens where taken without aseptic technique such as opening the tubes for putting the blood in it, and this technique is used for the microbiology cultures and some other special tests, tubes must not be opened and samples must be in a closed system from the time they were taken from the patient until they reach the laboratory, in addition to collecting blood specimens, specimens must be inverted 6-8 times to avoid clotting in blood for some tests, and to mix the blood with the different additives in each tube to get the optimum result, and not to have the sample rejected in the laboratory.

Also, 88% of the needles that were used for the patients were recapped and not thrown in the sharp box, because the tray was not having a small sharp box, or no sharp boxes were present in some departments, and this is a high risky biohazard situation.

5.3.4 Troubleshooting While Processing the Venipuncture:

While doing the venipuncture process sometimes obstacles are faced and in this section the observers noticed the reaction that were done while facing it.

The highest percentage was 42.8% in repositioning the needle during the puncturing process, from the 42.8% of the times that the needles were repositioned only 13.4% of them another punctures were made to the patients, and 14% of the needle repositioned patients have their vein collapsed during the puncturing process. The materials of venipuncture must be inspected immediately before doing the venipuncture, and 89.1% of the observations the inspection was made in the exact way, as shown in Table (5.4):

Table 5.4: Troubleshooting observational frequencies.

#	Troubleshooting	Observation	Frequency
1	Repositioning the needle during puncture process.	No Repositioning	262 (58.2%)
		Repositioned	188 (42.8%)
2	Inspection the syringe and needles for any malfunction before puncturing the vein.	Inspected	401 (89.1%)
		Not Inspected	49 (10.9%)
3	Have the patient make a fist and flex the arm, which helps engorge muscles to fill veins.	Fist Was Made	436 (96.9%)
		No Fisting	14 (3.1%)
4	Another puncture in a site below the first	No	390 (86.6%)

	(repetition or venipuncture).	More Than One Puncture	60 (13.4%)
5	The vein may have collapsed; loosen the tourniquet to increase venous filling.	vein Collapsed	63 (14.0%)
6	A hematoma forms under the skin adjacent to the puncture site release the tourniquet immediately and withdraw the needle. Apply firm pressure.	Hematoma	12 (2.6%)

5.3.5 Specimen handling:

After withdraw the samples they must be handled to the right place at the right time and timing is preferred to be received within less than 1 hour according to Tuck(2009) because samples that stay longer than 1 hour are likely to be hemolized.

This section of the observation was the best one, and all the items in it were with highest percentage, after samples were taken 99.7% of them were handles in a proper way at the proper temperature needed, 95.8% of the samples were collected with sufficient volume to do all the tests that were ordered and 99.5% of the samples were handled to the right place, but unfortunately there was some delay with 86% of the samples for 1 about hour to reach the correct place, as shown in Table (5.5):

Table 5.5: Sample handling observational frequencies.

#	Sample Handling	Observation	Frequency
1	Proper handling tubes (Closed well, handled with care)	Properly Handled	398 (99.7%)
		No Proper Handling	1 (0.3%)
2	Sufficient specimen volume is obtained for test	No sufficient Volume	17 (4.2%)

	requirements.	Sufficient Volume	382 (95.8%)
3	Is the specimen sent to the laboratory immediately?	After 30 min	37 (9.2%)
		After 45 min	19 (4.7%)
		After 1 Hour	343 (86.0%)
4	Sample Sent to the correct place (blood bank or laboratory, other).	Correct Place	397 (99.5%)
		Samples Not Found	2 (0.5%)

5.4 Post-analytical Phase

This section presents errors occur from the laboratory team and from the nursing station in the wards, 2.7% of the results were with wrong name or wrong information, 5% of the results are lost and a copy is done due to sending the result to other department or putting the results in wrong patient files, 4.3% of the tests are repeated due to insufficient samples, hemolized samples or wrong tube is used in venipuncture process, as shown in Table (5.6):

Table 5.6: Post-analytical phase observational frequencies.

#	Post-Analytical Phase	Observation	Frequency
1	Post-analytic data entry error (wrong name, wrong information) reports will have data errors.	Wrong Name Or Wrong Information	11 (2.7%)
2	Physician or other provider fails to retrieve test result due to loss of results or they are sent to other departments.	Result Lost	20 (5.0%)

3	Results delay (Turnaround time for each test) The normal time table for the tests: Chemistry normally needs about 2 hrs. Microbiology normally needs about 2-3 days. Routine normally needs about 1 hr. Blood banking normally needs about 1 hr.	Tests Are Delayed	4 (1.0%)
4	Repeated Tests & Samples (Hemolyzed, insufficient, other errors).	Hemolyzed or Insufficient	17 (4.3%)

Chapter six: Discussion and Recommendation

6.1 Introduction

The purpose of this study was to check the patient safety during the pre and post analytical phases of laboratory testing.

The study assessed certain departments in Beit Jala Hospital (Surgical, Maternity, Pediatric, Internal medicine and oncology) in the area of patient safety in the Pre- and Post-analytical phases, also it focuses on the personnel characteristics of the medical staff who did the work in the pre-analytical phase, step by step beginning with the tray or rack of the specimen collector passing to the clerical work, then to the venipuncture process, and then to trouble shooting, and finally handling the samples to the right place at the right time. The post analytical phase focuses on the data entry, communication of results, result losses and repeated tests.

6.2 Checklist Observations for the Pre-analytical Phase

The observations in the per-analytical phase were separated into categories in the checklist, the separation was done to insure that each category was observed and checked in all respects, those categories must be organized and cannot be skipped, so to insure that the procedures were done in the right way.

6.2.1 Preparation for the Tests (Clerical Work)

In this category the preparation for the tests such as telling the patient about special tests, laboratory test orders have to be ready in the departments and signed by physicians, the time of samples are clearly present, the test order is filled out with all the required information.

In the observations it was found that 35.7% of the patients with the special tests requirements were not informed about those requirements, if tests are done for those patients without preparing themselves such as fasting the results of the tests will be wrong. Also some of the test orders were missing room numbers and bed number, other test orders were missing physician signature. If a patient was not informed about a test and he did not prepare himself for it the results will be wrong, also if room number or bed number is missing they may withdraw blood for another person by mistake, and one of the venipuncture procedures is to check the room and bed number and the name before doing the venipuncture procedure.

The results of the study done by Da Rin 2009 at San Bassiano Hospital showed that they had the same types of pre-analytical errors such as labeling problems and missing information on the laboratory test orders, but they reduced those errors in this category by doing a computerized system, introducing barcode ID bracelets, and standardizing collection of samples depending on the sample collection guidelines.

6.2.2 Trolley or Rack (Needed Materials) for the Specimen Collector:

Overall in this category most of the materials and equipment were present, but there was a major problem in the use of tourniquets and sharp disposal containers, no tourniquets were used in 350 observations, moreover sharp disposal container were used in a few number of observations. When sharp box were not present, used needles were recapped or left open and it may be a source of hazard, the contaminated needles, syringes and other materials if used must be put in sharp disposal boxes, the reasons of not using sharp boxes is the neglecting of the staff because sharp boxes where present is some departments, for that the staff can carry a sharp box while doing the venipuncture process.

A contagious disease may be transmitted to phlebotomist or any other person who may touch the contaminated parts by mistake or the needle could miss the cap and stab the hand of the person holding it or it could pierce the cap and stab the hand and sometimes the poorly fitting cap could slip off a recapped needle and stab the hand holding it while recapping the needles or when it was left open in the tray, for that phlebotomists need to put a system for dealing with the disposals after withdrawing the blood.

The JCI and CDC mentioned the worldwide standards and process of dealing with the sharp disposals and infectious wastes, this process begins with using a small disposal sharp boxes or plastic jars, these boxes must be on every tray, moreover when these boxes are filled they must be secured and transmitted by to a waste burning equipment by trained persons on handling these disposals.

6.2.3 Venipuncture Procedure:

In this category there were some of the good points and some other point that weren't done on the procedures and protocols of venipuncture.

The point in this category that were done in the right way are: good positioning of the patient, selection of appropriate vein, proper technique of venipuncture, draw blood into syringes correctly, right order of blood collection tubes.

From that the study of Codagnone et.al (2014), it was found that the percentage of errors is the highest in the pre-analytical then the post-analytical phase. Also the types of errors were the same type of errors in this study, such as hemolysis, sample loss, insufficient volume.

On the other hand some techniques were not done in the right way such as hands washing between patients, 98.2% of the venipuncture's were done without hand washing between

patients, moreover while making the observations 29.8% of the patients were not asked about their full name, and some of the tubes were labeled after blood withdrawal.

The study of Wager et.al (2006) discussed about patient identifying and specimen labeling and the study showed that the errors in those jeopardize patient safety but on the other hand they are avoidable through improving the total testing process, in this study it was shown that there were some errors in patient identifying and tube labeling, and those errors in Beit Jala hospital can be easily treated form the part of phlebotomists, but after highlighting those points form a third party they will notice them and correct them, the solution for this problem in Beit Jala hospital is to introduce a management information system that deals with stickers that contains full name and ID numbers or barcodes, and the nurses on each department must but those stickers on the laboratory tests order, moreover the phlebotomist must put a sticker that contain the patients information on each test tube he or she used for blood withdraw

6.2.4 Trouble Shooting:

In this category the observations showed noticeable problems while doing the venipuncture process which were repositioning the needle during the puncture process and this was noticed mostly while the trainees were drawing the blood samples because they lack experience in venipuncture, and this requires the attendance of trained phlebotomists to supervise the trainees while drawing blood. From the Association of Nuclear Medicine Physicians Of India (ANMPI) guidelines for trainees, it was found that the trainee is to work only under Personal supervision of the Physician or technologist during the first year of training depending on the nature of the procedure being performed either the physician or the technologist will be required to be present physically in the room while performing the

procedure. Moreover, the trainees should always wear a badge indicating that he/she is a trainee. The trainee can be authorized to perform venipuncture on a patient under direct supervision of the physician / technologist/ other senior technician / nurse. This decision will be solely at the discretion of the physician in-charge of the trainee and the responsibility of the Physician in-charge to ensure that the trainee does not perform any task which is outside his or her level of competence.

6.2.5 Sample Handling:

The sample handling category was the best of all other categories, and the lowest number of errors was noticed in that category, the noted points were that they handle the tubes properly, at the right place, and at the right time, the procedures of this section are discussed in the NHS (2010).

6.3 Post-analytical Phase

The major problem that was noticed in the post-analytical phase was found in retrieving the results in the patient files with a percentage of 5% lost results, and that leads the head nurse in that department to orders another copy, this situation is costly for the laboratory in two ways, time wise, because they need to leave what he is working on and search for the result then make the copy and money, they need to re-print same results again and again.

Moreover, the laboratory technicians have to reject and repeat about 4.7% of the results because the clotted samples or insufficient or other sampling problems. To reduce the number of rejection and repetitions, they must communicate with the phlebotomists team to

tell them which tubes they must use, the quantity of the blood that they need for the tests, and to tell them how to avoid hemolysis and clotted samples, in the other hand the phlebotomists team must ask the laboratory specialists if they have any question about a specific sample they must feel free to ask about it.

The good thing that was noticed in the post-analytical phase in Beit Jala Hospital is that because of sufficient number of the team working in the laboratory there was only 1% delay in the results and this happens only when they receive the samples delayed.

The same errors were found in the study of Shams (2012) in evaluating the rate and cause of post-analytical errors with a conclusion that most of the errors relating to reporting results were in post-analytical phase.

6.4 Conclusions

To conclude, there was found no significant relation between the results in the pre- and post-analytical phases because of the different health workers who do the job in each phase, and also the percentage of errors that were found in the pre-analytical phases are more significantly than the errors in the post-analytical phases, it can be noticed that the results of the observations were found to be the same in other studies globally, and the other researches also was found that the percentage of errors were higher in the pre-analytical phase than the post-analytical phases in their results.

In addition, the laboratory departments in Beit Jala hospital must build a program of continues training for all health workers specially the freshmen, and infection control must be given more effort and be practiced well.

6.5 Recommendations

Increasing the level of patient safety in the pre and post-analytical phases of laboratory testing in Beit Jala Hospital needs several recommendations at the operational level

1. Develop policies and guidelines to the pre- and post-analytical phases of laboratory testing and ensure that everyone knows it and works on protocols.
2. Training programs should be introduced for new employees and also for trainees (Laboratory technicians or Nurses) to help them knowing the best way of collecting samples without any harm to them and to the patients. And also continues educational programs for the rest of the health workers.
3. Introduce an infection control program that is special for the sample collecting techniques and enhancing it by putting sharp box in every room, and also be assured that every health worker who deals with the patient is wearing gloves.
4. Providing adequate supplies and resources and equipment which are necessary to use such as tourniquets, syringes, test tubes.
5. Reporting all errors if it happens so to investigate it and to get experience so not to repeat it again.
6. Introducing management information system program to the hospital to eliminate the post analytical errors, and to reduce the pre-analytical errors by using barcodes that has all the patient information, and to reduce the physician order errors by having the order printed and readable.
7. Monitoring and evaluations the procedures of pre- and post- analytical phases.

8. Introducing patient safety programs, such as comprehensive plan designed to improve patient safety, reduce the risk to our patients and decrease medical errors.
9. Introducing some actions related to trainees and training them before doing the venipuncture process on patients, or one of the staff must observe them and help them while doing those processes.

6.6 Areas for Future Researches

The results of the study can lead us to do further researches in:

1. Conducting a cross sectional study after introducing the recommended programs to check the prevalence on the patient safety in both phases.
2. Implementation of the policies and guidelines of patient safety in the pre- and post-analytical phases into other governmental hospitals.

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Appendix 1: Observational Checklist Form

A study for the Pre- and Post-analytical phase of laboratory testing in Beit Jala hospital

Case Number: _____ Date: _____

Description of the Person who draw the sample

Gender ☐ Male ☐ Female
2. Job Position: ☐Nurse ☐Laboratory technician ☐ Physician ☐ Trainee (Nurse/Lab)
3. Years of experience ☐ Less than 1 year ☐ 1-3 years ☐ 3-6 years ☐ 7-10 years ☐ >than 10 years
4. Department: ☐ Pediatric ☐ Maternity ☐ oncology ☐ Surgical ☐ Internal Medicine
5. Educational level: ☐Diploma ☐Bachelor ☐Higher Studies(MSc, PhD) ☐ Other
*****This questionnaire focuses on the venipuncture pre analytical phase.

Pre-analytical Phase

#	Preparation for the tests (clerical work)	Yes/No	Not needed - not used	Notes
1	Is there a physician request to do the test/s in patient file?			
2	The time of sample requisition is clearly stated in patient file.			
3	Is there any special requirement for the tests (Fasting, taking a special drug).If yes, has the patient been informed or instructed about such requirements.			
4	The request of lab tests is clearly filled out with all information required			

	(type of test, the room number and the bed number of the patient, full name, ID Number).			
5	relevant clinical information about the patient case are clearly stated for the sake of staff precautions.			

#	Needed Materials / Disposables	Yes/No	Not needed not used	Notes
1	Routine use of Safety Needles, 22g or less.			
2	Routine use of Butterfly needles. 21g or less.			
3	Availability of Syringes of all volumes.			
4	Blood Collection Tubes. With different additives.			
5	Tourniquets.			
6	Antiseptic. Individually packaged 70% isopropyl alcohol wipes.			
7	2x2 Gauze or cotton balls.			
8	Sharps Disposal Container. Puncture proof container marked "Biohazards".			
9	Bandages or tape.			

#	Venipuncture Procedure Checklist	Yes/No	Not needed not used	Notes
1	Identify the patient.			
2	Check the requisition form for requested tests, patient information, and any special requirements.			
3	Hand washing between patients.			
4	Put on gloves.			
5	Assemble the necessary equipment appropriate to the patient's physical characteristics.(dissension making and puncture method).			
6	Ask the patient for their full name and date of birth this information must match the requisition form and their arm band.			

7	Labeling the tube before blood withdraws.			
8	Appropriate selection of needle size.			
9	Preparation of equipment to obtain blood (select syringe, needle, tube that are needed).			
10	Position the patient with the arm extended to form a straight-line from shoulder to wrist.			
11	Tourniquet applied above the site.			
12	Select the appropriate vein for venipuncture from the appropriate arm (not with IV line hand).			
13	Puncture site prepared in sterile fashion, (Clean the puncture site by making a smooth circular pass over the site with the 70% alcohol pad, moving in an outward spiral from the zone of penetration. Allow the skin to dry before proceeding).			
14	Proper technique of venipuncture? a. Angle/direction appropriate: approximately 30° angle to skin surface b. # of times redirect:_____ c. # attempts total:_____			
15	Verification placement in vein that are connected in catheter or at hub.			
16	Blood draw back into syringe correctly (the velocity).			
17	After blood starts to flow, release the tourniquet and ask the patient to open his or her hand.			
18	Gauze/ cotton placed over puncture site.			
19	Needle is withdrawn after gauze is placed.			
20	Ask the patient to apply pressure for at least 2 minutes then apply band aid.			
21	Blood transferred from syringe to test tube with aseptic technique.			
22	Blood collection tubes must be drawn in a specific order to avoid cross-contamination of additives between tubes.			
23	Invert the tube 6 – 8 times to avoid clotting formation.			
24	Place needle in sharps container.			

#	Troubleshooting	Yes/No	Not needed not used	Notes
1	Repositioning the needle during puncture process.			
2	Inspection the syringe and needles for any malfunction before puncturing the vein.			
3	Ensure that the collection tube is completely pushed onto the back of the needle in the hub.			
4	Use another tube as vacuum may have been lost.			
5	Have the patient make a fist and flex the arm, which helps engorge muscles to fill veins.			
6	Another puncture in a site below the first (repetition or venipuncture).			
7	The vein may have collapsed; rescuer the tourniquet to increase venous filling.			
8	A hematoma forms under the skin adjacent to the puncture site release the tourniquet immediately and withdraw the needle. Apply firm pressure.			

#	Sample Handling	Yes/No	Not needed not used	Notes
1	Proper handling tubes (Closed well, handled with care)			
2	Sufficient specimen volume is obtained for test requirements.			
3	Is the specimen sent to the laboratory immediately.			
4	The optimal temperature needed for the sample after phlebotomy (room temperature, putting on ice).			
5	Sample Sent to the correct place (blood bank or laboratory, other).			

#	Post-Analytical Phase	Yes/No	Not needed not used	Notes
1	Post-analytic data entry error (wrong name,			

	wrong information) reports will have data errors.			
2	Oral miscommunication of results between the lab and the nursing station or physicians.			
3	Error in reporting to downstream printer, fax, or electronic medical record (EMR).			
4	Physician or other provider fails to retrieve test result due to loss of results or they are sent to other departments.			
5	the nurse put the right results in the right files the tests that are ordered are same tests that are done.			
6	Results delay (Turnaround time for each test) ➢ Chemistry about 2 hrs. ➢ Microbiology about 2-3 days. ➢ Routine about 1 hr. ➢ Blood banking about 1 hr.			
7	Repeated Tests & Samples (Hemolyzed, insufficient, other errors).			
8	If any error occur: Specify the error _____ Is it reported (informed)_____to whom_____ IS it Documented in the patient file_____			

***Remarks for the observers:**

- Do not make any observation if the phlebotomist of the patient refused.
- The observation results are confidential.
- Do not note any observation that is not in the field of this checklist.
- Do not interfere in the procedure of the phlebotomist.
- Do not judge any action from the phlebotomist of the patients.

Remember: **i don’t see, i don't hear, i don’t talk.**

Appendix 2: List of Persons shared the Questionnaire Preparation and critique:

No:	Name	Title	
1	Dr. Asma Imam	Ph.D. Supervisor / Associate Professor, School of Public Health	Al-Quds University
2	Dr. Motasem Hamdan	Ph.D. Dean of Public Health Department	Al-Quds University
3	Dr. Mahmoud Srour	Ph.D. Hematologist, Dept. of Medical Laboratory Sciences	Al-Quds University
4	Dr. Atif Remawi	JCIA Specialist - Hospital Quality Program, Director of Administration, Director of HR at Augusta Victoria Hospital	Augusta Victoria Hospital
5	Miss Abir Hananiah	M.Sc. Laboratory Supervisor, Holy Family Hospital	Holy Family Hospital Bethlehem
6	Dr. Muna Ahmead	Assistant professor at the School of Public Health / Community Mental Health master program	Al-Quds University

Appendix 3: The Names of the researchers who collected the data

No:	Name	Title
1	Michael W. Lama	Laboratory technician
2	Charlie G. Alamma	Laboratory technician
3	Daisy W. Lama	Laboratory technician

Appendix 4: The Collage Letter to Holy Family Hospital – Bethlehem to facilitate the Student's mission to do the Pilot Study

بسم الله الرحمن الرحيم

Al-Quds University
Jerusalem
School of Public Health

جامعة القدس
القدس
كلية الصحة العامة

التاريخ: 2013/9/8
الرقم: ك ص ع/423/2013

حضرة السيد حسام وهاب المحترم
المدير الإداري لمستشفى العائلة المقدس/ بيت لحم

الموضوع: مساعدة الطالب ميشيل وليم إبراهيم لاما

تحية طيبة وبعد،،
يقوم الطالب ميشيل وليم إبراهيم لاما برنامج ماجستير السياسات والإدارة الصحية/ كلية الصحة العامة/ جامعة القدس، بإعداد بحث رسالة الماجستير بعنوان:

Patient Safety during the pre-and post-analytical Phases of labrotory testing in Bet Jala Hospital.

يحتاج الطالب إلى عمل دراسة تجريبية عن طريق المشاهدة. لذا نرجو من حضرتكم مساعدة الطالب لإجراء الدراسة في المستشفى. علماً بان البحث سيكون لأغراض البحث العلمي فقط.

شاكرين لكم حسن تعاونكم،،

عميد كلية الصحة العامة
Faculty of Public Health

نسخة: الملف

Jerusalem
P.O.Box 51000
Telefax +970-2-2799234
Email: sphealth@admin.alquds.edu

فرع القدس / تلفاكس 02-2799234
ص.ب. 51000 القدس
البريد الالكتروني: sphealth@admin.alquds.edu

Appendix 5: Holy Family Hospital – Bethlehem Confirmation to do the Pilot Study

HOLY FAMILY HOSPITAL

An institution of
THE SOVEREIGN ORDER OF MALTA

322 – 326 Paul VI Street
P.O.Box 8 - Bethlehem
Palestinian Authority
Tel: 970 2 274 1151
Fax: 970 2 274 1154
E-mail: info@holyfamilyhospital-bethlehem.org

التاريخ: 2013/09/14
REF:HW/0/0909

حضرة د.معتصم حمدان المحترم ،
عميد كلية الصحة العامة /جامعة القدس

تحية طيبة وبعد ،

لا مانع لدينا في أن يقوم الطالب ميشيل وليم ابراهيم لاما بالقيام بدراسة تجريبية داخل مستشفى العائلة المقدسة ضمن برنامجه الماجستير الذي يقوم به في السياسات والإدارة الصحية في جامعة القدس.

مع الاحترام

مستشفى العائلة المقدسة

مستشفى العائلة المقدسة
Holy Family Hospital

Appendix 6: The Collage Letter to The Ministry of Health to facilitate the Student's mission in Beit Jala Hospital

بسم الله الرحمن الرحيم

Al-Quds University
Jerusalem
School of Public Health

جامعة القدس
القدس
كلية الصحة العامة

التاريخ: 2013/9/10
الرقم: ك ص ع/427/2013

حضرة الدكتورة أمل عوض المحترمة
القائم بأعمال مدير عام التعليم الصحي/ وزارة الصحة الفلسطينية

الموضوع: مساعدة الطالب ميشيل وليم إبراهيم لاما

تحية طيبة وبعد،،

يقوم الطالب ميشيل وليم إبراهيم لاما برنامج ماجستير السياسات والإدارة الصحية/ كلية الصحة العامة/ جامعة القدس، بإعداد بحث رسالة الماجستير بعنوان:

Patient Safety during the pre-and post-analytical Phases of labrotory testing in Bet Jala Hospital.

يحتاج الطالب إلى عمل دراسة عن طريق المشاهدة. لذا نرجو من حضرتكم مساعدة الطالب لإجراء الدراسة في مستشفى بيت جالا الحكومي. علماً بان البحث سيكون لأغراض البحث العلمي فقط.

شاكرين لكم حسن تعاونكم،،

كلية الصحة العامة
Faculty of Public Health

د. معتصم حمدان
عميد كلية الصحة العامة

نسخة: الملف

Appendix 7: The Ministry of Health Confirmation to facilitate the Student's mission in Beit Jala Hospital

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State of Palestine
Ministry of Health - Nablus
General Directorate of Higher & Continuing Education

دولة فلسطين
وزارة الصحة- نابلس
الإدارة العامة للتعليم الصحي

Ref.: .....
Date:.....

الرقم: ...
التاريخ: ...

الأخ مدير عام الادارة العامة للمستشفيات المحترم،،،

تحية واحترام،،،

الموضوع: تسهيل مهمة – جامعة القدس

تماشياً مع سياسة وزارة الصحة المتعلقة بتعزيز التعاون مع الجامعات والمؤسسات الأكاديمية بإتاحة فرص التدريب أمام الطلبة والخريجين والباحثين في المؤسسات الوطنية وإسهاماً في تنمية قدراتهم.

يرجى تسهيل مهمة الطالب ميشيل وليم ابراهيم لاما – ماجستير سياسات وإدارة صحية –كلية الصحة العامة – جامعة القدس، في عمل دراسة بحث للماجستير بعنوان " Patient Safety during the pre-and-post analytical phases of Laboratory testing in Beit Jala Hospital" ، وذلك من خلال السماح للطالب بعمل البحث عن طريق المشاهدة، للحصول على المعلومات التي يحتاجها البحث، وذلك في مستشفى بيت جالا، وانه سيتم الالتزام بمعايير البحث العلمي والحفاظ على سرية المعلومات.

مع الاحترام،،،

د. أمل ابو عواد
ق. أ. مدير عام التعليم الصحي

State of Palestine - Ministry of Health - Directorate General for Higher & Continuing Health Education - M.O.H Directorate General Higher & Continuing Health Palestine

نسخة: عميد كلية الصحة العامة المحترم/ جامعة القدس

P.O .Box: 14
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pnamoh@palnet.comE-mail:
ص.ب. 14
تلفاكس: 09-2333901

سلامة المرضى خلال المرحلة ما قبل و ما بعد التحليل المخبري في مستشفى بيت جالا الحكومي

إعداد الطالب : ميشيل وليم لاما

المشرف: د. أسمى الإمام

ملخص

خلفية: تبين معظم الدراسات الحديثة أن العمل الذي تم القيام به على سلامة المرضى في المختبرات الطبية ضمن المرحلة التحليلية أن نسبة الأخطاء في تلك المرحلة ليست كبيرة للغاية مقارنةً مع أخطاء أكثر ضمن المراحل ما قبل و ما بعد المرحلة التحليلية, و إن معظم الدراسات الحالية عن سلامة المرضى تصب اعتمامها على المراحل ما قبل التحليلية وما بعد التحليلية, و عذه المراح هي المراحل التي وجدوا فيها غالبية الأخطاء التشخيصية للمرضى.

المنهجية: إن الهدف من هذه الدراسة هو تحديد مستوى سلامة المرضى خلال مرحلة ما قبل وما بعد التحليلية في المختبرات داخل مستشفى بيت جالا الحكومي, وقد تمة الدراسة بواسطة المشاهدات هناك لفترة ستة أشهر في خمسة أقسام , ضمن دراسة مكونة نم 450 عينة مخبرية، وهذه المشاهدات تم اخذها خلال فترة ذروة العمل.

النتائج: أظهرت نتائج الدراسة أن مرحلة ما قبل التحليلية تحتوي على نسبة أخطاء اعلى من المرحل الاخرى بعد الاطلاع على النتائج و تقييمها في أقسام مستشفى بيت جالا (الجراحة, الولادة, طب الأطفال, الطب الداخلي والأورام) , كما أن الدراسة تركز على خصائص أفراد الطاقم الطبي الذين قاموا بالعمل في المرحلة ما قبل و ما بعد التحليلية، وخطوة خطوة بدءاً بعلبة جامع العينان, تحضير المعدات اللازمة, عملية سحب الدم, الأخطاء و معالجتها و أخيراً التعامل مع العينات و إرسالها الى المكان الصحيح. الملاحظات الاكثر تكراراً في هذه الفئات كانت في استخدام حاويات التخلص من الادوات الحادة, و أيضن بينت الدراسة أن نسب الاخطاء تزداد عنت تعامل المتدربين مع المرضى, من من جهة أُخرى كانت فئة التعامل مع العينات و ارسالها إلى المكان الصحيح و في الوقت المناسب هي أفضل فئة ضمن جميع الفئات الأخرى, وقد لوحظ ان أقل عدد أخطاء حصل في تلك الفئة, وقد تم التعامل مع العينات بالشكل صحيح و ارسالها الى المكان المناسب وفي الوقت المناسب.

المرحلة ما بعد التحليلية تصب اهتمامها على إدخال البيانات وو ارسال النتائج, وضياع النتائج و اعادة عمل الاختبارات. فإن المشكلة الرئيسية التي لوحظت في هذه المرحلة ما بعد التحليلية عي ضياع النتائج و عدم و كانت البنسبة 5٪ للنتائج المفقودة. أيضا تم رفض وتكرر حوالي 4.7٪ من العينات لأن الدم في العينات كان متخدر أو غير كفايةأو غيرها من المشكلات. الشيء الجيد في هذه الفئة حيث أنه بسبب العدد الكافي من فريق العمل في المختبر كان هناك فقط 1٪ نسبة التأخير في النتائج وهذا يحدث فقط عند استلام العينات متأخيراً.

الخلاصة والتوصيات: لم يتم العثور على علاقة ذات دلالة إحصائية بين النتائج في مراحل ما قبل وما بعد التحليلية بسبب اختلاف العاملين الصحيين في كل مرحلة، وأيضا نسبة الأخطاء التي تم العثور عليها في المرحلة ما قبل التحليلية هي أكثر بكثير من الأخطاء في مراحل ما بعد التحليلية, وعلى الصعيد العالميحيث وجد أيضا أن نسبة الأخطاء كانت أعلى في مرحلة ما قبل التحليلية من مراحل ما بعد التحليلية في نتائجها. إن بعض التوصيات لتطوير السياسات والمبادئ التوجيهية إلى مرحلة ما قبل ما بعد تحليلية للمختبرفإنه يجب إدخال برامج تدريب, و إدخال برنامج مكافحة العدوى، وتوفير الإمدادات والموارد الكافية والمعدات التي تعتبر ضرورية للاستخدام مثل الحاويات المغلقة المستخدمة للادوات الحادة، ايضاً يجب تسجيل اي خطاء ان حدث, وإدخال برنامج إدارة نظام المعلومات إلى المستشفى للقضاء على الأخطاء في المرحلة ما بعد التحليلية.