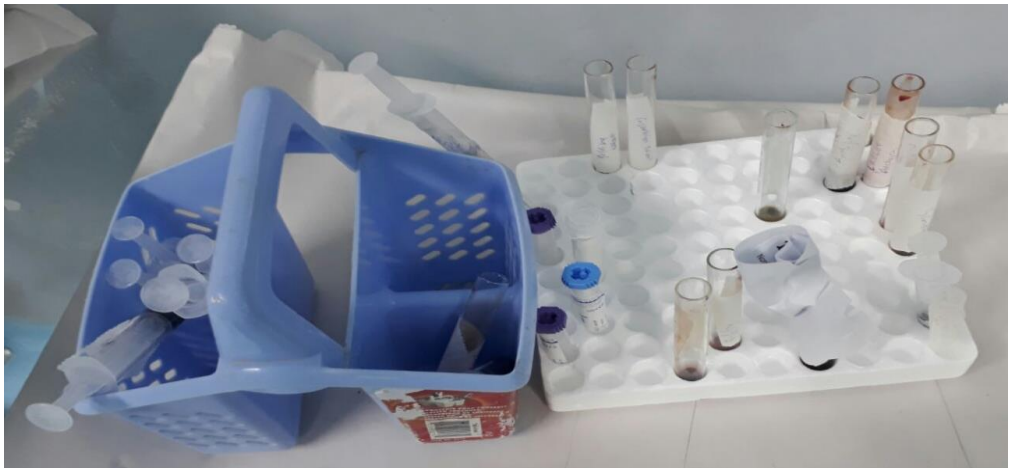
Effects from the Absence of Protocols in Phlebotomy and the Impact on Outcomes

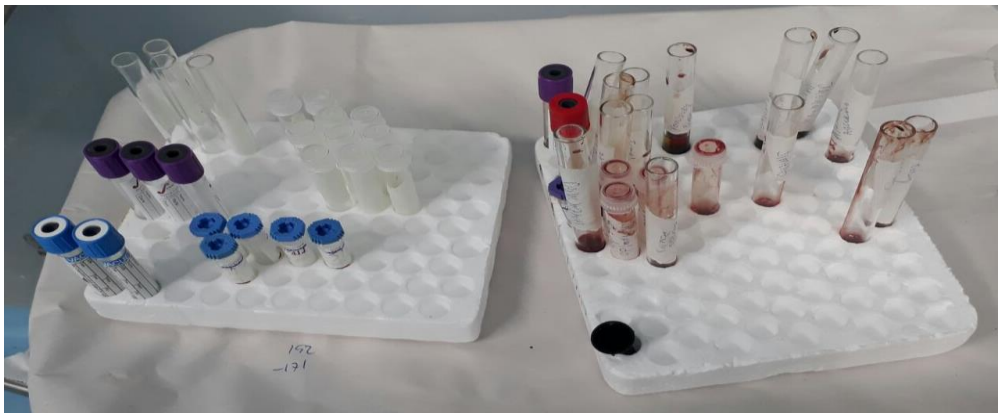


Introduction

Knowledge of most performance and pre-analytical errors in the blood collection are caused by the non-existence of institutionalized protocols. These errors directly impact the patient directly, as well as indirectly during the pre-analytical, analytical and post-analytical phases, thus affecting the outcomes, and patient condition and care.

Objectives

1) Determine whether there is protocol entity that governs hospital laboratories established in the Dominican Republic.
2) Perform an analysis, through observation, of the incidence of error.
3) Correlate the absence of blood collection protocols as the primary facilitation of impact by determining if any institutionalized protocols are being followed at the Marcelino Vélez Hospital, Robert Reid Pediatric Hospital and Las Caobas Municipal Hospital.
4) Determine the error specifications during each phase, and identify the results.
5) Identify whether the staff that is present throughout blood collection phases are properly trained in how to proceed at the time of drawing the blood sample.



Methods

The theoretical framework was built to evaluate and analyze procedures where blood is obtained, through observation and level of sentinel event or negative patient outcome, and to identify whether the absence of an institutionalized protocol was the direct impact of these outcomes.

An exploratory, descriptive and cross-sectional study aiming to determine the potential errors caused by failure to follow the blood collection protocol at the Hospital Marcelino Vélez Santana, Robert Reid Pediatric Hospital and Las Caobas Municipal Hospital, Santo Domingo occurred during a 3 month period in 2016.

The subjects consisted of all the staff working at the laboratory whom were responsible for the blood collection at different phases. In each of the health centers, a minimum of 100 patients each were selected for observation in need of blood collection services in the hospitals Marcelino Velez Santana, Robert Reid and at the Las Caobas Municipal Hospital.

These standards and protocols used as comparison for evaluation were set by CLSI, the Clinical Laboratory Standards Institute, and NCMA, the National Certification Medical Association, whose goal is to promote the use and development of pre-analytical laboratory and scope of practice guidelines worldwide.

The data collection method was performed through the observation of processes related to sampling and implementation of a survey about the laboratory service by means of a structured closed-questions questionnaire according to the variables in the study.

All information collected was obtained through informed consent in writing from the patients involved in the study and was be handled by complete discretion and exclusively by the researcher.

Outcome Measurements

Errors	Negative Patient Outcome
1. Failure to properly identify the patient or label the specimen	Transfusion or medication-related death. Patient mismanagement
2. Underfilling collection tube	Coag tube: Stroke/hemorrhage due to unnecessary modification of blood thinner dosage EDTA tube: Patient mismanagement from falsely decreased results
3. Additive carry-over due to incorrect order of draw	Cardiac arrhythmia; Seizure and death due to falsely elevated potassium level
4. Specimen was not protected from light	Falsely lower result prevents physician intervention. Newborn suffers irreversible brain damage.
5. Underfilling blood culture bottles	Death from septicemia due to false-negative result
6. Failure to properly cleanse Venipuncture site	False-positive blood culture leads to unnecessary administration of antibiotic/extended length of hospitalization
7. Prolonged tourniquet application	Seizure and death due to falsely elevated potassium level Cardiac arrhythmia Undetected anemia
8. Failure to inquire about patient allergies to latex	Sensitization/Anaphylactic shock
9. Failure to label the specimen at the patient's side	Transfusion- or medication-related death. Patient mismanagement
10. Delay in transporting/testing coagulation specimens	Stroke/hemorrhage due to modification of blood thinner dosage based on inaccurate aPIT result
11. Delay in separating serum from cells	Seizure and death due to falsely elevated potassium level Patient mismanagement
12. Patient allowed to pump fist	Cardiac arrhythmia Seizure and death due to falsely elevated potassium level Patient mismanagement
13. Specimen drawn above IV	Patient death/mismanagement

Errors That Injure Patients	Negative Patient Outcome
1. Arterial nick and/or inadequate pressure applied to Venipuncture site	Hemorrhage that leads to nerve injury, compartment syndrome or limb amputation
2. Lack of knowledge of the anatomy of the antecubital area	Permanent, disabling nerve injuries
3. Bandage applied to heelstick	Newborn choking death
4. Failure to anticipate syncope	Fractures, contusions, concussions, paralysis

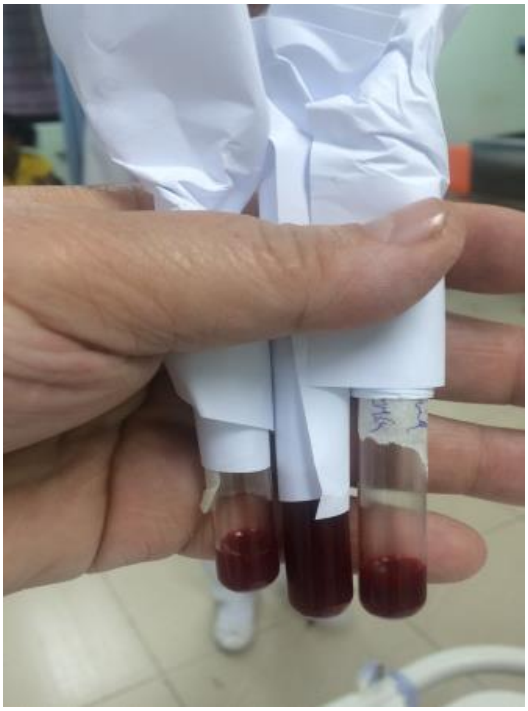
5. Failure to inquire about patient allergies to latex	Sensitization/anaphylactic shock
6. Drawing from the side of a mastectomy	Lymphedema
7. Excessive needle manipulation	Permanent, disabling nerve injuries/arterial laceration
8. Failure to survey both arms for medial vein	Impaling median nerve while attempting to access basilic vein when safer vein was available/permanent nerve injury
9. Failure to use a tourniquet	Permanent nerve injury while attempting to access basilic vein when safer vein was available, but not made evident
10. Failure to remove needle upon shooting pain sensation	Permanent disabling nerve injuries

Errors That Cause Employee Injury	**Negative Employee Outcome**
1. Accidental needlestick	Acquiring HIV, hepatitis, or any of 20 diseases known to be transmitted by blood exposure
2. Exposure to breaks in skin from drawing or processing blood without gloves	Acquiring HIV, hepatitis, or any of 20 diseases known to be transmitted by blood exposure
3. Repeated use of latex gloves/ tourniquets	Sensitization/anaphylactic shock

Independent Variables

VARIABLES	DEFINITION	INDICATORS	DIMENSION	SCALE
Staff training	Staff participation in clinical laboratory training programs on the implementation of the rules or protocol for sample extraction in the pre-analytical phase.	Trained staff	1. Participated 2. You have not participated	Nominal
Existence of rules or protocols	Availability of standards or protocols for sampling at the preclinical phase.	Standards available for care	1. There are rules or protocols. They do not exist	Nominal
Proper application of rules	It refers to compliance with the procedures established protocols for sample collection.	How to apply rules or protocols	1. It is correct 2. It is not correct	Nominal
Pre analytical errors	Errors in the pre-analytical phase made by clinical laboratory personnel in each of the phases.	Percentage of samples that were found with errors in the pre-analytical phase.	1. In drawing blood by syringe 2. Tourniquet use 3. Patient Identification 4. In order blood collection 5. In the centrifugation of the samples 6. Bio-safety errors 7. Errors in preventing glycolysis 8. The use of vascular accesses devices 9. Hemoconcentration, hemolysis, nerve trauma errors (median nerve). 10. In selecting veins 11. Contamination in blood culture	Nominal
Tourniquet application	It refers to compliance with the procedures established protocols for tourniquet application.	Percentage of samples found to have been obtained with proper	1. It is correct 2. It is not correct	Nominal

		application of tourniquet		
Tourniquet application time	It refers to the adequacy of the average time of tourniquet application at the time of sample collection	Percentage of samples found to have been taken within the time limit.	1. It is suitable 2. Not suitable	Nominal
Hemoconcentrated Samples	It refers to samples that are hemoconentrated, not positioned three to four inches above the site of venipuncture	Blood samples found to have been obtained below the site of the Venipuncture.	1. Yes 2. No	Nominal
Sample identification	It refers to whether the staff correctly identified clinical laboratory samples	Number of samples found to have been correctly identified.	1. Yes 2. No	Nominal



Results

Among the 473 patients, there was a total of 3,049 errors detected in the pre-examination phase. An average of 6.4 errors per patient were observed on venipuncture procedures. The protocol errors observed were categorized based on:

1) Order of Blood Extraction
2) Amount of Blood Drawn by Syringe
3) Tourniquet Use
4) Biosafety Errors
5) Patient Identification
6) Post-draw Hematomas
7) Hemolysis

It was determined that while there was general knowledge of the blood collection process, most healthcare professionals lacked the fine, specific technical skills. These errors furthermore hampered the quality of care, as well as increased the operating costs of each facility as more supplies and disposable materials were wasted in addition to the extended time employees spent. To exasperate the situation, the absence of protocols and benchmarks not only negatively impacted the patient and the patient's care, it also compromised the integrity of the blood sample due to the lack of storage knowledge. It can be said, however, to no fault of the facility or staff, that the absence of a universal protocol, and the ambiguity of the application of protocols, are a contributing factor to the negative outcomes related to blood collection.