Effects of Pre-analytical Variables on the Quality of Laboratory Testing

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In this presentation: We will look at...

1. Current status of Quality in today's Medical Laboratories
2. Examples/ types of preanalytical variables
3. What can be done to control/ reduce errors caused by these variables
Modern laboratories around the world are now enjoying the benefit of decades of development in technology.

“State of the Art” instrumentation are common in most laboratories.

Walkway, high throughput analyzers are employed for routine and specialized testing.
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- The result of this is significant gains in analytical performance in terms of precision, accuracy, sensitivity and specificity.
- Complementing these gains has been a steady improvement in quality control and quality assurance programs.
Concurrently, there has been an increase in the level of participation in external quality assurance programs. All of this has combined to deliver high standards of analytical performance within the laboratory.
Laboratories are finding that increased competition is driving them to improve the quality of their services while maintaining sustainable cost.

By benchmarking their laboratories with international standards,

This has led to increasing demand in achieving national/ international accreditation such as CAP, ISO, JCIA and others.
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- Laboratories who achieved or working towards achieving accreditation find themselves implementing Quality Systems that standardizes laboratory operations, provide and controls policies and procedures, and ensures safe work environment for patients and staff.

- All of this has lead to overall improvements in Quality Controls, Quality Assurance and Quality Improvements.
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- For many years however, there has been increasing recognition that the situation is less favorable in the preanalytical phase of the testing process.
- Since preanalytical errors have been reported to account for more than two thirds of all laboratory errors.
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- It is clear that regardless of the advances of laboratory technology at the analytical stage, improvements in preanalytical areas will remain to be a challenge.
- Such improvements will deliver the greatest incremental gains in the overall quality of clinical laboratory services.
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Many things can go wrong in the preanalytical arena……..

These often result in sub-optimal specimen quality, the implications of which will be “Errors in patient test result”
What are preanalytical variables?

These are variables that can occur from the time when the test is ordered by the physician until the sample is ready for analysis. Preanalytical variables can account for up to 75% of laboratory errors.
Examples of possible preanalytical variables:

**Patient Identification:** It is important to identify a patient accurately so that blood is collected from the correct person. Drawing blood from the wrong person, or labeling the correct patient’s sample with a different patient’s label can certainly contribute to laboratory error. (Mislabeling ???)
When identifying the patient, have them provide their full name, address, identification number and/or date of birth. Hospital inpatients should be wearing an identification band with the above information, which the phlebotomist should confirm before the venipuncture.
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**Patient Preparation:** Prior to collecting specimens for chemistry, certain patient variables need to be considered. For certain chemistry analytes, such as glucose and cholesterol, patients need to be fasting for at least 12 hours prior to venipuncture. Other analytes, such as cortisol and adrenocorticotropin, have diurnal variations, where the analyte is at its highest level in the morning, and the levels gradually decrease during the course of the day.
Selecting the Site: Selecting the appropriate site for venipuncture can contribute to a better quality sample. The preferred site is the median cubital vein. This vein is usually the easiest to access. Generally, there is less need to probe to find the vein, which in turn should cause less trauma during the venipuncture. This will usually be the most comfortable for the patient.
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Site Preparation: Prior to venipuncture, the site should be cleansed with alcohol. Cleansing starts at the center of the vein, and should continue outward in concentric circles. Before performing the venipuncture, the alcohol should be allowed to air dry. This will help to ensure that the specimen is not contaminated with alcohol, as this can lead to hemolysis. Hemolysis can result in the spurious elevation of such analytes as potassium, lactate dehydrogenase (LD), iron and magnesium in the chemistry lab.
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**Tourniquet Application and Time:** The tourniquet should be applied approximately three to four inches above the venipuncture site. The tourniquet should be on the arm no longer than one minute. A good rule of thumb to determine the one-minute tourniquet time is to remove the tourniquet when blood starts to flow into the first tube of blood being drawn. Prolonged tourniquet time can lead to an increase in various chemistry analytes, including serum protein, potassium and lactic acid due to hemoconcentration of blood at the puncture site.
Proper Venipuncture Technique: During phlebotomy, avoid probing to find the vein and achieve blood flow. Excessive probing and/or “fishing” to find a vein can result in a poor quality sample, including hemolysis. As mentioned previously, hemolysis can affect several chemistry analytes.
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**Order of Draw:**

- Following the **correct order of draw** during venipuncture is critical to ensure accurate test results.
- The BD and **CLSI** (Clinical and Laboratory Standards Institute, formerly NCCLS) **have established recommendations** for the proper **order of draw** for evacuated blood collection tubes.
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Recommended order of draw (NCCLS):

1. Blood Culture Bottles (Aerobic-Anaerobic)
2. Coagulation Tube
3. Serum Tube with or without clot activator, with or without gel separator
4. Heparin Tube with or without gel plasma separator
5. EDTA
6. Glycolytic Inhibitor
The Pre-Analytical process

- Order Test
- Collect Sample
- Transport To Lab
- Receive In Lab
- Prepare For Testing
- Transport To Sections
The Pre-Analytical process

Order Test:
- Receive Test order
- Complete Order form
- Deploy Staff for collection
- Note urgency level
- Collect Supplies
The Pre-Analytical process

Collect Sample:
- Locate Patient
- Prep Patient
- Draw Sample
- Bedside
- Doctor’s Office
- Draw Station
- Label
- Dispose of supplies
The Pre-Analytical process

Transport To Lab:
- Prioritize sample for transport
- Send sample to lab
  - Pneumatic tube
  - Robot
  - Hand carry
  - Courier
The Pre-Analytical process

Receive In Lab:
- Accession
- Apply/ verify sample label
- Barcode for testing
- Identify STAT tests
- Rack sample
The Pre-Analytical process

Prepare For Testing:
- Centrifuge
- Aliquot
- Pre-treat
- Re-rack
The Pre-Analytical Process

Transport To Sections

- Send sample to appropriate lab section
  - Main lab
  - Reference lab
  - Re-rack
An example of improper order of draw that can lead to an incorrect chemistry result is drawing an EDTA tube prior to a BD SST™. The potential cross contamination of K2 or K3EDTA on the needle from the lavender top tube to the chemistry tube can lead to an elevated potassium result.
Proper Tube Mixing: All tubes with additives need to be inverted to mix the additive evenly with the blood. Plastic serum tubes and BD SST ™ tubes contain clot activator and should be inverted 5 times to mix the activator with the blood and help the specimen clot completely. Improper mixing of the tube after venipuncture could contribute to a gelatinous serum sample.
Correct Specimen Volume: All blood collection tubes need to be filled to the correct volume. This will ensure the proper amount of blood for the amount of additive in the tube (blood to additive ratio). For example, if a 5 mL draw heparin tube is only filled with 3 mL of blood, the heparin concentration is erroneously high and may potentially interfere with some chemistry analytes.
Expiration dates: Should also be checked on the evacuated tubes

Expired tubes should not be used, as they may have a decreased vacuum, as well as potential changes in any additives in the tubes
Proper Tube Handling and Specimen Processing

- **Serum specimens**: Namely red top tubes and BD SST™ gel tubes, need to clot completely prior to centrifugation and processing. Blood specimens in red top tubes should clot for **45 to 60 minutes**, and those in BD SST™ tubes should be allowed to clot for **30 minutes** to ensure complete clot formation.
Blood from patients who are receiving anticoagulant therapy, such as heparin or coumadin, may take longer to clot. Tubes should be allowed to clot at room temperature, upright in a test tube rack, with the closures on the tubes. Spinning the tube too soon may result in a gelatinous and/or fibrinous serum sample that will require respinning.
Centrifugation: The next step in sample processing is the proper centrifugation of the blood collection tubes. Both BD SST™ and BD PST™ tubes are centrifuged at the same speed and for the same amount of time. In a swinging bucket centrifuge (preferred type of spin for gel separation tubes), the tubes should be spun for ten minutes at a speed of 1100 to 1300 relative centrifugal force (RCF). A fifteen-minute spin at the same speed is required for spinning tubes in a fixed-angle centrifuge. Serum and plasma tubes without gel can be spun at a speed of 1000 RCF for ten minutes.
Special Handling of Blood Specimens:
Certain chemistry analytes will require the tube of blood to be chilled after collection in order to maintain the stability of the analyte. A slurry of ice and water is recommended for chilling the tubes of blood. Examples of specimens that need to be chilled or transported on ice include adrenocorticotropic hormone (ACTH), angiotensin converting enzyme (ACE), acetone, ammonia, catecholamines, free fatty acids, lactic acid, pyruvate and renin.
Paying close **attention to** the **preanalytical variables** associated with blood collection **is critical** in ensuring **accurate test** results in all areas of the clinical laboratory.
Quality Assurance Testing Variables can effect all the stages of analysis:

- Preanalytical
- Analytical
- Postanalytical
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Pre-analytical Variables
- Test requests/ordering
- Patient identification
- Specimen acquisition
- Specimen transport
- Specimen processing
- Preparation of worklists and logs
- Maintenance records
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Analytical Variables
- Competency
- Controls
- Methodology
- Procedures
- Monitoring of equipment
- Monitoring of materials
- Test validation
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Postanalytical Variables

- Result reporting
- Result interpretation
Effects of Pre-analytical Variables on the Quality of Laboratory Testing

Laboratory errors and patient-safety
What can we do?

We need to accept that to Err is Human
"I didn't say you were to blame...
I said I'm blaming you."
Although the previous chapter talked about creating and disseminating new knowledge to prevent errors from ever happening, this chapter looks at what happens after an error occurs and how to learn from errors and prevent their recurrence. One way to learn from errors is to establish a reporting system. Reporting systems have the potential to serve two important functions. They can hold providers accountable for performance or, alternatively, they can provide information that leads to improved safety.
Implement an Error Reporting System
by developing a multifaceted strategy to enhance quality throughout the total testing process

- Systematic analysis of workflows and bottlenecks in the system and identification of solutions for critical processes to suit local circumstances
- Do not blame individuals
- Continues process monitoring through development and implementation of suitable error tracking systems
- Continuous education through reliable recommendations, improved communication by multidisciplinary meetings or interpretive rounds within and outside the laboratory environments
- Definition and implementation of representative quality indicators and outcome measures
- Elimination or redesign of flawed/mishandled procedures
In our experience, implementation of systematic error tracking system in daily practices has provided meaningful information on the preanalytical processes which are more susceptible to errors, providing an ideal foundation for efficient feedback and enabling evaluation of specific responsibilities.
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Suggested indicators for the preanalytical phase

1. **Standard operating procedures** for specimen acceptance /rejection to be followed by all staff
2. Identification and **monitoring of reasons for specimen rejection**
3. **Effect of improvement initiative** in decreasing the rate of specimen rejection
4. Comparison between clinical laboratories (**benchmarking**) of frequency and reasons for specimen rejection
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Potential performance measures for pre-analytical phase

*Indicators of patient identification*
- Wrong patient ID on the sample
- Missing patient ID on the sample
- Illegible patient ID on the sample
- Request unintelligible

*Indicators of Sample collection*
- Wrong collection time
- Inadequate/ inappropriate container
- Inadequate volume, Inappropriate volume to anticoagulant ratio
- Contaminated from IV line
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- **Indicators for sample transport**
  - Storage condition (temperature, high exposure)
  - Sample deliver to the lab outside specified time
  - Sample lost or not received in the laboratory

- **General indicators**
  - Physician complains
  - Sample recollection
  - Sample retesting
  - Correction of ordered test
  - Results delivery to the physician outside specified time
To conclude this presentation
We need to look at these questions:

- What can we actually do at this time??
- What we should know by now as someone who collects blood samples??
- In addition to what was covered so far in the presentation, we need to keep in mind the following basic points:
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- The **pre-analytical** stage is the most important and can be **critical** to patient wellbeing.
- The **analytical** stage and **post analytical** stages depend primarily on the **Quality** and **Integrity** of the **specimen** submitted to the laboratory (Pre-Analytical).
- Laboratory **staff involved** in specimen **collection** have a **direct impact** on the **outcome** of patients' lab results.
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Pre-analytical Variables

- **We should** all accept and **believe** that **there is indeed room for improvement**

- **Most errors** affecting laboratory test results **occur** in the **pre-analytical phase**, primarily because of the difficulty in achieving standardized procedures for sample collection.
Finally…

- The **human role** in sample collection **makes complete elimination of errors** associated with laboratory testing **unrealistic**
- However, **good practices** and **compliance** with the new **strategies** for **error prevention** can lead to a **substantial reduction in pre-analytical errors**.
THANK YOU

Questions/Answers

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