BD Diagnostics
Preanalytical Systems

Tracking the Cost of Poor Quality and Errors in Preanalytical Processes:
– Proven Steps Labs Can Use to Boost Patient Outcomes

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렌 The Facts
렌 Preanalytical Variables
렌 Cost of Poor Quality Model
렌 The Solutions
Medical Errors Significantly Impact Healthcare Providers

- Medical errors are the 8th leading cause of death in the US with over 32,000 reported deaths
- Errors result in 2.4M extra days of hospitalization and increase hospital costs by $17B
- *NEJM* study of medical errors showed 11% of patients received potentially harmful care; 46% did not receive recommended care
- Medication errors result in 1.5M preventable adverse drug events annually – increased cost of $3.5B
What is the real cost of a preanalytical error to your healthcare system?

- Patient Safety
- Efficiency
- Financial
- Reputation

What is a preanalytical error?

- Unlabelled specimen
  - No test result reported

- Mislabeled specimen
  - Test results incorrectly reported – two patients are affected – medical error??

- Incorrect phlebotomy technique
  - Hemolyzed sample – inaccurate test result (e.g. Falsely elevated potassium)
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The Facts

- 70% - 85% of clinical decisions are based upon information derived from laboratory test results
- Poor quality samples affect test result accuracy
- Inaccurate test results impact your institution's ability to provide optimal clinical outcomes for your patients

Preanalytical errors impact the patient, clinician, the laboratory & your health care system

Considerable evidence in the literature about the impact of Preanalytical Variables (PAVs) but no quantifiable evidence of the real cost to both the patient and the hospital.
The Facts

Where do the errors occur?

The Laboratory Test Phase

Preanalytical

Analytical

Post-Analytical

68% Preanalytical

13% Analytical

19% Post-Analytical

Test Process

0% 60% 100%

Preanalytical

Reference | Time | Preanalytical % | Analytical % | Post-Analytical %
--- | --- | --- | --- | ---
Goldschmidt and Lent | 6 years | 53.0 | 23.0 | 24.0
Nutting et al. | 6 months | 53.6 | 13.3 | 30.0
Mebani and Carraro | 3 months | 68.2 | 13.3 | 18.5
Stahl et al. | 3 years | 75.0 | 16.0 | 9.0
Hofgartner and Tait | 1 year | 60.0 | 19.0 | 15.0

26% have significant effects on patient outcome
The Facts

- The preanalytical phase is a complex process.
- A preanalytical error causes a random error – undetectable by conventional Quality Control.

Preanalytical Errors – What’s the real cost to your healthcare system?

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- One small failure in your system can multiply to a large cost
Preanalytical Errors – What’s the real cost to your healthcare system?

- The preanalytical phase is a **complex process**.
- A preanalytical error causes a **random error**
  - undetectable by conventional Quality Control.
- **One small failure** in your system can multiply to a **large cost**
- But do you know how much & where it is in your system?

Human error cannot be totally eliminated
- **BUT** good practices and compliance can significantly reduce the errors.
Factors contributing to increased preanalytical errors

Past
- All specimens collected in hospital
- Collected by Biomedical Scientists
- Specimen carried to Lab
- Limited test menus and No. instruments
- Tests were a snapshot in time
- Analytes relatively high concentrations
- Large Sample Volume

Modern Healthcare Trend
- Specimens collected in & out of hospital
- Diverse range of Healthcare Workers collecting sample
- No. of instruments & methods increasing
- Frequent staff turnover – training issues
- Test menu exploding
- Analytes monitored over time
- Test sensitivity is increasing
- Low sample volumes required

RESULT OBTAINED

RESULT OBTAINED
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Modern Healthcare Trend

RESULT OBTAINED

Is a sample just a tube? No!

Improved analytical sensitivity has driven test tube innovation that delivers improved sample purity and extended analyte stability.

Sample Volume and Reagent Use

Analyte Concentration

Semi-automated sampling from body of supernatant

Fully-automated sampling from supernatant surface
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The Facts

Preparing the lab for the future

Who are your customers?
- The physician
- Phlebotomist
- Nursing Staff
- and
- The patient who demands:
  - speed
  - accuracy
  - accessibility of results

To support customer demands, diagnostic technology advances at a rapid pace.

For example:
- Accurate diagnosis: physicians require more information from a blood sample.
- Technological innovation – higher levels of analytical sensitivity using decreasing sample volumes.
- Analysis at picomole level is now routine. That’s equivalent to a tiny drop of H2O in an Olympic size swimming pool!
Preanalytical Variables

Specimen quality is affected by preanalytical variables (PAV) and these fall into two categories; some that the Healthcare practitioner cannot control and others that it can control.
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**Examples of preanalytical variables that cannot be directly controlled:**
- Physiological status of the patient:
  - Dietary
  - Medication
  - Physical Activity
  - Stress
- Endogenous Interfering Substances:
  - Lipemic samples
  - Icteric samples

**Examples of preanalytical variables which can be controlled:**
- Specimen collection
- Order of draw
- Transport of specimen to laboratory
- Sample Processing
- Sample Handling

**Common causes of preanalytical errors**

1. Hemolysis
2. Incorrect patient identification
3. Insufficient sample volume
4. Incorrect tube
5. Clotted sample
Common causes of preanalytical errors

1. Hemolysis
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Hemolysis: the rupture of red blood cells leads to contamination of the serum or plasma with intracellular components.
- Many tests can be affected by hemolysis
- Errors arising from this may not be detected
- Examples of tests significantly affected: Potassium (K⁺), Lactate dehydrogenase (LD), Creatine kinase (CK)

Possible causes: catheter collections, delayed processing, difficult collections, choice of needle gauge as well as improper tube mixing or incorrectly filled tubes.

Incorrect patient identification
- Misidentification can lead to incorrect diagnosis and treatment and, in some cases, can be fatal for the patient (e.g. pre-transfusion testing)
- Misidentifying a patient or mislabeling a specimen is a very serious issue
- The healthcare practitioner may be held legally responsible for the consequences

Possible causes:
- Failure to follow all patient identification procedures.
- Pre-labeling tubes before collection.
Common causes of preanalytical errors

1. Hemolysis
2. Incorrect patient identification
3. Insufficient sample volume
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5. Clotted sample

Insufficient sample volume
- There is either insufficient blood volume to perform a test or the concentration of additive may be high enough to interfere with lab test accuracy.

Possible causes:
- Tube is withdrawn prior to total exhaustion of the ‘vacuum’
- Inappropriate transfer of blood by needle and syringe into tube

Incorrect tube
- Collection of sample into incorrect tube
- Tubes contain different additives – different effects on the blood specimen
- A specific test requires specific additives e.g. heparin is unsuitable as an additive for specimens required for analysis of the blood coagulation system

Possible causes:
- Not following correct blood collection procedures
- Color code confusion between different suppliers’ tubes
Common causes of preanalytical errors

1. Hemolysis
2. Incorrect patient identification
3. Insufficient sample volume
4. Incorrect tube
5. Clotted sample

Clotted Sample / Fibrin Formation
- Immediate and thorough mixing is essential to prevent platelet clumping and clotting
- Clotted samples can lead to instrument sampling system downtime

Possible causes:
- Inappropriate mixing
- Incorrect filling of tube
- Insufficient clotting time
- Patient medication

Improving sample quality in the preanalytical phase is key
How do you assess the cost impact of a PAE?

- **Redraw costs**
  - Blood Collection supplies, resources etc.

- **Lab reanalysis costs**
  - Instrument analyzer, reagents, resources, etc.

- **Lab Instrument downtime due to PAE**
  - Labor, parts, repair time etc.
  - Impact on Lab/Hospital reputation?

- **Patient treatment costs**
  - Additional stay, additional diagnostic procedures, etc.

- **Others??**

That’s only part of the financial picture.

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**BD Diagnostics**

Preanalytical Systems

- The Facts
- Preanalytical Variables
- Cost of Poor Quality Model
- The Solutions
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Cost of Poor Quality Model

- Developed with healthcare economist – Frost & Sullivan
- Helps healthcare providers understand impact of PAE on total operating cost
- Provides a benchmark for quality with peers in the database
- Provides a metric for tracking errors and setting targets
- Provides a breakdown by patient category
  - Hospitalized Critical Patient
  - Outpatient Routine Test
  - Hospitalized Elective Surgery Patient

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Cost of Poor Quality Model

Methodology and Approach

Blood Collection Process

1. Patient admitted to hospital
2. Blood specimen taken
3. Calculate probability of rejected specimens due to PAE
4. Calculates impact of errors on patient treatment
5. Calculates opportunity cost for patient treatment lost in time and money

Methodology
Cost of Poor Quality Model

Based on survey data compared to industry data

- Quantitative data
  - Hospital
  - Laboratory
- Qualitative data
  - Clinician interviews as to practices related to scenarios where specimen rejection occur

<table>
<thead>
<tr>
<th>Patient Impact Level</th>
<th>Percentage of Specimen Rejections Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical Impact</td>
<td>3%</td>
</tr>
<tr>
<td>Medium Impact</td>
<td>2%</td>
</tr>
<tr>
<td>Low Impact</td>
<td>95%</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
</tr>
</tbody>
</table>

Let's look at the real cost of a PAE

1. Hospitalized Critical Patient
2. Outpatient Routine Test
3. Hospitalized Elective Surgery Patient
Cost of Poor Quality Model

Let's look at the real cost of a PAE

**Background:** A 55 year old male arrives at ED complaining of chest pains and shortness of breath. They are overweight with a history of elevated cholesterol and cardiac disease.

**Error:** False positive results for AML.

**Impact:**

- **Low:** Lab spots error, length of stay (LOS) is minimized and corrective action taken. Rerun test after 1 hour.
- **Medium:** If the lab does not spot the error but the physician catches it, patient retested. This means a retest, more retesting, physicians and lab time. If one result is positive and one is negative, may require further collaborative testing (<24 hours).
- **Critical:** If the physician does not spot the PAE but the Intensive Care Unit (ICU) does, patient stay extended by several days.

**What was the cost of poor quality impact?**

<table>
<thead>
<tr>
<th>Cost of rejected samples over one year</th>
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</thead>
<tbody>
<tr>
<td>Total number of patient treatment hours lost</td>
</tr>
<tr>
<td>2,986</td>
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</tbody>
</table>

**Total number of specimen rejections affected**

- **Patient Impact level** | Percentage of specimens affected |
  - Critical impact | 7% |
  - Medium impact | 8% |
  - Low impact | 85% |
  - Total | 100% |

**Total cost of preanalytical specimen rejection by percentage contribution**

- **Patient Treatment Costs** | 78.75% |
- Blood collection consumables | 0.13% |
- Redraw costs | 14.32% |
- Lab investigation costs | 3.89% |
- Instrument downtime costs | 4.91% |
- Patient treatment costs | 100% |
- **TOTAL cost of rejection** | $114,161 |
Let's look at the real cost of a PAE

**Background:**
A 40 year old female type 1 (insulin dependent) diabetic patient attends an outpatient clinic to monitor a number of routine tests including potassium.

**Error:**
Hemolysed sample leads to elevated potassium masking real issues.

**Impact:**

- **Low:** Lab spots error, then length of stay (LOS) is minimized, a redraw is requested but patient has eaten, so the patient goes home and has to go back another day.
- **Medium:** Laboratory does not spot error but Physician reacts on potassium result and sends patient to ED, but after reevaluation is sent home.
- **Critical:** Patient has gone home. The patient’s records are not up to date and they cannot be contacted, their condition deteriorates and they are admitted to hospital as an emergency.

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<table>
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<tr>
<td>Patient's impact level</td>
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<td>------------------------</td>
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**Total cost of preanalytical specimen rejection by percentage contribution**

- Patient Treatment Costs: 83.42%
- Blood collection consumables: 0.02%
- Redraw costs: 9.11%
- Lab investigation costs: 1.96%
- Instrument downtime costs: 5.47%
- Patient treatment costs: 83.42%

**TOTAL cost of rejection:** $648,564
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Cost of Poor Quality Model

Let’s look at the real cost of a PAE

**Background:** Following thyroid surgery due to cancer on a 55 year old male, post surgery requires appropriate critical laboratory testing.

**Error:** Incorrect result, lab rejects critical sample and requires additional sample for testing.

**Impact:**
- **Low:** Lab rejects sample, a new sample is drawn and appropriate results are obtained.
- **Medium:** Lab rejects sample, a new sample is drawn but the results are obtained late for the physician’s ward visit. This means that the patient’s length of stay (LOS) is increased using a high dependency bed.
- **Critical:** Lab rejects sample and Physician is unable to make a critical decision regarding the patient’s treatment. As a result, patient’s condition deteriorates and a transfer to a higher dependency ward (Intensive Care Unit) is required.

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<td>Total number of patient treatment hours lost</td>
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Hospitalized Elective Surgery Patient

Preanalytical Cost of Poor Quality Survey, 2019 Hospital Care (Inc.)
Cost of Poor Quality Model

Preliminary Studies in USA

- Cost of PAE is 70% higher (less favorable) than European institutions in the database
- Average cost of a PAE is $349

![Graph showing Total Cost of Preanalytical Specimen Rejection in 2010](chart1.png)

- Hospital X Total Cost of Poor Quality USA: $5,583,513
- Benchmark Cost of Poor Quality EUROPE: $3,276,512

Cost of Poor Quality Model

Financial Impact – Cost by Category

- Patient treatment cost is the largest category of cost at 71.8%
- Laboratory investigation and redraw costs is 25.9%
- Collection consumables cost is 0.16%

![Pie chart showing Total Costs by Category](chart2.png)

- Patient Treatment Costs: 71.85%
- Blood Collection Consumables: 0.16%
- Redraw Costs: 20.86%
- Lab Investigation Costs: 5.47%
- Instrument Downtime Costs: 2.97%
- Patient Treatment Costs: 100%

TOTAL cost of rejection: $5,583,513
Cost of Poor Quality Model

Hours Lost Due to Sample Redraw – Efficiency Impact

- 22,275 lost patient treatment and redraw hours
- An additional 1,983 patients could be treated annually

Number of Redraw Hours Lost in Each Category as a Percentage of Total Redraw Hours Lost

- Inpatient Critical: 48.0%
- Inpatient Elective: 11.2%
- Outpatient: 40.8%

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The Facts
Preanalytical Variables
Cost of Poor Quality Model
The Solutions
The blood collection process is a complex one.

In a large, dynamic organization like yours, you don’t have the time or resources to identify where an error occurs.

Pneumatic tube (blood sample transportation device)
• Identifying the causes of preanalytical errors.

• Identifying solutions to improve workflow & efficiency.

• Understanding & documenting current practices.

• Improving practice & HCW Safety.
The Solutions

Preanalytical Improvement Methodology

Improving the Preanalytical Process involves four key steps

Step 1: Benchmark COPQ

Step 2: Root Cause Analysis

Step 3: Change Management & Education

Step 4: Optimization and Control

Reducing the cost of a preanalytical error

Quality Control
- Identify and monitor possible causes of preanalytical errors
- QA Programs should include monitoring the sample collection process

Good Practice
- Understand your current practices vs. hospital procedures and best practices

Training & Education Programs
- Support your staff by providing clear and effective training

Quality Products
- Don’t forget the tube and needle!
- The tube is the primary element that links every part of the specimen process
- Labs should treat the tube and sample collection device as they would an instrument reagent
The Solutions

- Manage budgets more effectively
- Maximize capital investment
- Improve sample quality
- Improve efficiency & performance
  - Reducing patient waiting times
  - Re-engineer processes & procedure
  - Develop your people
- Benchmark costs vs. other hospitals

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In Summary:

- Preanalytical errors cost the patient, clinician, the laboratory & your health care system.
- PAEs can be reduced by improving Compliance through improved processes and good practice.
- The lab will continue to play a pivotal role in supporting clinical decision making.
- The laboratory service will be judged on its ability to produce accurate test results. Poor specimen quality affects test accuracy.
- An efficient Turn around Time (TAT) becomes irrelevant if the result is inaccurate due to a simple quality error made when collecting the specimen in the PA Phase.