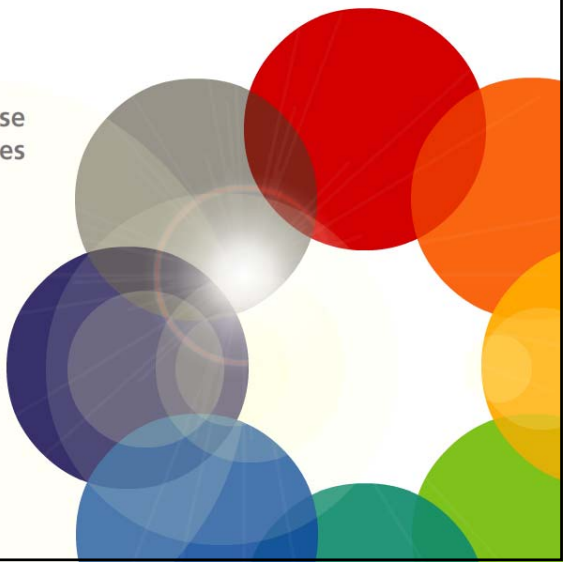
BD Diagnostics
Preanalytical Systems

v6

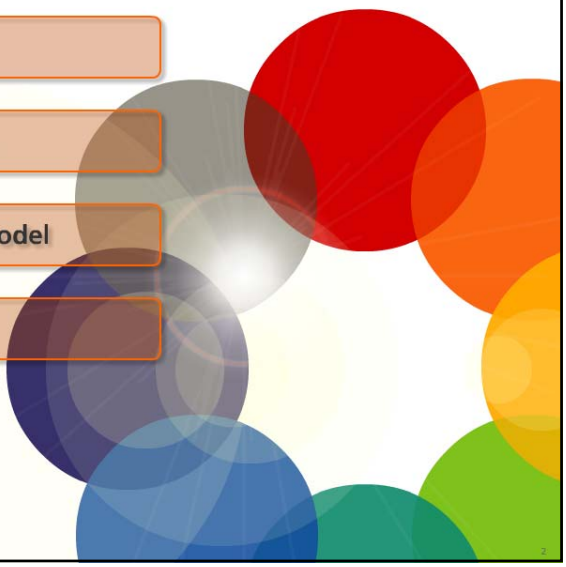
Tracking the Cost of Poor Quality and Errors in Preanalytical Processes:
– Proven Steps Labs Can Use to Boost Patient Outcomes

Sol F. Green, Ph.D., FACB.
Director, Medical Affairs
North and Latin America
BD Preanalytical Systems,
Franklin Lakes, NJ.



BD Diagnostics
Preanalytical Systems

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



BD Diagnostics
Preanalytical Systems

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

BD Diagnostics
Preanalytical Systems

The Facts

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

BD Diagnostics
Preanalytical Systems

The Facts

What is the *real cost* of a preanalytical error to your healthcare system?

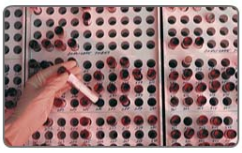
- Patient Safety
- Efficiency
- Financial
- Reputation

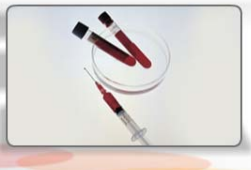
BD Diagnostics
Preanalytical Systems

The Facts

What is a preanalytical error?

- **Unlabelled specimen**
  - No test result reported
- **Mislabelled specimen**
  - Test results incorrectly reported – two patients are affected – medical error??
- **Incorrect phlebotomy technique**
  - Hemolysed sample – inaccurate test result (e.g. Falsely elevated potassium)





BD Diagnostics
Preanalytical Systems

The Facts

- 70 – 85% of clinical decisions are based upon information derived from laboratory test results

- Poor quality samples affect test result accuracy

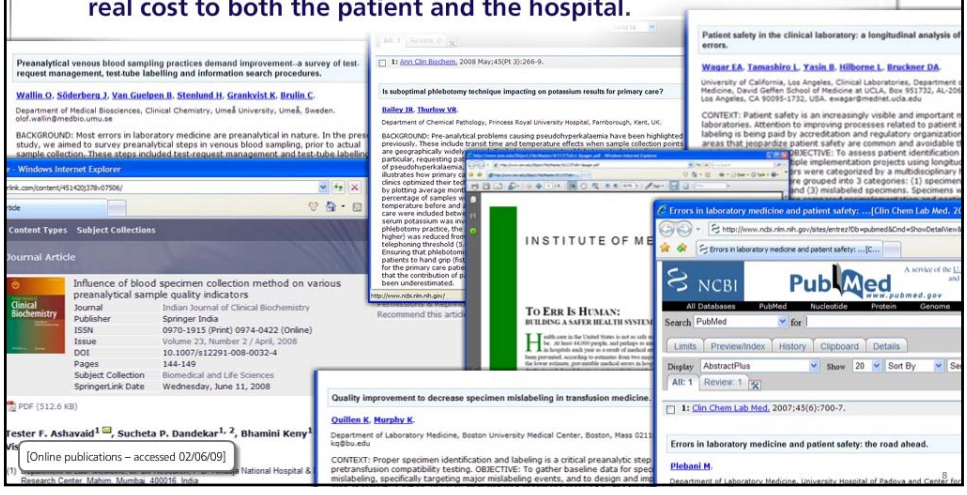
- Inaccurate test results impact your institution's ability to provide optimal clinical outcomes for your patients

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

BD Diagnostics
Preanalytical Systems

The Facts

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.

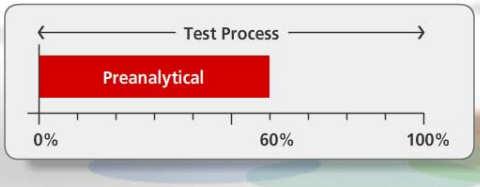


BD Diagnostics
Preanalytical Systems

The Facts

Where do the errors occur?

The Laboratory Test Phase



BD Diagnostics
Preanalytical Systems

The Facts

Review of medical errors by processing phase

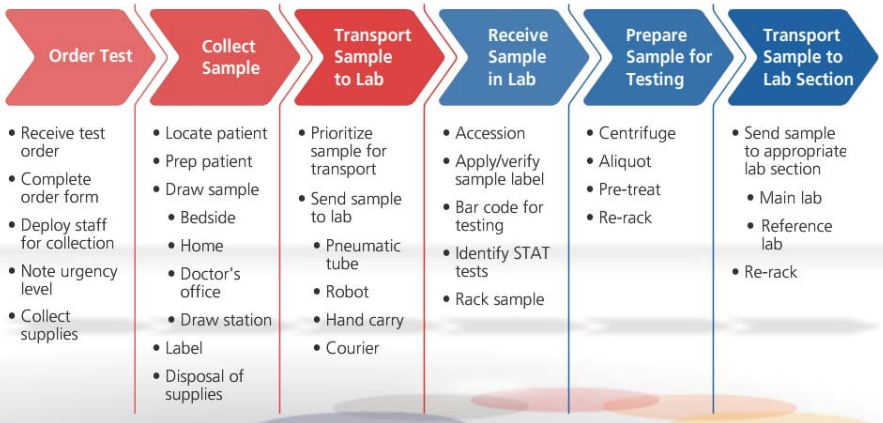
Reference	Time	Preanalytical %	Analytical %	Post-Analytical %
Goldschmidt and Lent Whole laboratory: total 133 errors	6 years	53.0	23.0	24.0
Nutting et. al. Primary care: 160,714 patients: error 0.11% of patients	6 months	55.6	13.3 4.4% Referral lab 40% POCT	30.0
Plebani and Carraro STAT laboratory: 40,490 tests; error 0.47% of test results	3 months	68.2	13.3	18.5
Stahl et. al. Whole laboratory: 676,564 tests; error 0.61% of test results	3 years	75.0	16.0	9.0
Hofgartner and Tait Molecular genetic tests: 88,394 patients; error 0.33% of test results	1 year	60.0	19.0	15.0

26% have significant effects on patient outcome

BD Diagnostics
Preanalytical Systems

The Facts

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



11

BD Diagnostics
Preanalytical Systems

The Facts

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

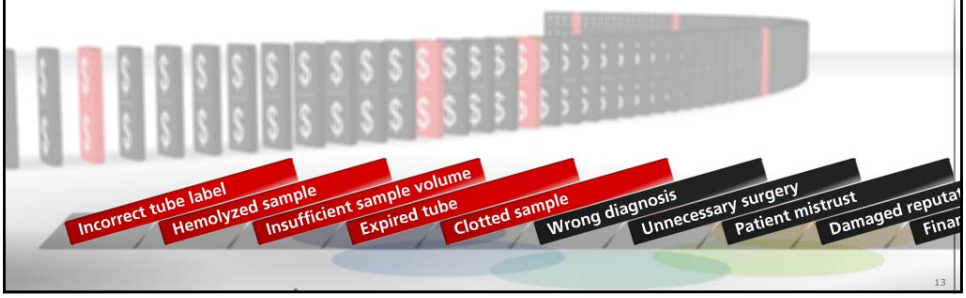
12

BD Diagnostics
Preanalytical Systems

The Facts

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?



13

BD Diagnostics
Preanalytical Systems

The Facts

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.

13

BD Diagnostics
Preanalytical Systems

The Facts

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
- RESULT OBTAINED

Modern Healthcare Trend

BD Diagnostics
Preanalytical Systems

The Facts

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
RESULT OBTAINED

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

BD Diagnostics
Preanalytical Systems

The Facts

Factors contributing to increased preanalytical errors

Past	Modern Healthcare Trend
All specimens collected in hospital	[redacted]
Collected by Biomedical Scientists	[redacted]
Specimen carried to Lab	[redacted]
Limited test menus and No. instruments	[redacted]
Tests were a snapshot in time	[redacted]
Analytes relatively high concentrations	[redacted]
Large Sample Volume	[redacted]
RESULT OBTAINED	RESULT OBTAINED

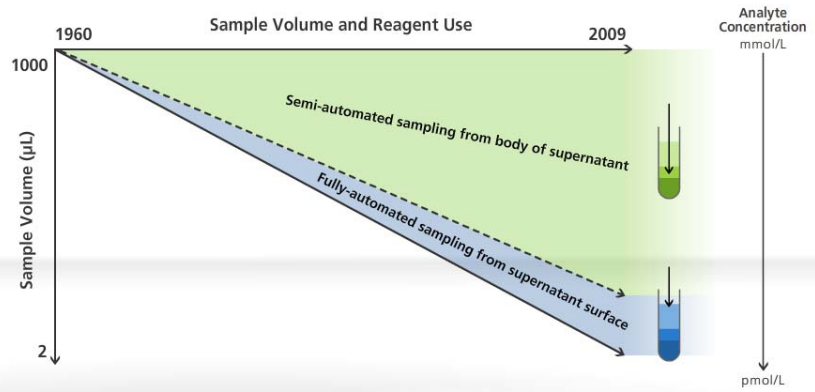
15

BD Diagnostics
Preanalytical Systems

The Facts

Is a sample just a tube? No!

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



16

BD Diagnostics
Preanalytical Systems

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 H_2O in an Olympic size swimming pool!

BD Diagnostics
Preanalytical Systems

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 H_2O in an Olympic size swimming pool!

BD Diagnostics
Preanalytical Systems

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

BD Diagnostics
Preanalytical Systems

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.

BD Diagnostics
Preanalytical Systems

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.

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

BD Diagnostics
Preanalytical Systems

Preanalytical Variables

Common causes of preanalytical errors

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

BD Diagnostics
Preanalytical Systems

Preanalytical Variables

Common causes of preanalytical errors

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

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.

BD Diagnostics
Preanalytical Systems

Preanalytical Variables

Common causes of preanalytical errors

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

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 mislabelling 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-labelling tubes before collection.

BD Diagnostics
Preanalytical Systems

Preanalytical Variables

Common causes of preanalytical errors

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

BD Diagnostics
Preanalytical Systems

Preanalytical Variables

Common causes of preanalytical errors

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

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

BD Diagnostics
Preanalytical Systems

Preanalytical Variables

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

BD Diagnostics
Preanalytical Systems

Preanalytical Variables

Improving sample quality
in the
preanalytical phase
is key

Improving sample quality
in the
preanalytical phase
is key

BD Diagnostics
Preanalytical Systems

Preanalytical Variables

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.

BD Diagnostics
Preanalytical Systems

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

BD Diagnostics
Preanalytical Systems

Cost of Poor Quality Model

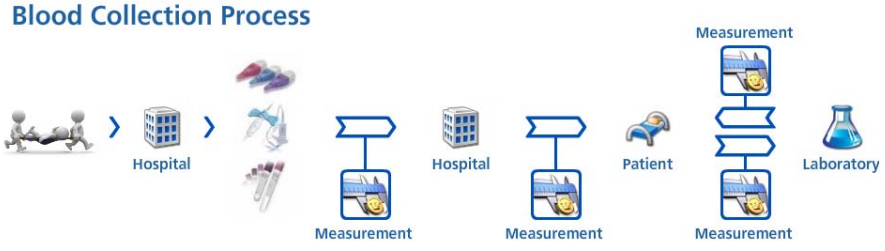
- Developed with healthcare economist – Frost & Sullivan
- Helps healthcare providers understand impact of PAE on total operating cost
- Provides a benchmark for quality with peers in the database
- Provides a metric for tracking errors and setting targets
- Provides a breakdown by patient category
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

BD Diagnostics
Preanalytical Systems

Cost of Poor Quality Model

Methodology and Approach

Blood Collection Process



Methodology

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

BD Diagnostics
Preanalytical Systems

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**

Patient Impact Level	Percentage of Specimen Rejections Affected
Critical Impact	3%
Medium Impact	2%
Low Impact	95%
Total	100%

BD Diagnostics
Preanalytical Systems

Cost of Poor Quality Model

Let's look at the real cost of a PAE

1	2	3
Hospitalized Critical Patient	Outpatient Routine Test	Hospitalized Elective Surgery Patient



BD Diagnostics
Preanalytical Systems

Cost of Poor Quality Model

Let's look at the real cost of a PAE

1
Hospitalized Critical Patient

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 AMI.

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 restest, more redrawing, physician 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.

Back to Menu

What was the cost of poor quality impact?

BD Diagnostics
Preanalytical Systems

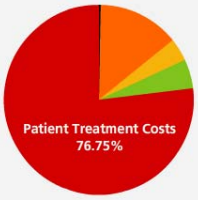
Cost of Poor Quality Model

Let's look at the real cost of a PAE

Cost of rejected samples over one year	
Total number of patient treatment hours lost	Cost per patient per rejection
2,986	$2,712

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



Blood collection consumables	0.13%
Redraw costs	14.32%
Lab investigation costs	3.89%
Instrument downtime costs	4.91%
Patient treatment costs	76.75%
	100%
TOTAL cost of rejection	$114,161

Back to Menu

Hospitalized Critical Patient

BD Laboratory Consulting Services℠
Preanalytical Cost of Poor Quality Survey. EU Hospital Data on file 2008

BD Diagnostics
Preanalytical Systems

Cost of Poor Quality Model

Let's look at the real cost of a PAE

2
Outpatient Routine Test

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: Hemolysized 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 revaluation 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.

Back to Menu

What was the cost of poor quality impact?

29

BD Diagnostics
Preanalytical Systems

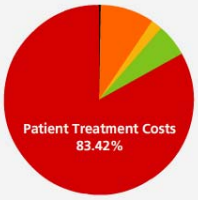
Cost of Poor Quality Model

Let's look at the real cost of a PAE

Cost of rejected samples over one year	
Total number of patient treatment hours lost	Cost per patient per rejection
71,778	$20

Total number of specimen rejections affected	
Patient impact level	Percentage of specimens affected
Critical impact	0%
Medium impact	5%
Low impact	95%
Total	100%

Total cost of preanalytical specimen rejection by percentage contribution



Blood collection consumables	0.02%
Redraw costs	9.13%
Lab investigation costs	1.96%
Instrument downtime costs	5.47%
Patient treatment costs	83.42%
	100%
TOTAL cost of rejection	$648,564

Back to Menu

Outpatient Routine Test

BD Laboratory Consulting Services℠
Preanalytical Cost of Poor Quality Survey. EU Hospital Data on file 2008

29

BD Diagnostics
Preanalytical Systems

Cost of Poor Quality Model

Let's look at the real cost of a PAE

3
Hospitalized Elective Surgery Patient

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.

Back to Menu

What was the cost of poor quality impact?

29

BD Diagnostics
Preanalytical Systems

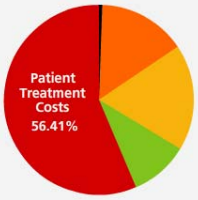
Cost of Poor Quality Model

Let's look at the real cost of a PAE

Cost of rejected samples over one year	
Total number of patient treatment hours lost	Cost per patient per rejection
1,388	$2,952

Total number of specimen rejections affected	
Patient impact level	Percentage of specimens affected
Critical impact	0%
Medium impact	7%
Low impact	93%
Total	100%

Total cost of preanalytical specimen rejection by percentage contribution



Blood collection consumables	0.58%
Redraw costs	15.01%
Lab investigation costs	18.00%
Instrument downtime costs	10.00%
Patient treatment costs	56.41%
	100%
TOTAL cost of rejection	$56,049

Back to Menu

Hospitalized Elective Surgery Patient

BD Laboratory Consulting Services℠
Preanalytical Cost of Poor Quality Survey. EU Hospital Data on file 2008

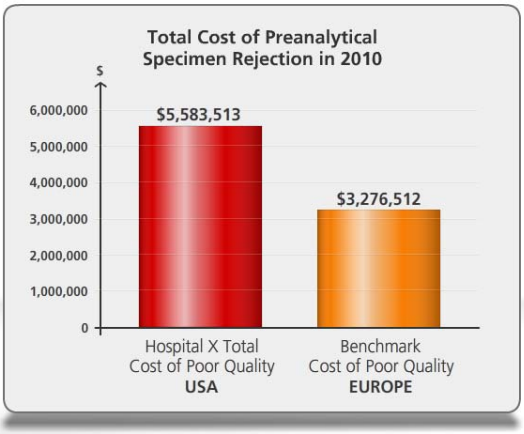
29

BD Diagnostics
Preanalytical Systems

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

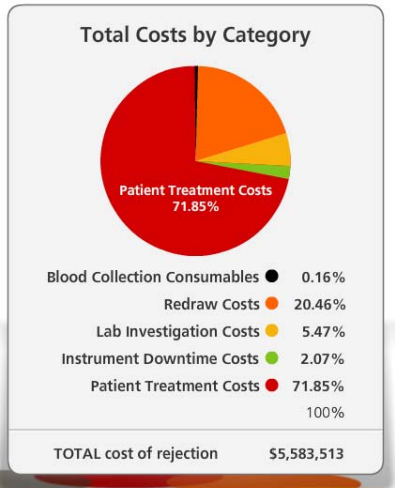


BD Diagnostics
Preanalytical Systems

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%

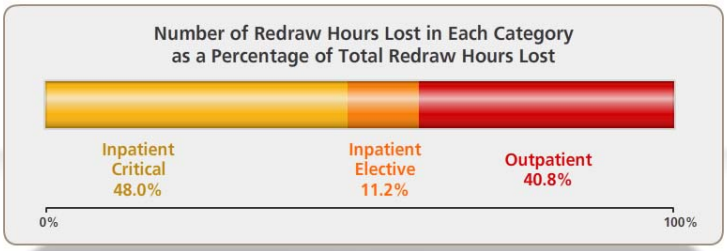


BD Diagnostics
Preanalytical Systems

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



BD Diagnostics
Preanalytical Systems

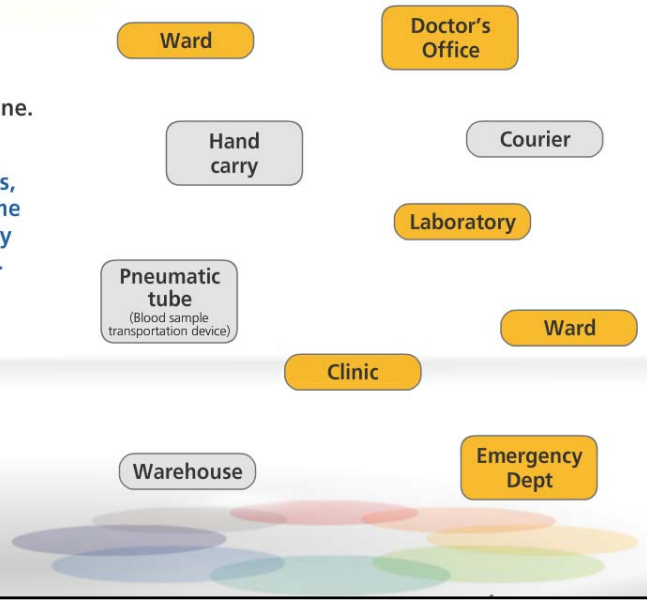
- The Facts
- Preanalytical Variables
- Cost of Poor Quality Model
- **The Solutions**

BD Diagnostics
Preanalytical Systems

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.

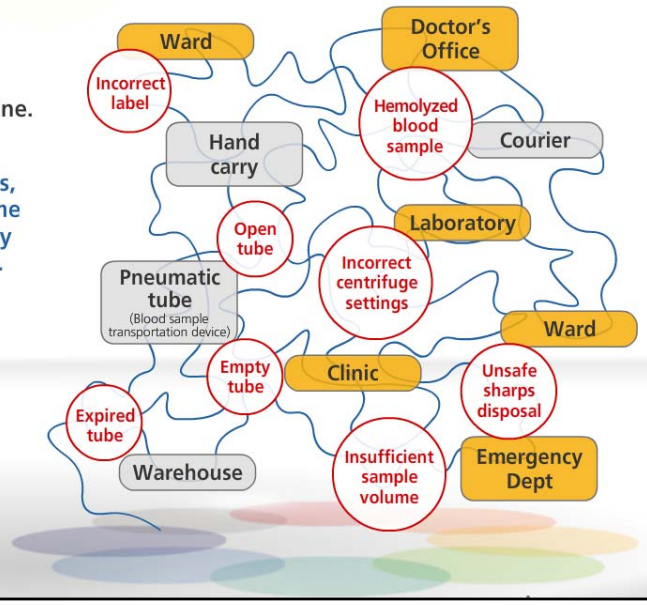


BD Diagnostics
Preanalytical Systems

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.



BD Diagnostics
Preanalytical Systems

The Solutions

Expired tube | Incorrect label | Empty tube | Open tube | Incorrect centrifuge settings | Insufficient sample volume | Hemolyzed blood sample | Unsafe sharps disposal

- Identifying the causes of preanalytical errors.

Ward
Doctor's Office
Hand carry
Courier
Pneumatic tube (Blood sample transportation device)
Laboratory
Clinic
Emergency Dept
Warehouse

BD Diagnostics
Preanalytical Systems

The Solutions

Expired tube | Incorrect label | Empty tube | Open tube | Incorrect centrifuge settings | Insufficient sample volume | Hemolyzed blood sample | Unsafe sharps disposal

- Identifying the causes of preanalytical errors.
- Identifying solutions to improve workflow & efficiency.
- Understanding & documenting current practices.
- Improving practice & HCW Safety.

Storage
Warehouse

Blood Collection
Clinic
Ward
Doctor's Office
Emergency Dept

Transport
Courier
Hand carry
Pneumatic tube (Blood sample transportation device)

Preanalytical Phase & Sample Quality
Laboratory

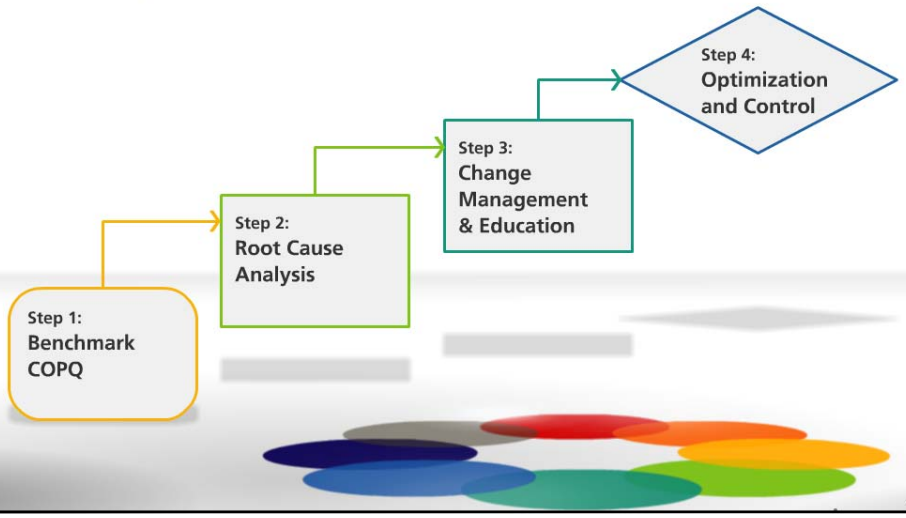
35

BD Diagnostics
Preanalytical Systems

The Solutions

Preanalytical Improvement Methodology

Improving the Preanalytical Process involves four key steps



BD Diagnostics
Preanalytical Systems

The Solutions

Reducing the cost of a preanalytical error

26% have significant effects on patient outcome

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

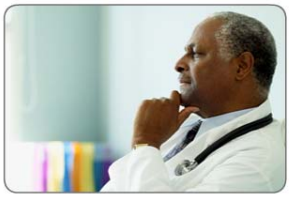
Training & Education Programs
- Support your staff by providing clear and effective training

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**

BD Diagnostics
Preanalytical Systems

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



BD Diagnostics
Preanalytical Systems

The Solutions

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.