**Specimen Collection Regulations and Standards**

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**Scope**

- Specimen collection could be occurring:
  - In your laboratory
  - In your hospital
  - In another hospital, nursing home, or physician’s office before reaching your facility.

- It may include:
  - Venous samples
  - Urine
  - Sputum
  - Arterial blood
  - Other

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**Specimen Collection Considerations**

- Blood draw
  - Tubes and collection containers
  - Patient identification
  - Collection site
  - Interfering substances
  - Cleaning the site

- Transporting the sample
  - Environment (motion, temperature, separating serum, etc.)
  - Timing to get to laboratory
### Test Request Form

- Physician’s order
- Identifies test, which determines:
  - Site
  - Container
  - Handling
  - Patient Identification

### Staff

- May be dedicated laboratory staff
- May be staff within your own organization
  - Nurses
  - Doctors
  - Respiratory therapists
  - Others
- Collection staff may belong to an outside organization
- Couriers may be contracted or internal

### The BIG Question

- How do you control your preanalytical process with this many variables?
- Is it any wonder that preanalytical error contributes to 40-60% (depends on citation used) of total error with this much process variability?
Regulations and Standards Can Help

- The Clinical Laboratory Improvement Amendments (CLIA) are only applicable to nonwaived testing facilities so there is a gap in facilities, without laboratories and for controlling areas outside the laboratory.
- Clinical accreditation organizations can help with the other staff collecting samples.
- Clinical accreditation programs should also be looking at specimen collection.
- CLSI documents provide best practice guidance.
- Laboratory Medicine Best Practices Group data can drive operational decisions.

IATA/DOT Shipping Instructions

- FedEx® has an excellent brochure

Wrong Way
Right Way

1. Watertight primary receptacle, usually test tube
2. Watertight secondary receptacle, usually leak-proof bag or polystyrene box
3. Absorbent material
4. Sturdy outer packing. If shipping by air, it must be shatterproof.

CLIA Regulations - Quality Systems

§493.1200 Introduction.
(a) Each laboratory that performs nonwaived testing must establish and maintain written policies and procedures that implement and monitor quality systems for all phases of the total testing process (that is, preanalytic, analytic, and postanalytic) as well as general laboratory systems.
(b) Each of the laboratory’s quality systems must include an assessment component that ensures continuous improvement of the laboratory’s performance and services through ongoing monitoring that identifies, evaluates and resolves problems.

§493.1240 Condition: Preanalytic systems
(a) overall quality

§493.1232 Standard: Specimen identification and integrity
The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient’s specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.
§493.1241 Standard: Test request

a) The laboratory must have a written or electronic request for patient testing from an authorized person.
b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.
c) The laboratory must ensure the test requisition solicits the required information (see CLIA regulation for list of eight elements)
d) The “patient’s” chart or medical record may be used as the test requisition or authorization but must be available to the laboratory at the time of testing and available to CMS or a CMS agent upon request.
e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

§493.1242

Standard: Specimen submission, handling, and referral

- Includes storage and transportation
  (b) The procedure manual must include the following when applicable to the test procedure:
  (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242

§493.1249 Standard: Preanalytic systems assessment

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at Sec. Sec. 493.1241 through 493.1242.
(b) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems assessment reviews with appropriate staff.
(c) The laboratory must document all preanalytic systems assessment activities.
§493.1251 Standard: Procedure manual

(a) A written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the "laboratory's" written procedures for testing or examining specimens.

(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in Sec. 493.1242.

Accreditation Programs

- Hospitals - also under CMS and are typically accredited
- Physician’s offices
- Nursing homes
- Behavioral health
- Home care
- And, of course, the majority of laboratories use an accreditor for deeming and build on the CLIA regulations.

Accreditation Standards for Clinical Areas

- There are Joint Commission standards in each of these programs that two identifiers must be used to identify patients.
- The standards also specify to label samples in the presence of the patient.
- Active patient involvement is best practice whenever possible.
Staff Competency Standards Applicable to All Clinical Areas

- Surveyors should watch a blood draw.
- Staff should be trained to perform their duties in any setting.
- Staff are competent in their duties.
- Staff are evaluated for performance expectations.

Infection Control and Safety

- There are universal standards regarding hand hygiene and use of personal protective equipment in the clinical settings.
  - Gloves for blood draws
  - Do not cut off the finger to palpate the vein!
- Management of biohazards and sharps are also universal and are required by the Occupational Safety and Health Administration.

Diagnostic Care Standards for Hospitals

- The facility provides for diagnostic testing and procedures as ordered.
  - Remember: CLIA requires a physician order for all nonwaived testing.
Performance Improvement

• Again, expectation is for all accreditation programs to track and document performance.
  – Intent is to see improvement over time.
• Sentinel event reporting will capture delay that results in death or serious injury, requiring root cause analysis.
  – This becomes an organizational issue, not just one for the laboratory.
• National Quality Forum also includes delay resulting in death or harm as a serious reportable event.
  – Also an organizational issue.

CLSI Documents to Assist

• GP34-A Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline
• H03-A6 Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition
• H18-A4 Procedures for the Handling and Processing of Blood Specimens for Common laboratory Tests; Approved Guideline - Fourth Edition
• H01-A6 Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard- Sixth Edition

New: AUTO12-A. Specimen labels: Content and Location Fonts, and label Orientation; Approved Standard

• Identifies required human-readable elements
• Goal is to minimize the errors from the label quality itself, which will:
  – Improve turnaround time
  – Reduce misreads, including wrong identification
Five Required Elements

1. Patient name
2. Unique patient identifier
3. Date of birth
4. Specimen collection time and date
5. Designated space for the collector's identification (ID) (handwritten or electronic)
   • Also requires location of label relative to stopper

Recommended Reserve Space

• General location for Laboratory information system accession number
• Institutional specifications
  – Critical result call
  – Tube type
  – Type and volume of specimen
  – Specific handling requirements such as pH, temperature, preservatives, routing, test codes and order status

Laboratory Medicine Best Practices

Identified sample collection as a priority because:
• Improving the accuracy of patient identification, including laboratory specimens, continues to be the #1 Joint Commission NPSG and has been for years.
• Improving patient and sample identification at the time of specimen collection, analysis and resulting continues to be the #1 PSG of CAP.
• It's expensive … for example, a mislabeled specimen cost one provider $15K not counting legal fees
• A mislabeled specimen could prove fatal
• It's the definitive ‘zero tolerance’ error in laboratory medicine
(Source: futurelaboratorymedicine.org)
Laboratory Medicine Best Practices

Methods

- System evidence review methods were used and validated.
- Uses published and unpublished data sources to do meta-analysis.
- Rate the quality of the data.
- Evaluate several aspects of the study to develop an overall rating of high, moderate, suggestive, or insufficient.

Laboratory Medicine Best Practices

Recommendation: Bar Coding Systems

The Laboratory Medicine Best Practices Workgroup recommends the use of a bar coding process to consistently link patients and their specimens through the entire testing process to reduce or eliminate Patient Specimen Identification errors. This is based on the strength of evidence for this practice and consistency of observed effects.

Source: futurelaboratorymedicine.org

Laboratory Medicine Best Practices

Recommendation: Blood Culture Contamination

- The use of venipuncture for sample collection when this option exists in the clinical setting is identified as a best practice for reducing blood culture contamination rates (7 studies, OR = 2.63, 95% CI 1.85-3.72).

- The use of dedicated phlebotomy (teams) to collect blood culture specimens is identified as a best practice for reducing blood culture contamination rates (6 studies, OR = 2.76, 95% CI 2.2 - 3.5).

- No recommendation is made for or against identifying the use of pre-packaged preparation kits (4 studies, OR =1.1, 95% CI 0.99-1.41) as a best practice.

Source: futurelaboratorymedicine.org
Summary

- Specimen collection has many variables to control, which are often not under the laboratory’s direct control.
- Regulations and voluntary standards can assist in getting compliance from the key stakeholders.
- The stakes are too high not to get this right, and ultimately it will reflect on the organization and impact patient safety.

Preanalytical Variables

Specimen Quality Issues
Randy Gruhlke, BS, CPT(NHA)

Objectives

- Define preanalytical variables.
- Identify different issues related to venipuncture collections vs line collections.
- Discuss collection techniques.
- Recognize CLSI documents related to collection methodology.
Preanalytical Variables – A Definition

• Defined as those factors that are evident during the period of time that begins when a physician orders a test and ends with the testing of the specimen.

• There are many factors present during this timeframe that could greatly affect the outcome of the test. Some may be mere inconveniences while others can be quite costly, perhaps even life-threatening.

• Preanalytical variables can be further categorized into two distinct groups:
  - Uncontrollable
  - Controllable

Controllable Variables – Phlebotomy

• There are many variables that the collecting technician has direct control over; many of these can and often do have significant effects on the outcome of the tests.

• Let’s examine each of these individually, identifying the potential effects they have on the specimen and what the collecting technician can do to eliminate or minimize the likelihood of skewed results.

Damaged Veins

• Chemotherapy – Sclerosis – Thrombosis – Inflammatory diseases – Intravenous drug users
  – Impeded blood flow (hemoconcentration)

• The technician should:
  – First, choose another site.
  – Warm the site to promote vasodilatation.
  – Draw distal to the area affected.
  – Use the largest gauge needle possible.
Hematoma

- Venipuncture through an existing hematoma can result in:
  - Contamination from hemolyzed cells
  - Contamination from clotted blood
  - Skewed results, especially coagulation tests
- The technician should:
  - Choose another site, if possible.
  - Draw distal to the hematoma.
  - Consider the use of a discard tube.

Edema

- Excess interstitial fluid results in specimen contamination.
- The phlebotomist should:
  - Attempt to “manually” move fluid away from site.
  - Use a tourniquet/gauze to remove fluid.
  - ALWAYS draw a discard tube.
  - Choose the proper equipment to allow a quality specimen.
    - Syringe would not allow for a discard
    - Butterfly needle may not “reach” the vein

Arterial Line Collections

- Contamination and hemolysis are two primary concerns.
- Technician should consider the following:
  - Review tests (heparin flush and coagulation specimens to be collected – venipuncture/POC an option?)
  - Correct amount of waste (heparin flush ~10mL waste for coagulation tests)
  - Equipment choices (vacutainer vs syringe to minimize chances of hemolysis)
  - Assure the correct amount of “waste” drawn
Central Venous Lines

- Two primary concerns: Contamination and Hemolysis
- The phlebotomist should consider the following:
  - Have nursing shut off all infusions for 2-minutes
  - What has been infused? What has been used for a flush? Are these compatible with the test?
  - Collect the appropriate waste (heparin flush/coagulation tests, 10-mL of waste)
  - Proper collection equipment – (vacutainer vs syringe to minimize hemolysis)

Follow your institutional guidelines

Heparin/Saline Locks

- The two primary risks, in order, are contamination and hemolysis.
  - Cannot draw coagulation samples.
  - A “waste” should always be drawn.
  - Risk of hemolysis is significant based on collection technique.
  - Only specially trained phlebotomists should collect from “locks”.

Above/Below Intravenous Lines

- The potential for contamination is extremely high; attention to detail is crucial.
- The phlebotomist should consider the following:
  - Using the other arm, whenever possible
  - What is “running” and what is to be collected? (Dextrose/TPN and a glucose is ordered?)
  - Asking Nurse to shut off IV line for 2-minutes
  - Best specimen will be obtained distal to/below to the IV
  - To waste, or not to waste – that is the question.
Difficult Collections

- Difficult collections lead to a higher risk of hemolysis, and often minimum volumes, which can lead to:
  - EDTA – can shrink red blood cells, causing low blood cell counts and hematocrits
  - Heparin (green tubes) – skew some chemistry results
  - Sodium Fluoride – can result in a hemolyzed specimen
  - Sodium Citrate – incorrect ratio of blood to anticoagulant

Collection Techniques

- Collection technique issues to consider:
  - Tourniquet application (hemoconcentration)
  - Tube inversions
    - Not enough, or timely but with micro-clot formation
    - Too much or too aggressive and with hemolysis issues
  - Equipment choices (metal testing, discard tubes, etc.)
  - Use of equipment (incorrect use – hemolysis)
    - Too large of a syringe with a small needle
    - Pulling back on syringe too forcefully (lines or venipuncture)
    - Small butterfly needle and aggressive syringe use
    - "Forcing" or pushing blood into tubes

Antiseptic Issues

- Antiseptic concerns include:
  - Metal collections when iodine is applied to site
  - Alcohol (isopropyl) for blood alcohol collections, especially "chain-of-custody" collections
  - Improper aseptic technique skewing blood culture collections
  - Not allowing alcohol to dry – contamination and hemolysis
  - Not wiping away the first drop when performing a capillary collection – contamination and hemolysis
Clerical Errors

- **Clerical errors include:**
  - Patient ID (manual entry – “fat-fingering” the keyboard)
  - Erroneous data entry (test, date, and/or time entry)
  - Informational errors (technician ID – blood bank)
  - Mislabeled tubes
  - Unlabeled tubes

- **Institutional behaviors**
  - Develop standard operating procedures (SOP’s) and/or procedures
  - Implement a quality control plan/audit
  - Perform “Real-time” order entry (no future order entry)
  - Investigate technological advances (wireless laptops, scanners, and/or printers)

Transport Variables

- **Skewed results – or complete loss of specimen integrity. Considerations include:**
  - Ambient vs special requirements (iced, heat)
  - Light-sensitive specimens (vitamins, bilirubin)
  - Pneumatic tube systems (LD/centrifuge first)
  - Time (limitations in regards to quality – arterial blood gases)
  - Hand delivery – prevent agitation (BAL)
  - Validation of transport methods

Add-on Tests... Clinician Beware!!!

- **Test results from stored serum/plasma specimens can be inaccurate. Is the stored sample “appropriate” for the add-on?**
- **Concerns include:**
  - Samples collected from lines (what was infused, flushed, wasted?)
  - Samples collected above/below an IV line
  - Samples collected requiring special considerations (ice/heat/light)
Institutional Actions

- Develop SOP and policies targeting preanalytical variables using CLSI document H03-A6
- Continue educational opportunities
- Resources – paper and electronic based
- Initiate redraw reports – use them to train
- Event management – used as nonpunitive corrective action
- Track successes – share them!!!