Improving Patient Safety by Reporting Problems with In Vitro Diagnostic Devices



Medical Product Safety Network

Reporting Problems with In Vitro Diagnostic Devices (IVDs)

At the end of this session you will be able to:

1. Identify several types of IVDs
2. Explain why reporting problems with IVDs is important
3. Describe your role in promoting patient safety with IVDs
4. Describe the steps to take to report an adverse event or problem with IVDs in our hospital

Types of IVDs and Examples

- **Capital Equipment**
  - large automated analyzers, microscopes, and centrifuges
- **Instruments**
  - glucose meters, bench top analyzers, pipettors/dispensers
- **Reagents**
  - laboratory test kit components (e.g. antigens, monoclonal antibodies), single use devices (e.g. pregnancy tests, rapid flu tests), quality control (QC) materials
- **Disposables & Accessories**
  - blood collection tubes, cuvettes, pipettes, test tubes, latex gloves
- **Computerized Medical Systems**
  - laboratory information systems

"Medical errors most often result from a complex interplay of multiple factors. Only rarely are they due to the carelessness or misconduct of single individuals."

Lucian L. Leape, M.D.
A leading patient safety expert
from Harvard University

Where Laboratory Problems Can Occur

- Pre-Analytical Phase
  - Sample collection (ex. wrong anticoagulant used)
  - Sample processing (ex. inappropriate storage)
  - Patient status (ex. fasting/non-fasting)
- Analytical Phase
  - Inadequate instrument maintenance
  - Calibration problems
  - Quality control trends of shifts
- Post-Analytical Phase
  - Errors in reporting results
  - Delays in calling panic values

Error Reduction Example: Automated Laboratory*

Prepare analyzers (calibration)

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Review quality control values (QC in/out of range)

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Analyze samples (label applied correctly)

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Review results (review limit flags)

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Release results (check for change of status)

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Report results

*Riebling N, et al, Six Sigma project reduces analytical errors in an automated lab, Medical Laboratory Observer, June 2005

Think About the IVD and its Environment

Environment

- Electric Power, Heat, Humidity,
- Light, Other Devices (EMI)

Staff

Accessories & Disposables

- Test Strips
- Lancets
- Control Solution

What Types of IVD Problems Should I Look for?

- Instructions/labeling/packaging
- Defects
- Software problems
- Failure to work as intended/malfunction
- Interactions with other devices
- Use errors related to poor design of the IVD
- Manufacturer is unresponsive to feedback or slow to notify the lab about problems
- Combinations of the above

Examples of Problems

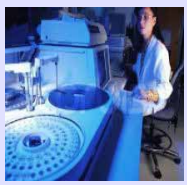
- **Instructions/Labeling/Packaging**
  - procedural steps are missing or confusing
  - reagents are mislabeled
  - sterile packaging is compromised
  - sample type is not specified
  - test limitations are not clear
  - operating temperature is not specified
  - unclear diagrams for test interpretation of a positive/negative result

Examples of Problems (continued)

- **Defects**
  - pipettor delivers short samples or jams repeatedly
  - repeated malfunctions occurring on the same analyzer
  - frequent instrument breakdowns (hardware failure)
  - negative control line reads positive for all samples
  - contaminated reagents

Examples of Problems (continued)

- **Software problems**
  - problems with the interface between the instrument software and the hospital's Information System
  - software upgrades change performance of the assay (e.g. assay cut-off)
  - virus infects device operating software



Examples of Problems (continued)

- **Failure to work as intended/ malfunction**
  - blood collection tube has inadequate vacuum
  - package insert performance claims not met
  - quality control materials give unacceptable results leading to invalid/unreportable patient results
  - external liquid control results do not match built-in control results for a single use device

Examples of Problems (continued)

- **Interactions with other devices**
  - electromagnetic interference (e.g., cell phones, pagers, etc.) cause lab instruments to give erroneous results
  - instrument components are not communicating with each other

Examples of Problems (continued)

- **Use Errors**
  - poor instrument design/poor instructions that leads to user confusion and error
  - lab test used for another purpose, e.g., testing pediatric samples when performance claims are based on adult testing

Why Reporting Problems With IVDs Is Important In Our Hospital

- Prevent future problems and protect our patients, staff, families, and visitors
- Other users may be having the same problems
- Achieve performance improvement goals
- Assist Risk Management with claims or litigation
- Provide information to manufacturers and/or U.S. Food and Drug Administration
- Impact the public health for the nation's patients and/or health care providers
- Effect changes in policies and procedures

When Do I Report?

- When you think an IVD has or may have caused or contributed to any of the following outcomes (for a patient, staff member or visitor):
  - death
  - serious injury
  - minor injury
  - close calls or other potential for harm

What Do We Mean by "Potential for Harm?"

- **Events that are caught before anything harmful occurred**
  - false positive or negative results were identified before results are reported
- **Important observations of a chronic problem with an IVD**
  - instrument needs calibration more often than recommended in order to obtain correct results
- **Problems which lead staff to develop "work-a-rounds"**
  - software error messages that staff override
- **"Out-of-the-box" problems that are identified before the IVD is used**
  - contaminated reagents

What Do I Report?

- **If there was an injury, what happened to the persons affected?**
  - hemorrhage from excessive anti-coagulant therapy
- **What were the problems with the IVD involved?**
  - recurrent failed runs
- **What, if any, were the follow-up medical procedures required because of the event?**
  - hospitalization
- **What are the names of the manufacturers and/or distributors of the IVDs involved?**
- **What are the relevant manufacturer device identification numbers?**
  - serial, model, lot, catalog, and any other specific information
- **What did you do to solve the problem?**

How Do I Report?

Our Reporting System Involves . . .

(Customized responses would be listed below)

- *Online reporting system via hospital intranet*
- *Verbal or written reporting to supervisor*
- *Written acknowledgment to the reporter including any follow up actions*
- *Reward system for "best catches" that make patient care safer*

When You See an IVD That Presents a Problem You Should . . .

(Customized responses would be listed below)

- *If possible, determine whether the problem was related to an instrument, reagent, or instructions for use*
- *Return unused reagent vials, test packs, etc., to the manufacturer for investigation of the problem*
- *Do not report patient results if the quality control materials give unacceptable results*
- *Report even minor reagent or instrument problems*
- *Save the device and packaging and put it in a clear plastic bag*

Some Issues We've Addressed at Our Hospital

What Was Reported . . . *(Customized responses to appear below)*	**What We Did . . .** *(Customized responses to appear below)*
Analyzer giving erratic results	*Found the source of electromagnetic interference, removed it and reported to MedSun*
Contaminated reagents	*Contacted manufacturer who replaced the reagents; reported to MedSun*
Instrument pipettor continually out of alignment	*Called the manufacturer who installed a new pipettor; reported to MedSun*

Some Issues We've Addressed at Our Hospital Cont'd

What Was Reported . . .	What Was Reported . . .
(Customized responses to appear below)	*(Customized responses to appear below)*
Reagents outdated when received	*Contacted the manufacturer and was instructed to extend the date and still use the reagents; reported to MedSun*
Calibration successful but controls out	*Contacted the Hotline. Instructed to open new lot of controls; reported to MedSun*

Fostering a Climate of Patient Safety

(Customized responses would be listed below)

- *Feedback and communication*
- *Learning from errors*
- *Compliance with policies and procedures*
- *Teamwork*

If You're Not Sure What or How to Report

(Customized responses would be listed below)

- *Refer to the incident reporting section in our Policy and Procedures manual*
- *Ask your supervisor, or*
- *Call our reporting hotline at extension* _____

Your Role

- Identify actual and potential problems, adverse events, close calls with In Vitro Diagnostic devices
- Report the problem or adverse event to your supervisor, according to policy and procedure
- Make sure your report includes details
- Remove the device and save the packaging
- Return to the manufacturer for evaluation if possible

In Summary . . .

Our objectives were to:

1. Identify several types of In Vitro Diagnostic Devices (IVDs)
2. Explain why reporting problems with IVDs is important
3. Describe your role in promoting patient safety with IVDs
4. Describe the steps to take to report an adverse event or problem with an IVD in our hospital

Have we met them?

And Remember . . .

We can't address issues we don't know about.

Please report.