MedSun Educational Training Program

"Improving Patient Safety by Reporting Problems with In Vitro Diagnostic Devices"
INSTRUCTOR GUIDE and SCRIPT

LAB VERSION

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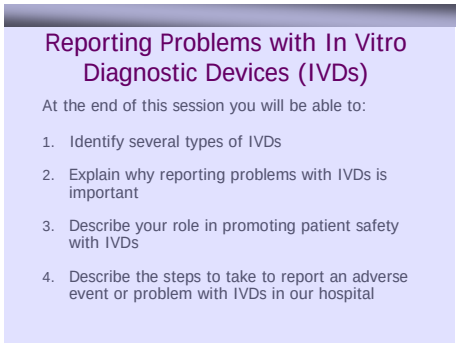
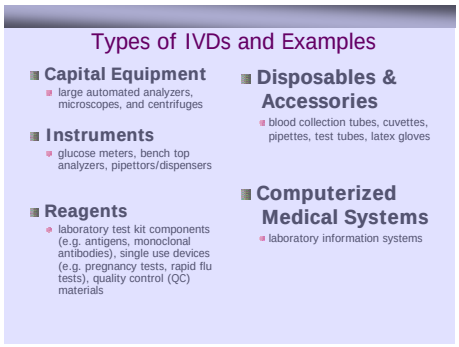
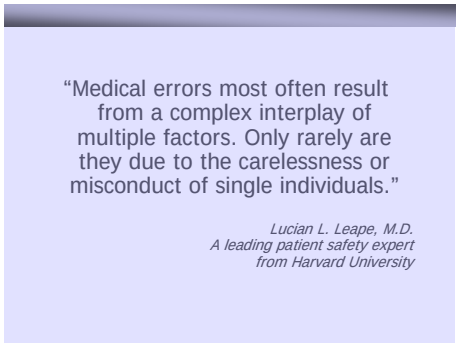
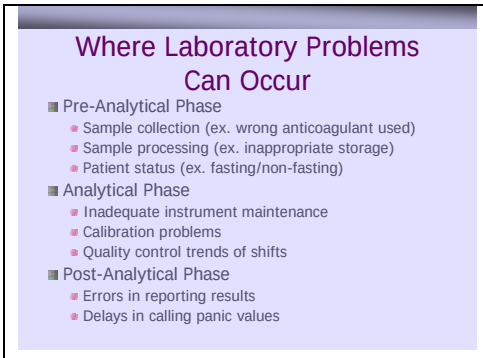
INSTRUCTOR GUIDE and SCRIPT**- LAB VERSION**

SLIDE #	SCRIPT
1. 	**DISPLAY SLIDE # 1** **Welcome participants**. **STATE**: For the next 10 minutes we'll be talking about improving patient safety in our hospital. As you may know, our hospital is involved in a project called MedSun, which is a device-reporting project with the FDA. MedSun involves many other hospitals that are working with FDA to ensure patient safety by reporting adverse events involving medical devices.
2. 	**DISPLAY SLIDE # 2** **STATE:** Our goal for the session is to 1) increase awareness of incidents that potentially involve an In Vitro Diagnostic device and 2) encourage our staff to report it quickly. **STATE OBJECTIVES ON SLIDE**: At the end of the session you will be able to: ° Identify several types of In Vitro Diagnostic devices ° Explain why reporting problems with In Vitro Diagnostic devices is important ° Describe your role in promoting patient safety with In Vitro Diagnostic devices ° Describe the steps to take to report an adverse event or problem with an In Vitro Diagnostic device in our hospital **CLARIFY AND CONFIRM AS NEEDED**

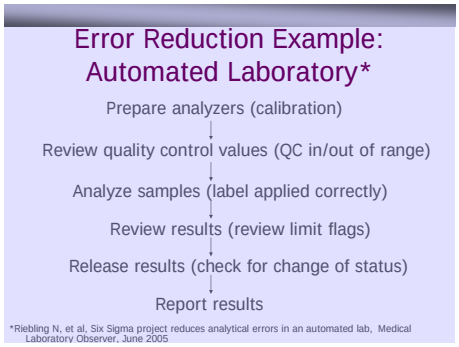
3.  	**DISPLAY SLIDE # 3** **EXPLAIN:** This slide lists types of medical devices in some general categories that you may be familiar with or work with on a daily basis. This list is not all-inclusive but gives you some idea of the spectrum of devices. An IVD could be an instrument or analyzer, individual reagents used while performing a test, any component used with the test/assay, a single use/unit use cassette or dipstick and blood collection tubes. It's important to note here that regardless of how simple the device may be, it can still be problematic and contribute to an adverse event for a patient.
4.  	**DISPLAY SLIDE # 4** **STATE:** This next slide is a quote from Dr. Lucien Leape from Harvard that reads, " Medical errors most often result from a complex interplay of multiple factors. Only rarely are they due to the carelessness or misconduct of a single individual." This quote addresses the complexity of a medical error and the challenges of determining what happened, who's involved and why. The kinds of adverse events we're discussing with devices, falls under the general category of medical error.
5	**DISPLAY SLIDE # 5** **READ SLIDE**



If needed, additional examples provided for the pre-analytical phase are as follows:

- Sample collection – hemolysis, tissue fluid contamination, inadequate sputum specimen, throat swab of wrong area
- Sample processing – red cell contamination
- Patient status – drug or disease state interference

6.



DISPLAY SLIDE # 6

READ SLIDE

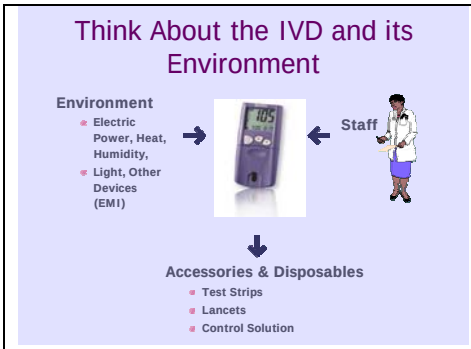
If needed, additional examples provided are as follows:

- Prepare analyzers – maintenance, reagent preparation, instrument status reports
- Review quality control values – trends, shifts, corrective action if out of limits
- Analyze samples – transfer list received with samples, samples accessioned properly, bar codes readable
- Review results – automatic verification manual verification, check critical flags and delta flags, linear ranges and dilutions if applicable
- Release results – check previous results, check for inconsistent values

7.

DISPLAY SLIDE # 7

We know of the interface between IVDs and

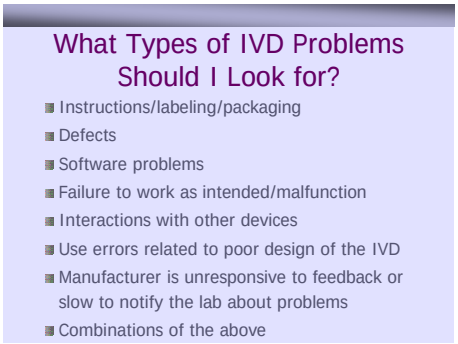


patients, but it's important to consider the device in its many interfaces as well. The device shown here is a glucose meter. When an adverse event occurs, it's important to consider all characteristics of the

- **Environment:** such as the power source, lighting, and other devices, and the
- **People** involved: who may be the patient, device-operator, or visitors, and any
- **Accessories and disposables**: such as test strips, lancets, control solution

Any or many of these aspects of an adverse event may be the reason or a contributing factor and warrants further investigation to determine what may have happened.

8.



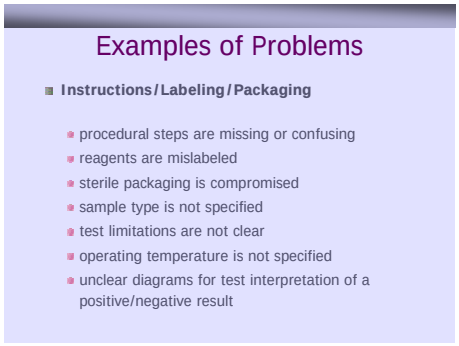
DISPLAY SLIDE # 8

What Types of IVD Problems Should I Look for?

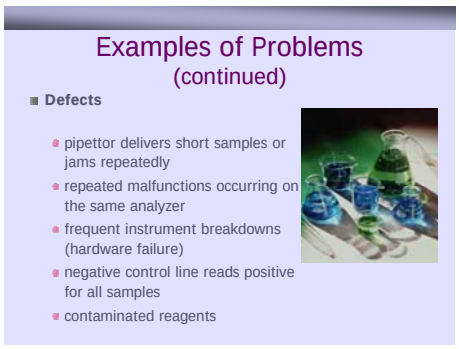
STATE:
This is a list of broad categories or ways to classify possible causes of adverse events. Some of what is listed here may remind you of problems you've had or times you have questioned an IVD as the reason for a problem.

Let's briefly run through the list here and we'll cover more detail with examples in the next several slides.

NOTE TO INSTRUCTOR: read the list and move to next slide.

	◦ **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**
9. 	**DISPLAY SLIDE #9** NOTE to instructor: **Briefly** describe the examples on each slide. It's important to maintain a steady pace as you move through these next few slides to keep within the time frame. **Spend approximately 1 minute per slide**. ***Instructions/Labeling/Packaging*** ◦ procedural steps are missing or confusing ◦ reagents are mislabeled ◦ sterile packaging is compromised or reagents show signs of contamination ◦ sample type is not specified ◦ test limitations are not clear ◦ operating temperature is not specified or instrument does not maintain stable temperature ◦ unclear diagrams for test interpretation of a positive/negative result

10.

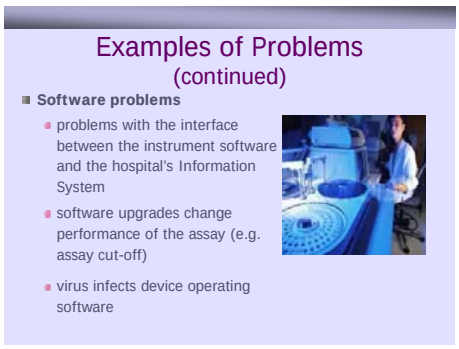


DISPLAY SLIDE # 10

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 and positive control reads negative for all samples
- contaminated reagents

11.

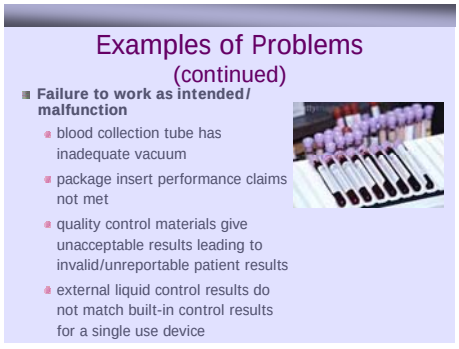


DISPLAY SLIDE # 11

Software Problems

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

12.



DISPLAY SLIDE # 12

STATE: Some examples of . . .

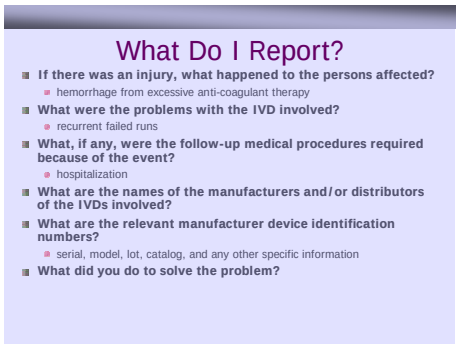
Failure to work as intended/malfunction include:

- 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
13. 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 	**DISPLAY SLIDE # 13** **Interactions with other devices includes:** ◦ electromagnetic interference (e.g., cell phones, pagers, etc.) causes lab instruments to give erroneous results ◦ instrument components are not communicating with each other
14. 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	**DISPLAY SLIDE # 14** **STATE:** In looking at . . . **Use Errors, we've had reports about** ◦ poor instrument design 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 **STATE:** It's important to note here that although you may think of these examples solely as "use error" they may be the result of a poorly designed IVD or inappropriate claims so it's important to report it to us.

15.  	**DISPLAY SLIDE # 15** **STATE:** So let's talk specifically about our hospital and. . . **"Why Reporting Problems with In Vitro Diagnostic devices is Important in Our Hospital. It will, most importantly, . . . "** (Read slide) ◦ Prevent future problems and protect our patients, staff, families and visitors ◦ Other users may be having the sample 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 nations' patients and/or healthcare providers ◦ Effect changes in policies and procedures
16.	

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	**DISPLAY SLIDE # 16** **STATE:** So you may ask. . . **"When Do I Report?"** When you think an IVD has **caused** or **contributed** to any of the following outcomes for a patient, a staff member, or a visitor: ◦ Death ◦ Serious injury ◦ Minor injury, or ◦ Close calls or other potential harm
17. 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	**DISPLAY SLIDE # 17** **STATE:** Next, let's look closely at . . . **"What Do We Mean by "Potential for Harm?"** ◦ **Events that are caught before anything harmful occurred** **STATE:** For example, false positive or negative results were identified before results are reported; controls were out of range so no patient results were reported, defective fluorescent microscope bulb detected before false negative results reported, bent sample probe noticed before injury to staff. ◦ **Important observations of a chronic problem with a device**

	STATE: For example, instrument needs calibration more often than recommended in order to obtain correct results; automatic shut-down of an instrument due to environmental conditions. ◦ **Problems which lead staff to develop "work-a-rounds"** **STATE:** For example, software error messages that staff override; or something we have all done – taping instrument pieces together or substituting an instrument part of accessory ◦ **"Out-of-the-box" problems that are identified before used on a patient** **STATE:** For example, contaminated reagents; inadequate vacuum in blood collection tubes.
18. 	**DISPLAY SLIDE # 18** **STATE:** We've looked at **when to report**, let's focus now on **what to report**. This information is so valuable because it's focused on getting complete information initially and possibly from the staff person who may have been directly involved. Then the effort is made to have a complete report and it expedites any follow up steps. **What Do I Report?** ◦ **If there was an injury, what happened to the persons affected?** **STATE:** Did the patient hemorrhage from excessive anti-coagulant therapy? Other examples include unnecessary

	procedure/treatment performed, necessary treatment/intervention not done, harm to fetus, and wrong level of medication administered. ◦ **What, if any, were the problems with the IVD involved?** **STATE:** Was there recurrent failed runs? Other examples include erratic test results, instrument drain line crimped, reagents fail before expiration date, software problems, poor test design/poor instructions. ◦ **What, if any, were the follow up medical procedures required because of the event?** **STATE:** Was hospitalization necessary? Other examples include change of medication dose and time interval; additional treatment. ◦ **What are the names of the manufacturers and/or distributors of the IVDs involved?** ◦ **What are the relevant manufacturer device identification numbers?** **STATE:** what are the serial numbers, or model, catalog and lot numbers, or any other device information. And, finally. . . . ◦ **What did you do to solve the problem?**

19.

DISPLAY SLIDE # 19

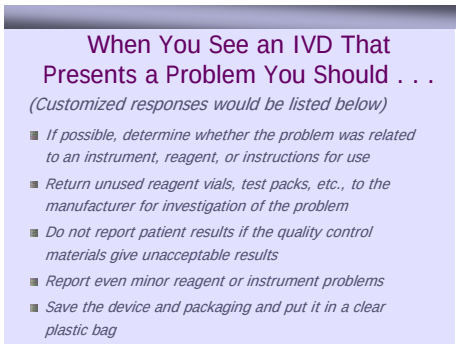
STATE: And lastly,

How Do I Report?

Our Reporting System Involves. . .

(NOTE: Add hospital specific information here)

20.



DISPLAY SLIDE # 20

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

(NOTE: Add hospital specific information here)

21.

22.

DISPLAY SLIDE # 21, 22

STATE: We've listed
Some Issues We've Addressed here at Our Hospital . . .

With IVD problems and the actions we took to solve them. We hope this will reinforce with everyone the importance of reporting what you've seen so we can intervene and prevent any harm to patients, staff, and visitors to our hospital.

READ SLIDE

What Was Reported. . .
(NOTE: Add hospital specific information here)

What We Did. . .

(NOTE: Add hospital specific information here)

23. Fostering a Climate of Patient Safety *(Customized responses would be listed below)* ▪ *Feedback and communication* ▪ *Learning from errors* ▪ *Compliance with policies and procedures* ▪ *Teamwork*	**DISPLAY SLIDE # 23** **STATE:** Here's what we need to do as an organization to **"Foster a Climate of Patient Safety"** **STATE:** We need to • Provide **feedback and communication** about adverse events and close calls • **Learn from our errors** • **Comply with our policies and procedures** • And promote and exhibit **teamwork**
24. 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* _____	**DISPLAY SLIDE # 24** **If You're Not Sure What or How to Report. . .** ***(NOTE: Add hospital specific information here)***
25. 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	**DISPLAY SLIDE # 25** **STATE:** And, **Your Role. . .** is to. . .(read slide)

26. 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?***	**DISPLAY SLIDE # 26** **In Summary** **NOTE to Instructor:** Read slide
27. And Remember . . . We can't address issues we don't know about. Please report.	**DISPLAY SLIDE # 27** **And Remember. . . .** **We can't address issues we don't know about. Please report.**