

FDA's LabNet Program: Improving Patient Safety by Increasing Reporting from Hospital Laboratories

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What is Post-Market Surveillance?

- To monitor medical device performance after a device is approved or cleared for marketing to identify problems and safety issues that occur during widespread clinical use.
 - Detect and evaluate problems early.
 - Address those problems that may emerge with real-life use.
 - Minimize risks.
 - Monitor known risks over the lifespan of the device.

Post-Market Surveillance and MedSun

- **MedWatch** – Nationwide FDA Adverse event reporting system that includes both voluntary and mandatory reporting. The majority of reports are sent by manufacturers.
- **MedSun** - FDA’s enhanced post-market surveillance program under MedWatch. Allows healthcare facilities to participate in a “real-time” network to report adverse events or potential for harm directly to FDA. FDA sends reported events to manufacturers and shares safety information with participants.

MedSun Facts

- **Membership:** A nationwide network of 350 facilities.
- **Sponsorship:** Sponsored and funded by FDA.
- **Improved Communication:** Between the clinical community, the device industry and FDA
- **Expanded Reporting:** Deaths, serious injuries, close-call, potential for harm events
- **Stakeholders Benefit:**
 - **Clinical Community:** obtain valuable educational tools and feedback to improve internal processes and patient safety
 - **Patients:** safety!
 - **FDA:** high quality reports, partnerships to understand problems with device use

MedSun Goals

- Assess emerging safety signals through adverse event reporting.
- Validate early warning signals.
- Increase understanding of actual or potential patient safety issues.
- Improve patient safety.

How Are We Doing?

510784.36
579 ÷ 1
2.719372

More than 14,000 reports since 2002:

- 3 % involve deaths
- 11 % involve serious injuries
- 14 % involve minor injuries
- 72 % are cases with potential for harm, close calls, other situations generally not reported by users under other systems.

Lessons Learned in Improving Patient Safety

- Training and motivating reporters is a resource intensive, iterative process– but critically important!
 - User Recognition

- **Feedback is key**
 - From FDA to MedSun sites
 - Feedback about reports
 - Certificates
 - Newsletter articles and device summaries
 - Safety tips and webcasts
 - From MedSun site to hospital staff
 - Tell staff outcome of the report they submitted
 - Internal change made
 - Manufacturer made a change to address problem

FDA's LabNet Program



Subnetworks at a Glance

- **LabNet – devices used in laboratory settings.**
- KidNet – devices used in pediatric population especially PICU and NICU.
- TissueNet – tissue and cell products regulated by CBER and CDRH.
- HeartNet – devices used in EP and cath labs.
- SightNet – ophthalmic devices used in in-patient and out-patient settings.
- HomeNet – devices used in the home care environment.

LabNet Goals

- Provide a more active surveillance of in vitro diagnostic devices (IVD) while ensuring their safety and effectiveness.
- Promote awareness within the clinical communities of IVD adverse events (actual or potential) and cultivate a learning environment where FDA interacts with the clinical communities and manufacturers while understanding and solving problems.
- Identify barriers to reporting IVD adverse events to FDA.

LabNet Current Status

- **Pilot began September 2006**
- **50+ MedSun hospitals participate, including the National Institutes of Health Clinical Center laboratory**
- **60+ participants representing lab managers, supervisors, and bench staff**
- **100+ reports to date**
 - **More than half of the reports have led to significant regulatory actions**

Top 5 Reported LabNet Devices

- 1. Chemistry Analyzer**
- 2. Glucose Meter, OTC**
- 3. Blood collection tubes, vials, systems, serum separators**
- 4. Multipurpose system for in vitro coagulation studies**
- 5. Iontophoresis Device**

Types of Medical Device Problems To Report

- Instructions/labeling
- Packaging
- Defects
- Software problems
- Failure to work as intended/malfunction
- Interactions with other devices
- Problems encountered with off-label use
- Human factors issues
- Incorrect diagnosis as the result of inaccurate results
- Repeated QC failure
- Calibration failures
- Inadequate service response
- Lost data



Reported Events With Adverse Outcomes

- Erroneous troponin results were reported in 28 patients. One patient was sent for a catheterization procedure, but it was cancelled before it began. Several patients were given heparin that was not needed.
- A Luer slip syringe was being used to draw blood from a patient. The syringe of blood was pushed into a culture bottle. The tip of the syringe cracked and the blood sprayed.
- An RN took the fasting blood sugar using and the result was 247 on one glucometer. The patient was treated with 5 units of regular insulin. About 15 minutes after the administration, the patient's husband stated that his wife was having a hypoglycemic reaction. The RN rechecked the blood sugar on another glucometer and found it was 259. The physician and NP came right away and determined that the patient might have been experiencing a stroke. The stroke team was called. The blood sugar was rechecked again and found to be 12 by the lab method.

Reported Events Involving Potential for Harm

- **Packaging, product defects, product not performing as intended**
 - Sterile cup in urinary collection kit leaks after the lid is screwed in place.
 - Centrifuge smoking, sparking, and vibrating in the laboratory area.
 - Influenza swab inserted into nostril of infant; tip of applicator noted missing after removal from nostril; tip found to be defective.

- **Problems occurring during clinical use**
 - Test results from a hematology analyzer were filed to an incorrect patient after a sample was run in “Manual Mode.”

Recent LabNet Device Recall

- Reported Problem:

Patient demographics do not match the barcode on the printed label.

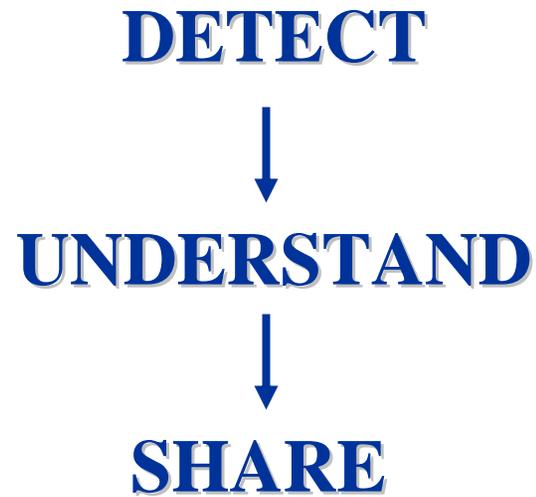
- Cause of the Problem:

The defect occurs when the user scans the wristband barcode of the first patient (Patient A) and then uses the “back arrow” on the Internet Explorer (in which the software is based) navigation bar after the label is printed, instead of the software navigation controls. The device’s user guide does not mention that the Internet Explorer “back arrow” button should not be used to navigate the software. The user then scans the next patient (Patient B). The printed labels for patient B will print with patient A’s eye-readable demographics, but patient B’s machine-readable information.

- If Device Failure Occurs is it Easily Recognized by User?

Unless the user checks the printed label against the known patient information, the device failure may not be readily discovered.

MedSun Summary





Sources for More Information

- New website:

<http://www.fda.gov/cdrh/medsun>

- Phone: 1-800-859-9821

- Fax: 1-800-859-1292

- E-mail: medsun@s-3.com

LabNet Contact Information

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