MedSun
Medical Product Safety Network

Medical Product Safety Network (MEDSUN) an Interactive Surveillance System: Eliminating Barriers to Reporting and Creating Two-Way Communication with FDA

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FDA
Center for Devices
and Radiological Health

Social & Scientific Systems, Inc.

Learning Objective

- To show how medical device problem reporting is enhanced by a program that addresses reporting barriers by developing an interactive relationship between FDA and the clinical community that also provides manufacturers with information they need.

MedSun's Context

- FDA has a wide ranging **regulatory authority** over food and drugs as well as medical devices, biologics, cosmetics, and certain other products.
- FDA's Center for Devices and Radiological Health [**CDRH**] is responsible for premarket evaluation and postmarketing surveillance of **medical device safety and effectiveness.**
- The Medical Product Safety Network (MedSun) is part of CDRH's program for **postmarket surveillance involving a sample of "user facilities"** to ensure that FDA has 2-way communications with clinical sites.

What is MedSun?

- A voluntary program of with 350 sites in U.S. hospitals and health care facilities
  - Focused on an interactive relationship between FDA/MedSun and the clinical community to prevent adverse events (AE)
  - Objectives:
    - To detect, understand, solve, and, to the extent possible, prevent medical device problems
    - to provide timely feedback to health professionals to improve patient safety.

Causes of Adverse Events

AEs are frequently complex and difficult t
characterize.

Three broad categories:

- Device Problem
- Use Error
- Poor Device/User Interface Design

Example: AEs associated with use of intravenous infusion pumps sometimes result from a keypad interface design unsuited to multiple users in a busy intensive care setting where keypad errors can translate into catastrophic overdoses

Addressing the Challenges

To progressively improve an interactive surveillance system that:

- Eliminates reporting barriers, *e.g.*, liability, paperwork burden, lack of problem recognition
- Improves quality of reports and better identifies emerging problems
- Enhances 2-way communication between sites and FDA/MedSun

MedSun Project Features

- **Detection**
  - Recruits and trains site reporters to recognize device problems
  - Provides report follow-up
  - Implements special studies
- **Communication**
  - Provides FDA and sites with useful, actionable information
- **Dissemination**
  - *MedSun News,* educational programs, audio conferences, answers to questions from sites, database searches, safety tips, and meetings.
- **Coming Soon**: MedSun information on www.fda.gov

Reporting Sites

- In 2002, 25 sites on the East Coast began reporting as a feasibility group
  - Expansion over time to 350 current sites
  - Geographic representation from across the continental United States
  - mix of ownership types—teaching hospitals and others
- Emphasis on recruiting high-priority site types—pediatric hospitals and hospitals with home health services, allowing FDA to learn about problems that occur within particular clinical settings.

What's Been Reported

More than 9,000 reports:

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

Top 10 Devices in MedSun Reports

1. Infusion Pumps
2. ESU
3. Intravenous Catheters and Administration Sets
4. Automatic Implantable Cardiac Defibrillators
5. Endoscopes and/or Accessories
6. Ventilators
7. Surgical Staplers
8. Laparoscopes
9. Physiological Monitors
10. External Defibrillators

MedSun – More Than a Reporting System

- FDA communicates with sites to learn quickly about product problems or verify early signals
  - Through focus group participation, individual interviews, and rapid-response surveys to learn more about particular issues
  - To evaluate impact of possible regulatory strategies and determine usefulness of manufacturer's action in improving patient safety

New Subnetworks

- Build relationships with medical product users in
  - Hospital Electrophysiology Labs
  - Hospital Laboratories (with Office of In Vitro Diagnostic Device Evaluation and Safety)
  - Pediatric ICUs and Neonatal ICUs

Unique Opportunities

- Focus on high-risk products, *e.g., defibrillators,* and special populations, *e.g., children*
- Work with sites to assess impact of regulatory actions
- Encourage methods to reduce medical error
- Facilitate FDA's work with industry to improve device safety using emerging MedSun data
- Create research opportunities, *e.g., human factors research*

Keys to Success

- MedSun representatives in each hospital and site have access to device-related information
- Follow-up on each report received so FDA has comprehensive picture of problems as they unfold
- Timely, useful feedback to MedSun sites (newsletters, audio conferences, database searches, safety tips and conferences)
- Easy-to-use, web-based reporting tool consolidates information in real time, providing FDA staff with 24/7 access

Summary

- MedSun is an interactive model that facilitates early investigation of AEs before they become trends
- MedSun provides FDA with mechanisms for two-way interactions and communications with users of devices and manufacturers of devices
- FDA and manufacturers take regulatory and non-regulatory actions based—at least in part—on MedSun information

AND

- MedSun promotes patient safety by providing information needed for FDA/manufacturer actions and by providing feedback to the clinical community

Thank you

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