FDA's Home Use Medical Device Initiative

FDA

Speakers

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Objectives

- Understand the organization of FDA and CDRH
- Understand the role of CDRH in premarket and postmarket regulation of medical devices
- Understand CDRH's thinking on the home use of medical devices
  - Home Use Medical Device Initiative
  - MedSun and the HomeNet Subnetwork
- Understand your role in working with CDRH to assure the safety of medical devices used in the home
  - Learn about reportable issues with home health medical devices
  - Learn about the importance of reporting these issues to FDA

How are FDA and CDRH organized?

FDA at a Glance

FDA is comprised of several Offices and Centers

- Office of the Commissioner (OC)
- Office of Regulatory Affairs (ORA)
- **Center for Devices and Radiological Health (CDRH)**
- Center for Drug Evaluation and Research (CDER)
- Center for Biologics Evaluation and Research (CBER)
- Center for Food Safety and Applied Nutrition (CFSAN)
- Center for Veterinary Medicine (CVM)
- National Center for Toxicological Research (NCTR)
- Center for Tobacco Products (CTP)

Center for Devices and Radiological Health

CDRH promotes and protects the health of the public by ensuring the safety and effectiveness of medical devices and the safety of radiological products including non-medical radiological products

What is a Medical Device?

Medical Device Definition

- an FDA regulated device is an “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them.
  - Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.
  - Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.”

U.S. Food and Drug Administration. Food, Drug and Cosmetic Act. Section 201(h) definition of device. Available at: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChaptersIandIIShortTitleandDefinitions/ucm086297.htm.

CDRH at a Glance

***Center for Devices and Radiological Health* Offices**

- Office of Device Evaluation - premarket review, clearance, approval
- Office of Compliance - inspections, quality systems, recalls
- Office of Science & Engineering Laboratories - research, device testing
- Office of Communication, Education & Radiation Programs - advisories, notifications, work with the public, mammography, non-medical radiation products
- Office of In Vitro Diagnostic Device Safety & Evaluation - diagnostic and screening devices
- Office of the Center Director – network leaders, regulatory staff, special health interests
- Office of Management Operations - panel meetings, operations
- ***Office of Surveillance and Biometrics (Post-Market Surveillance)*** - adverse events, statistics, epidemiology
  - ***Division of Patient Safety Partnerships***
    - ***MedSun***
      - ***HomeNet Subnetwork***

Postmarket Surveillance

What is Postmarket Surveillance?

- Monitoring medical device performance after a device is approved or cleared for marketing to identify problems and safety issues that occur during widespread clinical and home use.
  - Detect and evaluate problems early
  - Address those problems that may emerge with real-life use

FDA's Postmarket Surveillance System: MedWatch

- FDA's nationwide adverse event reporting system
- Relies on reports of problems by the user and manufacturer
  - **Manufacturers**, **Consumers** and **User Facilities** (such as hospitals) report under MedWatch

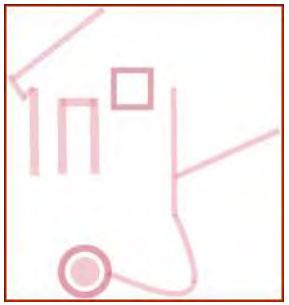
MedWatch Reporting

- **Manufacturers** must report:
  - Deaths
  - Serious injuries
  - Malfunctions
- **User Facilities** must report:
  - Deaths to FDA and to the manufacturer
  - Serious injuries to the manufacturer
  - Alternative mechanism for user facilities is MedSun
- **Voluntary Reporting** at 1-800-FDA-1088

What is MedSun?

- **MedSun, FDA's newest postmarket surveillance program under the MedWatch system, offers the clinical community an opportunity to participate in a "real-time" network of healthcare specialists sharing ALL information about medical device problems.**
- Nationwide Network of 350 User Facilities
- **More later….**

FDA/CDRH Home Use Medical Device Initiative



CDRH Operational Definition of Home Use Medical Devices

(developed by the CDRH Home Care Committee July 2008, revised post workshop May 2010)

"a home use medical device is intended for users in any environment, apart from the professional healthcare facility or emergency medical services, requires adequate instructions for use, and may also require training for the user by a qualified healthcare professional to assure safe and effective use."

-a user is a care recipient or patient, and caregiver or family member that directly uses the device or provides assistance in using the device.

-a qualified healthcare professional is a licensed or non-licensed healthcare professional with proficient skill and experience with the use of the device so that they can aid or train care recipients and caregivers to use and maintain the device.

Types of Medical Devices and Examples of Home Healthcare Devices

- **Capital Equipment /mobility/assist**
  - Medical beds, bedrails, scales, wheelchairs, walkers, IV poles, lifts, shower chairs, blood pressure equipment,
- **Home Therapeutics**
  - home hemodialysis, negative pressure wound therapy, infusion pumps, enteral feeding pumps,
- **Instruments**
  - glucose meters, pulse oximeters, insulin pumps
- **Self Diagnostic and Monitoring Systems**
  - cardiac, telemetry, patient call systems
- **Disposables & Accessories**
  - ventilator breathing circuits, filters
  - oxygen therapy related devices
  - needles, syringes, IV catheters, IV tubing, foley catheters, feeding tubes, gloves
- **Implantables**
  - defibrillators, hip/knee implants, drug-eluting stents
- **Computerized Medical Systems**
  - **Hardware**
  - **software**
- **Reagents**
  - **Fecal occult blood tests**

Home Use Medical Device Initiative

- FDA launched the **Medical Device Home Use Initiative** to improve the safe use of medical devices in the home.
- **Why?**
  - Patient demographics, economic forces, and technological advancements contribute to the rise in home care services.
  - Advanced medical devices and equipment originally designed for use by trained personnel in hospitals and clinics are migrating into the home.
  - Unlike the clinical setting, the home is an uncontrolled environment with additional hazards.

Impact of Healthcare Trends on Homecare

- Setting
  - hospital to home
- Caregivers
  - clinicians to family caregivers and to patients
- Medical Technology
  - devices have become more complex, smaller, and portable
- Patient
  - increase in knowledge about healthcare options
  - more empowered and active in the decisions related to care

Home Care Facts

- 17,000 home care organizations (9284 Medicare certified)
- 7.6 million individuals in home care
- $57.6 billion per year
- Growing 20% per year
- 75% receive skilled nursing
- 69% > 65 years old
- 44 million are caregivers of someone >18
- 2/3 are women
- By 2030, 71.5 million over 65
- 1/5 US adults report a disability (47.5 million)

(National Association for Homecare 2008 and BCC Research 2010

Cost of Inpatient Care (Per Patient Month) Compared to Home Care

- Examples show where devices play a major role

Conditions	Hospital Cost	Home Care Cost	Savings
Ventilator dependent adults	$21,570	$7,050	$14,250
Oxygen dependent children	$12,090	$5,250	$6,840
Chemotherapy for children	$68,870	$55,950	$13,920
Congestive heart failure in adults	$1,758	$1,605	$153
IV antibiotic therapy	$12,510	$4,650	$7,860

(NAHC 2008)

Medical Devices Migrating Into the Home – New Risks

- Environment
  - Children
  - EMI
  - Location
  - Noise
  - Pets and vermin
  - Power outages and sources
  - Public emergencies
  - Safety
  - Sanitation
  - Space
  - Temperature, air quality, humidity
  - Water
- Use
  - Compatibility with lifestyle and usefulness
  - Instructions for use are poor or nonexistent for lay users
  - Interface and ease of use
  - Off label use
  - Ruggedness of the device for many conditions
  - Selling Rx devices on the Internet
  - User's educational level
  - User's emotional stability
  - User's physical capabilities

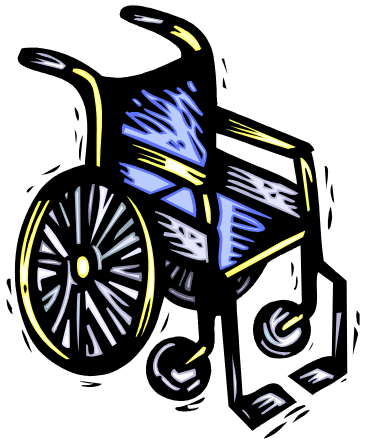
Top Reported Adverse Device Events in MAUDE July 2009 – July 2010

(total number of events = 1243 where location states "home")

- Implantable cardioverter defibrillators
- Piston syringes
- Insulin infusion pumps
- Glucose monitors
- Ventricular (assist) bypass devices
- Automatic implantable cardioverter defibrillators with cardiac resynchronization
- Tracheostomy tubes and cuffs
- Mechanical walkers
- Permanent and implantable pulse-generator pacemakers
- Intravascular administration sets

Home Use Devices Must Be…

- Useful
- Usable
- Iterative
- Intentional
- Intuitive
- Integratable
- Informative
- Address the risks unique to the home



What About a Device That Uses a Drug in it?

- Combination Products
- A Special Office in the FDA handles these
- Regulated as a drug or device depending on primary action

Examples of Emerging Technologies for the Home

- Health informatics
- Nanotechnology
- Sensors
- Smart homes and interoperable technology
- Telehealth
- Wireless Technology

Home Use Medical Device Initiative cont'd…

FDA will take the following actions to support the safety and safe use of medical devices in the home:

1. Establish guidelines for manufacturers of home use devices;
   - *Develop Guidance*
   - *Public workshop held May 24, 2010 to collect information for Guidance document*
2. Develop a home use device labeling repository;
   - *Medical devices cleared/approved for home use.*
   - *Pilot program for 10 months where manufacturers may submit their labeling*
3. Partner with home health accrediting bodies to support safe use;
   - *Meeting with accrediting bodies to incorporate medical devices into their standards. The main three accrediting bodies are on board with us: ACHC, CHAP, and The Joint Commission*
4. **Enhance postmarket oversight**; and
5. Increase public awareness and education.

Enhancing Postmarket oversight

The MedSun Program

- **The MedSun program is dedicated to developing a relationship with the clinical community to**
  - **Learn about**
  - **Understand**
  - **Solve**

Problems with the use of medical devices

AND

***to provide timely feedback* information to health professionals so they may improve patient safety**

MedSun…More than a Reporting System

- **Use sites as 'laboratory'**
- Contact sites for focus groups, individual interviews, and surveys to learn more about emerging signals.
- Contact sites to evaluate impact of possible regulatory strategies and to determine how useful a manufacturer action has been in improving patient safety.

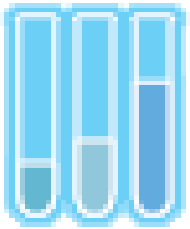
MedSun's Subnetwork Goals

Enhance relationships with device users to aid in overcoming barriers to reporting by doctors and nurses

TO DO THIS, WE BUILT VARIOUS SUB-SPECIALTY NETWORKS:

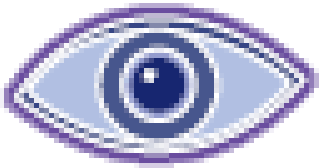
HeartNet
Cath and EP labs

KidNet Pediatric ICUs



LabNet
Hospital labs

SightNet
Eye care clinics



HomeNet

HomeNet Project

HomeNet Project

A targeted network that focuses on:

- identifying
- understanding
- solving problems

with medical devices
USED IN THE HOME ENVIRONMENT

Why was HomeNet created?

- Collaborate directly with the medical device users, patients, caregivers and **homecare providers**
- Increase FDA understanding of **home use device safety issues.**
- Amplify signals and share safety information focused on particular devices used in the **home environment**.
- Work more effectively with home care community and the manufacturer resulting in more timely interventions to mitigate risk.

Enhance postmarket oversight as part of the Home Use Medical Device Initiative

Examples of problems with Medical Devices used in the home

What is an Adverse Event?

- An event whereby a medical device has, or may have, caused or contributed to a death or serious injury.
- Includes events resulting from:
  - Device failure
  - Device malfunction
  - Improper or inadequate device design
  - Manufacturing problems
  - Labeling problems
  - Training issues
  - Use error

Think About the Device and its Environment

Environment

- Electric Power, Heat, Humidity, Temperature, Stability
- Light, Other Devices or Electronics in home (EMI)
- Pets, Kids, Noise level

Staff

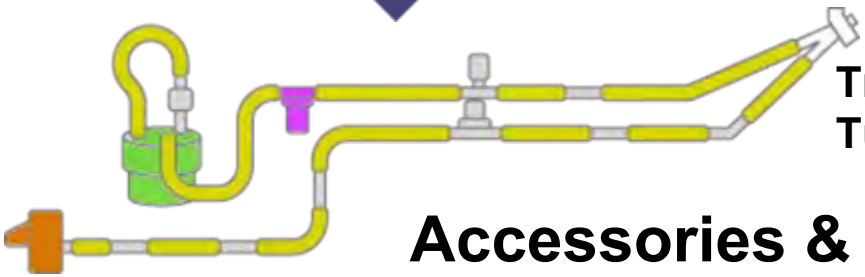
Patient/ Caregiver

Medication Port & Filter

Heated Humidifier

Exhalation Filter

Pressure Valves



Tracheal Tube

Accessories & Disposables

What Types of Medical Device Issues Should You Look for?

- Defects
- Software problems
- Failure to work as intended/malfunction
- Instructions/labeling/packaging issues
- Interactions with other devices, or other electronic equipment in the home
- Use errors
- Human Factors issues
- Combinations of the above

Examples of Problems (continued)

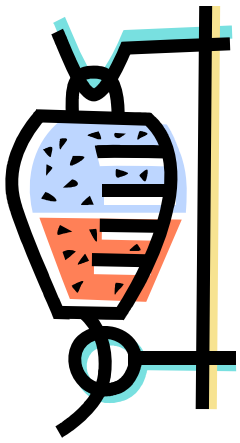
- Defects
  - IV pump bracket found with large crack and sharp edges
  - Ventilator started smoking
  - Gloves found discolored and with holes
  - Crutches collapse

Examples of Problems (continued)

- Software problems
  - Vital signs monitor did not transmit information to central station
  - Software glitches with new software installation
  - Virus infects device operating software
  - Day-light savings software considerations

Examples of Problems (continued)

- Failure to work as intended/ malfunction
  - IV pumps not infusing as programmed
  - Safety mechanism on IV catheters/syringes failing
  - Medical bed would not maintain position
  - Shower chair collapse
  - Walker leg malfunction
  - Broken connector clip on patient lift



Examples of Problems (continued)

- Instructions/Labeling/Packaging issues
  - Instructions for use (includes graphics/icons/charts)
    - Unclear
    - Misleading
    - Incomplete
    - Difficult to see, i.e. too small, colors
    - Absent
    - Complex, i.e. written for healthcare provider and not for patient or family caregiver
  - Packaging
    - Damaged package
    - Missing components
    - Sterility issues
    - Device size is incorrect

Examples of Problems (continued)

- Interactions with other devices
  - Electrical instrument deactivates pacemaker
  - Cell phone use interferes with monitoring equipment

Examples of Problems (continued)

- Use Errors
  - Electric-powered wheelchair joystick is too close to speed button

Human Factors (continued)

Human Factors – the science of how humans interact with technology; focuses on the device-user interface, incorporates the following:

- Device Design
- Environment of Use
- User Characteristics

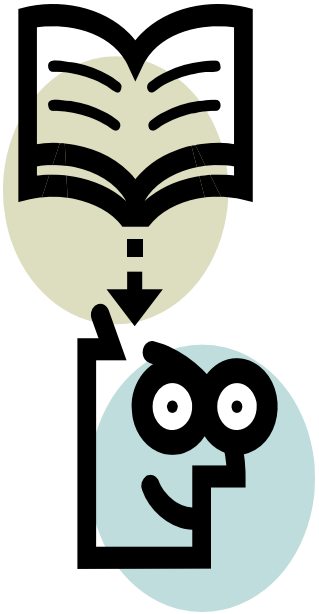
Human Factors (continued)

- User Considerations
  - Abilities and capabilities
  - Expectations
  - Familiarity with device

Human Factors (continued)

Issues with patient or family caregiver training and education

- Training is not appropriate to audience
  - Unclear
  - Misleading
  - Incomplete
- Training is not provided
- Training only addresses device set up but does not include information about:
  - Device maintenance
  - Troubleshooting
  - Device replacement parts



Other Considerations (continued)

- Number of different brands

How can you help us assure the safety of home use medical devices?

Your Role in Medical Device Patient Safety

- **Recognize, report, and understand device problems**
  - Identify actual and potential problems, adverse events, close calls with medical devices
  - Ask the end user questions about their device
  - Include details in your report, i.e. where did this event occur, what happened, device identifiers
  - Notify the manufacturer
  - Notify FDA via MedWatch

Why Reporting Medical Device Problems Is Important?

- Prevent future problems and protect your patients and families
- Impact the public health for the nation's patients, family caregivers and/or health care providers
- Effect changes in policies and procedures

When Do I Report?

- When you think a device has or may have caused or contributed to any of the following outcomes
(for a patient, caregiver, staff member):
  - Death
  - Serious injury
  - Minor injury
  - Close calls or other potential for harm

What Do I Report?

- If there was an injury, what happened to the persons affected?
  - Respiratory arrest
- Where was the patient at the time of the event?
  - Home, car, work, school, etc.
- What happened while the device was in use?
- What, if any, were the problems with the device(s) involved?
  - IV tubing found to have holes due to pets in the home
- What is the intended use of the device or why was the patient prescribed this device to use in their home?
  - Diabetic patient
- What, if any, were the follow-up medical procedures required because of the event?
  - Antibiotics administered
- What are the names of the manufacturers of the devices 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?

Voluntary reports can be submitted by calling the FDA at 1-800-FDA-1088 or by mailing in the MedWatch 3500 form, available online at:

http://www.fda.gov/downloads/Safety/MedWatch/DownloadForms/UCM082725.pdf

And Remember . . .

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

Please communicate with your provider and with FDA.

Please report.

THANK YOU!

Resources for You

- **Device Listing:** http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

This database contains a listing of medical devices in commercial distribution by both domestic and Foreign manufacturers.

- **FDA Patient Safety News:** http://www.fda.gov/psn

A monthly video news show for health professionals, presents timely information on new product approvals, recalls, and safety alerts, and offers important tips on protecting patients.

- **Home Use Device Website:** http://www.fda.gov/homeusedevices

This site provides resources and safety information about medical products used in the home environment.

- **Human Factors Website:**

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/HumanFactors/ucm119185.htm

This site provides information on human factors design, testing and use considerations for Healthcare professionals, manufacturers and consumers.

- **Infusion Pumps Website:**

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/default.htm

This website provides information about infusion pumps, actions FDA is taking to improve pump safety, strategies to reduce pump-related risks, and steps you can take to report problems to FDA.

Resources for You

- **Luer Misconnections Website**:
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm134863.htm
This site provides information for healthcare professionals about hazards that occur when different device delivery systems are mistakenly connected to each other facilitated by the use of Luer connectors.
- **MAUDE (Manufacturer and User Facility Device Experience)**:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.
- **Medical Device Safety Website:** http://www.fda.gov/cdrh/medicaldevicesafety/
One-stop for safety information with links to published safety tips and articles, archived patient safety news programs, safety alerts, recalls, and a link to report a device-related problem.
- **MedSun Website:** http://www.fda.gov/cdrh/medsun/
This site provides patient safety information via current and past issues of the MedSun newsletter, educationalmaterials, and search capability for MedSun adverse event reports.
- **Product Classification**:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
This database can be used to determine the classification of a device and the regulations it is subject to.
- **Warning Letters**: http://www.accessdata.fda.gov/scripts/wlcfm/recentfiles.cfm
This database contains the most recent manufacturer warning letters.

Questions and Answers