

Promoting Patient Safety with Home Use Medical Devices

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Objectives

- Understand what is postmarket surveillance and how it relates to Home Use Device Initiative
- Learn about reportable issues with home health medical devices.
- Describe your role in promoting patient safety with medical devices used in the home.
- Describe the steps providers and patients can take to report an adverse event or problem with a medical device used in the home.
- Understand your role in working with CDRH to assure the safety of medical devices used in the home.

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
 - Minimize risks
 - Address those problems that may emerge with real-life use
 - Monitor known risks

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 the Medical Product Safety Network (MedSun)?

- **MedSun** is a postmarket surveillance program under the MedWatch system, which 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

Home Use Medical Device Initiative

Home Use Medical Device Initiative

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
2. Develop a home use device labeling repository
3. Partner with home health accrediting bodies to support safe use
4. **Enhance postmarket oversight**
5. Increase public awareness and education

Top Reported Adverse Device Events in MAUDE Jan 2010 – Jan 2011

(total number of events = 1103 where location states "home")

- Invasive glucose sensor
- Implantable cardioverter defibrillators
- Ventricular (assist) bypass devices
- Tracheostomy tubes and cuffs
- Insulin infusion pumps
- Piston syringes
- Automatic implantable cardioverter defibrillators with cardiac resynchronization
- Peritoneal automatic delivery system
- Mechanical walkers
- Glucose monitors

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

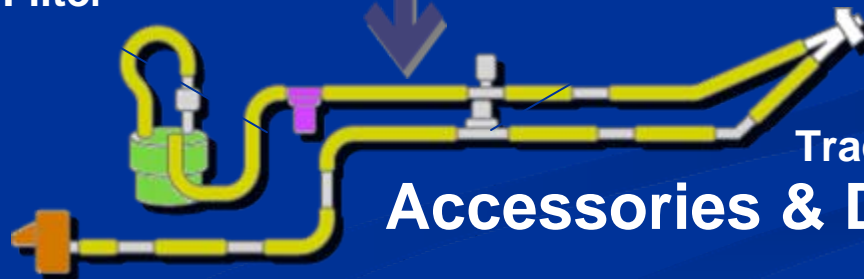
Heated Humidifier

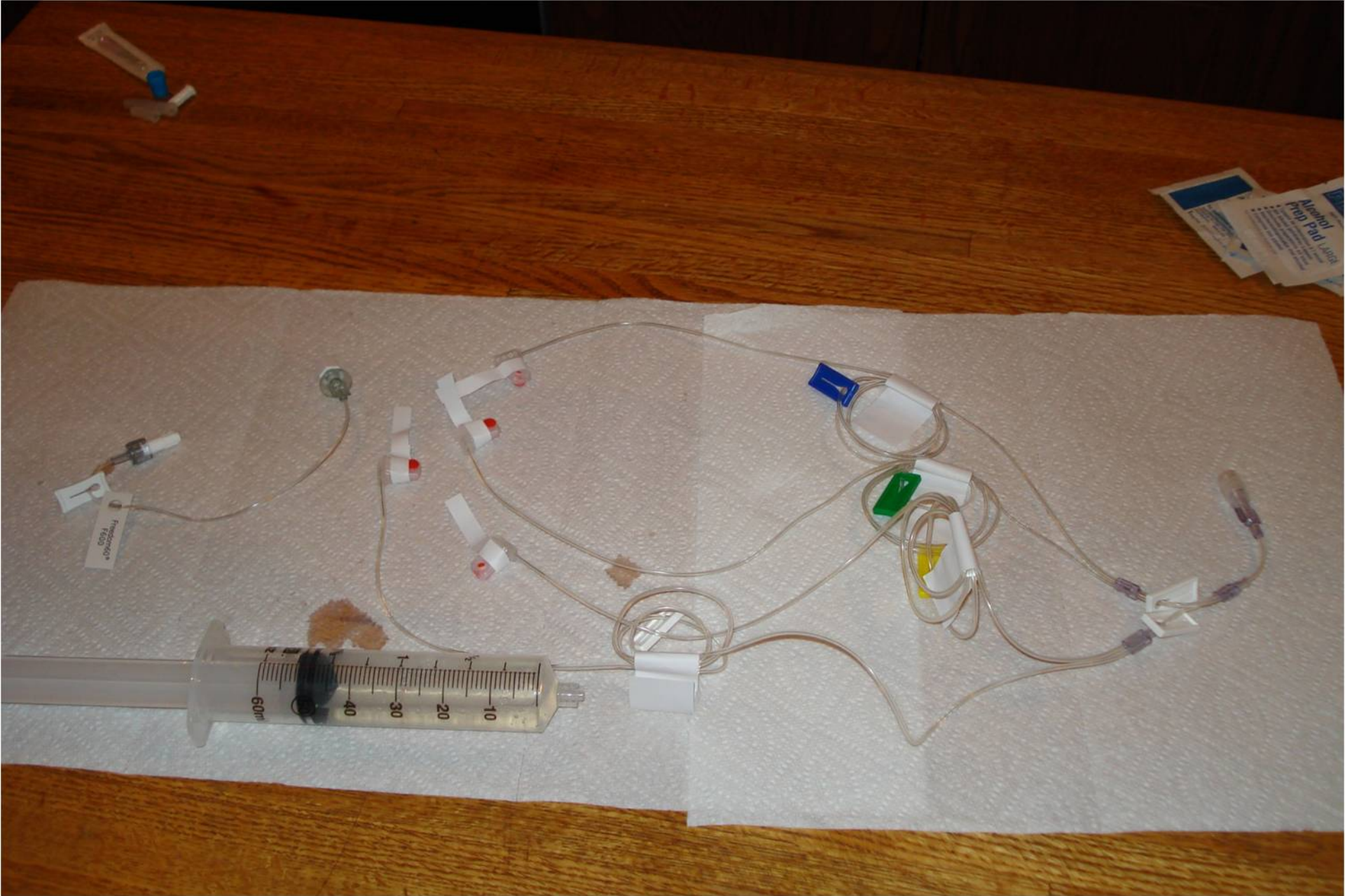
Exhalation Filter

Pressure Valves

Tracheal Tube

Accessories & Disposables







Examples of Problems With Home Use Medical Devices

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

- 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 cont.

- 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 cont.

- 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 cont.

■ 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



Examples of Problems cont.

■ Instructions/Labeling/Packaging issues

- Packaging
 - Damaged package
 - Missing components
 - Sterility issues
 - Device size is incorrect



Examples of Problems cont.

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

Examples of Problems cont.

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

Human Factors

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 cont.

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

Human Factors cont.

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

How Can You Help Us Assure the Safety of Home Use Medical Devices?

Your Role

- **Recognize, report, and understand device problems**
 - Identify actual and potential problems, adverse events, close calls with medical devices
 - Ask the end user (patient) 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 Should You Report?

- 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

What Can You Do?

- **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**

When Do You 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 Information Can You Report?

- The event (injury)
- Place or location of the event
- How the event occurred
- Related factors that may have caused the event
- The prescribed use of the device

What information Can You Report? cont.

- Medical procedures and follow up
- Manufacturer information
- Device Information
- Action taken to solve the problem

How Do You 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:

[www.fda.gov/downloads/Safety/MedWatch/
DownloadForms/UCM082725.pdf](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.

Summary

- Postmarket surveillance and the Home Use Device Initiative
- Reportable issues that may occur in the home
- Your role in promoting patient safety
- How you can make a difference and report to FDA
- Your role to help assure safety of medical devices used in the home

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.

Resources for You

- Human Factors Website:

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:

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:

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):

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:

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.

Resources for You

- **MedSun Website:**

www.fda.gov/cdrh/medsun/

This site provides patient safety information via current and past issues of the MedSun newsletter, educational materials, and search capability for MedSun adverse event reports.

- **Product Classification:**

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:**

www.accessdata.fda.gov/scripts/wlcfm/recentfiles.cfm

This database contains the most recent manufacturer warning letters.