

Improving Patient Safety by Reporting Problems with Medical Devices Used in the Home







Medical Product Safety Network

Reporting Problems with Medical Devices Used in the Home

At the end of this session you will be able to:

1. Identify several types of medical devices used in the home
2. Explain why reporting problems with medical devices in the home environment is important
3. Describe your role in promoting patient safety with medical devices used in the home
4. Describe the steps to take to report an adverse event or problem with a medical device used in the home

Impact of Health Care Trends on Home Care

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

Home Care Facts

- 20,000 home care organizations (13,000 Medicare certified)
- 7.6 million individuals in home care
- \$50 billion per year
- Growing 20% per year
- 75% receive skilled nursing
- 69% > 65 years old
- 44 million are caregivers of someone > 18
- 66% are women
- By 2030, 71.5 million over 65 years old
- 20% of U.S. adults report a disability (47.5 million)



National Association for Home Care & Hospice. Basic Statistics About Home Care: Updated 2008. http://www.nahc.org/facts/08HC_Stats.pdf (accessed February 16, 2010).

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
- Availability and usefulness of instructions
- Interface and ease of use
- Off-label use
- Durability
- Acquiring prescribed devices on the Internet
- User's educational level
- User's emotional stability
- User's physical capabilities

Types of Medical Devices and Examples of Home Healthcare Devices

■ Capital Equipment

- medical beds, bedrails, scales, wheelchairs, walkers, IV poles, infusion pumps, enteral feeding pumps, lifts, shower chairs, blood pressure equipment, home hemodialysis, negative pressure wound therapy

■ Instruments

- glucose meters, pulse oximeters, insulin pumps

■ Monitoring Systems

- cardiac, telemetry, patient call systems

■ Reagents

- fecal occult blood test

■ 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

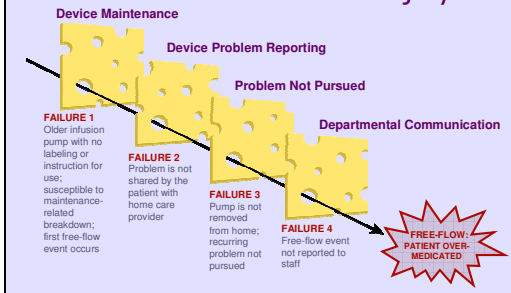
■ Computerized Medical Systems

- hardware
- software versions

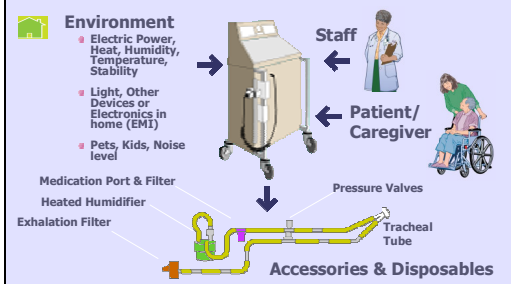
“Medical errors most often result from a complex interplay of multiple factors. Only rarely are they due to the carelessness or misconduct of single individuals.”

*Lucian L. Leape, M.D.
A leading patient safety expert
from Harvard University*

“Swiss Cheese” Model of System Failure that Can Lead to Injury



Think About the Device and its Environment



What Types of Medical Device Issues Should I 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 (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

- Infusion pumps that are made by the same manufacturer and look similar but operate differently so misprogramming of a medication occurred
- Electric-powered wheelchair joystick is too close to speed button



Examples of Problems (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
- Expectations and familiarity with device
- Training

Human Factors (continued)

- **Issues with patient/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

- **Number of different brands**

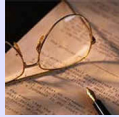
Why Reporting Medical Device Problems Is Important In Our Home Care Agency

- Prevent future problems and protect your patients, families, staff
- 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 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 We Mean by "Potential for Harm"?

- **Events that are caught before anything harmful occurred**
 - packaging defect → product not sterile
- **Important observations of a chronic problem with a device**
 - cannot hear device alarms
 - device not easy to use
- **Problems which lead staff to develop "work-arounds"**
 - taping devices together, or substituting parts because of problems with a certain part
- **"Out-of-the-box" problems that are identified before use on a patient**
 - cracked tubing noted during setup

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 patient or caregiver was using the device?**
- **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?

Our Reporting System Involves . . .

(Customized responses would be listed below)

- Online reporting system via home health agency intranet
- Verbal or written reporting to supervisor
- Written acknowledgment to the reporter including any follow up actions
- Reward system for "best catches" that make patient care safer

When You See a Device That Presents a Problem You Should . . .

(Customized responses would be listed below)

- Attach an "out of service" tag and complete any questions to explain what happened
- Inform your supervisor or biomedical engineering
- Complete an incident report
- Save the device and packaging and place in a clear plastic bag

Some Issues We've Addressed at Our Agency

What Was Reported . . .

(Customized responses to appear below)

■

What We Did . . .

(Customized responses to appear below)

■

Fostering a Climate of Patient Safety

(Customized responses would be listed below)

- *Feedback and communication*
- *Learning from errors*
- *Compliance with policies and procedures*
- *Teamwork*

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*

Your Role in Home Care Medical Device Patient Safety

- Recognize, report, and understand device problems
 - Identify actual and potential problems, adverse events, close calls with medical devices used in the home
 - Ask your patients questions about their device
 - Are they confident using their device?
 - Is the device easy to use?
 - Are the instructions clear?
 - Report the problem through your organizations' chain of command
 - Include details in your report, i.e. where did this event occur, what happened, device identifiers
 - Notify the manufacturer

In Summary . . .

Our objectives were to:

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Have we met them?

And Remember . . .

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

Please report.
