



MEDICAL DEVICES IN THE HOME

FDA BASICS WEBINAR

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Why Care About the Home?

- Patient demographics
- Economic forces
- Technological advances in devices
- Devices not intended for the home are going home
- The home is an uncontrolled environment
- Patients are smarter about their health
- Quality of life better when living at home





Home Care Facts

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





“A home use medical device is:

intended for users in any environment, apart from the professional healthcare facility or emergency medical services, and may require training for the user by a qualified healthcare professional to assure safe and effective use.”





Regulated Devices in the Home

- **Capital Equipment**

- Beds, wheelchairs, lifts

- **Therapeutics**

- Hemodialysis, infusion therapy, wound therapy

- **Instruments**

- Pulse oximeters, AEDs

- **Telemonitoring**

- Telemedicine, cardiac monitors



- **Disposables and Accessories**

- Filters, canisters, needles, tubing

- **Implantables**

- Pacemakers, aneurysm clips

- **Computer Systems**

- Hardware, software, mobile applications

- **Reagents**

- Fecal occult blood

- **Over the counter**

- Band aids, toothbrushes



Technology for the Home

- Sensors
- Smart Homes or Medical Homes
- Health Informatics
- RFID for orthopedic implants





More Technology for the Home

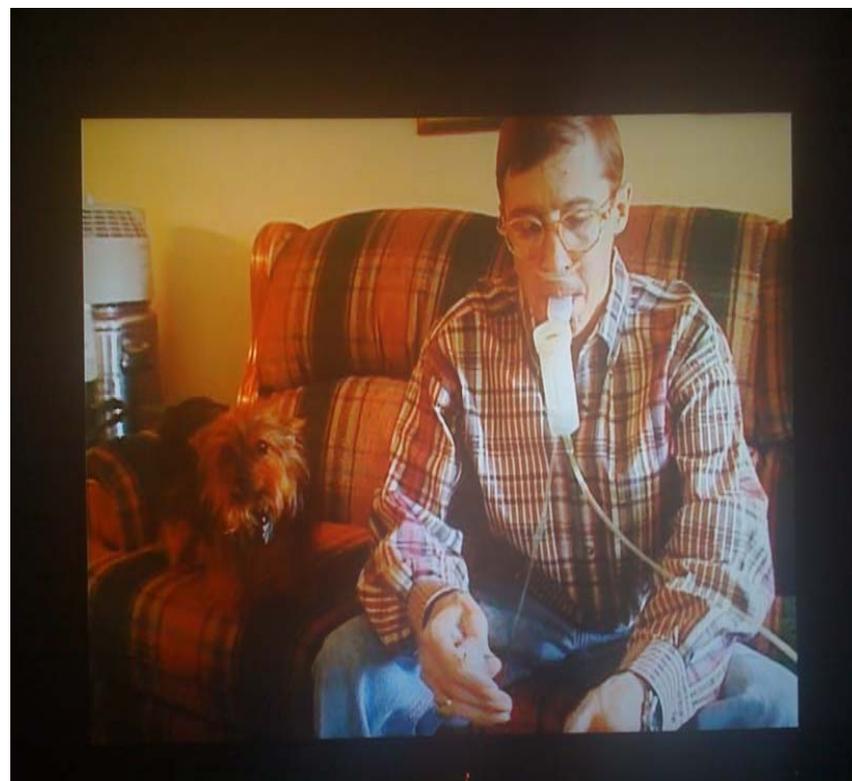
- Wireless and Broadband
- Mobile Apps
- Telehealth
- Remote Monitoring





Unique Challenges in the Home

- **Unpredictable environment**
 - Children
 - EMI
 - Location
 - Noise
 - Pets and vermin
 - Power outages and sources
 - Public emergencies
 - Safety
 - Sanitation
 - Space
 - Temperature, air quality, humidity
 - Water



Unique Challenges in the Home

Device Usability

- Compatibility with lifestyle
- 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
 - emotional stability
 - physical capabilities





Newer Technology? New Problems

- Assurance that messages are transmitted
- Failure in one part of a system
- Hacking into systems
- New versions of software or apps
- Privacy of information
- Security
- Support of the “old” apps or software



#1: Guidelines

- Develop a total product life cycle guidance for manufacturers
 - Covers
 - design and human factors
 - labeling and instructions for use
 - design for use in an uncontrolled environment
 - the user
 - post market oversight
 - Public Workshop held May 2010
 - Out for public comment this year
 - Incorporates an international electrical standard for home use medical equipment



#2: Home Use Labeling Repository

- Receive labeling for home use labeled products
- Electronic transfer of information
- Pilot test ongoing until August 2011
- 6 volunteer manufacturers
- System is new to devices
- Make the labeling searchable and readable by anyone, includes pictures and graphs
- Have all device labeling on a website?



#3: Partner With Home Health Accrediting Agencies

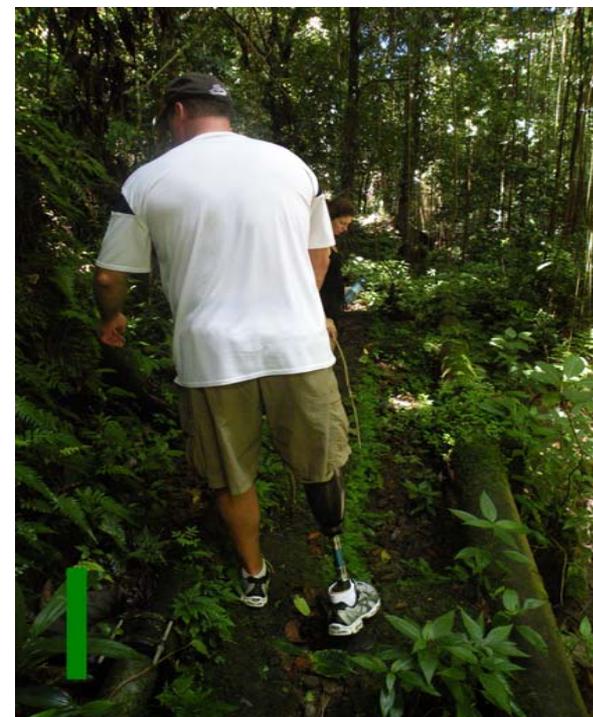
- 4 main accrediting bodies in
- Review their standards
- Incorporate medical devices
- Incorporate Unique Device Identifiers when this is ready





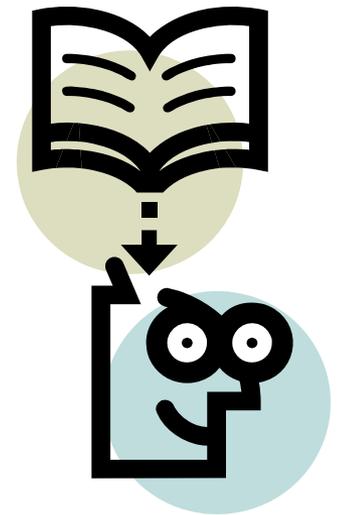
#4: Enhance Post Market Oversight

- Monitor device performance in use
- Identify problems and safety issues
- Detect and evaluate problems early
- Address problems that occur with use
- Require post market studies as needed



#5: Increase Public Awareness and Education

- Work with non-profit organizations to educate their customers about devices
- Developing You Tube videos
- Brochures and booklets
- Website
(www.fda.gov/homeusedevices)
- Numerous presentations, webinars, and articles





MedWatch



- US adverse event reporting system
- Passive
- Voluntary reporting of product problems
- Mandatory reporting by manufacturers and user facilities
 - Manufacturers report deaths, serious injuries, and malfunctions to FDA
 - User facilities report deaths to FDA and the manufacturer, and serious injuries to the manufacturer



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>



Home Use Devices Must Be...

- Useful
- Usable
- Iterative
- Intentional
- Intuitive
- Integratable
- Informative
- Address the risks unique to the home
- Address human factors design requirements





Questions?

