

Healthcare Technology in Non-Clinical Environments: Challenges and Opportunities for Home Care

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Why This Move of Healthcare Into the Home?

**Contributing to the rise in home care services,
improving the quality of life:**

- Patient demographics
- Economic forces
- Technological advancements
- Patients are smarter about their health

The Statistics

- **8.6 million to 12 million** people receive home healthcare (The Joint Commission, 2011; National Association for Home Care & Hospice, 2010).
- **More than 1 million** home healthcare and hospital workers care for these patients (The Joint Commission, 2011).
- **65.7 million** informal and family caregivers (29% of the U.S. adult population) care for the ill, disabled or aged (Family Caregiver Alliance, 2012).

The Statistics

- Estimates of the size of the home healthcare market range from **\$68 billion** to **\$85 billion**.
- ***FUTURE:*** The aging population (65+) will more than double between 2000 and 2030, increasing from 35.1 million to **71.5 million** (Family Caregiver Alliance, 2012).
- By 2050, **27 million** people are expected to receive home healthcare (Home Care & Hospice, 2012).

So...Everything is Great...Right??

Well.....No.

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

***Many barriers to the “perfect” future for home
healthcare***



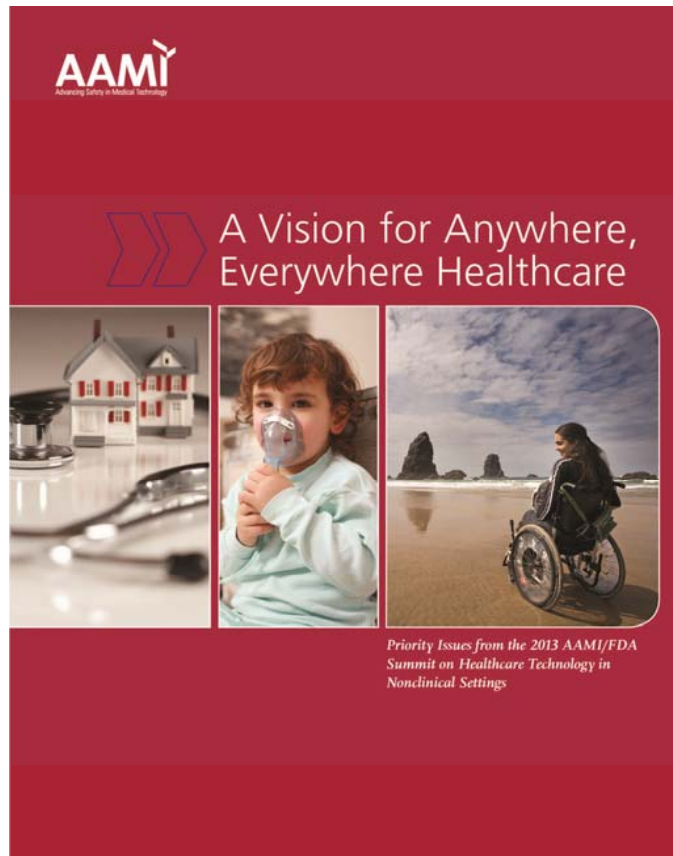
The Perfect “Future”

Healthy, happy, patients who have great technology anywhere, anytime!

- Independent and control over health conditions
- Portable, appealing, intuitive-to-use healthcare technology
- Homes that are “technology ready”
- Low-cost healthcare; excellent payer coverage
- All processes and support systems in place producing safe, seamless care from the hospital to the home

The right technology for the right patient in the right environment!!

“Current State” AAMI/FDA Summit 2013



Examples of Healthcare Technology Used at Home

Assistive Technology

- Medical beds and rails
- Wheelchairs
- Walkers
- IV poles
- Patient lifts

Home Therapeutics

- Hemodialysis
- Negative pressure wound therapy
- Infusion pumps
- Enteral feeding pumps
- Ventilators



Examples of Healthcare Technology Used at Home

Instruments

- Telemonitoring equipment
- Glucose meters
- Pulse oximeters

Implantables

- Defibrillators
- Hips and knees
- Drug-eluting stents
- Aneurysm clips

Self Diagnostic and Monitoring Systems

- Cardiac, telemetry
- Patient call systems
- Blood pressure equipment

Disposables & Accessories

- Ventilator breathing circuits, filters
- Oxygen therapy related devices
- Needles, syringes, IV catheters, IV tubing, foley catheters, feeding tubes, gloves

New Technology for the Home = New Challenges!

- Sensors
- Smart Homes or Medical Homes
- Health Informatics
- Wireless and Broadband
- Mobile Apps
- Remote Monitoring



AAMI/FDA Summit: Clarion Themes

- Variability of use environments
- Technology needs to be designed for home use
- Poorly coordinated transitions
- Need clear regulatory framework
- Need for “systems” approach



Unique Challenges in the Home

Unpredictable environment

- Children
- Location
- Pets and vermin
- Power sources
- Power outages
- Sanitation
- Space
- Temperature, air quality, humidity
- Water

Unique Challenges in the Home

User Considerations

- Physical
- Size, mobility, dexterity, strength, stamina
- Sensory/perceptual
- Vision, hearing, tactile
- Cognitive
- Literacy, comprehension, learning
- Emotional
- New diagnosis, treatment, device

Unique Challenges in the Home

Device Design/Usability

- Compatibility with lifestyle
- Instructions for use are poor or nonexistent for lay users
- Interface and ease of use
- Ruggedness of the device for many conditions
- Good battery back-up



FDA Guidance to Develop and Design Home Use Devices

- Design Considerations for Devices Intended for Home Use; Draft Guidance for Industry and FDA Staff

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm331675.htm>

Poorly Coordinated Transitions of Care

A fractured delivery model

Lack of smooth hand-offs with feedback loops in place on patient progress.

- Devices shown in hospital may not be the one sent to the home
- Patients and caregivers in a confused state during training
- Delivery person tasked with training on some devices
- Lack of rigorous maintenance on devices
- Payment issues!!!!!!

A Muddy Regulatory Playing Field

- Which regulations apply to which stakeholders?
- Hospitals regulations and standards don't necessarily translate well to nonclinical settings
- Accuracy and safety of wirelessly transmitted data
- Cyber security



A Muddy Regulatory Playing Field

- Food and Drug Administration (FDA)
- Center for Medicare Services (CMS)
- The Joint Commission (TJC)
- Federal Communications Commission (FCC)
- Office of the National Coordinator (ONC)
- Department of Transportation (DoT)
- Federal Aviation Administration (FAA)
- State regulatory agencies
 -and don't forget about the role of IT and data exchanges!!

Pulling it all Together -- Systems Approach!!

- Focus on people, workflows, transitions of care, therapies, technology, and payment—must redesign the full spectrum of healthcare in nonclinical settings.
- No one coordinating this large national effort.



Keys to Success: The right technology for the right patient in the right environment!!

- Culture of innovation
- Promote a culture of safety and readiness – promote use of home technology assessments
- Needs an integrator to encourage a team approach to address transitions and to integrate a systems approach to improving moving complex healthcare technology into the home
- Champions
- Forward-looking IT
- Comprehensive payer program

Conclusion

Home care promises:

- Improved health outcomes
- Better quality of life
- Reduced costs

Many challenges....but none insurmountable!

- Solutions and leading practices exist
- *We can create a culture of safety and improved results in this emerging frontier!!*