**Agenda**

**Wednesday, October 9, 2013**

**Welcome and Summit Overview**
Mary Logan, JD, CAE, AAMI
Video of Michele Demeo
John Deadwyler, Bernard Consulting Group (Summit facilitator)

**DESIRED OUTCOME STATEMENT**

The desired outcome for the summit is to have participants develop and agree on a list of priority issues that the healthcare community together can commit to address related to the use of healthcare technology outside of "controlled" clinical settings. The priorities will come from a list of challenges that summit participants together will develop through deep, moderated discussion following brief presentations from subject experts. Attendees also will be asked to suggest “what groups in healthcare should be responsible for addressing” each priority issue.

The goal is for work on the priorities to commence immediately following the summit, coordinated through the AAMI Foundation’s Healthcare Technology Safety Institute (HTSI).

**Comments:**

- Inside and outside the healthcare enterprise
- Who has clear or shared responsibility? Medical professional or family member/caregiver
healthcare technology outside of traditional clinical environments [traditional = hospitals and doctor offices]
TIR49--"where there is not a full-time health care professional present"

Keynote Presentation: Joseph A. Cafazzo, PhD, PEng

- Where would the profession be without diagnostics, home products, environments we've created in biomedics?
- There are a lot of technologies that we've developed that haven't helped patients.
  [Video of difficulties working with technical devices.]
- Providers have difficulties with technical devices. Think about the home environment.
- We've lost "empathy of the user" in design.
- Top 6 chronic conditions consume about 75% of healthcare.
- We're spending all of our money in acute care space, where cost of care is extremely expensive and quality of life is poor.
- Patient self-care will require a lot of empathy in design.
- There are serious aspects to usability that gives misinformation or confusing information.
- Even a ballot can be confusing (e.g., election of George W Bush instead of Al Gore). Bush won by 537 votes in an election where there was major confusion with the ballots in Florida.
- In 2001 we took the dialysis machine to the home. Benefits have been numerous (e.g., pregnancies, improved health)
- If given the right circumstances, patients can do a lot more than we give them credit for.
  A Chinese man built his own dialysis machine because he ran out of money for that care.
- Teenages with Type I diabetes don't do what they're told. They get tired of the care of diabetes.
- They developed "bant" and took a social media approach that is multilingual. 10,000 people are using the device today.
- They created a private version of twitter which allowed kids to meet others with Type I diabetes. They get rewards every time they take a reading (up to 5 a day). They can redeem rewards for itunes.
- The medical device changed behaviors.
- Social media network called "banter" was developed to identify trends and prompt patients to consider cause and effect.
- The device capitalized on kids' natural competitiveness to track progress and see how they are doing relative to their peers.
They are trying to make bant standards-based so it will have a longer life and interoperability with various devices.

The near future--the artificial pancreas.

In outpatient setting they're using the personal phone as a dashboard.

"bant" came from famous Canadian who discovered insulin.

Blood pressure monitor combined with blue tooth device resulted in 20% drop in mortality, greater awareness by the patient of their condition.

Combining medical devices with mobile apps showed improved health across many studies.

"Breathe" is first attempt at responsive design application. We have to have a high quality level to compete with other apps. It allows you to track symptoms and pulls data to warn of triggers.

Breathe is now being used in Ontario and is hoped to be available to general public soon.

Heart monitor--they had to think about what would be meaningful to the patient in terms of designing the application.

Majority of tracking devices in the market are designed for basically healthy people (e.g., wrist band that tracks steps walked).

More devices for chronic care are needed.

Healthcare Human Factors group criticizes technology to help move it forward.

Assumption: Environment of care is focused on U.S. healthcare environment

Environment of Use Considerations: How Can We Ensure that the Right Technology Is Being Used in the Right Environment?

Session Goals:
a. Identify the key environment of use issues for medical technology outside of a controlled clinical setting.
b. Identify the barriers to overcoming these issues (including research gaps)
c. Agree on what needs to change in order to overcome the barriers
d. Based on the issues, barriers, and what needs to change, Identify the top 3-5 priorities for follow up assessment and action (and by whom).

Speakers:
Jim Keller, MS, ECRI Institute

Environment of Use Considerations--How Can we Ensure that the right technology is being used in the right environment?
• ECRI's 2012 Top Ten Hazard list included poor usability of medical devices.
• There was a growth of health technology in the home. It's a completely uncontrolled environment. There's been a lack of attention to design of these medical devices.
• Jim is a biomedical engineer.
• His mother-in-law came home from the hospital with a number of medical devices. They got a little instruction on how to use the infusion pump.
• Jim was scared to death to touch the infusion pump because of the types of medicine his mother-in-law was getting.
• He imagined what it would be like for someone who doesn't know anything about medical devices.
• Jim's cousin on a CPAP monitor lost power for a couple of months after Hurricane Sandy. He had a generator during the day to keep his food from spoiling.

Considerations:
• Typical technologies used in nonclinical settings is long.
• Typical location--home, car, plane, park, stadium, doctor's office, school, etc.
• Typical environment of use challenges--power supply, cleanliness, security, user's ability and minset, pets, etc.
• Bottom line--We can't ensure the right technology is being used in the right environment because it's going to be used everywhere. We need to expect this.
• ECRI has collaborated on a series of patient guides. There are links to the brochures in Jim's presentation.

Kathy Puglise, MSN/ED, BSN, RN, CRNI, BioScrip, Inc., speaking on behalf of Infusion Nurses Society today

Environment of Use Outside the Hospital Walls
• Nursing is 50 shades of gray!
• In critical care setting you see everything your patient is doing and that's being done to them.
• INS looks at Standards Of Practice (re-written every 5 years).
• Per TJC, 8.6 million people receive home care services today, a large portion who receive infusion therapy.

Considerations:
• No longer a "safe environment"; not controlled
• Sicker patients; don't necessarily have access to screenings done in clinical setting
• Use of more sophisticated technology
• There can be multiple devices in the patient's home that use one line.
• Patients do better in their own homes.
• Pumps are tracked, monitored and tested each time they come back.
• Patients are educated and they help them develop emergency/disaster plans, including providing backup batteries, etc.

Mary Logan: HHS has made home health care a strategic priority. That’s a big deal. At the highest levels of the fed'l gov't in US moving healthcare out of hospitals and into other settings is a priority.

Session Questions:

1. What are the key environmental issues relative to using medical technology outside of a controlled clinical setting?

Themes:
- Variability and complexity is overarching
- Generally, patient engagement
- Good human factors and usability
- Variability of the environments makes professional care much more difficult
- Inability to anticipate what the professional is walking into or dealing with; don't have the support in the hospital
  - Power requirements for devices
  - Integration to information technology and systems
  - Care is professionally managed
  - Sterilization and cleanliness of equipment
  - Service and maintenance and calibration
  - State of patient access, history
  - Lack of patient observation--how do I know what happened before healthcare professional was there
  - Maintenance of equipment by patients
  - Education of patients, both to use and maintain equipment
  - Space--lack of space to store devices and supplies
  - Accessibility
  - Portability of the devices
  - Noise distraction for the patient
  - Access to troubleshooting and help
• Validation that the patient is using it and reverse validation that someone is not using the device
• Technical service and healthcare delivery is professionally coordinated
• Education and training for those who are responsible for caregiving
• Availability of replacement equipment
• Home assessment
• Isolation that can be part of home environment
• Burden of care for the patient and family members--patient burn-out
• Portability of devices (e.g., weight control)
• Patients call manufacturers and they can't help them
• 24/7 need without 24/7 support
• Patient's ability to manage the device failure modes
• EMC interference
• Lack of connectivity
• Kids having access to devices; controlling accessibility when appropriate
• Support for patient-owned devices
• Second-hand devices
• Device location tracking in event of recalls, etc.
• Reliability and durability of devices
• Reliability and EMC
• Robustness of devices; devices aren't hardened to variability of the atmosphere (e.g., static electricity)
• Reducing and controlling environmental hazards and risks
• Prevent accidents/injuries
• Maintain environment of care sensitive to patient needs
• Minimize unnecessary stress
• Maintain normalcy
• Equipment safety
• Improved health outcomes
• Right circumstance--"home health", "homebound status"
• Limitations on amounts of meds allowable to patient at any time
• Devices that were never intended for use in the home being used in the home
• Waste generated with many devices--amount and type that the patient has to dispose of in responsible manner
• Ease of ordering supplies and reliability of deliveries
• Reportability from the field; patient security; data capture and appropriate feedback
• Caregiver or patient's language skills and comprehension skills relative to use instructions
• Physiological and cognitive abilities of patients
• Adherence to procedures (e.g., refrigeration)
• Reconciling need for adequate security with usability
• Interaction between patient's disease progression and interaction with the device; we count on caregiver to be aware; how do devices interact with changing conditions of the patient
• Understanding complaints (e.g., mfc's don't get complaints back and can't address them)
• Integration with IT
• Reimbursements, home networks, security of devices from hackers
• Financial considerations
• When devices come back with patients into the hospitals
• Obsolescence of devices

2. What are the barriers to overcoming these issues (including research gaps)?
• Characterizing and prioritizing sources of variability
• Creating the transfer function to impact on safety, efficacy, burden and cost
• Distance between provider, supplier, and professional
• Who pays to retrofit the home to meet minimal standards
• Measuring the outcome and the care
• Cost of improving the design to be more suitable for home use
• Variability of settings where devices will be used
• How assessment of variables will be coordinated with the infusion nurse
  – Safety issues
  – Environment that will facilitate use (e.g., water, electricity)
  – Conditions not conducive to use of the device
• Ergonomics--clinical versus patient perspective
• Multiple regulatory bodies involved
• Several customer supplier relationships that need to be converged to resolve problems
• Costs involved in managing care at home
• Generalized understanding across mfc base of realities; designing from same set of constraints or inconsistencies
• Mental state of patients changes throughout their treatment; so does use of medical devices; impact of family
• Ability of particularly the aging population to deal with complex situations and systems--educational challenge
• Tendency to try to solve everything at once
• Traditional roles change in the home

3. What changes need to occur in order to overcome the barriers?
   1. Base engineering--avoid analysis paralysis
   2. It's not real-time monitoring of the use of the device; until the nurse shows up, we don't know what's happening
   3. Clinical staff who do home assessments
   4. 24/7 clinical staff on hand to answer questions
   5. Backup equipment especially with distance patients
   6. Biomedical department who do repair work for distance patients
   7. **Improve the home care delivery model for a continuum of patients**
      - The current model for how care is delivered to the home is based on a system that is changing dramatically; the process needs to change with it. Regulation is disbursed.
      - Home assessment
      - Sustainable business model
   8. Expand very early formulative studies to include professional users and those in home environments, non-professionals
   9. Clinical protocol should drive design; determine how to deliver care and then design the devices around that; include patient and family/caregiver input
   10. Cooperation and sharing between healthcare professionals of information and responsibility
   11. Paying to retrofit the home to use the device
   12. Infrastructure has to change--people and other infrastructure to support use of the device (e.g., network connection)
   13. Avoid trying to retrofit devices designed for the clinical environment and start from scratch.
   14. **Very early human factor assessment; undertake AAMI standards on human factors usability**
   15. Managing challenges within the home environment
   16. Simplicity of medical devices and ease of use
   17. Consistent user interfaces
   18. **Analyze what's working and what's not; identify best practices**
   19. Redesigning of therapy delivery to be safe at home--includes device, supplies, people, support
20. Consistent and appropriate regulatory framework
21. Manage workflow of home care delivery
22. Evaluate and continuously improve the process
23. Speed is critical

24. Based on the issues, barriers, and what needs to change, what are the top 3-5 priorities for follow up assessment and action?
   - Improve the home care delivery model for a continuum of patients
   - Very early human factor assessment; undertake AAMI standards on human factors usability
   - Analyze what's working and what's not; identify best practices
   - Consistent and appropriate regulatory framework (U.S.)

1. Who needs to address each of the top challenges?
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**Device Design Considerations: How Can We Ensure that Technology Is “Home Ready?”**

**What Is “Home Ready?”**

**Session Goals:**

a. Agree on what is “home ready” from a design perspective
b. Identify design challenges and limitations to “home” readiness
c. Identify the barriers to changing the design paradigm from “hospital” to “home” in order to overcome these issues (including research gaps)
d. Agree on what needs to change in order to overcome the barriers
e. Based on the issues, barriers, and what needs to change, identify the top 3-5 priorities for follow up assessment and action (and by whom).

**Speakers:**

Lane Desborough, Medtronic Diabetes
Device Design Considerations--How Can We Ensure that Technology is "Home Ready?" What is "Home Ready"?

Assertion 1: Vast majority of chronic disease management is done outside the clinic
Assertion 2: Chronic diseases are contact sensitive (lifestyle diseases)
Assertion 3: CDM is a team sport; people with chronic diseases don't live by themselves; CD impacts others in the home
Assertion 4: Coordination of stakeholders is key; needs to be a shared situational awareness; how to coordinate actions of multiple human agents and devices as well
   – Players are mobile, on a global playing field
Assertion 5: Non-clinical use conditions vary widely--different use conditions, e.g., alertness, attention, choice, complexity, confidence, consequence
Assertion 6: Sensors and smartphones and the Internet are changing everything; we have monitors now for stress, mood, #steps taken, etc.; these devices weren't designed to be used for healthcare applications; apps have consolidated a lot of other devices (e.g., digital cameras, electronic game devices)
   – There are formal and informal forums for sharing new ideas on how to improve chronic disease management
Assertion 7: ?? can be used anywhere; individuals are monitoring health conditions on their own using devices they own
Assertion 8: Devices bring new expectations and possibilities; new precedents are being set; expectations of patients are being raised ("why can't my device do xyz?")
Assertion 9: CDM takes a village; need to acknowledge variability in viewpoints of the stakeholders
Assertion 10: Demands of disease state mgmt are already high, let's not make them higher with devices. Consider physical, cognitive, financial, and emotional aspects. We can address fear, embarassment and frustration through device design.
Assertion 11: Burden has huge implications--misuse (slips and mistakes), disuse (compliance, adherence), waste (costs increase, value decreases)
Assertion 12: "Home Ready" = ready to add value in the complex, multiagent, rapidly changing, heterogeneous world outside of the clinic

Conclusions:
1. The real world is more complex and varying and has high consequences than hospitals
2. Draw system boundaries broadly at the societal level
3. Ensure variation in medical devices adds rather than subtracts value or devices won't be used

Vicki Lewis, PhD, MedStar Health’s National Center for Human Factors Engineering in Healthcare

A Systems Approach to Defining Home Ready
- Sociotechnical systems model
- If all we’re thinking about is technology and whether someone can do a few functions in a lab, we’re missing the boat.
- Internal environment (Patient's home) is at the center of the model
- Supporting components: organization/resources, technical, physical environment, people
- Needs assessment: Who and how, accessibility to information, feedback
- Gap - flow of information from mfc's to stakeholders and from users to mfc's.

Session Questions:

1. What is “home ready” from a design perspective?

"Home Ready" = ready to add value in the complex, multiagent, rapidly changing, heterogeneous world outside of the clinic

Value should be defined from the perspective of the patient
"Value" should be defined by who pays for it
Different stakeholders often define value in ways that are in conflict
Safety needs to be considered
"Value" is not a financial measure, it could be safety, quality of life
"Value" is in the eye of the beholder

- Intuitive user interface
- Robustness against unintended use
- Safety
- Minimal steps to reach desired outcome
- Durable
- Satisfies as many of the definitions of "value" that we can come up with
- Empathy to patient's situation; Empathy to patient situation and caregivers
• Flexible
• Easy to use (but with caution and controls for safety)
• Usability by all stakeholders (clinical and lay)
• Tolerance for error
• Evidenced based improvement in outcomes
• Robust in all environments--home care, outside of hospital
• Controlled Access to the device
• Facilitates effective care management
• Easily maintainable
• Simple operating manuals

2. What are the design challenges and limitations to “home” readiness?
• Electrical power availability, battery longevity
• Device fault detection and management
• Network--accessibility and ability to connect to EMRs with security
• User variability (even within users); design assumptions that understand home environment users
• Cultural barriers/language barriers
• Cost to develop a product that can be used in every setting may be prohibitive
• Designing to low educational levels so everyone can use products
• Very early input from patients prior to setting design specifications
• Modeling from existing consumer devices that are don't need maintenance (plug and play)
• Relying on training as opposed to human factors for risk mitigation
• Use of multiple devices/machines and interoperability
• User sensitivity to risks
• Managing the trade-offs

3. What are the barriers to changing the design paradigm from “hospital” to “home” in order to overcome these issues (including research gaps)?
1. Cost
2. Changing power relationships/responsibility
3. Where the input is coming from (e.g., highest paid person in the process or user)
4. Confusing the difference between market research, industrial design research, and human factors evaluations; all need to be considered
5. Industries that are regulated differently; e.g., design decision that's approved in one regulatory area, but not others; systems must be integrated
6. General skepticism by providers that patients can care for themselves; they continue to reinvest themselves into the process
   – High acuity cost, lower cost and higher quality of life--this is the goal. We need to get all stakeholders to agree to this goal.
   – Concept of risk and different views of risk associated with devices
7. Stop in the design analysis and get the product out the door; Cycle of product development is getting increasingly longer because of the steps and reloops
   – get human factor analysis involved early (this is not just a regulatory process); productization, good consumer product
8. Vendors are looking for ROI. A challenge is looking for consumer cost products where profit margins are small; Mfc's are looking for double digit profitability
9. Concern that design is aimed at person providing training rather than actual end user
10. Communication breakdown at the hand-off from hospital to home care
11. Mfc's who have traditionally sold to hospitals need to develop relationships with home medical technicians
12. Shift in who's making the choice for devices entering the field (e.g., consumer preferences vs. safety)

13. What needs to change in order to overcome the barriers?
   • Coverage (reimbursement); this will drive change
   • Comparison of home-based system with hospital in terms of cost and efficiency for approval purposes
   • Getting everyone on board (regulatory, health care providers, users)
   • Better reporting of what's actually happening in the field today
   • Rehabilitation engineering input early in the process

14. Based on the issues, barriers, and what needs to change, what are the top 3-5 priorities for follow up assessment and action?
   • Confusing the difference between market research, industrial design research, and human factors evaluations; all need to be considered
   • Industries that are regulated differently; e.g., design decision that's approved in one regulatory area, but not others; systems must be integrated
   • General skepticism by providers that patients can care for themselves; they continue to reinvest themselves into the process
     – High acuity cost, lower cost and higher quality of life--this is the goal. We need to get all stakeholders to agree to this goal.
     – Concept of risk and different views of risk associated with devices
Coverage (reimbursement); this will drive change

15.  Who needs to address each of the top challenges?

Message to Mary Brady, U.S. Food and Drug Administration

- Here's hoping that our congress and senate can actually work as a team
- We sorely miss your presence at this meeting
- Mary, as I've told you, you're the only person who uses the term "varments" when describing the home use environment.
- Dear Mary, I don't know how many people know that for the past 15 years you've been working on this as a one-woman show. If you didn't keep pushing on this, we wouldn't all be here today.

[Round of applause]

Certification of Devices in the Nonclinical Setting: How Are We Making Sure That Devices Being Used Outside the Hospital Are Safe?

Session Goals:

a. Identify primary safety issues with devices being used in nonclinical settings
b. Explore how the healthcare community, patients and families will know and can be assured that a device is safe for such use;
c. Agree whether certification is important; what “certified safe to use” should mean in the context of safety for “home” use; and what criteria should be required for such certification
d. Identify the top 3-5 priority follow up issues on this topic and who should be involved in addressing issues

Speakers:

Anthony Ciccarello, Philips Healthcare

- Device Certification to IEC 60601-1-11
- Environmental conditions—storage temps and humidity, operating temp, humidity and altitude, environmental shock, mechanical strength (shock, vibration, drop)
- Technical challenges—childproof, AC mains voltage variations, uncontrolled EMC
- Human factors challenges—usability, labeling and instructions, required labeling

Anil Patel, Underwriters Laboratories

Certification and Risk in Nonclinical Environments
- There are risks with any device you place in the home—business, product and regulatory risks
  - Range of audience (age, skill, ability)
  - Infrastructure
  - Environment
  - Location
- Regulators, user community and manufacturers
- How will a patient, caregiver or doctor know that a particular product is intended for home use?
- Regulators experience is with clinical use.
- Should there be a home use trademark? Who owns it? Will it be required?
- Who's responsible for training and how?

Elliot Sloane, PhD, CCE, FHIMSS, Center for Healthcare Research & Policy

Roles of Certification in Managing Risk
- Historical risks—environment, user ability
- In 2013, it’s estimated that over 300,000 medical devices will be used in the home.
- There are major issues of grounding in rural America.
- Insect infestation has not shown up yet in the discussion, but that is an issue.
- Tap water used instead of sterilized water, smoking around oxygen systems, alarm fatigue are other challenges.
- Interoperability—can devices send information to each other reliably; how do we address hacking and tampering threats?
- There’s enormous resistance to formalizing the evidence of performance (testing)
- Context/infrastructure consistency, e.g., consistent time, device ID, patient ID, drug ID
- IHE USAT testing doesn’t test environmental, user/usability, device features, performance, etc.
- Health technologies in nonclinical settings will improve health if safe, interoperable and easy to use.
- Interoperability for Dummies, IHE edition
Denny Treu, NxStage Medical, Inc.

- Experience getting products through certification process and ensuring they are safe.
- Our process: define everything up front, work through design, testing, approvals
- Considerations: Therapies needed and their complexity, user capabilities, environmental conditions
- These all feed into risk management process.
- You have to build the whole infrastructure around the treatment.
- Challenges:
  - Leverage existing designs
  - High costs for new products
  - High costs for shoe-horning products into markets for which they weren't designed
  - Complexity of doing products for both clinical and non-clinical markets
  - Regulatory--number of standards, different standard setting bodies, international harmonization, development time line
- Text houses--who will you use, what are their processes, have they done similar products, what are the expectations for support, do they use risk based standards for certification?
- Market requirements:
  - Find area experts
  - Multidisciplined approach
  - identify problems and issues
  - Determine overlap in requirements for different markets
- Overall system design is key--every aspect must touch patients and their experience, usability is for the whole system
- Minimize using the patient as the "safety"
- It's cheaper to start with a clean sheet than to redesign a product for home use
- Help shape the regulatory standards
- Internal expertise
- Risk management plan
- Design to the standards
- Plan for handling errors; build it into the process

**Session Questions:**

1. What are the primary safety issues with devices being used in nonclinical settings?
   1. Device or system doesn't know who's operating it
2. Device not designed to work in nonclinical environment
3. Power loss
4. Has the patient/caregiver been instructed what to do when device fails?
5. Device is not used per recommended use
6. Inability of ? to recognize devices suitable for use
7. Unknown state of the device
8. Hazard from underlying disease state and from improper use of the medical device; balance between these
9. Fire
10. Failure to design interoperable characteristics

2. How will the healthcare community, patients and families know and be assured that a device is safe for such use?
   1. They don't today
   2. Testing
3. Certification
   4. Labeling/branding; potential for counterfeiting
   5. Statement of standards of compliance of the device
4. Recommendation by health professional
5. Assure patients that the device is safe
6. Experience and trust; if patients are addressed in their own language
7. Patients and families don't understand the standards; effective communication of those standards
8. Patients and families don't understand the standards; effective communication of those standards
10. Self-test capabilities for devices
11. Inspection and maintenance strategies
12. Insurance for your home device to assure safety for home use
13. Access to trained professionals when something is unexpected or goes wrong
14. Put in documentation "safe for home use."
15. Have good fail-safe modes
16. The look of the labeling of the device
17. Closed loop--feedback

3. Is certification of devices important?
   • YES
4. If so, what does “certified safe to use” mean in the context of safety for “home” use?
   • "home use" is different for various people and depends in part on the environment it is being used (e.g., can you take in into a body of water or not?)
   • Clarify the certification body. What are you certifying to?
• Labeling needs to certify and state what environment you have so the physician can determine whether a device is appropriate for that patient.
• The wording sounds like there's one certification. A product may have many certifications needed for certain use.
• Different certifications for different aspects.

5. What criteria should be required for certification?
   1. Crossover to other industry standards; we don't need to start from scratch. Consider differing incentives for safety and reliability of other industries if you benchmark.
   2. Rehabilitative engineering people (RESNA)
   3. Guidance document from Mary Brady
   4. IEC60601-1-11; AAMI ANSI version. Requires that you spell out maintenance requirements. The healthcare org has to make sure the maintenance is done.
   5. When testing devices, consider the risks based on its use
   6. Certification for home use can't be one fits all; needs to be a system like, for example, fire extinguishers; must demonstrate that it's been maintained.
   7. A concern about requiring ongoing certification is money. Products need to be designed for a long life time.
   8. Signal on the device that it's not working properly.
   9. Service model = replace it
   10. Let manufacturers say what they want to be certified to. Checklist of what circumstances make the device unusable.
   11. Set-up and installation instructions should say "safe for home use."

6. What are the top 3-5 priority follow up issues on this topic?
   1. Device not designed to work in nonclinical environment
   2. Device is not used per recommended use
   3. Inability of ? to recognize devices suitable for use
   4. Hazard from underlying disease state and from improper use of the medical device; balance between these
   5. Failure to design interoperable characteristics
   6. Certification
   7. Recommendation by health professional
   8. Patients and families don't understand the standards; effective communication of those standards
   9. Self-test capabilities for devices
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16. Signal on the device that it's not working properly.

7. Who should be involved in addressing the priority issues?

Instructions for Use: Ensuring that Patients and Caregivers Understand and Can Perform

Session Goals:

a. Identify the training and instructions for use issues for medical technology outside of a controlled clinical setting.
b. Identify the barriers to overcoming these issues (including research gaps)
c. Agree on what needs to change in order to overcome the barriers
d. Based on the issues, barriers, and what needs to change, identify the top 3-5 priorities for follow up assessment and action (and by whom).

Speakers:
Johann Becker, RN, BSN, MAM, Wellspan VNA Home Care [Mary Logan filling in]

Use of Medical Device Technology in the Home Setting: Challenges and Mitigations
• Johann is the caregiver and life partner from the video clip this morning.
• She happens to be an RN and expert on home health and hospice.
• Care providers and patients are being left at risk for potential adverse events to occur.
  [include in report]
  • Hospitals know they need to ToC hand-offs when a patient leaves the hospital. Providers outside clinical settings need to coordinate ToC's as well.
  • The DME driver often becomes the patient educator.
  • The emotional and mental state of the person is different for every patient. It's impacted by their technology needs and situations.
  • Consider requirement of a "teach back" session with the patient.
  • Referrals are important for a patient who is struggling.
Tobey Clark, CCE, The Healthcare Technology Foundation

*Communicating Safe Practices To Patients And Caregivers*

- A large % of patients and caregivers have multiple limitations to understanding issues related to home health devices.
- We suspect under-reporting of errors with home devices.
- Devices come from various sources (e.g., hand me downs, Internet, legacy devices)
- We need to define who is responsible for training and education.
- Training at the time of delivery is more effective than pre-discharge training.

Patricia Patterson, Agilis Consulting Group, LLC

*IFU's—Ensuring User Performance*

- Presentation is framed around AAMI TIR 49:2013
- To support safe, accurate, and efficient user performance by providing guidance on the design of user instructions and training.
- The report presents research-based information on how to influence user performance with instructional materials.
- Instructional designers are not involved in development of most user instructions. Users need to be trained on how to use the user guide to improve user performance with the device.
- Consider the appropriate media other than print for instructional materials.
- Assess instructional materials in the early stage during product development.
- Avoid the myth of "writing instructions." It's not a writing process, it's an analytical process.
- Low literacy users--Typically defined as 6th or 7th grade reading level.

Suzanne Steidl, Your Daughter’s in Town: Health Advocacy for Elders

- Here as a healthcare consumer.
- I don't have slides and I don't have a smart phone.
- No one is ever asked if they require alternate formats of instructions.
- Bulleted and laminated instructions were included with every device that came into my home.
- Is anyone working on equipment that talks to a wrist band that the caregiver can use?
- Instructions for use have been discussed since 1997.
- Question: With all of the great work going on, why isn't it making it to me and the people that I know?
- I hope this comes out of this meeting: The tasks, assignments and timelines lead to real-world training, IFUs and regulations that require and enforce compliance.
Session Questions:

1. What are the training and instructions for use issues for medical technology outside of a controlled clinical setting?
   a. We have to look backwards as well as forwards in terms of IFUs for medical devices (legacy devices)
   b. Two types of devices--home health and home medical devices. I suggest another type--home health IT devices.
   C. **Multilingual instructions**
   d. Access to resources have to be simplified and standardized with a clear escalation process.
   e. Recurrence and repetition are important.
   f. Timing is important--people are too emotional at discharge.
   g. We make too many assumptions in regards to your audience.
   h. **Insurance carriers dictate how many times we can see a patient.**
   i. Embrace that the patient's partner has replaced the healthcare professional for advice and assistance. Instructions have to reach out to them.
   j. Multimedia--many people don't read anything anymore.
   k. **Use more visuals; keep it simple.**
   l. **Design IFUs for the user, not the manufacturer**
   m. Risk analysis determines potential for misuse. Include this in the IFUs.
   n. **Instructions have to address emergent situations and potential disasters.**
   o. There's no one responsible for creating instructions for the entire therapy. E.g., something that falls outside of the device.
   p. Ongoing assessment of the knowledge. Over time, the patient's procedures may slip and they may need retraining.
   q. A way for someone to find the right information (search function).
   r. Ability to change the font of instructions.

2. What are the barriers to overcoming these issues (including research gaps)?
   a. Training expectation is an afterthought.
   b. Cost
   C. **Reimbursement for training**
   d. Access
e. Assumption that the patient has ready access to IT tools (alternative access or access at all)
f. Technical documentation team is part of your home healthcare
g. There's a complex separation of roles in the market relating to reimbursement, clinical specialization, patients having multiple illnesses being treated by different parties with different devices.
h. Liability issues have driven the content of IFUs
i. Having access to the people who need to run through the training.
j. Product and feature terms (multiple versions)
k. Users or in-home trainers may not be familiar enough with the instructions to train other caregivers.
l. Need ability to control information in a human environment.
m. Attention to differently abled individuals. E.g., multiple languages, physical abilities.
n. Labeling can never replace a well-designed device.
o. Healthcare professionals sometimes refuse to use the instructions.

3. What needs to change in order to overcome the barriers?
a. Model of home care needs to change. Clinical staff instructs the family in the home how to use the devices, provides technical support information, provides laminated instructions that address the patient needs (e.g., language barriers, etc.) and a follow-up.
b. Gov’t is reviewing DME providers.
c. Infusion nurses get one visit. Negotiate different rates for different markets. Congregate into groups that can provide better comprehensive care.
d. Influence state legislature on access relative to home care.
e. Dissatisfaction, incentives to change
f. Coordination of hand-offs
g. Clearly define the training process and responsibilities
h. What’s not measured, doesn't get done. Design a metric that leads back to the physician who orders the equipment in the home. CMS policies and rules need revision--aggregation of data to measure outcomes and make changes. E.g., data indicates that limiting to one visit is not effective.
i. Trained, educated coaches for home care.

4. Based on the issues, barriers, and what needs to change, what are the top 3-5 priorities for follow up assessment and action?
5. Who should be involved in addressing these challenges?

Usability and Accessibility: Human Factors Considerations for Technology in the Home

Session Goals:

- Identify the key human factors issues for medical technology outside of a controlled clinical setting.
- Identify the barriers to overcoming these issues (including research gaps)
- Agree on what needs to change in order to overcome the barriers
- Based on the issues, barriers, and what needs to change, identify the top 3-5 priorities for follow up assessment and action (and by whom).

Speakers:

Ann Blandford, PhD, FBCS, CEng, University College London

Living with Medical devices: values and understanding

- Trading off of values of comfort and pleasure with safety.
- Actualized use (study people and how they are working with devices) versus idealized use
- You have to generalize across populations.
- Distinguish things which are formally described as medical devices against fit bits and other things used more for health devices.
- People don't want to criticize their devices for fear of being deemed incompetent.
- We need to design and regulate for real use, not idealized.
- Training, ongoing support, etc.

Melissa Griffin, HumanEra

Usability, Accessibility And Work-Arounds In Home Care

- Photographic walkabouts of home environments; client/caregiver takes professional on a tour of their home and routines
- Identify barriers and supports

Key issues identified:
- Equipment
- Unused equipment
Used to store others things on
Disassembled equipment
Awkward storage--small living spaces, boxes of supplies, oxygen tubing solutions

Medication management
- number of medications,
- complexity of medications,
- storage, inappropriate storage
- labeling,
- modification of devices to manage meds,
- patient-labeling of meds (does, time taken),
- paper medication records

User ingenuity
- Clients and caregivers are ingenious in finding workarounds and solutions
- How can we better integrate feedback and preferences of users in to the design of devices that people need and will use.

Linda Harley, Georgia Tech Research Institute
- Looking at a whole system of home care-- "ecosystem"
- Human systems integration approach

Considerations:
- Users' abilities
- Task demands
- Interaction between context and both the users' abilities and task demands

- Many times we design with one thing in mind, but users have multiple conditions.
- We have to start thinking beyond the immediate interaction to how the device will be used in the home environment.

**Session Questions:**

1. What are the key human factors issues for medical technology outside of a controlled clinical setting?
2. What are the barriers to overcoming these issues (including research gaps)?
3. What needs to change in order to overcome the barriers?
4. Based on the issues, barriers, and what needs to change, what are the top 3-5 priorities for follow up assessment and action?
5. Who should be involved in addressing these challenges?

Priorities to address the issue of human factors

a. Start human factors from the beginning of the design cycle and doing considering them throughout the process.
   - People will go for quality of life over safety at times. Think about this in the design.

b. Legacy devices

c. Expand your thinking of home environments as the use environment

d. Importance of actually testing in the home environment

e. The device may be manipulated by someone other than the patient.

f. Consider wearable devices as well as standalone devices.

g. Find a way to develop continuity from device mfc to clinician, to trainer, to user.
   - Eliminate some or connect them together better.

h. Ability of the patient to make connections to a smart phone. We need the mfc to work this into design.

i. In development, consider the potential for identifying what other med devices may be used along with a device.

j. Engage the disciplines who are actually working in the home healthcare environment.

k. Have a mechanism to gather problem information about what's going on in the home care setting.

l. Reinforce the point about post-market surveillance.

m. Don't assume the users are reporting all problems with the devices.

n. Have the patient consult in the design process. Walking in the shoes of the patient.

O. Consider and design for breadth of use conditions (e.g., alertness, attention, choice, motivation)

First Day Wrap Up
Thursday, October 10, 2013

Question: What's driving the move toward home healthcare? Baby boomers, ACA, Regulations, ACOs

Concern I'm hearing from some of the providers is that once they've gotten to the point where they've made savings, there are no more savings at the second tier, so they won't be rewarded appropriately.

We already have the AAMI standard on home care. What is the purpose of this meeting? What is the impact on the standard?

- The TIR is only about instructions for use and labeling. There are a lot of other pieces--design, human factors, patient perspective. There are a lot of issues that need to be addressed not only by AAMI. We need to look at "what's my role?"
- This event is to gather the collective wisdom of the group to identify the highest priorities. We'll put those in a publication with a call to action to the community to start addressing those issues.

**Telehealth Considerations and Challenges: From Remote Monitoring to Data Integration**

**Session Goals:**

- Identify the major technology-related challenges with telehealth
- Identify the barriers to overcoming these issues (including research gaps)
- Agree on what needs to change in order to overcome the barriers
- Based on the issues, barriers, and what needs to change, identify the top 3-5 priorities for follow up assessment and action (and by whom).
Speakers:
Neil Charness, MS, PhD, Florida State University

Connectivity Challenges in Remote Monitoring

- I'm representing CREATE
- What do we mean by telecare, telehealth, telemedicine? Remote provision of healthcare services and education by means of technology.
- Create is using the Capability-demand fit framework which starts with a telehealth tool.
- "Honor thy user" is the first commandment.
- The user needs to have motivation to use the tool.
- We need to understand the user differences. Degree of fit of the user with the tool determines the outcome.
- Efficiency, safety and comfort must be considered.
- Not all users are internet users. 65% report having used the internet in the past year.
- 55% of people are not smart phone users. You're going to have to train people how to use that. It also depends on income level and education.
- Home health users are age 65+. You need to keep this in mind in designing home health tools.

Considerations about devices:
- Steady power is not a given--thunderstorms, devices (e.g., smart phones) not being charged; even backup power isn't sufficient as we've learned from Hurricane Sandy.
- When lights come back on, in what state is your device? Resets don't necessarily occur properly. Data may be lost or inaccessible. Think about instructing the 65+ age user how to reset their device. Frequently requires someone to go out to the home.
- Cellular network connectivity is not universally available

Connecting Humans & Machines
- Design and train for usability considerations, but also for maintenance.
- We had to train older adults how to "touch" a Tablet with the fleshy part of the finger.
- Precision of touch can also be an issue.
- Display of information has to be quite different between lay people and healthcare professionals.

Challenges:
- Reliable & secure transmission. Store it forward may be better strategy.
- Setting the right balance for generating automated alerts based on sensor system data.
Bridget Moorman, MSBME, CCE, BMoorman Consulting, LLC

Thoughts on Telehealth Systems

- Talking about results of projects going on in Europe for remote launch
- Focusing on the three primary diseases
- Architecture: shows where you can have integration points to the health care provider
  - In Europe, they are looking at combining social services and clinical services that are provided
  - Goal is to get information on transmission medium
  - Fear in industry is having their products become commoditized.
  - Telehealth service provider → regional health center → healthcare enterprise
  - Clinicians don't want to be inundated with data unless there's something they need to act on. The regional healthcare center can filter the information.

- Service models--how to gain access to the system to ensure health and welfare
- Other considerations
  - Should service be outsourced
  - Accuracy of home technical "kit"
  - Scales?
  - Regulatory approval of home technical "kit"
  - Usability of home technical "kit"
  - Who owns/has access to data? Cloud vendors want to own information that flows through the infrastructure. Should family have access to your data? When you have something that's controlling a physiological component inside the body (e.g., heart monitor chip), you have to protect that data.
  - Security of telecommunications path
  - Innovation might occur outside the western or developed world
  - Need to manage expectations; not the same for any of the players; burden may fall more on the patient.

Brian Rothman, MD, Vanderbilt University Medical Center

Telehealth at the Intersection of People and Technology--Adoption and Overcoming obstacles other than People

- Importance of Situational Awareness--e.g., scraping the snow and ice off the wrong car!
- Inadequate situational awareness is a primary factor in human error.
- Transparency--information delivery without searching and sudden, unforeseen obstacles. People may become skeptical about using a device if they don't know what's being done with their information.
• Culture and Telehealth--computing is changing; new involves passive and active engagement; sense of "big brother"
• Software implementation--getting people to properly use your products is an issue. You have to get to the early majority. Even then, they’re probably not going to use it right.
• Adoption support--have to feed and water the early majority; teach them the skills they need to use the device. Show the benefits of using it properly.
• Early majority
• Adoption--sometimes you have to change your culture. Need to have an "adoption plan"
• Medicolegal Obstacles--No one wants to take responsibility. There can be technology failures (e.g., remote location, patient location, software, data carriers).
• Care Responsibility--guidance failure (inadequate situational awareness leading to wrong information) or execution failure
• Regulations

Session Questions:

1. What are the major technology-related challenges with telehealth?
   a. Connectivity
   b. Patient matching
   c. Security
   d. System reliability
   e. Reimbursement
   f. Signal control
   g. Privacy; ownership of information and transparency
   h. Quality of data and information
   i. Appropriate scaling of features (not too much, not too little); catering to both power users and the lay user (just wants red/green signals)
   j. Remote context understanding
   k. Point to point Interoperability--across the full spectrum; not just technical; all the different sensors in the home, some communicate with each other, others do not. Making all the system work together within the home.
Consistency of uploading information to the cloud and getting information to providers and caregivers.

1. Aggregating the data from the home, developing algorithms and providing warnings to providers

m. Prioritizing any inadvertent results--mixed warnings

n. Appropriateness of the technology to what you're trying to do. E.g., remote telesurgery vs. trying to get weight data to a centralized system

o. Integrating into the work flow; changing clinicians' jobs; work flow and technology need to be combined

p. patient training

q. latency and time stamping

r. patient adoption and compliance

s. Remote fixing when technical systems fail

t. You won't get it right the first time--plan for that

u. Redundancy is needed today

v. Fallback solutions

w. Training for other caregivers in the home and providing information back to providers

x. We don't regulate consumer products (e.g., cellular connections)

2. What are the barriers to overcoming these issues (including research gaps)?

a. Access to broadband throughout the country
   - Access to some type of telecommunication capability (e.g., broadband, other); appropriately applying technology to the situation

b. Cost; Who's paying?

c. Joint gov't agents--FDA and FCC; they need to collaborate
   - Evolving regulatory issues (e.g., medical/legal issues)
     - Net neutrality; how to prioritize traffic over communications infrastructure
     - On IT side, there's a lack of understanding of the healthcare environment

Kerry (former Dir of Healthcare with FCC):
• Executed MOU between FCC and FDA
• Agencies would agree they need to collaborate
• Would ask for specifics on where and how the trouble spots are occurring
• Reminder: They have actually collaborated for the past 30+ years; but there's room for improvement
• Regulatory framework for health IT in process

d. Flexibility of capabilities; options/devices that can transmit multiple ways; preferred and backups

e. Adoption and compliance

f. Getting stuck on solved problems; spending all resources on non-necessary issues

g. Controlling agent buy-in--vendors who control the signals need to be at the table

h. Data privacy is differently interpreted across the board; in the US we have "opt out" mentality; in Europe it's an "opt in."

i. Infrastructural maintenance over time

j. We're changing clinicians' jobs--work flow, guidance and technical support; preference to see patients in person rather than remotely

k. Standardization--talking the same language when aggregating data

3. What needs to change in order to overcome the barriers?
   See above

4. Based on the issues, barriers, and what needs to change, what are the top 3-5 priorities for follow up assessment and action?

5. Who should be involved in addressing these challenges?

Comments from Marilyn on Telehealth:
• Section 618--mandate for Congress for FDA, ONC and FCC to all work together. Report to come out in Jan 2014
• ONC is very involved in ARRA and the High Tech Act. Push for EHRA's to be spread throughout the land.
• All that is currently happening, and a large amount of funds were made available.
• ONC's charter was to make this happen.
• Along with that they have "meaningful use" that directs the requirements and functionality of directing what vendors will certify to and what hospitals/providers will certify to in order to reap the rewards of that.
• Office of Civil Rights (OCR) is another agency that needs to be brought along with this issue.
• BPC has produced documents to educate congress and the working group pertaining to development of a recommendation of an appropriate approach to a regulatory framework for patient safety for health IT. This is an important document.
• What should be regulated/how?

Identifying and Addressing Challenges With the Management of Technology in the Home

Session Goals:

a. Identify the key issues for the “management” of medical technology outside of a controlled clinical setting.
b. Identify unique training needed for technicians working inside patient homes
c. Identify the barriers to overcoming these issues (including research gaps)
d. Agree on what needs to change in order to overcome the barriers
e. Based on the issues, barriers, and what needs to change, identify the top 3-5 priorities for follow up assessment and action (and by whom).

Speakers:
Reginald Cyrus, Old Dominion University

Bringing it down to the ground
• Resources and tools to deal with a lot of the home care challenges are similar to what we've done in hospitals.
• Patient and caregiver is where triage starts.
• Home care organization gets the call and is responsible for the device.
• Manufacturers and vendors are always trying to show you a new thing. They are the accountable piece because liability will come back to them eventually.
• Sitting in a civilian hospital, I was concerned about who is taking care of medical devices in the community with the shift to home healthcare.
• Medicare and Medicaid have a lot of definitions. Commercial orgs follow along with what they are saying.
• Former air traffic control tech in the Navy said he was doing this since 2005. Device that continually fails.
• Management decides to call in a rep (vendor). Reginald repeats a lot of what he repeats in seminars.
• They decide to fly down to home health care org.
• Reginald explains the problem of the critical failure of an infusion pump.
• They start looking at the data of all the pumps the home healthcare org has been returning.
• The vendor says we are the only one in the country that has complained.
• How do they collect and assess the data relating to repairs. Come to find out, Reginald's org wasn't the only one complaining.
• A couple of weeks later, there is a Class II voluntary recall for this device.
• Home care companies don't have the payroll to hire a good certified technician for home medical devices.
• We have to look at who is doing the work, and can't get away from things we already known.
• We can't get bogged down in definitions. Look at existing definitions that Medicare and Medicaid have developed.
• We have to grab the data, determine what we need to do with it and address what needs to get better.
• Let's come down from the 10,000 foot level and see what's happening.
• Equipment is to assist physicians and healthcare workers in providing care. Not replace provider-led patient care.

Ant Ozok, PhD, The Johns Hopkins University
• Laundry list of problems that we see every day dealing with home technologies and our patients down at Hopkins.
• This is all about care not ending in the hospital. It continues at home. Just like the taking over of technologies at the hospital, technologies are also taking over home care.
• Managing multiple technologies in the home involves:
  – Training on multiple devices and of a variety of people--home nurses, patient/family caregiver; training on how devices work together
  – Usefulness of instructions presented with the technologies--more complex than even drug instructions.
  – How different technologies work together at home--rarely is there a single piece of technology for medical care in the home.
  – Reminder technologies/systems--could they be applied to other home technologies?
  – How much do we take the classic human factors principles (e.g., consistency, feedback) and apply it?
• Interactions with technology developers
  – What do customers want?
  – What are developers willing/able to do? There are a lot of constraints. Developers of health IT are willing to listen and have users involved at early stages of design.
  – Is there a disconnect? How often are developers and customers involved in the design?
• We need to work on our people skills in relation to user/developer interactions. Look at the patient as human first, and patient second. Pay more attention to improve our people skills/communication.

Margherita C. Labson RN, MSHSA, CPHQ, The Joint Commission
• If you're always talking about involvement of home health, hospice and medical equipment, you're mistaken. This only accounts for about 20% of population that are using technology in the home.
• You need to look at payer sources to determine how interactions are controlled (e.g., visits, telecare)
• Developing a sense of awareness that pose a risk to the environment--begin to learn what we have already lived with for many years.
• Perspective that direct line staff have with end care users gives the best insight into variables that need to be controlled and the risks.
• Prevailing wisdom has been to get right people involved and let them do their job.
• Leadership's responsibility is to help move boulders out of the way to allow staff members do their job to the best extent possible.
• Proactively bring forward risks without fear of repercussions. Always do the post-mortem.
• Reporting of adverse reactions has been around for years, but they are still around. They didn't think anyone would do anything about it or that there would be repercussions.
• How often are direct line staff involved in decision process of medical devices used in the home?
• There's no feedback mechanism.
• When company leadership makes a decision on a product, line staff have to make it work. There's no mechanism to help them uncover the risks.
• Leaders and payers should directly engage front line staff to identify the challenges and mitigate the risks.
• It's useful to begin to look at orgs that are highly reliable (e.g., aviation and nuclear industries). They have distinct leadership characteristics that make them highly reliable.
• They are extraordinarily aware of the operation.
• Rather than using licensed professionals in home care organization, there are many people being used who are not trained well. We need to ask if this is the best way.
• Commitment to being highly reliable is also their commitment to being resilient. Safety isn't just a poster on the wall.
• Deference to expertise changes the level of engagement between leadership and staff and as a result changes the engagement between the staff and the patients.
• There is a dearth of data/outcome reporting in home health care.
• We are beginning to experience metrics exhaustion. They're not uniform.
• Explosion of information today
  – Public perception that if a product is made available for sale, it's safe for use. Most devices were retrofitted for use in the home.
  – Patients are purchasing equipment in a variety of ways. Some of this equipment hasn't been sourced. It's been all around the world.
  – Do we need acknowledgement of shared liability?

Session Questions:

1. What are the key issues for the “management” of medical technology outside of a controlled clinical setting?
a. Collection of data using a common format. Reporting of data to get feedback. Look at AHRQ common format. We need to close the feedback loop.
   - Limited use of personal health records and how they might tie into a hospital EMR.

b. Effective train-the-trainer programs, especially challenges of staff turnover.
   - Staff level of knowledge.
   - Medical equipment management plan. Lack of training for the patient and also the caregiver.

c. Implementing equipment management programs similar to what's in the hospital.

d. For mfc's it's a matter of expect longevity of the product. May require more maintenance. Extended lifetime of equipment.
   - Identify or uncover the reverse incentives. Mfc's are reluctant to identify and define mandatory maintenance schedules to make sale of equipment more attractive. Variability in environment.
   - Efficient and effective deployment of field upgrades for devices.

e. Locating all your equipment in the field.

f. Need to relook at how home care is being delivered. There are "stove pipes" of people who do know what's going on. Look at what's already there and don't reinvent the wheel.

g. Every patient may be trained, but as first-time user they don't have experience with devices.

h. Equipment purchased through non-traditional means--how is safety managed? Patients don't look at/react to recalls. Patient safety.

i. Is there a regulatory gap? E.g., adverse event reporting, patient feedback reporting.
   - Training and reporting enforcement--who's overseeing, need for improved consistency.

j. Connecting information sources to people who need the information, e.g., home equipment techs.
2. What unique training is needed for technicians working inside patient homes?
   a. Soft (people) skills. You have to be an actor to some extent when you go into the home. The tech might need to comfort the patient and reassure them that his knowledge of the equipment is vital to safety.
      − Training tends to be technical. I'm hearing that there are social skills that have to be looked for and trained.
   b. Training specific to the technology, not general training on devices. e.g., if more than two technologies that have to work together.
   c. Never miss an opportunity to train. Follow-up visits.
   d. Just because you're servicing one device, you should look at what other devices they are using. There could be issues with other devices occurring simultaneously.
      − Techs should have a wider training/knowledge of the equipment that's within the setting.
   e. The tech is the front line and may see things that clinicians who have phone contact don't identify. Reinforce with techs that they need to communicate what they're seeing in the home session with other providers. Esp. complaints.
   f. Training of techs should have same priority as training of nurses. Salaries don't support this level of training.
   g. It has to be collaborative training--screen for skill levels, and train to weaknesses. Train for the environment through collaboration of all professionals involved instead of being siloed.
   h. We have listed a vast skill set for the technicians. We have to consider what these individuals want in their job as well.
      − I don't think what's being asked of the techs is inappropriate.
      − We were trained to have situational awareness of the clinical, technical and business environments. This is a differential of our field.
   i. If you learn from aviation, what does the box look like? Our job is to get rid of variability--all the misbehaviors. Look to the training, certification and
support model from aviation. Counter: People are not interacting with machines.

j. Have a uniform, defined role for the technician who goes into the home.
   – What's realistic in terms of the training a company will invest in them.
   – How do you retain these employees?

k. Visiting nurses and home infusion staff are important. A lot of information could be gathered from those that go into the home.

3. What are the barriers to overcoming these issues (including research gaps)?
   a. Cost and value
   b. Reimbursement
   c. The scope of training hasn't been defined.

4. What needs to change in order to overcome the barriers?
   a. Shared responsibility is a definite need.
   b. Creating a non-punitive learning environment is important.
   c. Allow enough time to train users on the devices.
   d.

5. Based on the issues, barriers, and what needs to change, what are the top 3-5 priorities for follow up assessment and action?

6. Who should be involved in addressing these challenges?

Marilyn: Comments on HTSI
   • There's a role for all of us to play in this space.
   • We need to bring together all of these pieces to reach our common goal.
   • AAMI will synthesize the outcome of this meeting and bring that back to you.
   • We ask you to commit your passion and time to help us.
   • Two pieces--Document about HTSI and commitment sheet.
   • Please complete the sheet with your interests and name.
Reimbursement Considerations for Technology Used in the Nonclinical Setting

Session Goals:

a. Identify the key reimbursement issues that need to be solved to meet the needs of patients and their non-clinical caregivers for safe and effective medical technology outside of a controlled clinical setting.
b. Identify the barriers to overcoming these issues (including research gaps)
c. Agree on what needs to change in order to overcome the barriers
d. Based on the issues, barriers, and what needs to change, identify the top 3-5 priorities for follow up assessment and action (and by whom).

Speakers:
Nancy Kramer, RN, BSN, CRNI, National Home Infusion Association

- Insulin pumps aren't in the equation for most of our members in the NHIA.
- NHIA complete a survey of its members three years ago. We have the largest providers and most of the providers as members.
- Estimated number of patients receiving care in the field is 1.2 to 1.5 million.
- Reimbursement doesn't necessarily follow the complexity of the home infusion.
- Payer types--commercial/private and government
- Commercial payers have been covering the field for over 30 years. They pay for the drug, supplies and equipment. They pay a daily rate as long as the patient is receiving therapy. The higher the technology costs, the less of the per diem is left to cover other costs.
- Their decisions have to be based on what's safe and effective for the patient, but also what's cost-effective.
- It's often limited by a frequency of visits based on what the average patient needs.
- Medicare reimbursement model--doesn't cover the full range of infusion therapy in the home.
- MRM is covered under Part B. The patient must meet strict medical criteria to qualify for the coverage.
• For nursing care, the patient must be homebound. They must also have a skilled need.
• MRM covers limited drugs.
• Medicare Part B categories--DMEPOS and POS.
• Competitive bidding poses a safety issue in the Round 1 Recompete.
• Useful life of equipment for Medicare purposes is 8 years.
• Many drugs in the anti-infective category aren't covered by Medicare.
• Independence of the patient works against covering them under Part B.
• Under Round 1 Recompete a pump supplier may win the bid but doesn't operate in a pharmacy. Question of who determines which pump to use.
• Shared reference to Nat'l Coding Standards Quick Reference Tool [see the presenter slides on AAMI website]

Q: When I heard competitive bidding, and the 13-month rental cap, what happens to the warranty?
Most home care companies don't have enough standing financially to get anyone from the mfc to check out the pumps.

A: Home Infusion Patients care for patients from 3 days to 30 years. We don't buy pumps for patients, but for the fleet. The patient purchasing the pump under Medicare, may be buying one that's five years old.

Q:
A: Medicare is very restrictive about what pumps are covered.

Q: What happens if the mfc has a recall on the pump outside the warranty period when the pump is owned by the patient?
A: Home Infusion provider. The pharmacy is responsible for retrieving the pump and any supplies.

Session Questions:
1. What are the key reimbursement issues that need to be solved to meet the needs of patients and their non-clinical caregivers for safe and effective medical technology outside of a controlled clinical setting?
2. What are the barriers to overcoming these issues (including research gaps)?
3. What needs to change in order to overcome the barriers?
4. Based on the issues, barriers, and what needs to change, what are the top 3-5 priorities for follow up assessment and action?
5. Who should be involved in addressing these challenges?

Single greatest critical issue in this area that AAMI or FDA could do something about:

- Greatest concern is competitive bidding in relation to the pumps. A pump also requires a drug to be used in conjunction.
- There needs to be a broader assessment of reimbursement in totality. Look at the Service/provider side as well as device/consumable side.
- Organizations should validate specific HCPCS codes. That tells what your reimbursement will be.
- Issue of decoupling of what should be co-located pump and accessory. Are you building something that should be integrated at the application standpoint?
- Competitive bidding should be on equipment that is appropriate to be competitively bid.
  - Competitive bidding resulted from MMA and was to gain control of highest utilization/cost to the market. There are opposing forces not looking at the big picture--equipment but not therapy. You have a treatment driven by a pharmaceutical that is to be delivered with a controlled vehicle. They carved out the pump.
  - Infusion therapy is not the dispensing of a drug.
Learning from Lead Innovators: Case Studies from the Field

Session Goals:

a. Learn “what’s working out there,” “lessons learned,” and “obstacles to success” from one another
b. Identify what is needed to build on these success stories
c. Give audience “take away” ideas for improving the use of medical technology outside of controlled clinical environments

Speakers:
William Gregg, MD, MS, MPH, Vanderbilt University Medical Center

Patient Centered Data: Experience at an Academic Medical Center

- Idea of introducing more data to medical colleagues is not appealing.
- "Vanderbilt Experience" focuses on chronic conditions and readmissions.
- They started with data capture within their portal--trying to engage their patients.
- They are getting up to 80% of their patients to journal.
- When patients become too passive in data capture, they lose patient engagement.
- Limitations include cost, risk stratification/patient selection; focus on appropriate populations
- New pilot--telephony pilot with West Health Institute; capture blood pressure, pulse and weight from the home. Focused on limited populations.
- Important not to limit to one technology or channel of data capture.
- Data doesn't automatically go to the physician but to the person who can address it at the top of their license. They screen it to determine if it needs to go to the physician.
- Second phase is to have process control/dashboards
- Mode of delivery needs to be ubiquitous
• Cost and patient selection is important--don't just collect data because you can.
• There should be 5-10% of situations that the physicians need to know about. Importance of decision support and data mining. Impact on workflow integration.
• Don't collect data unless there is a plan and a capability to use it.

Carol Davis-Smith, Kaiser Permanente
• Garfield innovation center--look at comprehensive environment all in one place.
• Scanning and testing new emerging technologies at the Garfield center.
• Simulated setting to identify use capabilities.
• They are exploring use of personal devices, such as television, phones, etc.
• "Gamification"--using X Box and other gaming applications to drive home care
• "Health 360" is underway today. Connecting people with health. Goal is to keep patients out of their institutions.

Q: Nutrition is a big component of home care. In data captured, is any related to nutrition? A: Only things other than weight and blood pressure is capturing dietary goals for patients to track over time. They're developing tracking software now. Interventions around nutrition are often low-yield.

Q: The one thing I wish this audience would do based on your experience, what might it be? Bill's A: Integration with the clinicians work flow--how we bring in data. How are we going to use and integrate the data? Carol's A: Just because you can, doesn't mean you should. Look for the right thing to do clinically. Importance of having a plan.

**Session Questions:**

1. From your perspectives, “what’s working out there,” what are the “lessons learned,” and “obstacles to success?”
   a. Have a blue sky vision of where you want to go. Develop indicators that you are achieving that vision.
   b. Technology is a tool that gets you where you want to go. You have to have a goal first.
c. If you're not an expert, think about outsourcing to an expert.

d. Define what you want at the interfaces and what you're going to do with that. It's iterative. You have to make decisions on where to do tech upgrades or not and why.

e. Most innovative approaches use old technologies.

f. Empower the patient and caregivers with IT tools and non-IT tools to manage challenges of daily life and use it. Provide guidelines for use.

g. Data shows that patient drop-out and failure happens at high rate in first 90 days. Great right at home program where nurses reach out to patients frequently during the first 90 days.

h. Coordination and collaboration with other organizations. Reengineering the care delivery model in the home. Start small, start now. Build strategic partnerships/relationships.

2. What is needed to build on these success stories?
   • We need FDA at the table. When we find right mix of work flow and technology, we don't have standards for how to make technologies talk to each other. We have to have providers, medical device mfc's and FDA/CMS at the table to have a productive conversation. Alignment of incentives is key. Include telecommunications and some other non-medical industries.
   • Having a forum for sharing success stories, even as simple narratives. What we did, population and how we interpreted it.

3. What are the “take away” ideas for improving the use of medical technology outside of controlled clinical environments?
   • "Triple aim"--All of us in home health have to answer three items: Does it improve the health of the patient? Does it improve quality of life of the patient? Are you controlling health care costs?
   • If you deliver information in a timely manner, there has to be an intervention that has been shown to be effective with improved outcome. Matching the intervention with the outcome.
• Manage and support the use of medical devices outside controlled environments, but you also have to monitor it.
• To not lose focus on policy and regulatory environment. Keep tabs on appropriate framework as we work together.
• Importance of training.

It Takes a Village: The Audience Sets Priorities and Action Plans

Session Goals:

a. Review the “Master List” of problems and issues from Day 1 and Day 2 discussions.

b. Identify the top 10 priorities on the Master List according to its importance and impact on patient safety.

c. Identify the potential time frame (short term/long term) to “address” or “solve” each issue.

d. Identify stakeholders who should be involved in addressing the priorities.

Session Questions:

1. What are the top 10 priorities on the Master List of problems and issues identified at this Summit, based on importance and impact on patient safety?

2. What is the potential time frame (short term/long term) to “address” or “solve” each issue?

3. What stakeholders should be involved in addressing the priorities?

Questions/comments directed to the FDA