Priorities from the Summit

1. Improve the home care delivery model for a continuum of patients

2. Very early human factor assessment; undertake AAMI standards on human factors usability
   - Use more visuals; keep it simple.
   - Multilingual instructions
   - Device not designed to work in nonclinical environment
     • 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.
     - Importance of actually testing in the home environment

3. Analyze what's working and what's not; identify best practices

4. Consistent and appropriate regulatory framework (U.S.)
   - Industries that are regulated differently; e.g., design decision that's approved in one regulatory area, but not others; systems must be integrated

5. Confusing the difference between market research, industrial design research, and human factors evaluations; all need to be considered

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. Coverage (reimbursement); this will drive change

8. Insurance carriers dictate how many times we can see a patient.
9. Device is not used per recommended use
10. Inability of ? to recognize devices suitable for use
11. Hazard from underlying disease state and from improper use of the medical device; balance between these
12. Failure to design interoperable characteristics
13. Design IFUs for the user, not the manufacturer
14. Instructions have to address emergent situations and potential disasters.
15. A way for someone to find the right information (search function).
16. Legacy devices
17. Find a way to develop continuity from device mfc to clinician, to trainer, to user. Eliminate some or connect them together better.
18. Engage the disciplines who are actually working in the home healthcare environment.
19. Have a mechanism to gather problem information about what's going on in the home care setting.
20. Reinforce the point about post-market surveillance.
21. Don't assume the users are reporting all problems with the devices.
22. Have the patient consult in the design process. Walking in the shoes of the patient.
23. Connectivity
24. Security
25. System reliability
26. Reimbursement
27. Privacy; ownership of information and transparency
28. 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.

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

30. 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

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

32. 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.

33. 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.

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Lead</th>
<th>Involvement</th>
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</thead>
<tbody>
<tr>
<td>1. Improve the home care delivery model for a continuum of</td>
<td>Ask Marguerite from TJC</td>
<td>All stakeholders CMMI</td>
</tr>
</tbody>
</table>
| **2.** Very early human factor assessment; undertake AAMI standards on human factors usability | **3.** Analyze what's working and what's not; identify best practices  
  - Complete a gap analysis | **4.** Consistent and appropriate regulatory framework (U.S.) | **5.** Coverage (reimbursement); this will drive change  
  - AAMI to get ADVAMED to work on this | **6.** Design IFUs (instructions for use) for the user, not the manufacturer  
  - This needs to follow the AAMI TIR guidelines |
|---|---|---|---|---|
| AAMI | AAMI  
  CHAP  
  TJC  
  AHCA  
  User advisory organizations (OLEY)  
  Researchers | FDA  
  FCC  
  CMS  
  ONC  
  FTC  
  DoT  
  FAA | CMS  
  Private payers  
  Trade associations | Manufacturers  
  FDA review  
  Agilis Consulting |

- **TJC**
- **CMS**
- **Payers, Clinical Societies**
<table>
<thead>
<tr>
<th></th>
<th>Find a way to develop continuity from device mfc to clinician, to trainer, to user. Eliminate some or connect them together better. [handoffs]</th>
<th>IHE Patient Care Coordination</th>
<th>PCMH community Med Group VGM Lincare/Linde APRIA</th>
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<tr>
<td></td>
<td>Have a mechanism to gather problem information about what's going on in the home care setting.</td>
<td>IHE Patient Care Device Domain MedWatch</td>
<td>Continua Health Alliance Mfc quality system</td>
</tr>
<tr>
<td></td>
<td>Privacy; ownership of information and transparency</td>
<td>OCR (Office of Civil Rights)</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>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.</td>
<td>AAMI/UL HIMSS</td>
<td>Continua HL7 IEEE Snomed ONC ONC IHE</td>
</tr>
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</table>
|   | Aggregating the data from the home, developing algorithms and providing warnings to providers  
|   | • Standardization of data sets | AHRQ AAMI | NQF Clinician organizations in support of helping that disease CMS Developers |
|   | Integrating into the work flow; changing clinicians' jobs; work flow and technology need to be combined | HTSI AAMI | IHE IHI (Inst for Healthcare Improvement) |
13. **Effective train-the-trainer programs, especially challenges of staff turnover.**
   - This needs to follow the AAMI TIR guidelines

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<th>Provider organizations VNA Agilis Consulting Supplier organizations</th>
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14. **Equipment purchased through non-traditional means—how is safety managed? Patients don't look at/ react to recalls. Patient safety.**

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<thead>
<tr>
<th>FDA</th>
<th>Consumer Union Consumer Product Safety Commission FTC</th>
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