Low Acuity Group Issues

Report back

1. The scope of FDA regulation. The circumstances when the following might be regulated *directly* (as opposed to simply being part of a system that must be validated):
   - Cell phone/smart phone (what functionality/use might cross the line)
     - Automatic data input
     - Data manipulation and analysis
     - Control required
     - Claims made, including consumer vs. medical
     - Method of distribution
   - Home hub use case that includes PCs and servers
   - Off the shelf software used on a cell phone or PC

2. The level of FDA regulation
   - Can home or mobile devices that may be swept into an FDA regulated system be placed in class I and exempted from premarket clearance (on the basis of a favorable risk benefit assessment)
   - Can connectivity devices remain in class I even when a class II medical device is added to the system

3. Intended use questions.
   - How do we cope with intended uses that evolve with new learning/experience? Can we get to market with tool claims that do not claim specific clinical utility?
   - Can we just get clearance for a general connectivity claim, without specifying the system?
   - Does co packaging or selling items together necessarily change the intended use?

4. Evidence required for clearance. If the medical device manufacturer is responsible for the claimed system, but the components of the system are open-ended—
   - How does the company demonstrate substantial equivalence?
   - Can the company demonstrate certification to a standard or specification for an interface, rather than validating every possible part of the system.
   - Can we come up with a new paradigm for clearing these connected devices that classifies or stratifies these devices based on risk (for example, based on acuity), and does not require the traditional evidence for validating systems designed for low risk/acuity devices.

5. Standards for clearance. Does FDA have any minimum requirements for substantial equivalence for remote monitoring devices or mHealth devices, such as
   - Latency
   - Human factors design issues
   - Limits on appropriate population
   - Ability to use open source platform
   - Acceptable use environment
   - Usability issues
   - Protection against interference by other software

6. Design control complexities for open ended system
7. Postmarket challenges for root cause analysis, reporting and remediation
8. Can industry benefit from learning from the collective adverse events

Process issues

1. In the right forum, industry needs to prioritize these issues
2. Then engage in policy development to tackle these regulatory issues (Continua volunteered to facilitate this work.)
3. Then approach FDA to get resolution
   - Perhaps through a specific case study to facilitate discussion
   - Perhaps through a draft guidance document
   - A single data point is less useful than a line