EHR Association Statement
HIT Standards Committee - Clinical Operations Workgroup
Medical Device Hearing - Device Accuracy and Integrity
Washington, DC
March 28, 2011

Good afternoon. My name is Tim Escher. I am a software developer and systems architecture engineer for Epic. My background includes medical data interfaces, especially HL7, device interfaces and system design. I have worked for Epic for 21 years in various technical capacities, most recently as the division manager for our Foundations database and reporting/data warehouse group.

I am not here to represent Epic, but rather as a member of the HIMSS EHR Vendor Association and in general, based on our experience in implementing device interfaces with our EHR.

I very much appreciate the opportunity to testify today, especially with such a distinguished group as this.

EHR Device Interface Environments

With regards to accuracy and integrity of data interfaced from devices into the EHR, the environment being considered is currently the largest differentiator - clinical (inpatient or ambulatory) vs. home monitoring.

Clinical settings

Our experience recently is that device interfacing in the clinical environment is a fairly mature technology. There are well-known standards available and a viable market of middleware devices that make device interfaces fairly straightforward and technically reliable. The implementation of the interfaces can be a project management challenge however. The project usually requires coordination of several inside and outside groups, including device vendors, EHR vendors, middleware vendors, facility and networking departments, biomedical departments, and clinical analysts. It also can be a significant testing effort since every installation needs to be tested with all possible parameters to ensure proper mapping and storage. The implementation timeline can therefore be several months in length.

Once the project is complete, however, our experience has shown that the collection of device data, whether metadata about the devices or the data metrics themselves, is reliable, well-trusted, and understood by clinical personnel.

It is imperative to ensure that there are reliable methods to associate the correct device with the patient is it actually monitoring. Reliable ADT and barcode processes have reduced patient identification risks in the inpatient environment. In the ambulatory settings, patient identification can be as reliable as along as the devices are matched through either integration with the EHR front-end or through location data from the connection to the device.

Our recommendation for Meaningful Use requirements for device interfaces in the clinical setting is that Stage 3 is the logical place to consider them. Since the technology is fairly mature, adoption by the clinical organizations is not so much a technical hurdle as an implementation one, possibly requiring some costly facility changes such as rewiring or construction. The maturity of the EHR interfacing standards and profiles (IHE PCD-01 and RTM) now available for deployment will even further facilitate adoption. Therefore, once organizations have finished implementing Stage 2 requirements, including device interface requirements in the clinical environment as part of Stage 3 seems reasonable.

Home Care Settings

The home environment is significantly different from the clinical setting, relative to accuracy, integrity, and adoption. In Epic's experience, very few organizations have interfaced home monitoring equipment to their EHR, either directly or through a middleware system or service. In our case only a handful of organizations have implemented, most only as pilots.

It is a rapidly evolving environment, with changes in available Internet access and bandwidth, changes in mobile technology (think smartphones and tablets), and expectations of patients. Although we appreciate the convergence between Integrating the Healthcare Enterprise (IHE) and the Continua Health Alliance choice of standards and alignment of profiles, issues such as patient education, correct usage of the devices, and understanding and automation, or not, of the upload process combine to create a lower level of data integrity and accuracy, and a corresponding lower expectation and trust on the part of the clinician.

Patients who most need home monitoring are often the least prepared to deal with today's technology challenges in the home. If you've ever tried to connect a Slingbox to your home network for Internet access, you'd probably agree. We think the secret to success in home monitoring is likely to occur as wireless 3G/4G type network support is actually built into these devices with simple ways to associate these devices with patient identification and confirmation that the device is being used on the patient of interest (rather than another family member).

Because of these issues, we believe it will take time for the industry, not just healthcare IT but also telecom and device manufacturers, to work out the reliability, accuracy, and usability issues inherent in any new technology area. Think about how much change has occurred since the iPhone was introduced in 2007, and try to predict the environment in three more years.

Although we think home monitoring can enhance care and outcomes, for now, we should leave the adoption of these devices and programs to a normal course of progression so that they evolve in sustainable patterns. Therefore, our recommendation is that home monitoring interfaces into the EHR not be included in Stage 2, and to re-evaluate the state of the technology before deciding on Stage 3.

Conclusion

In conclusion, to recap our recommendations:

- In the clinical setting, we feel that some aspect of device interfacing in the Stage 3 requirements is reasonable, given the technology maturity, but allowing for the implementation challenges that still exist.
- In the home setting, our recommendation is that no Stage 2 requirements be considered and to re-evaluate prior to Stage 3.

Thank you for your time and consideration, and we look forward to working with the HHS and the HIT Standards and Policy Committees in this important area.