Improving Patient Care by Making Sure Devices Work Well Together

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Interoperability refers to the ability of medical devices to interact and for electronic health record systems to talk to each other using a common vocabulary. It is similar to the concept of “plug and play” computer attachments like a web cam or mouse, which are made so that products can operate with different brands and models of computers.

While it may seem abstract, successful interoperability among medical devices can improve patient care, reduce errors, and lower costs.

As medical devices become increasingly connected to other medical devices, hospital information systems and electronic health records, there is a growing expectation that they will be interoperable – and that the data they transmit will be secure.

A few examples illustrate the need:

- An infusion pump that administers medication to a patient also connects to the hospital’s electronic health record system where the physician inputs orders for specific amounts of medication to be delivered at specific times. If the infusion pump and the electronic health record are not interoperable, with clocks that are synchronized, medication errors could occur.
- A patient in surgery is connected to a ventilator and a central monitoring station. If the two devices are not interoperable, the monitor may send a false alarm, or fail to send a needed alarm. Either error could increase the risk to the patient.
- Two patients with different medical conditions both have electrocardiogram (EKG) monitors attached to check their hearts’ electrical activity. Both monitors are connected to the same computer system that records the data for later review by a physician. It’s critical
that the computer system and the EKG monitors are interoperable so transmission errors do not confuse one patient’s data with the other patient’s data.

Making sure devices are interoperable requires the creation, validation, and recognition of standards that help manufacturers develop products that are harmonious and can “plug and play.”

We at the FDA have been hard at work on this issue with hospitals, health care providers, manufacturers, standards development organizations, and other interested parties. A 2012 summit organized by FDA and the Association for the Advancement of Medical Instrumentation (AAMI), for example, brought together 266 experts from many disciplines to further the goal of improving patient care and cybersecurity — while at the same time fostering innovation — through interoperability.

As a first step, FDA has recognized a set of voluntary standards that will help manufacturers create devices that work well together and are secure.

We hope this first set of voluntary standards will encourage further efforts to identify standards and create new ones for our review, because improving the care of patients through medical devices increasingly depends on those devices and information systems being “interoperable.”

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