Medical Device Interoperability

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Medical Device Interoperability

- Medical Devices
- Local Controller Devices
- Data Manager Devices
- Physicians & Nurses
- Electronic Health Records (EHRs)

EHRs
Medical Device Interoperability Vision: Medical devices will have the ability to interact with other devices in a multi-vendor, plug-n-play manner thereby creating the potential for enhanced patient care and safety by using open standards based devices.
Medical Device Interoperability

• Potential to increase efficiency and improve patient care.

• With the rapid adoption of EHRs, interoperability has come to the forefront.

• Can aid in the development of interchangeable devices within a given system.

• Currently each integrated system is a custom installed system.

• Interoperability failures are not always apparent to the user. The user cannot always tell if data has been corrupted or delayed.
Draft Guidance on Medical Device Interoperability

• Draft guidance released January 26, 2016

• Discusses both design considerations for interoperable devices and the recommended content of a pre-market submission
Consider the Following When Designing a Device to be Interoperable

- What is the purpose of the interface? How is the interface meant to be used?
- Who are the anticipated users of the interface?
- Have foreseeable risks been mitigated (ex. inappropriate access).
- Has the interface specification been tested/verified and shown that it performs as intended.
- Is there appropriate labeling?
FDA Pre-Market Recommendations

• Encourage manufacturers to provide information on their electronic data interfaces so that users or other devices can use them properly.

• Provide appropriate labeling.

• FDA recognizes there are different levels of risk based upon the device type, the interoperable scenario, and the clinical application.

• FDA is trying to find ways to balance our regulatory oversight with encouraging innovation, without overlooking the overall goal.
Interoperability Standards Activities

• FDA recognizes various standards that support interoperability
  – ASTM ICE Standard
  – IEEE 11073 Standards

• Current standards and standards development efforts:
  – AAMI SM-WG03 - Interoperability WG
  – AAMI/UL Joint Committee 2800
Modular Systems

• Think early!
• Standardize compatibility with physical connectors
• Standardize variables, interfaces, APIs, terminology, etc…
• Consider medical device security
Other Related FDA Activities

- Final Mobile Medical Apps Guidance
- Final Pre-market Cybersecurity Guidance
- Draft Post-Market Cybersecurity Guidance
- Final Medical Device Data System Guidance
Contact Information

• We are always happy to hear from you!

• For Digital Health questions email digitalhealth@fda.hhs.gov

• If you have any questions, please contact me:
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