

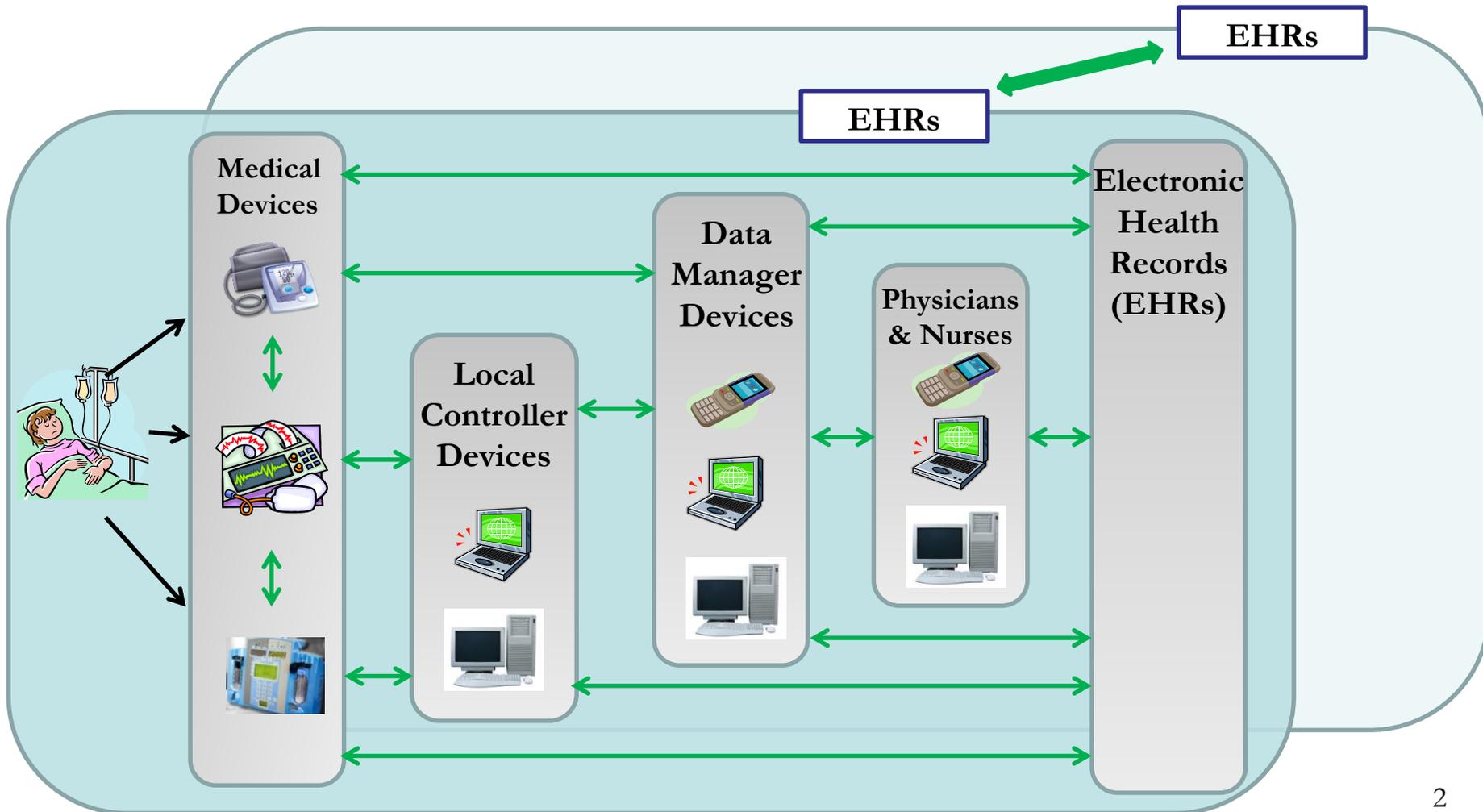


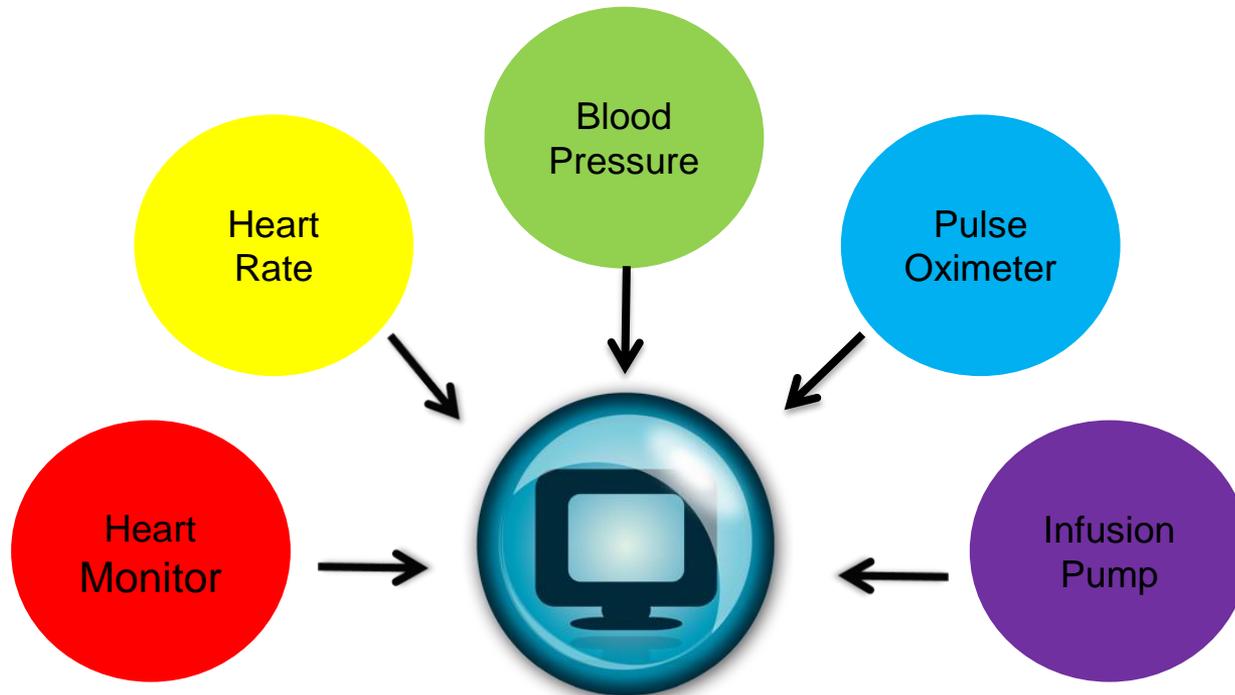
Medical Device Interoperability

**NIH-NINDS: Workshop on Standards and Modularity of
Brain-Computer Interfaces and Neuroprostheses
Rockville, MD
June 30, 2016**

Heather Agler, PhD
Senior Science Health Advisor
Center for Devices and Radiological Health
Food and Drug Administration

Medical Device Interoperability





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Draft Guidance on Medical Device Interoperability

- Draft guidance released January 26, 2016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
- Visit the FDA Digital Health Webpage
<http://www.fda.gov/medicaldevices/digitalhealth/>

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:
Heather Agler, heather.agler@fda.hhs.gov
(301) 796-6340