Medical Device Data and Patient Context Challenges

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Medical Device Patient Context

- Association of a patient identifier with medical device data.

- Identifier may be personally identifiable information (PII) or index.

- Proper patient context is essential to create electronic health records and enable future device interoperability.

Medical Device Data System and Interoperability Difficulty

- Medical devices (MD) need to receive and store context to provide it with device data.

- Currently few MDs receive or provide patient context.

  – Many simply don't have the capability.

  – Those that do, rely heavily on user workflow or interaction (manual entry), and inconsistent system interfaces.
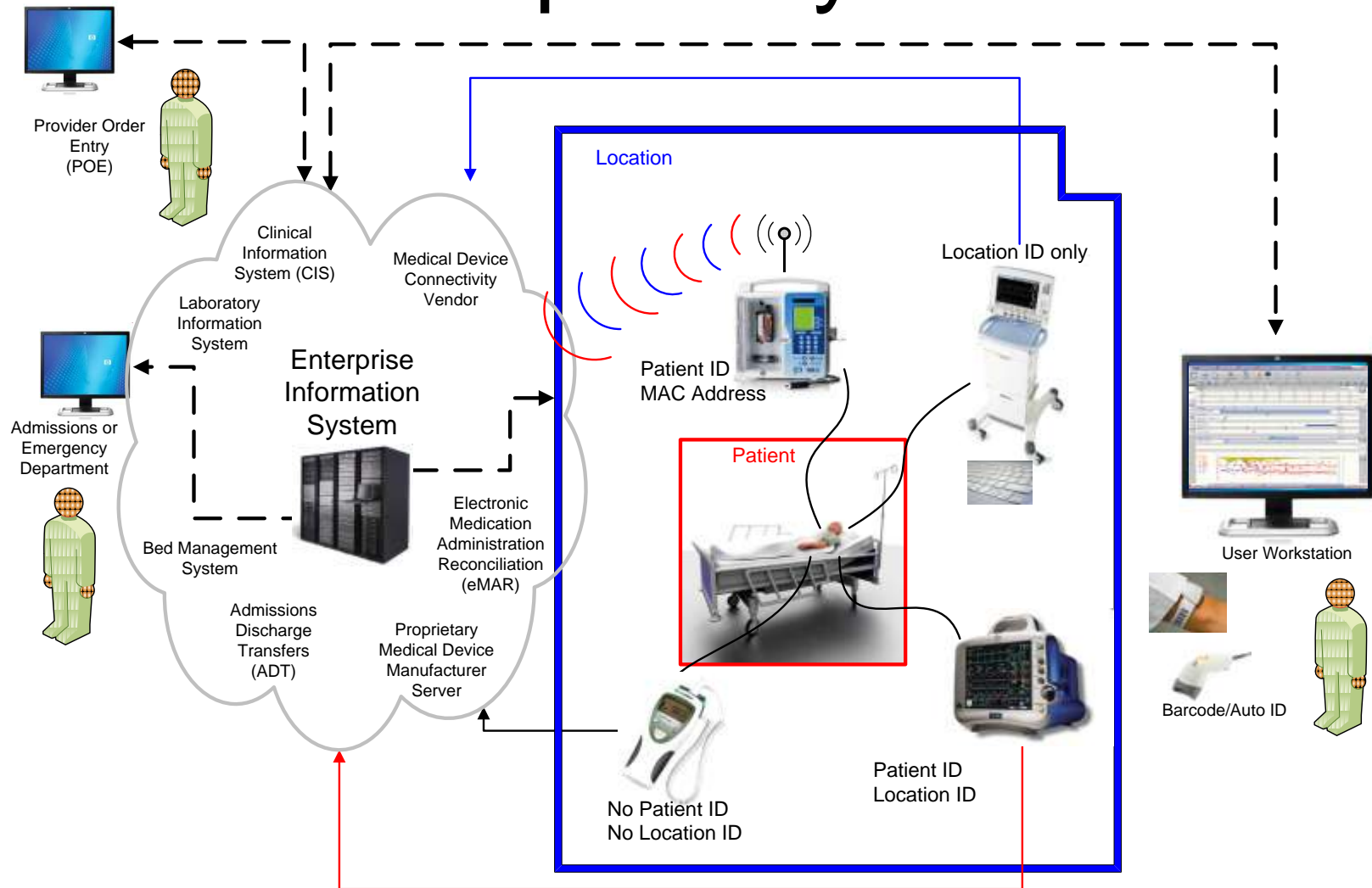
Medical Device Data System and Interoperability Challenge

- Today, lack accepted industry standard -> numerous possible approaches -> complex, potentially unreliable solutions for managing patient context.

- Suggest publishing Performance Standard enabling consistent patient context-MD data association.

  - Analogous Standard to CFR21.898 on Electrode Lead Wires and Patient Cables.

Why Must This Be Solved?

- Patient safety.
  - Accurate context is the basis for many current and proposed safety systems (e.g. medication safety).
  - Possible future use includes decision support.
- Reduce errors.
  - Too many possible solutions which increases the number of systems end users have to learn and interact with.
- Simplify.
  - Most every manufacturer (medical, IT or device integration) is developing their solution with no oversight on how their system integrates with others.
- Report.
  - Lack means to capture and correct conditions that allow data mis-association and how use of data may contribute to adverse event.

Complex System

Provider Order Entry (POE)

Clinical Information System (CIS)

Laboratory Information System

Medical Device Connectivity Vendor

Enterprise Information System

Admissions or Emergency Department

Bed Management System

Admissions Discharge Transfers (ADT)

Proprietary Medical Device Manufacturer Server

Electronic Medication Administration Reconciliation (eMAR)

Location

Location ID only

Patient ID MAC Address

Patient

Patient ID Location ID

No Patient ID No Location ID

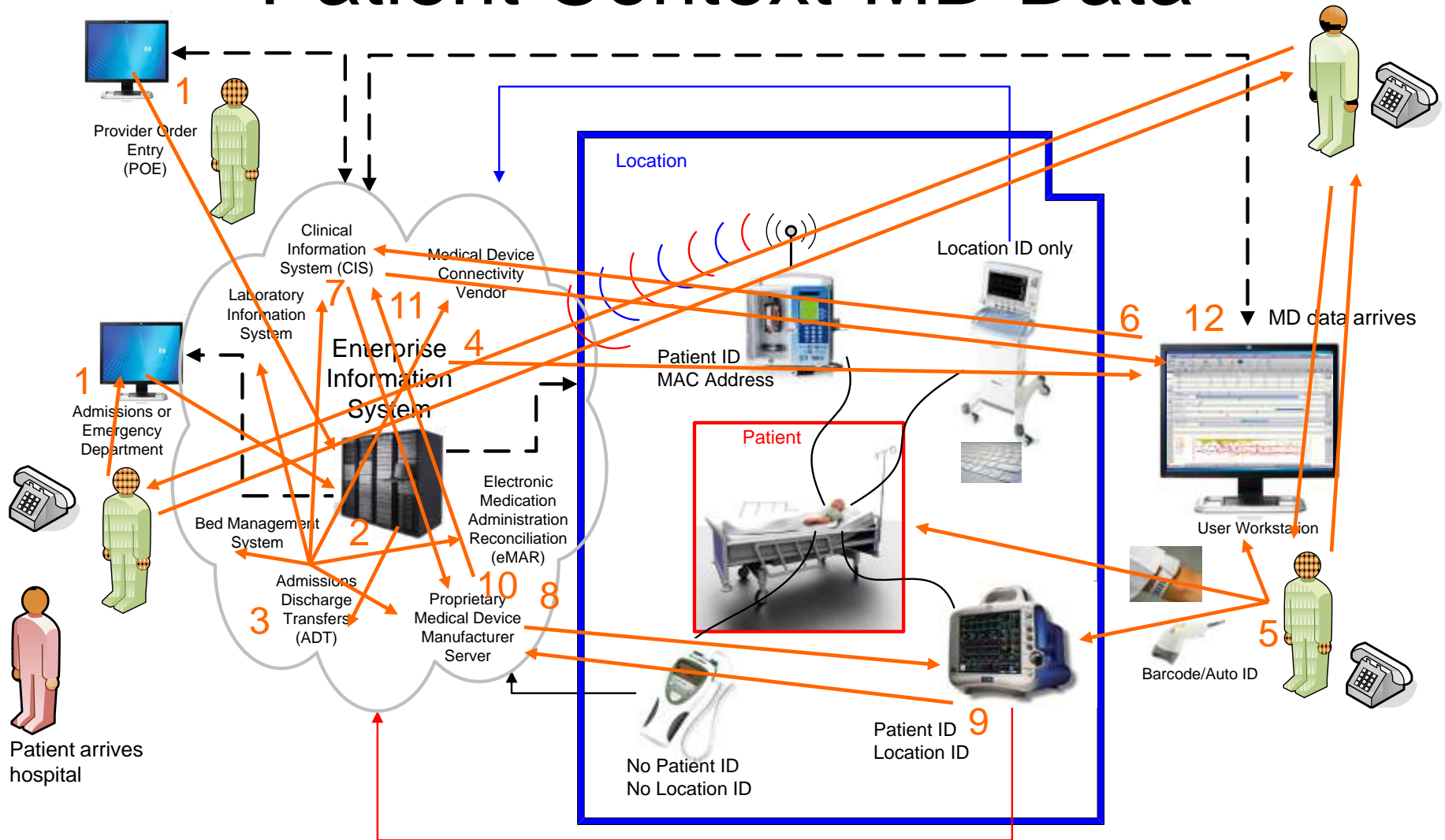User Workstation

Barcode/Auto ID

Partners will likely have three different infusion pump, two patient monitor, and expects at least three other systems (i.e. beds, CRRT, and most everything else) in place.

Hospital Challenges

- 3-sides to MD-patient context triangle.
  - User workflow, Clinical information systems (CIS), Medical device.
- Location- versus patient-specific data association.
  - Legacy technologies versus recent developments.
- Difficult, or confidential, to learn "what's under the hood".
  - Context may start patient-specific, but may not stay that way.
- Multiple vendors: medical manufacturers, connectivity and CIS.
  - Recent state-of-the-art survey indicates rapidly evolving market.
- System integrators.
  - Healthcare systems and IEC 80001.
- Data mis-association happens.
  - Not all systems tolerate last minute patient room changes, inadvertent wrong patient or room selection, and/or merged patients well.

The Path for Just One Device's Patient Context-MD Data

Provider Order Entry (POE)

1

Admissions or Emergency Department

1

Patient arrives hospital

Clinical Information System (CIS)

Laboratory Information System

Medical Device Connectivity Vendor

Enterprise Information System

Bed Management System

Admissions Discharge Transfers (ADT)

Electronic Medication Administration Reconciliation (eMAR)

Proprietary Medical Device Manufacturer Server

Location

Location ID only

Patient ID
MAC Address

Patient

Patient ID
Location ID

No Patient ID
No Location ID

MD data arrives

User Workstation

Barcode/Auto ID

7 **11** **4** **6** **12**

2 **10** **8** **3** **9** **5**

Note: Assuming all systems are working correctly and no last minute changes.

Technology and Industry Difficulties

- Patient context data enables interoperability, and differentiates a medical device from information technology equipment and/or consumer electronics.
- Infusion pump and electronic medication administration reconciliation challenges.
  - Three different pump vendors, three different PII-MD solutions.
  - Some rely on hospital integration.
- Barcoding/Auto-ID introduce another layer of complexity.
- Wireless connectivity.
  - Wired association is challenging, wireless introduces another realm of complexity.
- Constraints.
  - User overload, ADT timeliness, bed management systems…
- IHE PCD Effort.
- HL7 needs and/or is under development.

Summary

- Medical devices and information technologies converge.

- Associating patient context information to medical device data is important for current and future needs.

- Unregulated market creating disparate systems with little oversight in how they integrate.

- FDA Performance Standard (or something similar) could enable industry-wide, scalable system to associate patient context with MD data.

Thank you.

The Unix Philosophy: Write programs that do one thing and do it well. Write programs to work together. Write programs to handle text streams, because that is a universal interface.

- Doug McIlroy

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