NQF HIT Critical Paths: Patient Safety

Webinar
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NATIONAL QUALITY FORUM

Speakers

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  Founder, President, & Executive Director
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Meeting Objectives

1. Provide an overview of the Critical Paths: Patient Safety project
2. Review the work of the Technical Expert Panel (TEP) to define the requirements for measurement
3. Discuss the results from an environmental scan
4. Introduce the TEP's recommendations
5. Discuss the public comment process for this draft report

http://www.qualityforum.org/Topics/HIT/Critical_Paths/Patient_Safety.aspx

Critical Paths:
Project Overview

Critical Paths: Patient Safety Background

- **Scope** focused on "acute care infusion devices"
  - 90% of hospitalized patients receive intravenous IV medications
  - 35% to 60% of adverse drug events involve pumps and the majority are the result of incorrect programming
- **Goals:**
  - To assess the readiness of electronic data to support acute care infusion device quality reporting
  - To recommend actionable steps to address gaps and barriers
- **Future State:** Integrate Unique Device Identifiers (UDI) and associated meta-data into existing quality measurement methods using point of care data capture within electronic systems

Critical Paths: Patient Safety Project Approach

- Convened a ***technical expert panel*** to define data requirements for quality measurement of infusion devices and to develop criteria for evaluating data readiness for measurement
- Conducted a focused ***environmental analysis*** to develop a baseline understanding of current infusion pump electronic data capture and exchange for quality measurement purposes
- Developed a ***draft report*** with recommendations to advance the ability of existing health IT infrastructure to support quality reporting of infusion devices
  - Post report on NQF's website for ***public comment***
  - Host a ***webinar*** to encourage public comment for the final report
- Review and synthesize comments, and develop a ***final report***

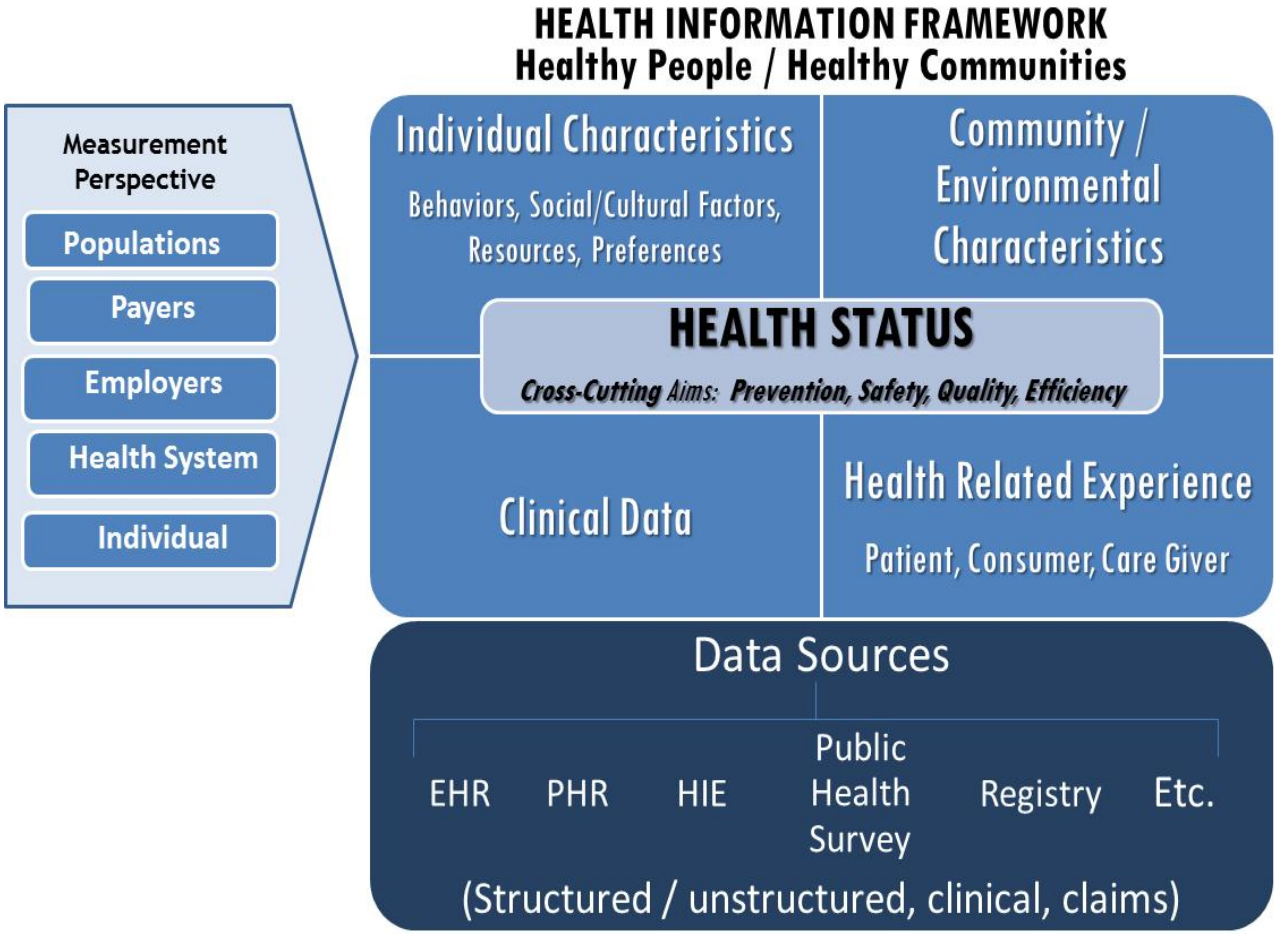
Impact for Infusion Pump Safety Improvement

- IV therapy accounts for 56% of medication errors and 61% of the most serious and life-threatening potential ADEs
- Estimated 23,000 CLABSIs among patients in inpatient wards in 2009

- Smart infusion pump implementation with dose error reduction systems can help reduce IV administration errors
- Smart infusion pumps that interface with other IT systems such as an EHR, CPOE, and BCMA can support further reductions in patient safety events related to IV therapies provided through infusion pumps

HHS' National Quality Strategy Aims and Priorities

HITAC QDM Health Information Framework



TEP work to define the data requirements

Patient Safety Technical Expert Panel Member Roster

David Classen, MD MS
Chief Medical Information Officer, Pascal Metrics, Inc.
Associate Professor of Medicine and Consultant in Infectious Diseases, University of Utah School of Medicine

Jason Colquitt
Director of Research Services, Greenway Medical Technologies, Inc.

Jay Crowley
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Senior Manager, Roche Molecular, CDISC Device Team Leader

Behnaz Minaei
Policy Analyst, Center for Devices and Radiological Health, Food and Drug Administration

Related FDA efforts on Medical Device Safety and Electronic Quality Reporting

- **FDA UDI System**
  - Develop a system to identify medical devices which is consistent, unambiguous, standardized, unique, harmonized and facilitate the storage, exchange, and integration of data systems
  - Proposed Rule released in July states most medical devices carry a unique device identifier (UDI)
  - UDI will be phased-in over 12-60 months after the Final Rule
- **MDEpiNet Initiative**
  - Develop white paper on implementation of UDIs in EHRs
  - Implement UDI- based surveillance activities and advance the incorporation of UDI into point-of-care spontaneous electronic adverse event reporting through the ASTER-D pilot project

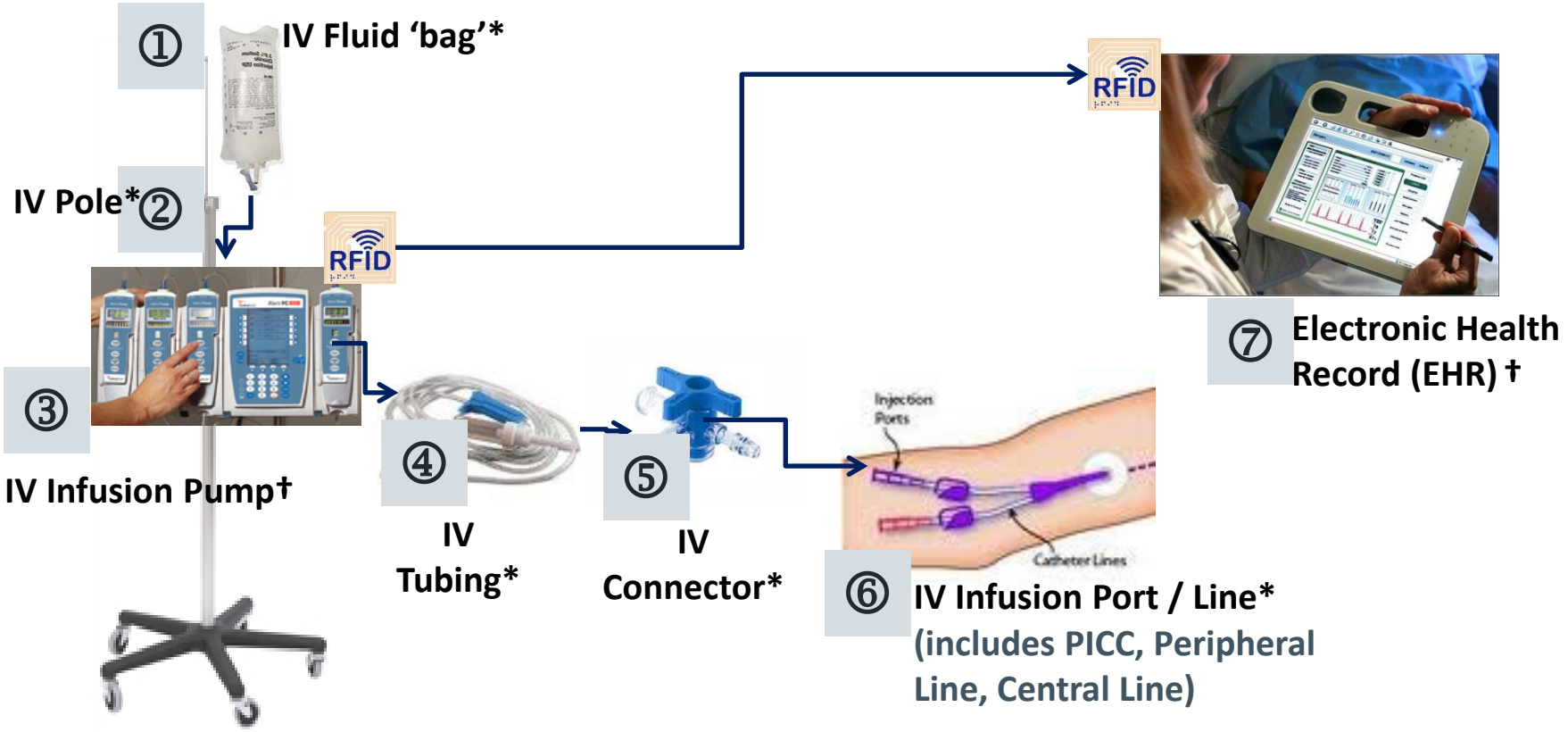
Related Industry Efforts on Medical Device Safety and Electronic Quality Reporting

- **AAMI Healthcare Technology Safety Institute**
  - Multidisciplinary safety initiatives that strengthen the development, management, and use of healthcare technology for improved patient outcome
  - Summit on interoperability of healthcare technologies October 2012
- **Integrating the Healthcare Enterprise Patient Care Device (IHE-PCD) Domain**
  - Document use case/profile requirements based on existing standards that are tested through Connectathons and easy to integrate into products
- **World Health Organization International Classification for Patient Safety**
  - Conceptual framework to define, harmonize, and group patient safety concepts into an internationally agreed classification.
- ***ASTER** (ADE Spontaneous Triggered Electronic Reports) Study
  - Piloted the use of EHRs for direct adverse event reporting
  - New projects looking at devices (ASTER-D) and the use of social media to capture data (ASTER-SM)

Related NQF Efforts on Patient Safety and Quality Reporting

- **Quality Data Model**
  - Organizes and describes information so that EHRs and other clinical electronic systems can consistently interpret and easily locate the data required
  - Provides the potential for more precisely defined, universally adopted eMeasures to automate measurement
- **Patient Safety Measure Portfolio**
  - Approximately 100 of the over 700 NQF endorsed measures are patient-safety focused
  - Also endorsed 34 Safe Practices for Better Healthcare and 28 Serious Reportable Events
- **NQF Process to Receive Comments on AHQR Common Formats**
  - Provide common language and reporting format for reportable events, including generic and event-specific forms and allow for the national aggregation of de-identified data
  - Common Formats—Hospital Version 1.2 incorporates an event-specific format entitled "Device or Medical/Surgical Supply including Health Information Technology (HIT) Device"
  - Enables AHRQ to receive and respond to stakeholder input and to receive expert guidance on refining the Common Formats

End to End Intravascular Infusion System

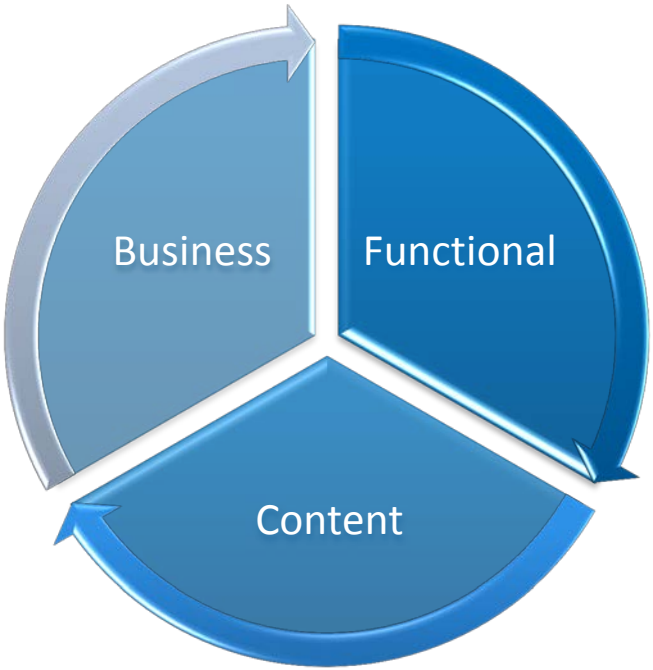


* Devices with static information only

†Devices that produce and manage information

Defining Requirements

Device-Related Information Categories



Examples:

1. Business
   - Protocols
   - Policies
2. Functional
   - Settings
   - Connections
3. Content
   - Demographics (identifiers)
   - Intrinsic to Device (software function)
   - Extrinsic to Device (Fluid, medication, human factors)

Data elements to support device safety measurement concepts

- Data and meta-data captured to track infusion pumps as medical devices
- Device data used for quality and performance reporting related specifically to infusion pumps as medical devices
- Correlation between data captured for medical devices and its corresponding use in quality measure reporting across all quality measures
- Types of electronic systems storing information about infusion pumps

Data elements to support device safety measurement concepts, cont'd

- Existing examples of interoperability between infusion pumps and electronic systems that enable quality reporting (e.g., Inpatient Acute Care EHR, Infusion Pump Information Systems, and Quality Reporting Systems)
- Future state examples of interoperability necessary for quality reporting
- Correlation between medical device data tracked and association with patient specific data stored in electronic systems.

Environmental Analysis

Patient Safety: Preliminary Findings from the Environmental Scan

- Methodology:
  - Pre-interview online survey (completed by 6 of 7 sites)
  - Telephone interview

- Sites:
  - 7 provider sites (3 multi-hospital systems, 4 single facilities)
  - 2 vendors

Results and Analysis

- Study sites are in varying stages of technology maturity – none are fully electronic
- All study sites gather and analyze data about infusion pump alerts and use data for quality improvement efforts
- Facilities differ in the capture and use of pump data for safety and quality reporting
  - Some manually download the data from each infusion pump individually
  - Others automatically send the data to a quality reporting system
  - Others interface data to an EHR

Common Metrics of Pump Usage and Pump Safety Practices

- Percent of smart infusion pumps linked to a wireless network
- Proportion of smart infusion pumps in the institution
- Timeliness of drug administration
- Compliance with use of pump data gathering and/or safety features
- Percent of scanned nurse IDs at the point of care
- Rates of averted adverse events

HIT System Characteristics of 6 sites

- All capture infusion pump data and store in a database; data captured varies
- All have a secondary alarm system
- All have implemented Electronic Health Records (EHRs)
  - All have implemented a CPOE system that interfaces with the Pharmacy System
  - All have an eMAR
- Most have some interoperability between the pump, the eMAR, and/or the EHR
  - None have bi-directional interfaces between the pump and EHR
- 5 have a bar code scanning process at the bedside
- All have a Quality Reporting Database
  - Several sites analyze bar code scanning data
  - All analyze infusion pump data but at varying levels

Pump Tracking and Identification

- Suppliers assign an internal unique serial number to each pump
- Some facilities use this serial number to track pumps in the facility but many apply their own pump identification process:
  - 2 sites use the supplier-generated serial numbers on the pumps
  - 2 sites track pumps through unique identifiers using a wireless network
  - 2 sites are using or will soon begin using RFID software to track and identify pumps.

Infusion Pump Data Gathered and Tracked Electronically

- Identifiers
  - Pump Number (from supplier or hospital)
  - Patient Identifier *(4 sites)*
  - Pump User Identifier *(2 sites)*
  - Model Number of Pump
  - Bag Number
- Medication and Fluid *(6 sites)*
  - Concentration
  - Changes in Concentration
  - Changes in Rate of Infusion from Previous Rate
  - Dose Number
  - Order Number
- Infusion Time
  - Infusion Date/Time (6 sites)
  - Length of Infusion
  - Start and stop time
- Patient Location and room number
- Pump Data
  - Pump Number (from manufacturer or hospital)
- Pump User Data
- Pump Over-Rides *(6 sites)*
- Type of Alert *(6 sites)*
- Only 1 site can associate the pump and medication order

Main Causes of Infusion Pump Adverse Events Cited by Participants

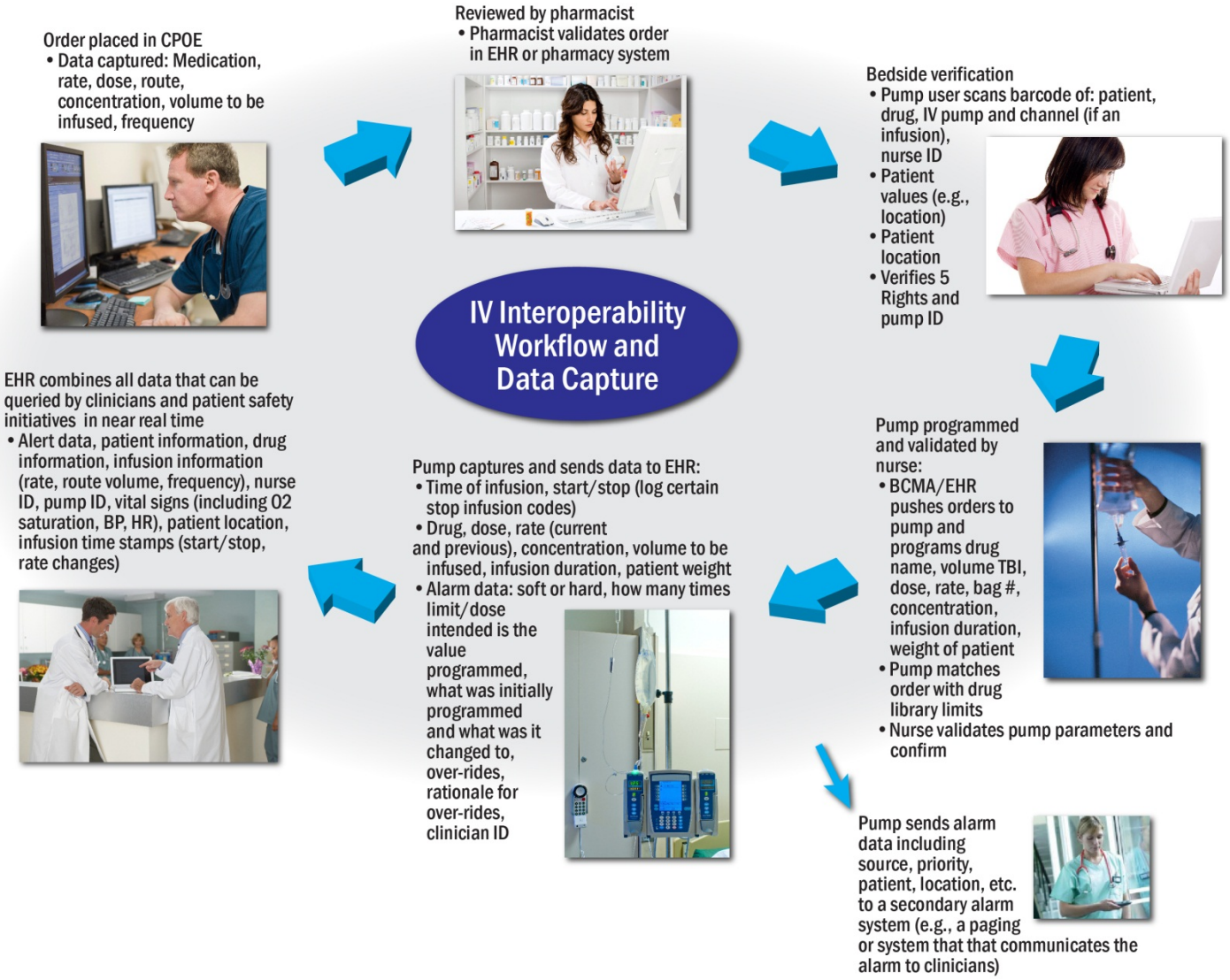
1. Improper programming of the infusion pumps
2. Circumventing the drug library
3. Pump user override of alerts

Recommendations

Recommendations: Infusion Pump Data Capture and Use

1. Identify key data elements and taxonomies required for electronic point of care documentation, communication between systems, and decision support
    - A standardized format for data collection will help to complement the Common Formats and the WHO's International Classification for Patient Safety
    - IHE- PCD Domain profiles should be expanded to consider infusion tubing, connectors, and ports as devices and to include UDIs for all devices
2. Infusion pump integration/interfacing with EHR applications: CPOE, electronic medication administration and documentation systems
3. Develop checklists that can integrate data capture including a unique device identifier UDI into the clinical workflow
    - Items pertaining to infection control/management should be prioritized and integrated into best practice processes for infusion

Fully Automated and Integrated IV Interoperability Workflow and Data Capture



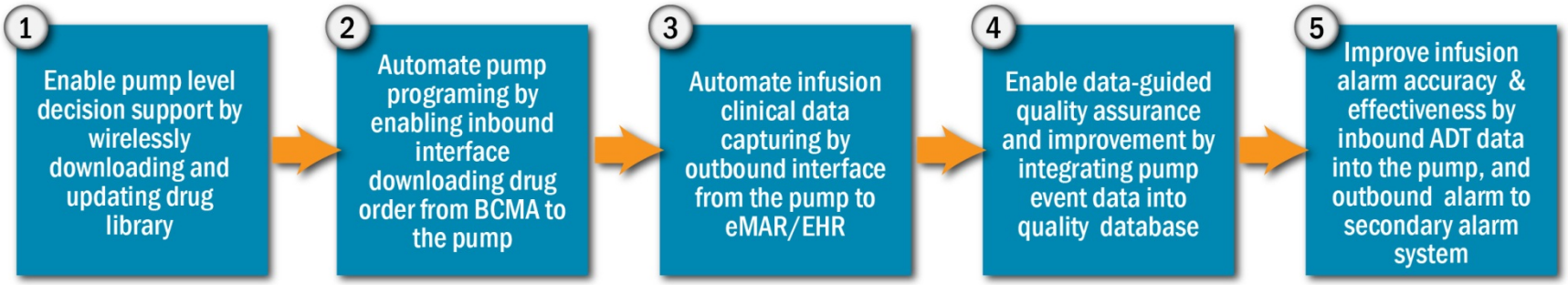
Recommendations: Infusion Pump Data Exchange between Systems (Standards-Based Interoperability)

4. Develop a standard for pump alerts and alarms that would advance data integration across systems
    - IHE is the appropriate organization to develop this standard
    - The WHO ICPS and The Joint Commission's Patient Safety Event Taxonomy can serve as starting points
5. Encourage pump manufactures, bar-code medication administration (BCMA) manufactures, and EHR vendors to adopt the following IHE-PCD Domain profiles for infusion care:
    - [PIV] Point-of-care Infusion Verification
    - [DEC] Device Enterprise Communication
    - [DEC-PIB] Patient Identity Binding
    - [ACM] Alarm Communication Management

Recommendations: Infusion Pump Data Exchange between Systems, cont'd

6. Create industry standards for categorizing and documenting events and alarms
    - An event tracking infrastructure is needed to more closely connect pump events with the order
    - Create a catalog of unique event identifiers to help capture and associate related infusion care events
    - Industry categorization and classification of events and alarms can guide safety and quality measurement

Maturity Model For Infusion Pump Automation



Recommendations: Decision Support

7. Identify and adopt a standard classification for high, medium, and low-risk alerts and alarms
   - A standardized taxonomy for alerts would allow hospitals to target their quality improvement resources on areas with most potential for risk reduction
   - There is also an opportunity to develop and implement metrics around compliance rates with various pump data gathering and safety features
8. Expand the IHE-PCD profiles to standardize clinical decision support (CDS) rules that use pump alerts and alarms as the triggers
   - The NQF CDS Taxonomy should be explored as the foundation for this effort

Recommended Metrics to Indicate Pump Safety Practices

1. Rate of Drug Library Compliance
2. Number of Soft and Hard Limit Alerts for Specific Meds by Type and Reason
3. Pump User Response to Alert (override, re-program, etc.)
4. Frequency of Patient Identification Entered into the Pump
5. Barcode Scanning Compliance

Recommendations for QDM Enhancement

- Converted the data elements identified by the TEP into possible QDM electronic measurement elements
- Areas for QDM development include: event definition, alarm definition, incident definition, processes of care, and circumstances
- Another area for future QDM development: the concept of e-Iatrogenic harm

Conclusions

- The Critical Paths Patient Safety established a baseline understanding of current electronic data capture and exchange involving infusion pumps
- The environmental analysis found:
  - All the study sites gather and analyze data about infusion pump alerts
  - All use data for quality improvement efforts
  - No sites are fully electronic
  - There is tremendous variation in data capture, exchange, and decision support.
- The TEP's recommendations leverage and build on many existing industry activities and standards
- Utilization of infusion pump data for decision support can advance quality reporting

Public Comment Period

August 24, 2012 12:00pm - September 24, 2012 6:00pm

http://www.qualityforum.org/Topics/HIT/Critical_Paths/Patient_Safety.aspx