NQF HIT Critical Paths: Patient Safety
Technical Expert Panel Summary

In-person Meeting
March 19 and 20, 2012

In attendance:
TEP members: David Classen, MD MS; Michael Ibara, PharmD (via conference call); Caterina E.M. Lasome, PhD, MBA, RN, CPHIMS; Behnaz Minaei; Terrie L. Reed, MSIE; Elliot B. Sloane, PhD CCE FHIMSS; Carey Smoak, MSPH

NQF staff: Floyd Eisenberg, MD MPH; Rosemary Kennedy, PhD MBA RN FAAN; Elizabeth Carey, MPP

DAY ONE

Welcome and Meeting Objectives

Dr. Eisenberg and Dr. Kennedy welcomed the Technical Expert Panel (TEP) panel members, and reviewed the agenda and the TEP objectives. The primary objective for the meeting is to begin defining data elements and processes of care associated with infusion pump quality reporting in acute care hospital settings.

Project Overview

Recent legislation and related regulations have identified a number of performance measurement concepts that challenge current measurement capabilities. The National Quality Strategy, Meaningful Use, and the innovative pilot programs stemming from the Affordable Care Act all call for new approaches to measuring quality and affordability. These approaches often require new measurement domains, data sources, and data platforms. Many also require novel approaches to patient and provider workflow for capturing, sharing and storing data. The *Critical Paths for Creating Data Platforms: Medical Device Safety* project will assess the readiness of electronic data to support selected innovative measurement concepts that are critical to HHS' policy needs.

This Critical Path project will assess the readiness of electronic data and health IT systems to support data capture, normalization and standardization to support patient safety reporting and evaluation across clinical information systems (e.g., electronic health records (EHRs) health information exchanges (HIEs), etc.). The project will specifically address medical device safety measurement concepts and then develop a critical path and action plan to address these key issues, gaps, and barriers. This project will assess the ability of existing health IT infrastructure

(Quality Data Model[1] (QDM), Healthcare Quality Measure Format (HQMF)[2], Measure Authoring Tool[3], electronic health records (EHRs)) to support the use of medical device data for purposes of quality measurement and reporting. The future state is to integrate Unique Device Identification (UDI)[4] and associated meta-data into existing quality measurement methods using point of care data capture within electronic systems. Achieving this integration will provide more accurate tracking of key performance metrics at both the individual and population levels.

The project is operating on a rapid timeline. The TEP will complete the requirements for the environmental analysis by the end of May. A subcontractor will then conduct the environmental analysis, with the results due by mid-July. At that time, the TEP will reconvene via conference call to review the results and draft the critical path and action plan report to address key issues, gaps, and barriers. The draft report will be posted for public comment in August. NQF will review public comments and deliver the final report to HHS by the end of October.

NQF Background and Related Efforts

To inform the work of this TEP, background information was provided on the Common Formats for Patient Safety Data Project and the NQF Patient Safety Measures Portfolio.

The "Common Formats" provide a common language and reporting format for reportable events, including generic and event-specific forms. In addition, Common Formats enable national aggregation of de-identified data. Dr. Classen provided the technical definitions and sample reports for "Device or Medical/ Surgical Supply, including Health Information Technology (HIT)" Common Formats. The vocabulary in the Common Formats provides a minimum standard for reporting patient safety data; it is an iterative process and the vocabulary will continue to be developed. Traditionally, the Common Formats have not been connected to the EHR.

The lack of standardized terminology, under-reporting of adverse or hazard events, and the absence of denominator data are limiting the field of quality measurement. During a recent NQF endorsement project, several medical device measures were identified as being more like "best practices" than actual measures.

[1] The QDM was formerly referred to as the Quality Data Set (QDS). The QDM is an information model that defines and describes clinical concepts in a standardized format to clearly and consistently represent concepts for use across all quality measures.
[2] The Health Quality Measures Format (HQMF) is a standard for representing a health quality measure as an electronic document.
[3] The Measure Authoring Tool (MAT) is a web-based tool that allows measure developers to create standardized electronic measures (eMeasures).
[4] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

Dr. Ibarra provided an overview of the *ASTER Project and the "lessons learned." ASTER stands for ADE Spontaneous Triggered Event Reporting". The ASTER study was The ASTER study was conceived as a proof of concept for a new model of gathering and reporting spontaneous adverse drug events (ADEs)[5].

This project piloted the use of EHRs for direct adverse event reporting. Data collection necessary for adverse event reporting was integrated within electronic point of care documentation. The study used digitized healthcare data collected at the point of care to create a triggered reporting system. Reports were sent directly to the FDA. There was discussion concerning the legal liability of direct reporting, which limits the ability of the hospital to intercede immediately in a situation. Also, direct reporting and automated triggers have important implications for the front-line practitioner's workflow process.

Dr. Sloane provided an overview of the IHE Patient Care Device Domain (IHE-PCD). This project documents use case/profile requirements based on existing standards that are tested through Connectathons and easy to integrate into products. The relevant IHE PCD Profiles include: Device to Enterprise Communication (DEC), Alarm Communication Management (ACM), Point of Care Infusion Verification (PIV), Point of Care Identity management (PCIM), and Medical Equipment management (MEM). It was also noted that Paul Schluter's Rosetta work is completed and available; however, IHE defines devices as electro-medical so that a catheter is classified as a supply not a device.

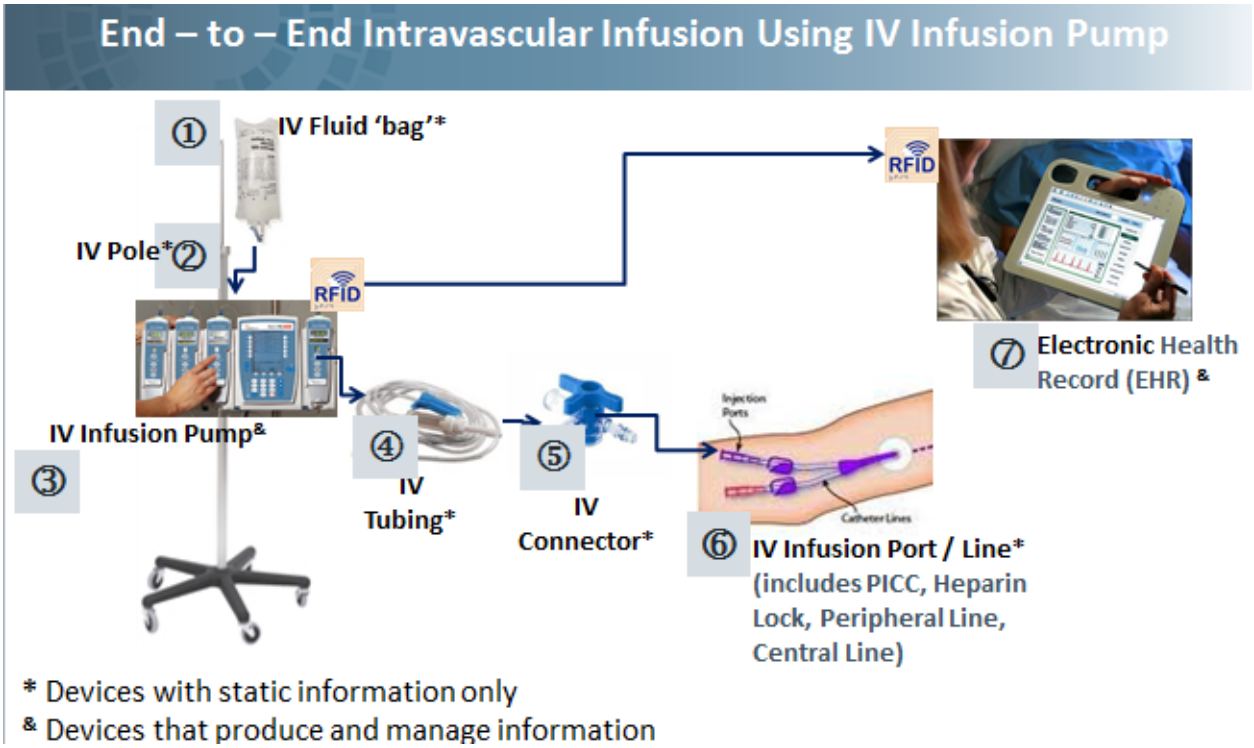
Defining the Scope for Requirements

Through discussion, the TEP determined that monitoring the infusion pump at the system level—rather than just the pump level—provides access to additional patient data in the EHR that is important for quality measurement. To scope this project, the system will focus on the end-to-end intravascular infusion system (see Figure 1), which includes:

1. IV fluid bag and piggyback bags;
2. IV pole;
3. Infusion pump;
4. IV tubing;
5. IV connector;
6. IV infusion port/line; and
7. EHR

[5] http://www.asterstudy.com/index.php?option=com_content&view=article&id=10:aster-description

Figure 1



Devices and accessory supplies that are external to this closed system were deemed out of scope, such as alcohol swaps, tray sets, and IV supports used to position the IV tubing on the patient's body.

Use of Data for Surveillance

There was discussion about the sources of data and how these data could be used. Sources of data include, but are not limited to, point of care manual and electronic documentation, quality reporting databases, supply management databases, biomedical and central supply tracking databases, and adverse event reporting solutions. Infusion pump device data can be used for point of care delivery and documentation, safety and quality reporting and improvement, as well as infusion pump device maintenance.

The TEP defined the two primary methods for generating infusion pump data: episodic or event-driven data collection and routine data collection as a byproduct of care delivery. Episodic or event-driven data could be used for individual case reporting to meet both voluntary and mandatory reporting requirements. The sources of this data include the health care provider, the clinician, biomedical or central supply resource, the infusion pump, and or the manufacturer.

Routine data can be generated by the infusion pump or captured by the clinician through the patient care delivery workflow through point of care documentation.

The TEP also discussed infusion pump metadata (data about data) information requirements. Metadata can include, but is not limited to, information about clinicians providing care (specialty, level of expertise, etc.), recorder for each activity completed with the infusion pump, and source of the data (these are examples of metadata and are not meant to be inclusive). Additionally, confounding environmental factors should be captured for root cause analysis. These factors include wound care, ventilator care, and patient factors such as home environment, nutrition, and co-morbidities.

To enable decision support, data requirements may lead to product suggestions for error-proofing, such as a tagging system for connecting lines to pumps. Data on anatomical structure/location and laterality would need to be captured.

Quality Data Model

Dr. Eisenberg presented an overview of the Quality Data Model (QDM), an "information model" that clearly defines concepts used in quality measures and clinical care and is intended to enable use of the EHR for quality reporting. The retooled National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) was shown as an example of an eMeasure using the QDM as its grammar. The TEP noted that information on infusion pumps and catheters is not traditionally found in the EHR. It was also noted that barcode readers are needed to complete the "5 Rights;" the environmental analysis will be able to determine how many facilities have barcode readers.

DAY TWO

Draft Data Elements

After a review of the scope discussion, the TEP members began to define the required data elements, workflow processes, and questions to ask during the environmental analysis for each of the seven devices in the end-to-end intravascular infusion system. This is summarized in Table 1 below. Decision support is outside the scope of this project.

Table 1: Data requirements for an environmental analysis of an end-to-end intravascular infusion system

Device	Environmental Analysis?	Data Required (draft list)
1. IV Fluid bag *Includes both main IV and piggyback*	1. Is the IV bag considered a device? 2. How are bags inventoried (tracked) 3. What data are captured? 4. What is the workflow? 5. What are the exceptions?	1. UDI 2. Labeling (includes contents and medications in the bag) 3. Bag # (1st, 2nd,) 4. Lot number and expiration date 5. Order (contents, medications, infusion rate along with other order data) 6. Order status (administered, etc.) 7. Time bag is hung and taken down (contents infused time) 8. Start-Stop date and time 9. Record rate, volume infused on I/O, and medication record (potentially)
2. IV pole	1. How are IV poles tracked, cleaned, and maintained 2. Who is responsible for IV pole management 3. Many people touch the IV pole – is this tracked	1. Data regarding cleaning frequency, method, and dates 2. Location of IV pole and location tracking 3. Tracking of IV pole use with pump number and patient 4. Storage and maintenance data
3. Infusion Pump	1. Pump tracking and maintenance 2. Pump alert classification 3. Methods for turning alerts off (and tracking of such activity) 4. Pump program error tracking	1. Pump Data • UDI • Add-on pumps 2. Data that the pump has access to (either in cassette or through interface to EHR)

Device	Environmental Analysis?	Data Required (draft list)
Infusion Pump, cont'd	5. Alarms and Pumps • Definition of alarms • Tracking human response to alarms • Adverse event tracking Hazard tracking 6. Number of infusions allowed through a single pump 7. Bolus management 8. Over-ride processes and tracking 9. Tags on pump-service range 10. Pump-patient connection 11. Cassette process 12. Filters and filter-pump match 13. Tubing and pump match 14. Add-on pumps 15. Incident Reporting • Automatic • Voluntary 16. Smart pump libraries 17. Tracking of logic changes in smart pumps 18. Smart system logic – who defines it, how is it integrated within the pump and EHR or other electronic systems 19. Pump programming process and tracking of errors or near misses	3. Pump Activity • Start / stop • Adjustments 4. Rate of Infusion • Initial rate • Within limits / Out of Limits • Over-ride • Rate changes (increase / decrease) and violation of pre-prescribed limits 5. Alarm / Alert Data • Activate • Terminate • Over-ride • Alert timing • Alert Notification • Alert data storage • Fixed alerts • Overridden alerts 6. Patient data and documentation in EHR
4. IV tubing	1. Process for changing 2. Process for documenting in chart 3. Adverse event reporting	1. UDI 2. Tubing and pump match documentation 3. Tubing data (date hung, etc.)

Device	Environmental Analysis?	Data Required (draft list)
IV tubing, cont'd	4. Labeling process 5. Connectors y/n 6. Insertion & doc into patient & pump 7. tracking	4. Type of tubing 5. Connection data 6. Medication/solution going through tubing – this is important for bolus doses administered outside the infusion pump
5. IV connector	1. Process for changing 2. Process for documenting in chart 3. Adverse event reporting 4. Labeling process 5. Insertion & doc into patient & pump	1. Connector Type 2. UDI 3. Port use and tracking use 4. Cultures? 5. Who is doing what- location patient-device point of origin
6. IV infusion port/line	1. Documentation process & protocols 2. Verify access/ correct 3. What is monitored and tracked? 4. Active/ inactive lines, leaving it in longer than recommended 5. Air embolism- location of port, associated with risk depending on location, air bubble removal	1. Port ID 2. Access d/t 3. Responsible party 4. Outcomes 5. UDI for device 6. Fluid flush 7. Bolus Medication(s) 8. Location 9. Skin doc 10. Line type 11. Catheter placement issues: • # of tries to insert • # of lines
7. EHR	1. What data doc during care delivery? 2. Are supplies charge linked to identifiers?	1. eMAR 2. Intake / Output Sheet

Device	Environmental Analysis?	Data Required (draft list)
EHR, cont'd	3. Adverse event data 4. IV pump database 5. Reporting processes- how report & track 6. Maintenance data: alarm tracking, IHE profile data	3. IV sheet 4. Site assessment 5. Problems/ dx 6. Orders, procedures 7. Labs- cultures 8. Supplies charge 9. Xray placement validation 10. Rx linked to emerging infections, med/antibiotics

Workflow

Documentation on standardized workflow protocols or checklists could be useful in determining the required data elements. The TEP discussed that there is usually a consistent workflow, starting with a patient order depicting the fluid type, medication, infusion rate, number of infusion bags, and other data pertinent to the IV medication. The medication order is communicated to the Pharmacy department and subsequently shows on the nurse's work list. IF there is no medication ordered for the IV bag, the nurse may get the fluid (normal saline, D5W as examples), from the central supply area. The IV fluid bag is hung using an infusion pump. The pump is programmed with the appropriate rate and is subsequently infused through the infusion line into the patient (either peripheral line or PICC line). The process is charted within the patient record (type of infusion, rate, volume of fluid, and date/time the infusion started and finished). There are varying levels of interoperability between the infusion pump and the EHR depending on each site. It was noted that some facilities may have a barcode that is entered into the EHR; this would have a time stamp. Also, if the pump is a "smart pump," additional functionality is present, providing the ability to 'send data to the EHR, and alert based on specified parameters (bag empty, line occlusion, etc.). In addition, EHRs can poll the infusion pump for data. The environmental analysis will provide addition input into current workflows.

Next Steps

The TEP is scheduled to review the draft data elements in two follow up conference calls (April 2 and May 2). The NQF staff will begin a comparison of these data elements to the data captured in Common Formats, IHE profiles, and the UDI elements.

NQF staff is proceeding with the RFP to select a subcontract to conduct the environmental analysis. The TEP suggested that the scan should include a few leading systems, such as Kaiser and the VA, as well as an average implementer. It was noted that a small hospital in big system is different than standalone small hospital. Additionally, larger pump installations, such as B. Braun, Care Fusion, and Hospira, should be included.

Dr. Kennedy thanked the TEP members for a productive discussion, and the wealth of information shared. The meeting was adjourned.