



NATIONAL
QUALITY FORUM

Critical Paths for Creating Data Platforms: Patient Safety

DRAFT REPORT FOR PUBLIC COMMENT

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Executive Summary

In 2011, the National Quality Strategy identified improvement in patient safety as a goal requiring focused national attention. National Quality Forum (NQF) carefully aligned its work with these goals, including focusing on making care safer by reducing harm. Health information technology (IT) – and its ability to capture, aggregate, and report data to enable more standardized and efficient reporting and assessment of performance at both the patient and population levels – will be integral to these efforts.

Patient injuries resulting from drug therapy are among the most common types of adverse events that occur in hospitals. 90% of hospitalized patients receive IV medications; 35% to 60% of adverse drug events involve infusion pumps, and the majority of infusion pump ADEs are the result of incorrect programming.¹ According to one US-based study, medication administration errors occur at a rate of 11.1 errors per 100 doses.² Of these preventable adverse drug events, 54% occur during intravenous (IV) drug administration.³ IV therapy accounts for 56% of medication errors⁴ and 61% of the most serious and life-threatening potential ADEs.⁵

NQF is working with the federal government to further use of health IT in health quality measurement to measure and improve patient safety. The goal of this Critical Paths Project is to understand the current state of electronic data readiness for quality measurement and current gaps in data exchange that, if filled, would allow for more robust infusion pump⁶ safety measurement and improvement. Smart infusion pumps can extract captured data, receive data from other systems, and subsequently transmit data for point of care and aggregate decision support for quality measurement.^{7, 8, 9} The implementation

¹ Enhanced Notification of Infusion Pump Programming Errors, Medinfo 2010, Evans, Carlson, Johnson, Palmer and Lloyd.

² Barker KN, Flynn EA, Pepper GA, Bates DW, Mikeal RL. *Medication errors observed in 36 health care facilities*. 2002. Archives of Internal Medicine. 162(16): 1897-1903.

³ Kaushal, R, Bates, DW, Landrigan, C, McKenna, KJ, CLAPP MD, Federico F, Goldmann DA. *Medication errors and adverse drug events in pediatric inpatients*. Journal of the American Medical Association. 2001. 285 (16): 2114-2120.

⁴ Ross L, Wallace J, Paton J, Stephenson T. Medication errors in a paediatric teaching hospital in the UK: Five years operational experience. Archives of Disease in Childhood. 2000 December; 83(6): 492-497

⁵ Vanderveen, Tim. *Averting highest-risk errors is first priority*. Patient Safety and Quality Health Care. May/June 2005.

⁶ An infusion pump is a medical device that transfers fluids to a patient's body in measured quantities.

⁷ Institute for Safe Medication Practices. (2009). Proceedings from the ISMP summit on the use of smart infusion pumps: Guidelines for safe implementation and use. Retrieved from <http://www.ismp.org/tools/guidelines/smartpumps/comments/>

⁸ Rothschild, J., Keohane, C., Cook, F., Orav, J., Burdick, E., Thompson, S., Hayes, J., & Bates, D. (2005). A controlled trial of smart infusion pumps to improve medication safety in critically ill patients. Critical Care Medicine, 33, 533-540.

⁹ Brady, J. First, do no harm: making infusion pumps safer. Biomedical Instrumentation & Technology. 2010; 372-380.

of smart infusion pumps¹⁰ with dose error reduction systems can help reduce IV administration errors. Most smart infusion pumps extract data into repositories which can be used for individual and aggregate decision-support, quality measurement, and subsequent quality improvement.

NQF convened a technical expert panel (TEP) to advance the ability of existing health information technology (health IT) infrastructure to support quality reporting of intravenous infusion therapy using infusion pump¹¹ medical devices. (See Appendix A for TEP members.) The TEP investigated electronic data elements and data exchange requirements that will help advance infusion pump safety measurement and quality improvement efforts. The TEP first discussed use of existing data sources available for surveillance. 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 to support medication/fluid administration; decision support; point of care documentation; safety and quality reporting and improvement; and infusion pump device maintenance.

The TEP identified a significant number of data elements that could support safety and outcome measurement for devices. The elements corresponded to three general types of factors: business, function, and content.

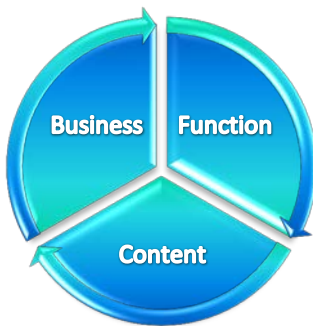


Figure 1: The three classes of factors that affect the safety of clinical devices: business, function and content.

Business factors include purchase or leasing decisions by the organization, policies, and procedures that can vary by organization, location within the facility, and/or the medication used in the infusion.

Function includes those human factors that affect how the device is used. These factors include the manual settings on the infusion pump, the connections to the device (inputs and outputs, and other factors related to human interaction with the device (workflow).

Content includes those factors *intrinsic* to the device (identifiers, software features and behavior programmed into the software), and those *extrinsic* to the device (the fluid moving through the tubing, the medication in that fluid).

Based on expert advice and requirements identified by the TEP, an environmental analysis was conducted to develop a baseline understanding of how infusion pump data are captured, used, and exchanged between electronic systems for purposes of quality measurement.

¹⁰ Smart infusion pumps contain dose-checking technology using rules contained in drug libraries and functions which apply the rules during pump programming to warn and guide clinicians about safe drug therapy. (Institute for Safe Medication Practices (ISMP), 2007).

¹¹ Infusion pumps are medical devices that deliver fluids, including nutrients and medications into a patient's body in a controlled manner (FDA, 2012).

The data gathering efforts focused on understanding what data are currently captured throughout the workflow of IV administration and how those data are currently used for patient safety and quality efforts. The scan included interviews with and a survey of key experts from nine stakeholder organizations, and a limited literature review. The interviews, surveys and research were synthesized to describe the current state of data readiness and ideal state of data functionality.

The sites involved in the environmental analysis varied in their ability to capture and transmit electronic data related to intravenous (IV) therapy administration through infusion pumps. In addition, facilities differed in the amount of data they can glean from their smart infusion pumps¹² and in their ability to access and/or use the smart infusion pump data for quality reporting and patient safety. Some facilities must manually download data from each infusion pump individually while other facilities have the data automatically sent to a quality reporting system and others have the data interfaced with an electronic health record (EHR). Some facilities only receive information on alerts that are overridden, whereas other facilities receive reports regarding all alerts and how those alerts were responded to (e.g., override, re-program, etc.). Most hospitals take these data from the pump and analyze it for trends of the most high-risk alerts, frequency of averted potential ADEs, or medications that most often trigger alerts and develop process improvements to address patient safety risks. Many facilities use alert data to inform their regular review and update of pump drug libraries.

Although sites vary in their sophistication, all are using electronic data to track at least limited elements of pump usage, maintenance, and operations. All sites included in the scan gather and analyze data about infusion pump alerts and as part of their quality improvement efforts. Although most sites analyze infusion pump data for quality and safety purposes, the analysis is focused exclusively on medication error measurement. Given that infusion pump data can be used for other areas of safety, such as infection rate measurement, the TEP identified use of infusion pump data for infection rate measurement as a gap area.

The main causes of infusion pump adverse events cited by participants include: improper programming of the infusion pumps, circumventing the drug library, and pump user override of alerts. Many facilities actively analyze their alert data to understand the types of overrides that are occurring and adjust their alerts accordingly. There are several metrics of pump usage and pump safety practices in use by the facilities that participated in the environmental scan including:

- Rate of drug library compliance
- Number of soft and hard limit alerts for specific medications by type and reason
- Pump user response to alert (e.g., override, re-program, etc.)
- Frequency of patient identification entered into the pump
- Barcode scanning compliance

¹² A smart pump is a device used for IV infusion containing electronic “drug libraries” of from which pump users can select. Smart pumps also include information on “soft” and “hard” limits for each drug in the library. These limits trigger alerts when pump users attempt to program a pump outside of the programmed soft and hard limits.

None of the sites that participated in the environmental scan have a fully electronic and integrated system for infusion therapy that allows for digital data capture and exchange at every step of the workflow. One facility discussed its ability to associate the pump and the medication order, but the facility does not routinely use the data. Interviewees consistently described a fully integrated system as one in which medication orders are generated electronically via a computerized prescriber order entry (CPOE) system and the order is verified electronically by the pharmacy for medication preparation. Hospital systems vary in their maturity of automation for infusion pumps tracking and identification. Moreover, there is no single unique identifier used to track pumps from supplier to facility.¹³ Facilities also vary in their ability to access and share these data with other health IT systems for patient safety and care delivery improvements.

The TEP recommends taking the following steps to ensure the readiness of electronic data to support measurement concepts related to acute care infusion devices:

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 World Health Organization's International Classification for Patient Safety (ICPS).
 - Integrating the Healthcare Enterprise (IHE) - Patient Care Device Domain (PCD) 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.

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.

¹³ The FDA recently released a Proposed Rule that most medical devices carry a unique device identifier (UDI), a unique numeric or alphanumeric code that includes a device identifier (specific to a device model) and a production identifier (includes the current production information for that specific device, such as the lot or batch number, the serial number and/or expiration date). The UDI will provide a standard and clear way to document device use in EHRs, clinical information systems, claim data sources, and registries. The Final Ruling will begin with Class III devices within 2 years.

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm>

- 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
 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.

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.

Additionally, the TEP recommends the development of quality measures in the following areas to advance infusion pump safety:

- Measures on infection management
- Measures on “end-to-end infusion system” device metadata, especially the use of Unique Device Identifiers (UDIs)
- In the future: Measures on “end-to-end infusion systems” interoperability (including the systems of systems that should share data, e.g. supply chain, pharmacy)

The promotion of a standardized format for data collection, the adoption of interoperability standards, and the utilization of electronic infusion pump data for decision support could greatly advance quality improvement and measurement activities of intravenous infusion therapy using infusion pumps.

Introduction

The Institute of Medicine (IOM) estimates at least 400,000 preventable adverse drug events (ADEs) occur among hospitalized patients annually; each of these events cost approximately \$8,750, totaling an estimated cost of \$3.5 billion annually.¹⁴ Patient injuries resulting from drug therapy are among the most common types of adverse events that occur in hospitals, given that 90 percent of patients receive intravenous (IV) medications. Incorrect programming of infusion pumps – used to control infusion rates and the catheters and ports used to access a patient’s bloodstream – account for close to 60 percent of ADEs.¹⁵ Central line associated blood stream infections (CLABSIs) are also a major concern, accounting for 23,000 ADEs among patients in inpatient wards in 2009.¹⁶

In 2011, the National Quality Strategy—heavily informed by the NQF-convened, private-public National Priorities Partnership—laid out a series of six goals (see Figure 1) for focusing the nation on how to best and most rapidly improve our health and healthcare. NQF has carefully aligned its work with these goals, including focusing on making care safer by reducing harm. Health information technology (IT) – and its ability to capture, aggregate, and report data to enable more standardized and efficient reporting and assessment of performance at both the patient and population levels – will be integral to these efforts.

Figure 2: National Quality Strategy Goals



¹⁴ Aspden P, Wolcott J, Bootman JL, Cronenwett LR, eds. *Preventing Medication Errors: Quality Chasm Series*. Washington DC: National Academies Press, 2007. Metrics provided in 2006 dollars.

¹⁵ Enhanced Notification of Infusion Pump Programming Errors, *Medinfo 2010*, Evans, Carlson, Johnson, Palmer and Lloyd.

¹⁶ Srinivasan A, Wise M, Bell, M, *et al*. Vital signs: central line-associated blood stream infections – United States, 2001, 2008, and 2009, *Morbidity and Mortality Weekly Report*. 60: March 1, 2011; 1-6. Available at: <http://www.cdc.gov/mmwr/pdf/wk/mm60e0301.pdf>

Accordingly, the Department of Health and Human Services tasked NQF with assessing the readiness of electronic data to support selected innovative measurement concepts that are critical to advancing national quality improvement efforts. In the *Critical Paths for Creating Data Platforms: Patient Safety* project, NQF looks to assess the readiness of existing health IT infrastructure to support quality reporting of intravenous infusion therapy using infusion pump¹⁷ medical devices, as well as provide recommendations for advancing such infrastructure.

Project Overview

This project will specifically address medical device safety measurement concepts and then develop a critical path and action plan to address key issues, gaps, and barriers. The project will evaluate the ability of existing health IT measurement infrastructure to express the data required to evaluate device safety. It will further assess the health IT infrastructure and electronic health records (EHRs) to support the use of medical device data for purposes of quality measurement and reporting.

It is likely that changes will be necessary in both the quality measurement and the health IT infrastructure to support device safety evaluation and measurement. The future state is to integrate Unique Device Identifiers (UDI)¹⁸ and important data related to infusion pump use 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.

Project Approach

NQF first convened a multi-stakeholder technical expert panel (TEP) focused on device safety with respect to acute care intravenous infusion therapy to define requirements for measurement and evaluation of readiness for measurement. The TEP completed a review of infusion pump data standards used and identified quality measurement data requirements for infusion pumps.

The work of the TEP informed an environmental scan focused on determining current practices related to data and workflow, as well as identification of data to reasonably expect in existing acute care settings. NQF worked with Booz Allen Hamilton to conduct the environmental scan.

This draft report is the culmination of that work, and contains the recommendations to advance the ability of existing health IT infrastructure to support quality reporting of intravenous infusion therapy using infusion pump medical devices.

To complete this project, NQF will:

- Post the draft report on NQF's website for public comment and host a webinar to encourage public comment for inclusion in the final reports

¹⁷ Infusion pumps are medical devices that deliver fluids, including nutrients and medications into a patient's body in a controlled manner (FDA, 2012).

¹⁸ <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm>

- Review and synthesize comments, and develop a final report on the critical pathways to improve data availability and data capture to measure acute care intravenous infusion therapy and thus enable electronic quality measurement
- Recommend enhancements to the Quality Data Model to support device management addressing data sources and data standards

Identification of Requirements and Methods for the Environmental Analysis

The TEP, during a series of conference calls and a face to face meeting, initiated the following steps to identify the requirements and methods for the environmental analysis:

- Review of federal and industry initiatives related to medical device safety and device metadata that may inform quality measurement;
- Identification of devices in the end-to-end intravascular infusion system pertinent to the scope of work; and
- Review of the workflow and data elements related to the infusion system.

A limited literature review was conducted on smart infusion pump infusion safety issues and IV infections to inform the TEP's work and the research questions for the environmental analysis. A list of the literature reviewed is provided in the Sources List (Appendix H). Because patient safety is one of the six priorities of the National Quality Strategy, there are several important federal and industry activities to improve the safety of medical devices using a health IT infrastructure. Information and knowledge described in the industry initiatives was shared with the TEP and subsequently used to identify requirements and methods for the environmental analysis.

Literature Review

Patient injuries resulting from drug therapy are among the most common types of adverse events that occur in hospitals. 90% of hospitalized patients receive IV medications; 35% to 60% of adverse drug events involve infusion pumps, and the majority of infusion pump ADEs are the result of incorrect programming.¹⁹

Of these preventable ADEs, 54% occur during IV drug administration.²⁰ IV therapy accounts for 56% of medication errors²¹ and 61% of the most serious and life-threatening potential ADEs.²² This is consistent

¹⁹ Enhanced Notification of Infusion Pump Programming Errors, Medinfo 2010, Evans, Carlson, Johnson, Palmer and Lloyd.

²⁰ Kaushal, R, Bates, DW, Landrigan, C, McKenna, KJ, CLAPP MD, Federico F, Goldmann DA. *Medication errors and adverse drug events in pediatric inpatients*. Journal of the American Medical Association. 2001. 285 (16): 2114-2120.

²¹ Ross L, Wallace J, Paton J, Stephenson T. Medication errors in a paediatric teaching hospital in the UK: Five years operational experience. *Archives of Disease in Childhood*. 2000 December; 83(6): 492-497

²² Vanderveen, Tim. *Averting highest-risk errors is first priority*. Patient Safety and Quality Health Care. May/June 2005.

with other studies of intravenous medications that found administration error rates between 34% and 49% per dose.^{23,24} Another adverse event related to infusion therapy, CLABSIs have decreased by 58% in intensive care units (ICUs) from 18,000 across the United States in 2009 compared with 43,000 in 2001. However, the problem still exists with an estimated 23,000 CLABSIs among patients in inpatient wards in 2009.²⁵ The Joint Commission defines CLABSI risk factors as intrinsic (non-modifiable patient characteristics) and extrinsic (modifiable factors associated with central line insertion or maintenance or the patient care environment).²⁶

The implementation of smart infusion pumps²⁷ with dose error reduction systems can help reduce IV administration errors; moreover, smart infusion pumps that interface with other IT systems such as an EHR, computerized prescriber order entry (CPOE), and bar-code medication administration (BCMA) can support further reductions in patient safety events related to IV therapies provided through infusion pumps.²⁸ Several sources identified other desirable features of smart infusion pumps including: a reliable wireless network for continuous, timely capture of information; integration with the electronic medication administration record (eMAR)²⁹, decision support guidelines, and dosing recommendations. More specific smart infusion pump features include the ability to prohibit bypass for specific high-risk medications and if there is a human initiated override, a subsequent request for the reason. Most smart infusion pumps have a capacity for large drug libraries which can be used to alert and guide clinicians during therapy. Smart infusion pumps can extract captured data, receive data from other systems, and transmit data for point of care and aggregate decision support for quality measurement.^{30, 31, 32}

²³ Wirtz V, Taxis K, Barber ND. *An observational study of intravenous medication errors in the United Kingdom and Germany*. Pharmacy World and Science 2003. 25(3):104-111.

²⁴ Taxis K, Barber N. *Ethnographic study of incidence and severity of intravenous drug errors*. British Medical Journal. 2003. 326(7391): 684.

²⁵ Srinivasan A, Wise M, Bell, M, *et al*. Vital signs: central line-associated blood stream infections – United States, 2001, 2008, and 2009, *Morbidity and Mortality Weekly Report*. 60: March 1, 2011; 1-6. Available at: <http://www.cdc.gov/mmwr/pdf/wk/mm60e0301.pdf>

²⁶ The Joint Commission. *Preventing Central Line–Associated Bloodstream Infections: A Global Challenge, a Global Perspective*. Oak Brook, IL: Joint Commission Resources, May 2012. <http://www.PreventingCLABSIs.pdf>.

²⁷ Smart infusion pumps contain dose-checking technology using rules contained in drug libraries and functions which apply the rules during pump programming to warn and guide clinicians about are safe drug therapy. (Institute for Safe Medication Practices (ISMP), 2007).

²⁸ Husch M, Sullivan C, Rooney D, *et al*. *Insights from the sharp end of intravenous medication errors: implications for infusion pump technology*. Quality Safety Health Care. 2005; 14:80-86.

²⁹ An electronic medication administration record (eMAR) records the medications administered to a patient during the course of a hospital stay. Typical data elements gathered include patient information (demographics, information on allergies, weight, etc.) and medication information (name of drug, dose, route, etc.).

³⁰ Institute for Safe Medication Practices. (2009). Proceedings from the ISMP summit on the use of smart infusion pumps: Guidelines for safe implementation and use. Retrieved from <http://www.ismp.org/tools/guidelines/smartpumps/comments/>

³¹ Rothschild, J., Keohane, C., Cook, F., Orav, J., Burdick, E., Thompson, S., Hayes, J., & Bates, D. (2005). A controlled trial of smart infusion pumps to improve medication safety in critically ill patients. *Critical Care Medicine*, 33, 533-540.

Although smart infusion pumps provide beneficial value in improving safety and quality, there are problems and limitations. According to the Food and Drug Administration (FDA), software defects, user-interface issues, and mechanical or electrical failures are the most common reported infusion pump problems.³³ The Association for the Advancement of Medical Instrumentation (AAMI) and FDA Summit on Infusion Devices noted specific infusion pump user-interface issues to be addressed related to: medication labeling inconsistency between pump, eMAR, computerized provided order entry (CPOE), and the medication label; hardware design, including control and keypad configuration inconsistency between different models, issues with display information, lighting, and readability; lack of differentiation between similar drug names; display of multiple drug concentrations for one drug; and alarm issues.³⁴ Several sources noted that drug libraries can be bypassed to remove the limit alarms that are used to prevent potential errors; soft stops alerts can be easily overridden including programming of inappropriate boluses; and workarounds to hard stops that negate any built-in safety measures.^{35, 36} In addition, existing efforts have not included methods to directly address tracking catheters (ports) used by type, manufacturer, lot and serial number similar to tracking medication usage for post-market surveillance regarding patient safety.

There are several initiatives and studies that offer recommendations for enhancing pump safety. In 2010, the FDA launched the Infusion Pump Improvement Initiative to address infusion pump safety problems and work towards developing safer, more effective infusion pumps industry-wide. Part of this initiative is to make it a requirement for all infusion pump manufacturers to administer real life environmental and user-interface testing, and to provide design and engineering information with their premarket submissions.³⁷ Additionally, FDA is involved in the development of model-based software engineering and verification methods. Through the Generic Infusion Pump project, an ongoing collaboration with outside researchers, FDA has helped to develop an open-source software safety model and reference specifications that infusion pump manufacturers can use or adapt to verify the software in their devices.³⁸

³²Brady, J. First, do no harm: making infusion pumps safer. *Biomedical Instrumentation & Technology*. 2010; 372-380.

³³ US Food and Drug Administration. White paper: Infusion Pump Improvement Initiative. April 2010. Retrieved from <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm205424.htm#types>

³⁴ Ravitz, A., & Doyle, P. Standardization of the User Interface. AAMI & FDA Summit on Infusion Devices. 2010. (PowerPoint)

³⁵ Institute for Safe Medication Practices. Proceedings from the ISMP summit on the use of smart infusion pumps: Guidelines for safe implementation and use. 2009. Retrieved from <http://www.ismp.org/tools/guidelines/smartpumps/comments/>

³⁶ Kirkbride, G., & Vermace, B. Smart pumps: implications for nurse leaders. *Nursing Administration Quarterly*. 2011; 35, 110-118.

³⁷ FDA White paper: Infusion Pump Improvement Initiative.

³⁸ More information about the Generic Infusion Pump project is available online at <http://rtg.cis.upenn.edu/gip.php3>.

In addition to national initiatives, there are research studies underway to identify the key issues around use of smart pumps with intent to develop strategies that will improve the prevention of intravenous errors and identify variables associated with infusion pump safety.³⁹ A study by Bates, is analyzing the frequency and types of IV medication errors and subsequently analyzing strategies to identify those that have the greatest potential for reducing IV medication error frequency. The Regenstrief Center for Healthcare Engineering (RCHE), a Purdue University research center, is working to establish infusion pump safety standards through the Infusion Pump Informatics Community, a partnership of several regional hospitals. Hospital users will be able to share analyses, report data, and access the best practices through the RCHE's web-based tool called the Infusion Pump Informatics System.⁴⁰

Methods to decrease the frequency of CLABSIs include the Institute for Healthcare Improvement's (IHI) Central Line Bundle and Central Line Insertion Checklist,⁴¹ and the Joint Commission's 2012 National Patient Safety Goals for the Critical Access Hospital program include a goal to use proven guidelines to prevent infection of the blood from central lines.⁴² Additionally, the Centers for Disease Control and Prevention (CDC), in conjunction with the Healthcare Infection Control Practices Advisory Committee (HICPAC), and the Infectious Diseases Society of America (IDSA), provide evidence-based recommendations for the prevention of intravascular catheter-related infections.^{43, 44} Beginning in 2013, hospitals' annual Medicare payment updates will be tied to submission of infection data, including CLABSIs. The reporting requirement utilizes the CDC's National Healthcare Safety Network (NHSN) Central line-associated bloodstream outcome measure,⁴⁵ an NQF-endorsed measure.⁴⁶

Reporting adverse events and determining the root cause of adverse events is critical for improving quality.⁴⁷ Capturing bedside pump programming history allows for measurement of infusion practices, capturing sentinel events, and monitoring nursing compliance related to drug libraries and overrides. In addition to technical features related to infusion pumps, the effectiveness in improving medication safety requires successful adoption and correct use of safety features, and institutional support and

³⁹ Bates, D. A National Study of Intravenous Medication Errors: Understanding How to Improve Intravenous Safety with Smart Pumps, January 2012.

⁴⁰ "Regenstrief launches hospital research community to improve infusion pump drug-delivery system." <http://www.purdue.edu/newsroom/general/2012/120716WitzInfusionPump.html>

⁴¹ Institute for Healthcare Improvement. Prevent central line infection, available at: <http://www.ihl.org/explore/CentralLineInfection/Pages/default.aspx>, accessed May 29, 2012.

⁴² The Joint Commission. Critical Access Hospital: 2012 National Patient Safety Goals. December 2011. Retrieved from http://www.jointcommission.org/standards_information/npsgs.aspx.

⁴³ O'Grady, N., Alexander, M., Burns, L., Dellinger, P., Garland, J., Heard, S., Lipsett, P., Masur, H., Mermel, L., Pearson, M., Raad, I., Randolph, A., Rupp, M., Saint, S., & the Healthcare Infection Control Practices Advisory Committee (HICPAC). (2011). Guidelines for the prevention of intravascular catheter-related infections. *Clinical Infectious Diseases*, 52, 162-193.

⁴⁴ Mermel, L., Allon, M., Bouza, E., Craven, D., Flynn, P., O'Grady, N., Raad, I., Rijnders, B., Sherertz, R., & Warren, D. (2009). Clinical practice guidelines for the diagnosis and management of intravascular catheter-related infection: 2009 update by the Infectious Diseases Society of America. *Clinical Infectious Diseases*, 49, 1-45.

⁴⁵ <http://www.cdc.gov/nhsn/PDFs/FINAL-ACH-CLABSI-Guidance.pdf>

⁴⁶ NQF Endorsement Summary: Patient Safety Measures. January 2012. Retrieved from http://www.qualityforum.org/News_And_Resources/Endorsement_Summaries/Endorsement_Summaries.aspx

⁴⁷ Brady 2010

behavioral improvements.⁴⁸ Implementation of smart infusion pumps requires commitment to a medication safety program, possible cultural change within an organization, encouraging compliance, and making workflow improvements as necessary.⁴⁹

Related NQF Efforts

NQF works with a diverse set of stakeholders to influence the U.S. healthcare system by building consensus on national priorities and goals for performance improvement and working in partnership to achieve them; endorsing national consensus standards for measuring and publicly reporting on performance; and promoting the attainment of national goals through education and outreach programs. NQF has several projects designed to support multi-stakeholder collaboration in the area of health IT, including its eMeasure Learning Collaborative⁵⁰ and the development 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 automation of EHR use.⁵¹

Quality Data Model

The QDM provides a way to describe clinical concepts in a standardized format so individuals (i.e., providers, researchers, measure developers) monitoring clinical performance and outcomes can clearly and concisely communicate necessary information. The QDM organizes and describes information so that EHR and other clinical electronic system vendors can consistently interpret and easily locate the data required.⁵²

The QDM provides the potential for more precisely defined, universally adopted electronic quality measures to automate measurement and compare and improve quality using electronic health information. Use of the QDM will enable more standardized, less burdensome quality measurement and reporting and more consistent use and communication of EHRs for direct patient care. In addition to enabling comparisons across performance measures, the QDM can promote delivery of more appropriate, consistent, and evidence-based care through clinical decision support applications. More information on the QDM can be found in Appendix B.

NQF Patient Safety Measure Portfolio

Of the over 700 NQF endorsed measures, approximately 100 are patient-safety focused. NQF has also endorsed 34 Safe Practices for Better Healthcare and 28 Serious Reportable Events. Despite these achievements, there are still significant gaps in the measurement of patient safety, and measurement related to medical devices is one of these gap areas. Through convening, technical panels, and other

⁴⁸ Association for the Advancement of Medical Instrumentation. Infusing patients safely: priority issues from the AMMI/FDA Infusion Device Summit. 2010.

⁴⁹ Kirkbride & Vermace, 2011

⁵⁰ http://www.qualityforum.org/Topics/HIT/eMeasure_Learning_Collaborative/eMeasure_Learning_Collaborative.aspx

⁵¹ <http://www.qualityforum.org/QualityDataModel.aspx>

⁵² <http://www.qualityforum.org/QualityDataModel.aspx>

educational forums, NQF works with measure developers and others in healthcare to help understand measurement gaps and encourage strategies to fill them.⁵³

Under the initial phase of NQF's most recent Patient Safety Measures project, NQF endorsed four healthcare-associated infection (HAI) measures as voluntary consensus standards suitable for accountability and quality improvement. The measures include updated versions of previously-endorsed HAI measures. These measures were submitted by the Centers for Disease Control and Prevention (CDC) and the American College of Surgeons (ACS), and included:

- 0753: National Healthcare Safety Network (NHSN) Central line-associated bloodstream infection (CLABSI) outcome measure (CDC).
- 0752: American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.
- 0754: National Healthcare Safety Network (NHSN) catheter-associated urinary tract infection (CAUTI) Outcome (CDC)
- 0751: Risk adjusted urinary tract infection outcome measure (ACS).⁵⁴

NQF Process to Receive Comments on Common Formats

NQF, on behalf of AHRQ, is coordinating a process to obtain comments from stakeholders about the Common Formats authorized by the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act). NQF's Common Formats project enables AHRQ to receive and respond to stakeholder input and to receive expert guidance on refining the Common Formats.

The term "Common Formats" refers to the common definitions and reporting formats that allow healthcare providers to collect and submit standardized information regarding patient safety events. The Common Formats establish a common method for healthcare providers to collect and exchange information for patient safety events.⁵⁵ The scope of Common Formats applies to all patient safety concerns including incidents, near misses or close calls, and unsafe conditions. Use of the Common Formats will ensure consistency of reporting among patient safety organizations (PSOs) as they begin to standardize the collection of patient safety event information using common language, definitions, and reporting formats.⁵⁶

AHRQ's Common Formats include technical specifications to promote standardization of collected patient safety event information by specifying rules for data collection and submission, as well as by providing guidance for how and when to create data elements, their valid values, conditional logic associated with data elements and values, and reports. These specifications will ensure that data collected by PSOs and other entities have comparable clinical meaning. They also provide direction to software developers, so that the Common Formats can be implemented electronically, and to PSOs, so

⁵³ http://www.qualityforum.org/Topics/Safety_pages/Patient_Safety.aspx

⁵⁴ NQF Endorsement Summary: Patient Safety Measures. January 2012. Retrieved from http://www.qualityforum.org/News_And_Resources/Endorsement_Summaries/Endorsement_Summaries.aspx

⁵⁵ <http://www.pso.ahrq.gov/formats/commonfmt.htm>

⁵⁶ The complete set of Common Formats, including generic and event-specific Common Formats, can be found at <http://www.psoppc.org/web/patientsafety>.

that the Common Formats can be submitted electronically to the Privacy Protection Center (PPC) for data de-identification and transmission to the Network of Patient Safety Databases (NPSD).

Most recently, AHRQ and the interagency Federal Patient Safety Workgroup (PSWG) developed *Common Formats—Hospital Version 1.2*, which features new content to incorporate the event-specific formats entitled *Venous Thromboembolism (VTE)* and *Device or Medical/Surgical Supply including Health Information Technology (HIT) Device*.⁵⁷

One of the most significant changes in this new version is the incorporation of new data elements for the Device module to include content for patient safety events related to a defect in, or failure or incorrect use of, a Health IT device.⁵⁸ This concept is also referred to as e-latrogenesis; that is, patient harm caused at least in part by the application of health IT.⁵⁹

As the TEP discussed important data elements related to performance measurement of infusion pumps, the Common Formats were used to provide data sources and definitions related to infusion pump quality reporting. Initial evaluation demonstrated the utility of Common Formats in identifying important data categories for infusion pump performance measurement. A comparison of the AHRQ Common Formats and the QDM is discussed later in this report.

Related Federal and Industry Efforts

In addition to NQF efforts, national efforts related to patient safety and infusion devices were reviewed by the TEP. The knowledge from these efforts helped the TEP identify the types of data necessary for quality measurement, workflow feasibility to capture the data, and methods to evaluate the data sources available within existing EHRs. The national efforts are described below.

For the purposes of this project, “alarms” are defined as events that were not anticipated, while “alerts” are programmed notifications that occur at specific points, such as the end of a programmed infusion.⁶⁰ An alert could escalate to an alarm if an action is not taken. However, for the review of industry efforts, the terminology used by that organization was maintained.

Unique Device Identification System

The FDA released a proposed rule that most medical devices carry a unique device identifier (UDI). The UDI system will provide a consistent, unambiguous, and standardized identifier on the device’s label that can be used to improve patient care, medical device recalls, adverse event reporting, and post-

⁵⁷ These Common Formats (dated April 2012) are currently available for public review and comment at www.psoppc.org.

⁵⁸ See https://psoppc.org/c/document_library/get_file?p_l_id=375679&folderId=409252&name=DLFE-14068.pdf for the definitions of events.

⁵⁹ Jonathan P. Weiner, Toni Kfuri, Kitty Chan, Jinnet B. Fowles [“e-latrogenesis”: The Most Critical Unintended Consequence of CPOE and other HIT](#) J Am Med Inform Assoc. 2007 May-Jun; 14(3): 387–388.

⁶⁰ See for example: http://www.carefusion.com/safety-clinical-excellence/perspectives/medication_management.aspx?p=53

market surveillance. The steps for establishing a UDI system include developing a standardized system of UDIs; placing the UDI in human and machine readable format on a device, its label, or both; creating and maintaining the UDI Database; and implementing the UDI to both new devices and devices currently being produced.

The UDI concatenates the Device and Production Identifiers according to ISO 15459. The UDI Database will collect:

- Device Identifier Type/Code
- Labeler name
- Contact information
- Global Medical Device Nomenclature (GMDN) code and term (or generic name)
- Brand/Trade/Proprietary Name (Make and model)
- Size (if available in more than one size)
- Unit of Measure/Packaging level/quantity
- Controlled by – Lot and/or Serial Number; Exp. Date
- Single Use; Sterility
- Contains known, labeled allergen (e.g., latex)
- FDA premarket authorization (510k, PMA)

The UDI code and database does not apply to devices already in the marketplace. They will be phased-in over 12-60 months after the final rule.⁶¹

It should be noted that the Global Medical Device Nomenclature Agency (GMDNA) responsible for the international naming system for medical devices (GMDN) and the International Health Terminology Standards Development Organization (IHTSDO), the leading provider of standardized clinical terminology (SNOMED CT), recently signed a Cooperation Agreement. The Cooperation Agreement shall result in the use of the GMDN as the basis for the medical device component of SNOMED CT and the opportunity for GMDN to be populated with any SNOMED CT medical device component content that is not pre-existing. The arrangement will provide patient safety benefits in terms of recall of defective devices, public health analysis on morbidity and mortality in correlation with medical devices, and will also ensure the quality of the supply chain.⁶²

The TEP integrated the UDI Database elements into the requirements for quality reporting of infusion pumps. The UDI Database elements were mapped within the documentation and workflow related to infusion pump management at the point of care.

MDEpiNet Initiative

The Medical Device Epidemiology Network Initiative (MDEpiNet) is part of the Epidemiology Research Program at the FDA's Center for Devices and Radiological Health (CDRH). The initiative is a collaborative

⁶¹<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm>

⁶²<http://www.gmdnagency.com/News.aspx>

program through which CDRH and external partners share information and resources to enhance our understanding of the safety and effectiveness of medical devices after they are marketed.⁶³

The MEDpiNet Initiative is developing a white paper on implementation of UDIs in EHRs. It is also implementing UDI- based surveillance activities and advancing the incorporation of UDI into point-of-care spontaneous electronic adverse event reporting through the ASTER-D pilot project. This Critical Path Patient Safety Project will inform future efforts related to incorporation of UDIs within EHRs with respect to any device, whether directly implanted in the patient (e.g., a heart valve or an implantable joint prosthesis) or used external to the patient.

The *ASTER Pilot Project

The *ASTER project was conceived as a proof of concept for a new model of gathering and reporting spontaneous ADEs. ASTER, which stands for “ADE Spontaneous Triggered Event Reporting,” implemented automated ADE collection in an ambulatory clinic EHR, using a flexible standard for data collection known as “Retrieve Form for Data” (RFD) from CDISC and Integrating the Healthcare Enterprise (IHE).

This project piloted the use of EHRs for direct adverse event reporting between December 2008 and June 2009. The process employed by ASTER was:

1. The physician discontinues a drug due to an adverse event in the Partners LMR (longitudinal medical record).
2. This will automatically trigger a prepopulated adverse event report which appears directly in the LMR.
3. The physician will complete a small amount of additional information and release the form.
4. The form is received and processed by CRIX International who will put the form in the proper format for electronic reporting to FDA. This study will test both the current International Conference on Harmonization (ICH) E2B ICSR standard as well as the developing Health Level 7 (HL7) ICSR standard.
5. FDA will receive a ‘triggered’ report which is equivalent to a reported spontaneous adverse event from the ambulatory care physician.⁶⁴

Since the completion of this pilot project, there are new pilots looking specifically at devices (ASTER-D) and the use of social media to capture data (ASTER-SM). The TEP integrated the findings from this project into their recommendations for data required for infusion pump quality measurement and reporting.

IHE Patient Care Device Domain

The IHE Patient Care Device Domain (IHE-PCD) documents use cases or profiles to address the integration of medical devices into the healthcare enterprise, from the point-of-care to the EHR,

⁶³ <http://www.fda.gov/MedicalDevices/ScienceandResearch/EpidemiologyMedicalDevices/MedicalDeviceEpidemiologyNetworkMDEpiNet/default.htm>

⁶⁴ http://asterstudy.com/index.php?option=com_content&view=article&id=10:aster-description

resulting in potentially significant improvements in patient safety and quality of care. IHE provides a detailed implementation and testing process to promote the adoption of standards-based interoperability by vendors and users of healthcare information systems. The process culminates in the Connectathon, a weeklong interoperability-testing event.⁶⁵ The IHE-PCD Profiles include:

- Alarm Communication Management (ACM): enables the remote communication of point-of-care medical device alarm conditions ensuring the right alarm with the right priority to the right individuals with the right content. It also supports alarm escalation or confirmation based on dissemination status, such as whether the intended clinician has received and acknowledged the condition.
- Device Enterprise Communication (DEC): supports publication of information acquired from point-of-care medical devices to applications such as clinical information systems and electronic health record systems, using a consistent messaging format and device semantic content.
- Patient Identity Binding (DEC-PIB): provides an optional extension to the DEC profile that supports a means of binding authenticated patient identity information to device data communication transactions.
- Subscribe to Patient Data (DEC-SPD): provides an optional extension to the DEC profile that supports a filtering mechanism using a publish/subscribe mechanism for applications to negotiate what device data they receive based on a set of client-specified predicates.
- Point-of-care Infusion Verification (PIV): supports communication of a 5 Rights- validated medication delivery/ infusion order from a BCMA system to an infusion pump or pump management system, thus “closing the loop.”
- Rosetta Terminology Mapping (RTM): establishes a set of tools that map the proprietary semantics communicated by medical devices today to a standard representation.⁶⁶

Each of these profiles is defined in full detail in the IHE PCD Technical Framework.⁶⁷ It should be noted that IHE defines devices as “electro-medical” so that a catheter is classified as a supply and not a device.

Additionally, IHE has a trial implementation for the PCD Infusion Pump Event Communication (IPEC) which specifies methods for communicating significant clinical and technical events from a Patient Care Device such as infusion pump to an information system which may present it to a clinical user, acts on it in some way, or records it. After testing at IHE Connectathons, it may be amended and then incorporated into the PCD technical framework.⁶⁸

The TEP reviewed these activities to determine what standards exist and are already incorporated in activities to share data about devices.

⁶⁵ Information about the 2012 Connectathon is available at: <http://www.ihe.net/connectathon/>. Accessed 14 May 2012.

⁶⁶ <http://www.ihe.net/pcd/>

⁶⁷ http://www.ihe.net/Technical_Framework/index.cfm#pcd

⁶⁸

http://www.ihe.net/Technical_Framework/upload/IHE_PCD_Suppl_Infusion_Pump_Event_Communication_IPEC_TI_2011-08-12.pdf

AAMI Healthcare Technology Safety Institute

Established under the AAMI Foundation, the Healthcare Technology Safety Institute (HTSI) aims to engage the healthcare community in multidisciplinary safety initiatives that strengthen the development, management, and use of healthcare technology for improved patient outcomes. HTSI initiatives are addressing infusion systems, clinical alarms, medical device reprocessing, and interoperability of healthcare technologies.⁶⁹ AAMI and FDA partnered to host a summit in October 2010 to facilitate extensive discussion between key stakeholders in order to set a clear direction for improving infusion systems safety.⁷⁰ A summit on interoperability of healthcare technologies is slated for Fall 2012.⁷¹

The Institute was awarded a grant to fund a three-year national study, led by David Bates, MD, to establish baseline information about the frequency and types of IV medication errors and determine strategies that have the greatest potential impact.⁷² This study builds on a 2005 study by Husch et al. that found 67% of IV infusions using smart pumps at Northwestern had one or more errors.⁷³

Recently, the HTSI released two papers as part of a series on technology-related challenges in healthcare. The first paper, “Best Practices for Infusion Pump—Information Network Exchange,” presents the steps a hospital must take to properly integrate an infusion pump with its wireless network. It includes five specific infrastructure requirements for pump integration, such as “a highly reliable method of associating a pump channel with a patient and a medication.”⁷⁴ The second, “Smart Pump Implementation: A Guide for Healthcare Institutions,” is intended to help hospitals navigate the purchasing and implementation of smart pumps. Recommendations include the development of a drug library for the smart pump system and the creation of a multidisciplinary committee to evaluate the devices.⁷⁵

The TEP reviewed these activities to determine what activities exist to standardize processes and improve patient safety with respect to device use, especially those related to infusion therapy.

World Health Organization International Classification for Patient Safety

The World Health Organization developed the conceptual framework for the International Classification for Patient Safety (ICPS), which defines, harmonizes, and groups patient safety concepts into an internationally agreed classification. The ICPS is not yet a complete classification; it is a conceptual framework for an international classification designed to provide a method of organizing patient safety

⁶⁹ <http://www.aami.org/htsi/>

⁷⁰ <http://www.aami.org/htsi/infusion/index.html>

⁷¹ <http://www.aami.org/htsi/>

⁷² *AAMI News*: June 2012, Vol. 47, No. 6

⁷³ M Husch, C Sullivan, D Rooney, C Barnard, M Fotis, J Clarke, and G Noskin. Insights from the sharp end of intravenous medication errors: implications for infusion pump technology. *Qual Saf Health Care*. 2005 April; 14(2): 80–86.

⁷⁴ http://www.aami.org/htsi/SI_Series/Infusion_Pump_White_Paper.pdf

⁷⁵ http://www.aami.org/htsi/SI_Series/Smart_Pump_Implementation.pdf

data and information so that it can be aggregated and analyzed to compare patient safety data across disciplines, examine the roles of system and human factors in patient safety, identify potential patient safety issues, and develop priorities and safety solutions.

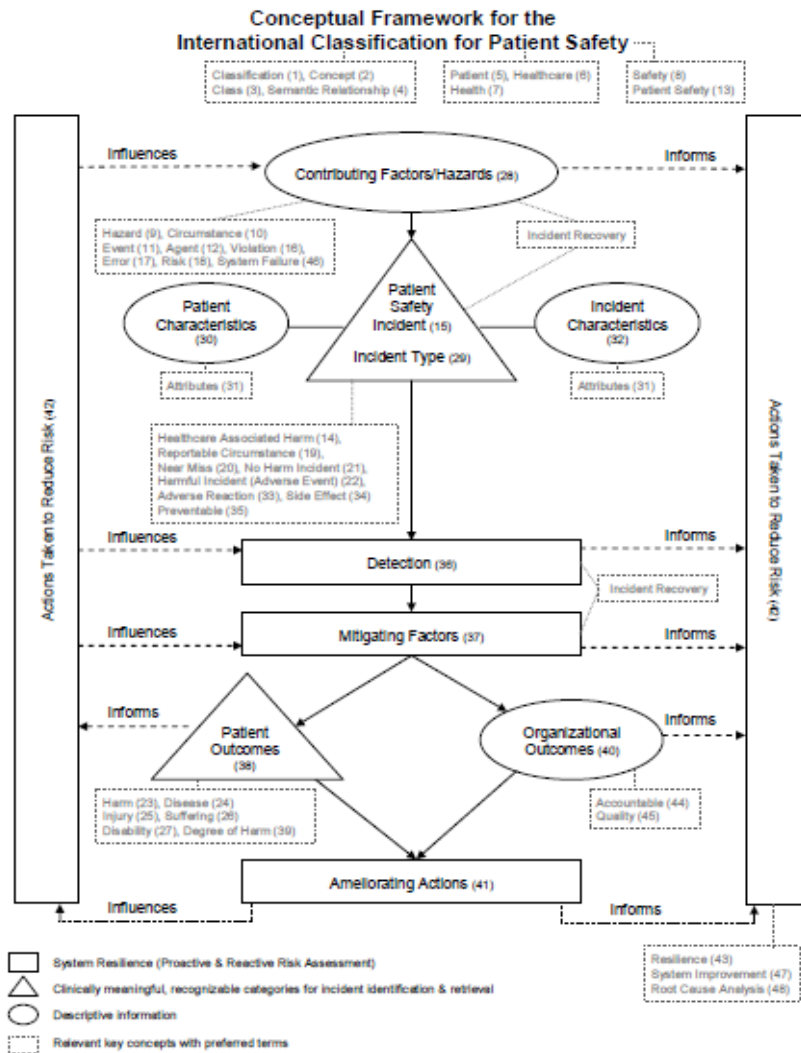
The conceptual framework for the ICPS consists of 10 high level classes:

1. Incident Type
2. Patient Outcomes
3. Patient Characteristics
4. Incident Characteristics
5. Contributing Factors/Hazards
6. Organizational Outcomes
7. Detection
8. Mitigating Factors
9. Ameliorating Actions
10. Actions Taken to Reduce Risk

It further identifies and defines 48 key concepts to enhance the study of patient safety and facilitate understanding and transfer of information. When possible, the concepts are consistent with concepts from other terminologies and classifications in the WHO-Family of International Classifications.⁷⁶

⁷⁶ World Health Organization. More than words: Conceptual Framework for the International Classification for Patient Safety, Version 1.1, Technical Report January 2009.

Figure 3: Visual Representation of the WHO International Classification for Patient Safety⁷⁷



The solid lines represent the semantic relationships between the classes. The black dotted lines represent the flow of information. The shaded dotted lines link the relevant concepts to the classes. The numbers next to the preferred terms represent the sequence in which they appear in the text and in glossary.

The TEP reviewed these activities to determine what activities exist to standardize processes and improve patient safety with respect to device use, especially those related to infusion therapy.

⁷⁷ © WHO, 2009. All Rights Reserved. World Health Organization. More than words: Conceptual Framework for the International Classification for Patient Safety, Version 1.1, Technical Report January 2009, page 20.

Required Data Sources and Data Elements

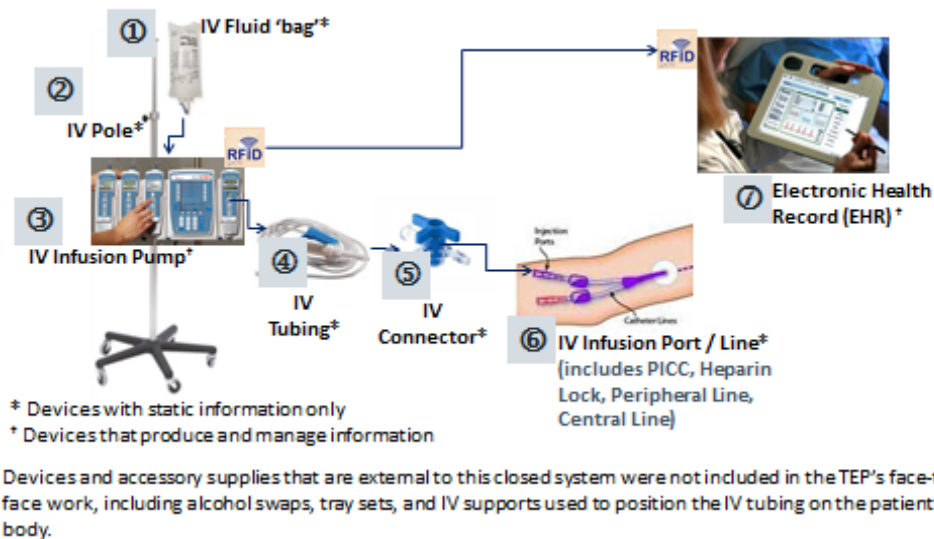
After reviewing the related NQF, federal, and industry efforts, the TEP defined major workflow processes and data related to use of infusion pumps at the point of care delivery. This discussion evolved into the types of data that are necessary, accuracy of data sources, workflow feasibility to capture data, and version control between various data element sources. The TEP defined requirements for measurement in the domain of infusion device safety.

Definition of Scope

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 and safety measurement. The TEP focused on the end-to-end intravascular infusion system (see Figure 3), 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

Figure 4: End to End Intravascular Infusion Using IV Infusion Pump



To scope the project, the TEP decided to focus on the infusion pump itself, including data captured in the infusion pump, unique identification data, data interoperability between the pump and electronic systems, and infusion pump safety and quality management.

The environmental analysis evaluated health IT systems' readiness to support external infusion pump quality measurement in acute care settings. This involved an environmental analysis of Acute Care EHRs, Quality Reporting Information Systems, and Infusion Pump / Device Information Systems, with respect to capturing and sharing information regarding infusion pump device usage, device identification, and infusion pump data used for safety and quality measurement and reporting purposes. The environmental analysis explored infusion pump data readiness and areas of need; for example: 1) infusion pump meta-data such as infusion pump brands, serial numbers, and other data that describes infusion pumps; 2) infusion pump safety data including reasons for device failures, failure types (external or internal to the pump); and 3) device use characteristics that includes information gathered on infusion pump safety and quality management.

Use of Data for Surveillance

The TEP first discussed use of existing data sources available for surveillance. 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 to support medication/fluid administration; decision support; point of care documentation; safety and quality reporting and improvement; and 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.

It was noted that an interface between the EHR and the infusion pump could populate data such as patient identification data, weight, and medication orders. This type of exchange between the infusion pump and the EHR would not only facilitate data analysis, but improve patient safety while also reducing workflow burden on healthcare providers.

Required Data Elements

The TEP identified a significant number of data elements that could support safety and outcome measurement for devices. The elements corresponded to three general types of factors: business, function, and content.

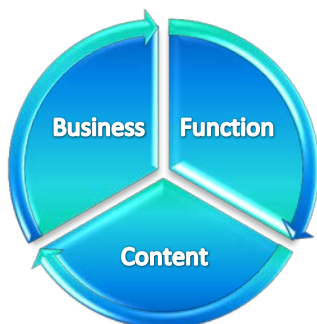


Figure 5: The three classes of factors that affect the safety of clinical devices: business, function, and content.

Business factors include purchase or leasing decisions by the organization, policies, and procedures that can vary by organization, location within the facility, and/or the medication used in the infusion.

Function includes those human factors that affect how the device is used. These factors include the manual settings on the infusion pump, the connections to the device (inputs and outputs, and other factors related to human interaction with the device (workflow).

Content includes those factors *intrinsic* to the device (identifiers, software features and behavior programmed into the software), and those *extrinsic* to the device (the fluid moving through the tubing, the medication in that fluid).

The specific data elements and questions for the environmental analysis are captured in Table 1. Note that all environmental analysis questions are intended to capture if data are tracked and, if so, the method by which they are tracked (e.g., paper, EHR, etc., and if there are linkages to claims or resource management system data).

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

Device	Environmental Analysis Questions	Data Required (draft list)
<p>1. IV Fluid bag <i>Includes both main IV and piggyback</i></p>	<p>Business: 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? Function: NA Content: NA</p>	<p>Business: NA Function: NA Content: <i>Intrinsic</i> 1. UDI <i>Extrinsic</i> 1. Contents a. Fluid i. Lot number ii. Expiration date b. Medication i. Lot number ii. Expiration date 2. Ordinality: Bag order (1st, 2nd,) 3. Infusion rate setting 4. Order workflow status (administered, etc.) 5. Start-Stop date and time (Contents infused time: time bag is hung and taken down) 6. Rate, volume infused recorded a. Input/ Output record b. Medication administration record</p>
<p>2. IV pole</p>	<p>Business: 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? Function: NA Content: NA</p>	<p>Business: NA Function: 1. Cleaning date / time (frequency) 2. Cleaning method 3. Location of IV pole ‘home’ Content: <i>Intrinsic</i> 1. IV Pole Identifier 2. IV Pole Location of Use <i>Extrinsic</i> 1. Patient to which IV Pole is assigned 2. Pump to which IV Pole is assigned 3. IV pole use locations</p>

Device	Environmental Analysis Questions	Data Required (draft list)
3. Infusion Pump	<p>Business:</p> <ol style="list-style-type: none"> 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 5. Alarms and Pumps <ul style="list-style-type: none"> • Definition of alarms • Tracking human response to alarms • Adverse event 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 & filter-pump match 13. Tubing and pump match 14. Add-on pumps 15. Incident Reporting <ul style="list-style-type: none"> • Automatic • Voluntary 16. Smart infusion pump libraries 17. Tracking of logic changes in smart infusion 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 20. What data elements are entered manually? <p>Function: NA Content: NA</p>	<p>Business:</p> <p>Function:</p> <p>Content:</p> <p><i>Intrinsic</i></p> <ol style="list-style-type: none"> 1. UDI <p><i>Extrinsic</i></p> <ol style="list-style-type: none"> 1. Add-on pumps 2. Data that the pump has access to (either in cassette or through interface to EHR) 3. Pump Activity <ol style="list-style-type: none"> a) Start / stop b) Adjustments 4. Rate of infusion 5. Initial rate 6. Thresholds (within limits / out of limits) 7. Over-ride 8. Rate changes (increase / decrease) and violation of pre-prescribed limits 9. Alarm / Alert Data <ol style="list-style-type: none"> a) Activate b) Terminate c) Over-ride d) Alert timing e) Alert Notification f) Alert data storage g) Fixed alerts h) Overridden alerts 10. Patient data and documentation in EHR

Device	Environmental Analysis Questions	Data Required (draft list)
<p>4. IV tubing</p>	<p>Business:</p> <ol style="list-style-type: none"> 1. Process for changing 2. Process for documenting in chart 3. Adverse event reporting 4. Labeling process 5. Connectors (yes/no) 6. Insertion & document into patient & pump 7. Tracking <p>Function: NA Content: NA</p>	<p>Business: Function: Content:</p> <p><i>Intrinsic</i> <i>Extrinsic</i></p> <ol style="list-style-type: none"> 1. UDI 2. Tubing and pump match documentation 3. Tubing data (date hung, etc.) 4. Type of tubing 5. Connection data 6. Medication/solution going through tubing – this is important for bolus doses administered outside the infusion pump
<p>5. IV connector</p>	<p>Business:</p> <ol style="list-style-type: none"> 1. Process for changing 2. Process for documenting in chart 3. Adverse event reporting 4. Labeling process 5. Insertion & document into patient & pump <p>Function: NA Content: NA</p>	<p>Business: NA Function: NA Content:</p> <p><i>Intrinsic</i> <i>Extrinsic</i></p> <ol style="list-style-type: none"> 1. Connector Type 2. UDI <p><i>Extrinsic</i></p> <ol style="list-style-type: none"> 1. Port use and tracking use 2. Cultures 3. Who is doing what- location patient- device point of origin

Device	Environmental Analysis Questions	Data Required (draft list)
<p>6. IV infusion port/line</p>	<p>Business:</p> <ol style="list-style-type: none"> 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, air bubble removal <p>Function: NA Content: NA</p>	<p>Business: Function: Content:</p> <p><i>Intrinsic</i></p> <ol style="list-style-type: none"> 1. UDI for device <p><i>Extrinsic</i></p> <ol style="list-style-type: none"> 1. Port ID (with respect to the patient) 2. Access date/time 3. Responsible party <ol style="list-style-type: none"> a) Inserting party b) Managing party 4. Insertion date and time 5. Removal date and time 6. Outcomes 7. Fluid flush 8. Bolus Medication(s) 9. Location 10. Skin documentation 11. Line type 12. Catheter placement issues: <ol style="list-style-type: none"> a) # of insertion attempts b) # of lines
<p>7. EHR</p>	<p>Business:</p> <ol style="list-style-type: none"> 1. What data documented during care delivery? 2. Are supplies charge linked to identifiers? 3. Adverse event data 4. IV pump database 5. Reporting processes- how report & track 6. Maintenance data: alarm tracking, IHE profile data <p>Function: NA Content: NA</p>	<p>Business: NA Function: NA Content:</p> <p><i>Intrinsic</i></p> <ol style="list-style-type: none"> 1. electronic medication administration record (eMAR) 2. Intake / Output record 3. IV record <p><i>Extrinsic</i></p> <ol style="list-style-type: none"> 4. Site assessment 5. Problems/ diagnoses 6. Orders, procedures 7. Labs – cultures 8. Supplies charge 9. X-ray placement validation 10. Orders (prescriptions) linked to emerging infections (medications, including antibiotics)

As the list of elements is quite extensive, the TEP decided that the environmental analysis should focus on essential elements related to infusion pump content (intrinsic and extrinsic) that could be expected

from a device. This includes infusion pump identifiers, software features and behavior programmed into the software, the fluid moving through the tubing and the medication contained within the fluid. Information contained within documentation checklists (e.g., insertion and daily maintenance activities for central IV line sites) are not part of the scope for this analysis. The refined list of data elements to support device safety measurement concepts involves the definition of the current state within organizations to identify:

- 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;
- 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; and
- Correlation between medical device data tracked and association with patient specific data stored in electronic systems.

Environmental Analysis

NQF contracted with Booz Allen Hamilton to perform an environmental analysis to develop a baseline understanding of current infusion pump electronic data capture and exchange for quality measurement purposes.

The goal of the environmental scan was to learn more about the current electronic data capture processes and data exchange surrounding infusion pumps. The data gathering efforts focused on understanding what data are currently captured throughout the workflow of IV administration and how those data are currently used for patient safety and quality efforts. See Appendix D for the specific research questions used for the environmental scan.

The environmental scan consisted of interviews and an online survey with industry experts to understand the current state of electronic data readiness as well as IT and interoperability gaps to be filled in order to advance the use of electronic infusion pump data to measure quality and safety. Specifically, seven hospitals/hospital systems and two vendors participated in the environmental scan. The facilities were selected to achieve a balance of geography, level of health IT sophistication, and size. Two of the facilities are in the west, two in the north east, two in the mid-west, and one in the south. Three participants represented multi-hospital systems and four participants were from single facilities. Facility size ranged from approximately 500 beds to over 4,000 beds. The two vendors are leading suppliers of infusion pumps and the suppliers used most frequently by the participating hospitals/hospital systems.

Each 60-minute interview involved one or more subject matter experts from a major hospital system or infusion pump vendor and delved into fourteen key questions ranging from patient safety measurement to interoperability of information technology systems, to the types of systems that store electronic information. The discussion guide and survey used in the environmental scan are included in Appendix E and F.

Results and Analysis

Facilities that participated in the environmental scan vary in their current ability to capture and transmit electronic data related to IV therapy administration through infusion pumps. Some providers have been using wireless smart infusion pumps for several years, whereas others have more recently switched to smart infusion pumps and others have newly acquired wireless connections. Smart infusion pumps support patient safety during drug administration through a pre-programmed drug library from which providers can choose the appropriate medication; the smart infusion pump includes “soft” and “hard” limits for drugs within the library and sound an alert if these limits are exceeded. Soft limit alerts, which afford an opportunity to correct the programming and/or can be overridden by the pump user, occur when dosing is out of the typically accepted range. Hard limits, which cannot be overridden, occur when dosing is beyond the recommended amount.⁷⁸

Smart infusion pumps can capture a variety of data that are useful for safety measurement and quality improvement; however, facilities differ in the amount of data they can glean from their smart infusion pumps and in their ability to access and/or use the smart infusion pump data for quality reporting and patient safety. Some facilities must manually download data from each infusion pump individually while other facilities have the data automatically sent to a quality reporting system and others have the data interfaced with an EHR. Although facilities vary in their sophistication, all are using electronic data to track at least limited elements of pump usage, maintenance, and operations.

Infusion Pump Safety Measurement

The main causes of infusion pump adverse events cited by participants include: improper programming of the infusion pumps, circumventing the drug library, and pump user override of alerts. Errors in infusion pump programming can lead to a variety of ADEs, such as the patient receiving the wrong medication, the wrong dose of medication, or receiving medication at the wrong rate. Manual programming of infusion pumps is at risk for human error. For example, a nurse could exclude a decimal point, inadvertently transpose numbers, or inadvertently program micrograms per kilogram per minute instead of micrograms per minute.⁷⁹ Circumventing the drug library (i.e., selecting a drug from outside the pre-programmed drug library) was cited by many participants as a patient safety risk with infusion pumps. Selecting a drug outside of the library can

⁷⁸ Harding, Andrew, *Increasing the Use of ‘Smart’ Pump Drug Libraries by Nurses: A Continuous Quality Improvement Project One hospital’s efforts to reduce the risk of medication errors*, *American Journal of Nursing*, 2012, Volume 112, p. 26.

⁷⁹ Wilson, K., & Sullivan, M. Preventing Medication Errors with Smart Infusion Technology. *American Journal of Health System Pharmacy*, 2004, 61(2), 177.

cause harm to the patient because drugs outside of the library are not “protected” by the soft and hard limit alerts described above. A third common cause of adverse events during IV therapy is pump users overriding pump alerts and proceeding with an infusion that is outside the soft limits programmed into the pump. Interviewees discussed many reasons for overriding alerts such as “alert fatigue” or pump users being rushed, busy, or in an emergency situation. Many facilities actively analyze their alert data to understand the types of overrides that are occurring and adjust their alerts accordingly. In addition to these three main causes of medical errors, errors can occur due to mechanical problems with the pump such as a dying battery and pump key “bounces” that lead to programming errors.⁸⁰ In addition, errors can occur due to pump user misunderstanding of pump interface and/or warnings.⁸¹

There are several metrics of pump usage and pump safety practices in use by the facilities that participated in the environmental scan, as summarized in Table 2.

Table 2. Metrics in Use by Facilities Interviewed

Metrics to Indicate Pump Safety Practices	Improvement Opportunity / Targeted Error Prevention
Rate of drug library compliance	Compliance with the drug library helps prevent dosing errors by engaging the soft and hard alerts. Tracking drug library compliance helps facilities identify opportunities for pump user education or other process improvements. Understanding rates of library compliance can also be used to tailor the drug library.
Number of soft and hard limit alerts for specific medications by type and reason	Analysis of frequency and types of alerts and alarms is used to develop process improvements and to tailor the drug library and the soft and hard limits that trigger alerts.
Pump user response to alert (e.g., override, re-program, etc.)	Analysis of pump user response to alerts can be used by facilities to tailor alerts (in response to alert fatigue, for example), to identify areas where the alerts are successful (e.g., by prompting the nurse to re-program the correct dose), and to identify areas for process improvement and/or pump user education. Some facilities have interviewed nurses to understand reasons for various responses to pump alerts; however, the main source for understanding the pump user response to alerts is in the data captured in the pump logs.

⁸⁰ A pump key “bounce” is when a user presses down firmly on a button and the pump registers the click on the keypad more than once, rather than the single click. This could lead to .22 being programmed rather than the intended .2, for example.

⁸¹ Guidance for Industry and FDA Staff. Total Product Life Cycle: Infusion Pump – Premarket Notification. Draft Guidance. April 23, 2010.

Metrics to Indicate Pump Safety Practices	Improvement Opportunity / Targeted Error Prevention
Frequency of patient identification entered into the pump	Facilities that tie data from the pump system to the EHR or eMAR track compliance with entering patient identifying information into the pump. Some facilities utilize a bar coding system that scans the wrist band of the patient as a tracking mechanism; however, some facilities rely on manual entry of a patient identifier.
Barcode scanning compliance	Barcode scanning of the patient, drug (and in some facilities, the pump user administering the medication and/or the pump itself) helps get the right drug to the right patient. Assessing rates of scanning compliance helps facilities identify areas for process improvement and/or pump user education.

Interviewees stressed the importance of drug library compliance to help prevent adverse drug events. As mentioned above, the smart infusion pump drug library helps prevent dosing errors by using soft limits (which alert the nurse that the medication will be delivered at a dose or rate outside of the typical range and can be overridden) and hard limits (which alert the nurse that the medication is beyond any recommended amount and cannot be overridden). Bypassing the drug library increases the potential for error identification because these error preventing alerts do not apply to drugs outside of the drug library.

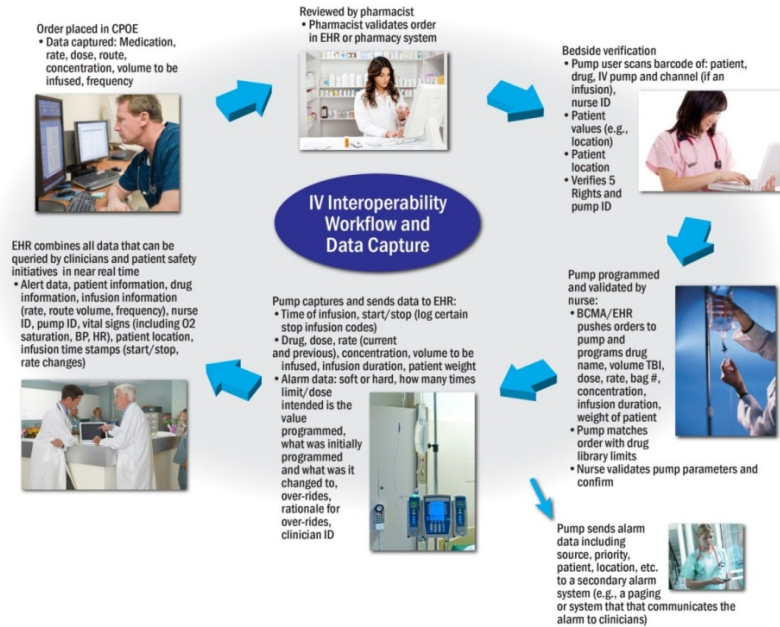
The number of alerts and other data gathered when alerts are triggered are widely used by participants to identify areas for targeted quality improvement initiatives. All hospitals that were part of the interview process gather and analyze data about infusion pump alerts and as part of their quality improvement efforts. However, facilities vary in the alert data they can access. Some facilities only receive information on alerts that are overridden, whereas other facilities receive reports regarding all alerts and how those alerts were responded to (e.g., override, re-program, etc.). Most hospitals take these data from the pump and analyze it for trends of the most high-risk alerts, frequency of averted potential ADEs, or medications that most often trigger alerts and develop process improvements to address patient safety risks. Many facilities use alert data to inform their regular review and update of pump drug libraries. One facility discussed how these data have informed tailoring its drug libraries for specific areas such as the intensive care unit, cardiology, and prenatal intensive care unit.

Current State of Electronic Data Capture & Interoperability

Hospital systems are at various stages of maturity in their electronic data capture and exchange throughout the medication administration workflow. None of the facilities that participated in the environmental scan have a fully electronic and integrated system for infusion therapy that allows for digital data capture and exchange at every step of the workflow. Interviewees consistently described a fully integrated system as one in which medication orders are generated electronically via a CPOE and the order is verified electronically by the pharmacy for medication preparation. The BCMA checks for the 5 Rights and the pump ID and sends the order information wirelessly to the infusion pump. The infusion pump is automatically programmed and validated by the clinician, who starts the infusion. Infusion data are gathered electronically during the infusion, and these data are sent to downstream

systems such as the EHR and quality reporting systems. Additionally, patient demographic and location data are electronically sent from the hospital information system (HIS)⁸² to the pump; pump events, including patient location, are electronically sent to a secondary alarm system.⁸³ The workflow of this fully integrated system is depicted in Figure 6.

Figure 6: Fully Automated and Integrated IV Interoperability Workflow and Data Capture



As noted above, facilities vary in the amount of data captured and accessed from the pump. A summary of data gathered and tracked electronically by the pump during infusion at most organizations that participated in the environmental scan is presented in Table 3.

Table 3. Infusion Pump Data Gathered and Tracked Electronically

Data Gathered and Tracked Electronically	
Length Of Infusion	Patient Identifier
Start And Stop Times of Infusion	Dose Number
Medication	Bag Number
Change In Rate of Infusion From Previous Rate	Room Number Of The Patient
Changes In Concentration	Order Number

⁸² Hospital information systems include systems such as the admission, discharge, transfer (ADT) system, the billing system, and the scheduling system.

⁸³ A secondary alarm system takes the signals of the alarm and works as a communication channel about the alarm going off. Examples of secondary alarm systems include the hospital paging system, smart phones, etc. There are many benefits of using a secondary alarm system, such as better audibility, better prioritization, lower noise level, etc.

Data Gathered and Tracked Electronically	
Patient Location	Model Number Of Pump
Pump Number (Serial # from manufacturer and/or hospital specific pump identifier)	Pump Over-Rides
Pump User Identifier	Type Of Alert
Fluid	Concentration

All facilities that participated in the environmental scan capture at least: type of alert, overrides, medication, and date and time of infusion. Four hospitals reported that they capture patient identifier information; however, for some it is voluntary so it is not always completed. Two facilities reported that they capture the pump user identifier information. One facility discussed its ability to associate the pump and the medication order, but the facility does not routinely use the data. Pump suppliers that participated in the environmental scan described that the technology to track both the pump user and the patient exists, but it is not routinely used by their customers.

Hospital systems vary in their maturity of automation for infusion pumps tracking and identification. Moreover, there is no single unique identifier used to track pumps from supplier to facility.⁸⁴ 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. Two facilities track infusion pumps through unique identifiers through a wireless network and two facilities do not have a system of tracking the pumps other than the supplier-generated serial numbers. Two other facilities are using or will soon begin using RFID software to track and identify pumps.

Facilities also vary in their ability to access and share these data with other IT systems for patient safety and care delivery improvements. For example, one facility only receives automated data on the pump server when an alert was triggered—to obtain any additional data would require manually downloading it from each pump. In another organization, data on medication administration are shared with the EHR continuously during the infusion.⁸⁵ One interviewee discussed the ability to share data from the pump to the pharmacy information system regarding the status of infusions. These data are used to help pharmacists plan when drug orders are changed as not to over or under prepare drugs; to date, these data are not used to support care delivery (e.g., to adjust dose amounts or timing) or quality

⁸⁴ The FDA recently released a Proposed Rule that most medical devices carry a unique device identifier (UDI), a unique numeric or alphanumeric code that includes a device identifier (specific to a device model) and a production identifier (includes the current production information for that specific device, such as the lot or batch number, the serial number and/or expiration date). The UDI will provide a standard and clear way to document device use in EHRs, clinical information systems, claim data sources, and registries. The Final Ruling will begin with Class III devices within 2 years.

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm>

⁸⁵ These data include: dose number, bag number, patient, room number, date/time, pump number, drug, current rate, previous rate, order number and pump model number.

improvement purposes. Pump vendor participants in the environmental scan reported the ability to interface with a variety of hospital IT systems, but not all of these interfaces are standard in all pump implementations.⁸⁶

Table 4 provides a summary of the data capture and exchange capabilities at each of the hospitals/hospital systems that participated in the environmental scan.

Table 4. Summary of Facility Data Capture and Exchange

Current Data Capture and Interoperability	
Site 1	<ul style="list-style-type: none"> • Data electronically captured in the EHR includes information from the bar code scanning process (including that the patient and the drug are verified via bar code wand; bar code wand also captures the identity of the nurse starting the infusion), the medication order, dosing information which includes frequency, rate of infusion and date/time of administration, and data from the pump on alerts and how the alerts were addressed • Pump data are shared wirelessly with the EHR but are not currently shared with the quality reporting system • Medication orders are generated via CPOE and electronically verified by the pharmacist. Orders are manually entered into the infusion pumps
Site 2	<ul style="list-style-type: none"> • Data electronically sent from the pump to the EHR include: patient, room number, medication, bottle number, dosing, dose number which includes current and previous rate and date/ time of administration, bag number, order number, any errors in programming the pump. Internal IT System can program the drug library from the EHR; the EHR provides a central database for all pumps to utilize • Data are sent from the pump to the EHR every minute and are compared to the data in the EHR to identify any discrepancies • Alert overrides trigger a pump log to be e-mailed to the clinical pharmacist • The logic for tracking IV administration resides in the EHR. The drug library is programmed via the EHR (as opposed to via the pump database as is typical in wireless pump programming), and the EHR identifies errors in programming based on the order and patient. • Medication orders are generated via CPOE and electronically verified by the pharmacist. Orders are manually entered into the infusion pumps.
Site 3	<ul style="list-style-type: none"> • The EHR captures the information on the bar code scanning of the patient, nurse, medication and pump at the point of care. The EHR also has information provided by clinicians during the course of care (e.g., the medication order, monitoring parameters, etc.); other than barcode scanning information, no data are currently shared directly from the pump to the EHR. • Medication orders are written manually and scanned to the pharmacy where they are entered into the EHR and verified. The EHR then wirelessly sends the medication order to the pump.

⁸⁶ IT systems with which pumps can interface, as reported by pump suppliers, include: electronic health records, facility ADT systems, pharmacy systems, BCMA systems, and asset tracking/management systems.

Current Data Capture and Interoperability	
Site 4	<ul style="list-style-type: none"> • Data sent from the pumps wirelessly to a server include: patient ID, drug, dosing, fluid, concentration, date/time, programmed amount, alert status and if they were overridden or re-programmed; no data are sent from the pump to the EHR or from the EHR to the pump • Medication orders are written manually and manually programmed into the pump. The order information is also transferred into the eMAR by the pharmacist
Site 5	<ul style="list-style-type: none"> • The pump cannot send or receive any information to the EHR or the eMAR. The facility has a CPOE system that communicates with the EHR, but no information is sent from the EHR to the pump. • The barcode scanning system is integrated with the EHR. The bar coding system captures the following elements: patient, medication, and the nurse that administers the infusion. However, there is no link of the pump to the patient. • Medication orders are written manually and manually programmed into the pump. The order information is also transferred into the eMAR by the pharmacist
Site 6	<ul style="list-style-type: none"> • Data elements captured from the pump include: facility within the system, care area, patient ID, medication, alert status and if they were overridden or re-programmed. These data are sent to a separate server for analysis, but are not shared with the EHR • Interfacing exists between the event reporting system, the EHR, and the bar code scanning system • Medication orders are entered via CPOE system CPOE and electronically verified by the pharmacist. Orders are manually entered into the infusion pumps
Site 7	<ul style="list-style-type: none"> • Information from the bar code scanning process (e.g., bar code on patient, medication, and pump if available) are stored in the EHR • Data are not currently being exchanged between the pump and any IT system. Pump data are sent to a separate server for analysis, but are not shared with the EHR • Medication orders are entered via CPOE system CPOE and electronically verified by the pharmacist. Orders are manually entered into the infusion pumps

Although none of the facilities interviewed are fully automated as described in Figure 5, most facilities have some level of automation in their infusion pump processes. All of the facilities interviewed have implemented a CPOE system in at least one unit. In all of these facilities, the order is generated through the CPOE and electronically sent to the pharmacy. The order is verified by the pharmacist and the nurse electronically verifies the medication order information with the EHR. The pharmacist verifies the order and programs it into the pharmacy information system. The pharmacy information system and the clinical information system communicate with the BCMA to program the pump based on the verified order and patient information (e.g., weight). The order is then manually programmed into the pump and infusion begins. One facility has automated pump programming, leveraging the bar code assisted medication administration technology to do so. During drug administration, the infusion pumps in this facility capture the information about the infusion process; however, these data are not yet shared electronically with the EHR. Next year, this facility will start receiving information electronically from the pump to the EHR.

All of the facilities have an EHR with an integrated eMAR, and five facilities have a bar code scanning process for scanning medications during pharmacy dispensing and at the patient's bedside. Several facilities capture bar code information automatically in the EHR, including scanning of the nurse ID, patient ID, pump ID, and the medication. This bar code scanning process helps to ensure the accuracy of the dose, drug, and patient location. Several facilities analyze bar code data to identify if and why flags are raised during the scanning steps (e.g., if the wrong medication is scanned at the point of care). In one facility that does not have integration between its pumps and its eMAR, only the nurse administering the drug is captured manually in the EHR; none of the bar code scans are automatically captured. In addition, data are put into the eMAR and EHR manually throughout medication administration (e.g., monitoring parameters, rate changes, etc.); no data are sent automatically from the pump to the eMAR or other modules of the EHR at this facility.

One organization that still relies on manual pump programming has built a process to integrate its EHR with its infusion pumps. In addition to the hard and soft alert limits as defined in smart infusion pump software at the initiation of drug administration, this system leverages communication between the pumps and the EHR to detect programming errors throughout drug administration. The EHR, which was built-in house, includes bedside charting of medication administration. The bedside computers query the pump routinely during drug administration and send information to a central server, which identifies if any changes are in line with rate change limits. If there is an error, the pump user has thirty seconds to recognize the error and adjust the infusion pump programming. If the error is not corrected within thirty seconds, an alert is activated. Alert notifications are sent to all computers within the surrounding care area and include a full-screen notification of the alert and in which patient room and on which pump the alert is. If one of these alerts is overridden, a log⁸⁷ is generated and emailed to the clinical pharmacist.⁸⁸

Future State of Electronic Data Capture & Interoperability

There are many enabling IT tools that hospitals participating in the environmental analysis would like to implement to further increase patient safety and quality of IV therapy. Although the majority of the participating facilities have some interoperability between the pump, the eMAR and/or the EHR, none of the hospital systems interviewed have bi-directional interfaces between the infusion pump and the EHR. One system is in the process of implementing bi-directional interfaces which allow data to be sent from the pump to the EHR in addition to allowing the EHR to communicate orders directly to the pump. This bi-directional integration has been shown to remove several manual steps in the process of programming the infusion pump, thereby improving patient safety.⁸⁹

⁸⁷ Log data include: patient encounter number, time of the alert, medication, dose rate, previous dose rate, device number, order number, bag number, room number, and how the alert was turned off.

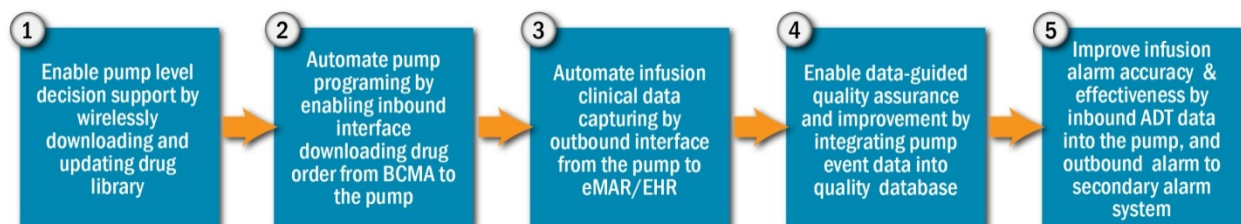
⁸⁸ Evans, Scott, Carlson, Rock, Johnson, Kyle, Palmer, Brent, Lloyd, James, *Enhanced Notification of Infusion Pump Programming Errors*. International Medical Informatics Association, 2010, p. 734-738.

⁸⁹ Prusch, Amanda E., Suess, Tina, Paoletti, Richard, Olin, Stephen, Watts, Starann, *Integrating Technology to Improve Medication Administration*, American Journal of Health-System Pharmacy, 2011, Volume 68, p. 838-841.

Facilities vary in terms of their “next steps” toward infusion pump interoperability depending on their current state of data readiness. The hospitals that participated in the environmental scan that have little or no electronic data from their infusion pumps are currently working toward automating data capture and analysis. Several hospitals have one directional data exchange between their pumps and their EHRs and consider a future state in which orders are sent directly to the pumps from the CPOE module within the EHR. Some organizations view integration between the pump to the eMAR as a high priority in order to gain access to information regarding medications administered outside the drug library, the rate at which the medication was administered, and the rationale for circumventing the drug library. One facility is working to develop an interface between its pumps and its clinical messaging systems so that nurses and/or pharmacists will receive pages or other notifications when a pump alert goes off.

Although sites are at varying levels of maturity in terms of capturing, sharing and accessing digital infusion pump data, all sites aspire to a bi-directional and fully automated system. There is not necessarily a one size fits all, step wise approach for developing into a bi-directional and fully automated system. However, based on the experience of the participants in the environmental scan, a potential “maturity model” for implementing an automated system is shown in Figure 7.

Figure 7. Potential Maturity Model for Infusion Pump Automation



An additional step toward advancing infusion pump interoperability would be to validate the “maturity model” presented above and begin to identify key stakeholders and gaps to fill at each step of the model. This would help define the scope of what is needed to help the overall industry expand the collection and use of digital data throughout IV administration.

Standards-based interoperability is both a common desire and challenge across the board for digital communications between the smart infusion pump and the enterprise systems such as EHR and secondary alarm systems. On the standard development front, the IHE-PCD domain has made significant progress since its inception in 2005 in defining the bi-directional data communications between an infusion pump and the hospital information systems.⁹⁰ Some notable work from the PCD includes the integration profiles of “Device to Enterprise,” which enables pump data to be sent automatically to a downstream system such as an EHR, and “Point of Care Infusion Verification,” which enables automatic programming of the infusion pump by transmitting order data from the BCMA/EHR system. Three interviewees expressed support to IHE PCD standard work, but also discussed their concerns that those

⁹⁰ http://www.ihe.net/Technical_Framework/upload/IHE_PCD_TF_Rev1-0_Vol3_FT_2012-03-21.pdf

standards are not being commonly adopted by the pump manufactures or BCMA/EHR vendors. In limited cases when interoperability is offered by certain pump vendors, the technical methods are a mixture of IHE conforming standards and proprietary application programming interfaces (API) due to the lack of standard adoption with the integration partners.

Beyond interfaces, the standardization of drug libraries used by the device makers is another challenge for care delivery organizations. Two of the interviewed organizations noted that there are variations with formularies, concentration units, and drug names from manufacturer to manufacturer. For facilities that work with heterogeneous pumps and makers, those inconsistencies increase pump management overhead and potentially decrease the effectiveness of the drug library if its update are not accurate or timely. One interviewee discussed the need to implement standard drug libraries not only between hospitals but also within hospitals.

As infusion pump data exchange matures, information security is another area that represents challenges and potential safety concerns. One interviewee noted that pumps need to be designed and manufactured to ensure that information is protected by proper security controls. These controls include data encryption, application and firmware vulnerability identification and remediation, and timely patching of operation systems, among other industry best practices. The importance of adequate security protection is further heightened for organizations planning to automatically download infusion orders from BCMA/EHR into an infusion pump. Although the final verification by a clinician is required to start the infusion process, the risk of the pump order being maliciously and electronically altered by an intruder, compounded by the published successful medical device hacking attempts, has drawn attention not only from the interviewed care organization, but also from the lawmakers and regulators.⁹¹

In addition to the technical and security challenges to expanded infusion pump data exchange, several participants in the environmental scan highlighted the role of human factors in infusion pump safety and the ability to expand use of electronic data in pump use and safety measurement. For example, the usability of the pump interface and ease of incorporating technology into the drug administration workflow will have a large impact on pump user compliance with data gathering and safety features. Understanding and addressing the human factor elements in the implementation of infusion pump technology will be important; as one participant in the environmental scan noted, “safety software and auto programming are like seat belts: they are only useful if they are used.”

⁹¹ <http://www.massdevice.com/news/device-hacking-federal-agencies-urge-heightened-review-device-cybersecurity>

Recommendations

Information gathered through this environmental scan demonstrates that there is opportunity to improve data infrastructure to enable more robust infusion pump quality measurement and safety. The industry has room to advance safety and quality through infusion pump digital data capture and exchange. To enable hospitals to move from the “current state” to the “future state” as described above, the TEP identified recommendations necessary to advance electronic data readiness (data capture, data exchange, and decision support) for infusion pump safety and quality measurement. These recommendations will enhance the ability of existing health IT infrastructure to support quality reporting of intravenous infusion therapy using infusion pump medical devices.

The TEP categorized the recommendations into three areas: infusion pump data capture and use, infusion pump data exchange between systems, and decision support.

Infusion Pump Data Capture and Use

Data necessary for intravascular infusion includes factors intrinsic to the device (identifiers, device type, software features and behavior programmed into the software), as well as those extrinsic to the device (medication/fluid order, rate of infusion, protocols, patient demographics, findings, and other information). Given the breadth and depth of data required for infusion therapy, as well as the tremendous variation in data currently captured by the sites, the TEP recommends identification of key data elements and taxonomies necessary for point of care documentation, communication between systems, and decision support. For this project, taxonomies of interest include areas like the sequencing of medications, devices, and procedures; the unique identification of tasks and processes needed for safe infusion therapy; the identification and relationship between infusion devices, tubing, bags, medications, and other accessories; and the relationships between common—and unusual—events and alarms. This will ensure agreement on all aspects of the data the infusion pump systems will capture in order to assemble electronic systems that are useful for analysis.

The TEPs’ identification of key concepts necessary to support the infusion management process (Table

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 WHO’s International Classification for Patient Safety.
 - IHE-PCD 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 UDI into the clinical workflow.
 - Items pertaining to infection control/management should be prioritized and integrated into best practice processes for infusion.

1 above) could be used as a starting point to identify standardized terminologies, as well as the relationships between the terminologies based on an explicit domain ontology—patient safety. In addition, the TEP recommends extension of the QDM based on these key concepts. The concepts were mapped against the QDM to further identify the necessary data infrastructure for quality measurement. Findings of this mapping are contained in the next section.

Standardization of documentation (at the point of care) and electronic communication (between pump and other systems) can only help to inform and complement the Common Formats and WHO's ICPS. The TEP recommends expanding IHE-PCD profiles to consider infusion tubing, connectors, and ports as devices and to include FDA's UDIs for all devices. This infrastructure is very important for quality reporting and measurement. A common infrastructure for quality measurement can be created by integrating the use of structured, coded data based on industry accepted vocabularies, combined with use of device UDIs throughout the infusion process. The promotion of a standardized format for data collection and standardized workflow practices (Figure 6 above) could greatly advance quality measurement activities.

The TEP recommends developing checklists that can integrate data capture into the clinical workflow. A recent IOM report on patient safety noted the importance of integrating health IT into the clinical workflow.⁹² While this IOM report excludes medical devices, the conclusions and recommendations can be extended to include medical devices. One of the conclusions of the authors in the IOM report is that patient safety depends on the coordinated effort and interaction between different parts of a large system, and extending this coordinated effort to include data from medical devices is necessary for real interoperability that fits within the clinical workflow. The TEP recommends an integrated approach to data capture that involves infusion pump integration/interfaces with CPOE systems, electronic medication / fluid administration, and documentation of patient response to the medication/fluid. This level of integration/interfaces is necessary for quality measurement and reporting.

The clinical workflow for IV infusion should identify points in the process where the UDIs for infusion devices are captured. Workflow checklists pertaining to infection control/management should be prioritized and integrated into best practice processes for infusion. To facilitate this process, the TEP recommends expanding the Automated and Integrated IV Interoperability Workflow developed during the environmental analysis (Figure 6) to include all the devices in the end-to-end infusion system (Figure 4).

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

Communication of data necessary for infusion management (medications and fluids) involves two-way data exchange between the infusion pump, CPOE, and eMAR, in order to support safety and quality. The TEP recommends broader-based system integration to support data elements such as patient

⁹² IOM (Institute of Medicine). 2012. *Health IT and Patient Safety: Building Safer Systems for Better Care*. Washington, DC: The National Academies Press

demographics, allergy information, vital signs, and other elements as defined in Table 1. These data elements are integral to quality measurement and reporting.

Two-way data exchange requires more robust data exchange standards that adequately address information security and regulatory barriers to bi-directional data exchange with infusion pumps. Standards-based interoperability is both a common desire and challenge across the board for digital communications between the smart infusion pump and the enterprise systems such as EHR and secondary alarm systems. The TEP recommends common adoption of standards by pump manufacturers, BCMA, and EHR vendors. As revealed during the environmental scan, when interoperability is offered by certain pump vendors, the technical methods are a mixture of IHE-PCD conforming standards and proprietary application programming interfaces (API) due to the lack of standard adoption with the integration partners.

The TEP recommends IHE as the appropriate organization to develop a standard for pump alerts and alarms that would advance data integration across systems. There are several existing taxonomies that could provide a starting point, including the WHO's ICPS, which defines, harmonizes, and groups patient safety concepts into an internationally agreed classification. Since this conceptual framework is still being transformed into a true classification system, it can be leveraged with health IT data system standards development for optimum semantic interoperability.⁹³ Additionally, The Joint Commission's *Patient Safety Event Taxonomy* was developed through a systematic literature review of existing patient safety terminologies and classifications to identify common terminology and classification schema (taxonomy) for collecting and organizing patient safety data.⁹⁴ The foundational taxonomy work completed can be leveraged to support data standardization necessary for quality measurement.

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, 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
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.

⁹³ <http://www.who.int/patientsafety/implementation/taxonomy/en/>

⁹⁴ <http://intqhc.oxfordjournals.org/content/early/2005/02/21/intqhc.mzi021.full.pdf>

The TEP's survey and analysis indicates that many hospitals are successfully transitioning from stand-alone infusion pumps to networks of infusion pumps, communication systems, and information systems. This presents an important opportunity to leverage the trend related to the automation of data collection, dissemination, and analysis from infusion systems, which, in turn greatly improves our ability to identify and rectify problems without burdening clinicians with data collection. In order to have comparable data from the majority of hospitals and infusion centers, though, the data and communication protocols must be standardized across the industry. Therefore, the TEP recommends broad-based adoption of the following IHE Patient Care Device Domain profiles for infusion care:

- **[PIV] Point-of-care Infusion Verification** supports communication of a 5-Rights validated medication delivery / infusion order from a BCMA system to an infusion pump or pump management system, thus "closing the loop." Optionally, the [DEC] profile and [DEC-PIB] below may be used to selectively monitor the status of the devices and to ensure that patient identity information is correctly matched to all device and medication data during the course of care.
- **[DEC] Device Enterprise Communication** supports publication of information acquired from point-of-care medical devices to applications such as clinical information systems and electronic health record systems, using a consistent messaging format and device semantic content.
- **[DEC-PIB] Patient Identity Binding** provides an optional extension to the DEC profile that supports a means of binding authenticated patient identity information to device data communication transactions that have been programmed.
- **[ACM] Alarm Communication Management** enables the remote communication of point-of-care medical device alarm conditions ensuring the right alarm with the right priority to the right individuals with the right content (e.g., evidentiary data). It also supports alarm escalation or confirmation based on dissemination status, such as whether the intended clinician has received and acknowledged the condition.

The above IHE data integration profiles define an open, cross-industry method for communicating significant events in medication administration by infusion pumps. Events are communicated as quickly as is technically feasible, and all related staff, devices, and information systems can share important event information in a timely way. Events are defined as operational milestones (infusion complete, change in rate, start/stop of infusion) and/or key parameter changes (change in pump settings, hardware failure, etc.). Recording and communicating these events is fundamental for quality measurement. Equally important are alarms, which are defined as events that require an immediate response from either a human or electronic system. Importantly, these IHE-PCD's are also designed to share data with a growing number of standardized electronic medical record systems, ensuring that patient care data is preserved in their own medical records.

The TEP also recommends industry adopted standards for categorizing and documenting events and alarms. Some events and/or alarms require attention at various levels of urgency. Events, although not requiring immediate response, are nonetheless time sensitive, e.g., as one infusion reaches "completed status," it may trigger the need to start another infusion. Infusion pump "events and triggers" are closely connected to the medication/fluid order which necessitates the need for an event tracking

infrastructure (either through clinical decision support or workflow engine technology), that more closely connects pump events with the medication order. The TEP recommends creation of a catalog of unique event identifiers to help in capturing and associating related infusion care events (delivery starts and delivery stops across multiple medications/fluids). In addition, the TEP recommends industry categorization and classification of events and alarms as a guide for safety and quality measurement.

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 CDS rules that use pump alerts and alarms as the triggers.
 - The NQF CDS Taxonomy should be explored as the foundation for this effort.

Decision Support

The TEP noted several actions that could be taken to begin to advance the ability to gather and use infusion pump electronic data for point of care and aggregate decision support. To set the foundation for this, the TEP recommends identification and adoption of a standard classification for high, medium, and low-risk alerts and alarms. Most of the hospitals analyze pump data for trends of the most high risk alerts, frequency of averted potential ADEs, or medications that most often trigger alerts, and many facilities use alert data to inform their pump drug libraries. Given these activities, the TEP noted a need for a standardized taxonomy for alerts, which would allow hospitals to target their quality improvement resources on areas with most potential for risk reduction. This could be used to develop and implement metrics around frequency of and response to various alerts and alarms. Similarly, there is an opportunity to develop and implement metrics around compliance rates with various pump data gathering and safety features.

Building on the environmental analysis participants' suggestion for a standard taxonomy for alerts and alarms, the TEP recommends expansion of the IHE-PCD profiles to standardize CDS rules that use pump alerts and alarms as the triggers. The NQF CDS Taxonomy⁹⁵ should be explored as the foundation for this effort.

Common Metrics and Areas of Measurement

In addition to alert data, the environmental analysis participants and the TEP indicated additional metrics on the infusion process would be helpful to measure as part of patient safety improvement efforts, including:

⁹⁵ National Quality Forum (NQF), *Driving Quality and Performance Measurement—A Foundation for Clinical Decision Support: A Consensus Report*, Washington, DC: NQF; 2010.

- 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; and
- Rates of averted adverse events.

The TEP additionally considered areas where quality measures could advance infusion pump safety:

- Measures on infection management
- Measures on “end-to-end infusion system” device metadata, especially UDI
- Measures on “end-to-end infusion systems” interoperability (including the systems of systems that should share data, e.g. supply chain, pharmacy) in the future

Recommendations for QDM Enhancement

A component of this project was to evaluate the ability of existing health IT measurement infrastructure, including the QDM, to express the data required to evaluate device safety. Based on the data elements defined by the Patient Safety TEP (See Table 1), the QDM update June 2012 was used to convert the data elements identified into possible electronic measurement elements. While the possible data sources of the QDM are not limited to EHRs (see the Health Information Framework in Appendix B), most experience to date has been applying the QDM to data in EHRs. The new companion document, the QDM Style Guide, was also utilized in the mapping exercise to determine which data elements are likely to be available within the current constraints of implemented EHRs. The mapping exercise is attached as Appendix G.

Additionally, the data elements captured by the AHRQ Common Formats were compared to the data elements of the QDM. Areas where the QDM maps well to the Common Formats include device identifiers for incidents that are device related, and medication information for events that involved a medication of other substance.

Many Common Formats data elements will be found in other hospital information systems or paper-based systems related to patient safety reporting, and are not currently included in the QDM data elements. Areas for QDM development as informed by the Common Formats and IHE Infusion Pump Event Communication Profile include: event definition, alarm definition, incident definition, processes of care, and circumstances. Further, the concept of e-Iatrogenic harm will become increasingly important to capture and report as more hospitals and providers implement EHRs. Currently the QDM does not have the capabilities to model this type of information, and this would be another area for future QDM development.

Conclusion

The Critical Paths Patient Safety project set out to establish a baseline understanding of current electronic data capture processes and data exchange involving infusion pumps, and to recommend the action steps necessary to advance current capabilities to the desired future state. The environmental

analysis found that while all the study sites gather and analyze data about infusion pump alerts and use data for quality improvement efforts, none are fully electronic.

The TEP's recommendations leverage and build on many existing industry activities. The promotion of a standardized format for data collection, the adoption of interoperability standards, and the utilization of electronic infusion pump data for decision support could greatly advance quality improvement and measurement activities of intravenous infusion therapy using infusion pump medical devices.

Appendix A: Critical Paths Patient Safety Technical Expert Panel

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Rosemary Kennedy, PhD, MBA, RN, FAAN

Vice President, Health Information Technology

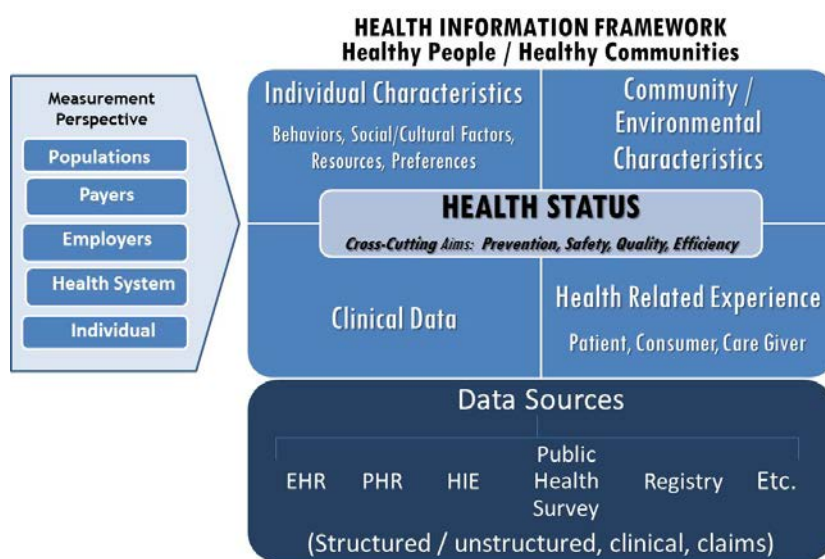
Elizabeth Carey, MPP

Project Manager, Health Information Technology

Appendix B: QDM Health Information Framework

NQF's Health Information Technology Advisory Committee (HITAC) developed a QDM Health Information Framework (see Figure 8) to describe the breadth of information needed to measure health.⁹⁶ The framework was envisioned to assist in the development of the national data platform that would provide the information necessary to support health improvement and measurement efforts. The framework provides the basis for a common model that can be used to describe data that are reusable for different purposes (a model of meaning).⁹⁷ The framework helps to identify the requirements and methods necessary to describe, capture and access reusable data for purposes of quality measurement.

Figure 8: HITAC QDM Health Information Framework



The HITAC QDM Health Information Framework (Framework) incorporates four domains of information that enable a broader reach for data and encourage attention to the entire spectrum of potential data sources: Individual Characteristics (encompassing the Behaviors, Social / Cultural Factors, Preferences, and Personal Resources), Health Related Experience (with the perspectives of patient, consumer, and care giver), Clinical Care Process (including proteomic and genomic data), and Community / Environmental Characteristics. Each of these dimensions has an individual consumer, a population (previously, community), and health system dimension – factors that can be attributed to the individual

⁹⁶ Quality Data Model June 2012 Update, Pre-publication Release.

⁹⁷ A model of meaning represents the underlying meaning in a way that is common to, and reusable between, different use cases. In contrast, a model of use represents the underlying meaning in a way that is determined by a limited set use cases. Excerpted from International Health Terminology Standards Development Organization (IHTSDO) Glossary, January 2012 International Release. Available at: http://www.ihtsdo.org/fileadmin/user_upload/doc/tig/glsct/glsct_ss_ModelOfUse.html#_c0cc3aca-4e72-40ba-af25-116e04a36fad, accessed 25 April 2012.

and factors that are influenced by local community and population demographics. It is likely that any comprehensive measure of health should address each of the dimensions. The information requirements for each dimension are grounded in sources such as EHRs, personal health records (PHRs), HIEs, public health surveys, and other sources.

The Framework is the conceptual platform on which the QDM structure is built. It encompasses data from EHRs and other sources to manage measures of health for populations, health plan members, health system participants (or an individual provider’s panel of patients), employers, or for measures of individual health for consumers. Examples of the many data sources are listed in Figure 2 (EHRs, PHRs, HIEs, public health surveys, and registries), but these are not intended to be exclusive. Information obtained from social media, hand-held and other devices will be increasingly significant for measuring health. The QDM is a model, or a grammar, to describe the information requirements (the model of meaning), based on the Framework, that can encourage innovation in data capture (multiple models of use) to enable easier access to data and an analysis of health. It is based on a patient-centered approach to health with careful attention to outcomes and patient engagement. The Framework is intended to encourage a more data-driven approach to health information applications to allow greater data sharing and transparency of health outcomes through measurement.

Figure 9: Flow of Activities for Critical Paths for Creating Data Platform Project

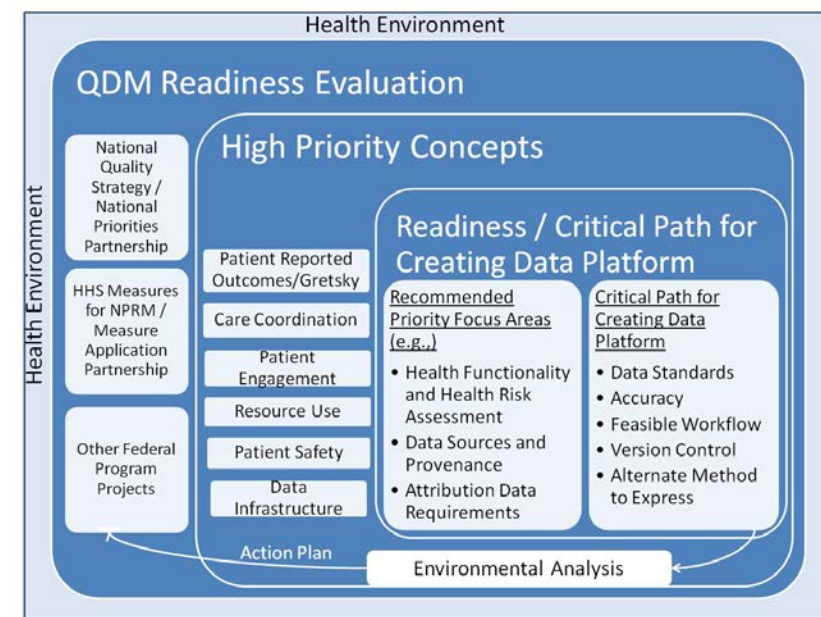


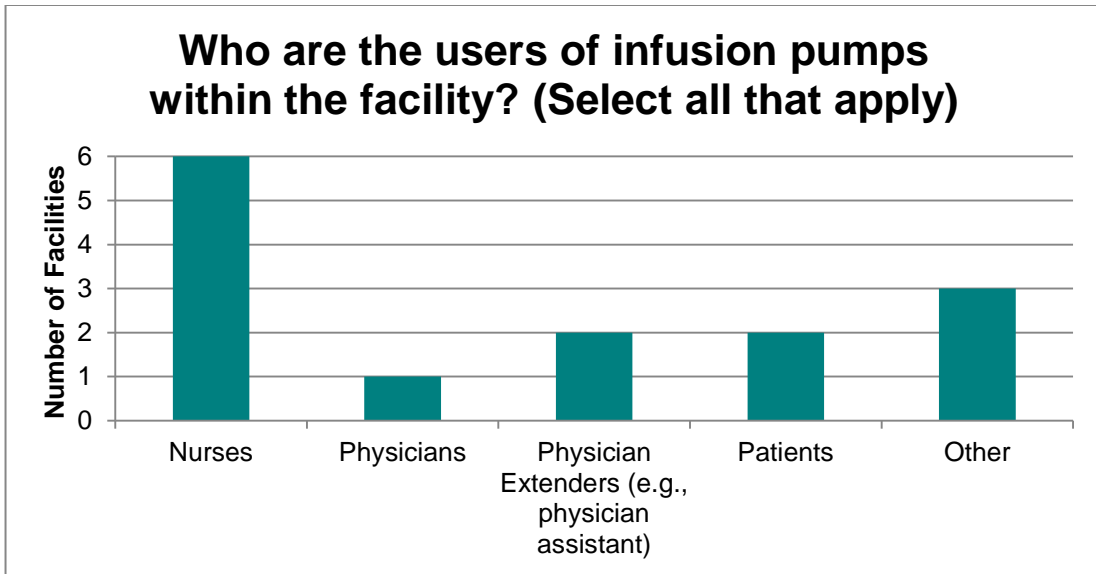
Figure 9 shows some examples of high priority concepts – patient reported outcomes, care coordination, patient engagement, resource use, patient safety, and data infrastructure. This project addresses patient safety, specifically focusing on infusion pump device safety with respect to acute care intravenous infusion therapy.

Appendix C: Survey Responses⁹⁸

Survey Question	Summary of Response
Does the facility have an EHR?	All six facilities have an EHR. Three of the facilities have been certified for meaningful use.
Does the facility have CPOE?	Five of the six facilities have a CPOE system. Four of the facilities have broad adoption of CPOE throughout the facility, while one facility plans for a facility wide expansion this year.
Does the facility have an electronic medication administration system?	All six facilities have an electronic medication administration system.
How many infusion pumps are used within the facility?	The facilities provided answers ranging from 800 smart infusion pumps to 3000 smart infusion pumps. Only two facilities have traditional pumps still in use. One facility has 30 traditional pumps in the NICU, while the other facility has 500 traditional pumps and 3000 smart infusion pumps in use. All of the facilities have implemented dose error software for their smart infusion pumps.
What data are used to track and identify infusion pumps?	Two facilities track pumps through unique identifiers through a wireless network. Two facilities have no system of tracking aside from supplier-generated serial numbers located on the pumps. Two other facilities are using or will soon be using RFID software to track and identify pumps.
In which IT system(s) do infusion pump tracking data reside?	Two facilities store infusion pump tracking data within the EHR. The other four facilities store infusion pump tracking data primarily in the pump vendor's software. One of these facilities has some limited connection to the EHR and event reporting systems.
How do you electronically track for whom each pump is used?	Four facilities require manual entry of the patient ID into the pump system. Two facilities do not track this information. In one of these two facilities, the pump is associated to the medication order but they do not track the data.
Are the data tracked by the infusion pump reconciled against the placed order?	Only two out of six facilities reconcile the data tracked by the infusion pump against the placed order.

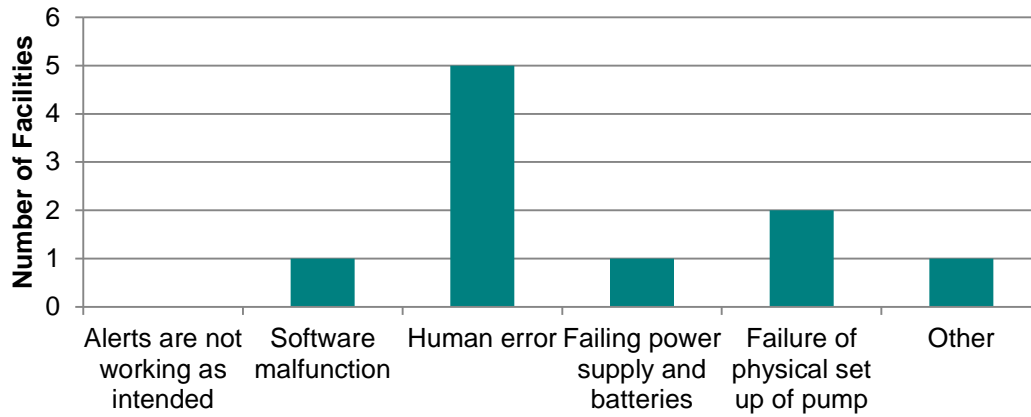
⁹⁸ Survey responses were received from six of the seven hospitals/hospital systems that participated in the environmental scan. The results presented here are from the six survey respondents. Survey information was also gleaned from the pump vendor participants and is incorporated in the narrative of the report.

Survey Question	Summary of Response
What data are captured regarding infusion pump maintenance?	One facility tracks only Continuous Quality Improvement (CQI) I data from its infusion pump. One facility tracks the pump, serial and model number and any maintenance work performed. Another facility tracks which version of the software the pump is using. Another facility tracks the preventative maintenance data. Two facilities provided no answers.
In which IT system(s) do infusion pump maintenance data reside?	The answers received were: vendor software (3), bio department software (2), and engineering department software (1).
What department is responsible and accountable for infusion pump management?	The answers received were: biomedical engineering for hardware, pharmacy for medication safety integration, nursing for library management, and materials management.
Are other IV supplies (e.g., IV fluid bags, tubing, ports) tracked and inventoried?	50% of the facilities answered no, and 50% of the facilities answered yes.
What data are captured to track other IV supplies?	Of the hospitals that track data for other IV supplies the answers were: inventory system, drip rate medications, and IV supply charges.
In which IT system(s) are tracking data for other IV supplies stored?	The hospitals that track other IV supplies store data in the EHR systems.
How do you identify which catheter (as a device) is used for which port?	Two facilities responded that they document this information in the EHR. One facility has no systemic approach, while another only tracks live catheters unrelated to the pump.
What data and messaging standards are used with the infusion pumps back to the EHR or other IT systems?	One facility uses an IHE specific interface. One facility uses XML. The remaining four facilities did not report having an interface between the infusion pump and the EHR.
Are the users of specific pumps (e.g., the nurses) tracked electronically?	Only one facility tracks the users of the specific pumps electronically and stores that data within the EHR. One facility can identify the nurse who initiated the IV administration but cannot track adjustments made outside the EHR.
Are the patients tracked electronically?	Only two facilities track patients electronically through the EHR system.



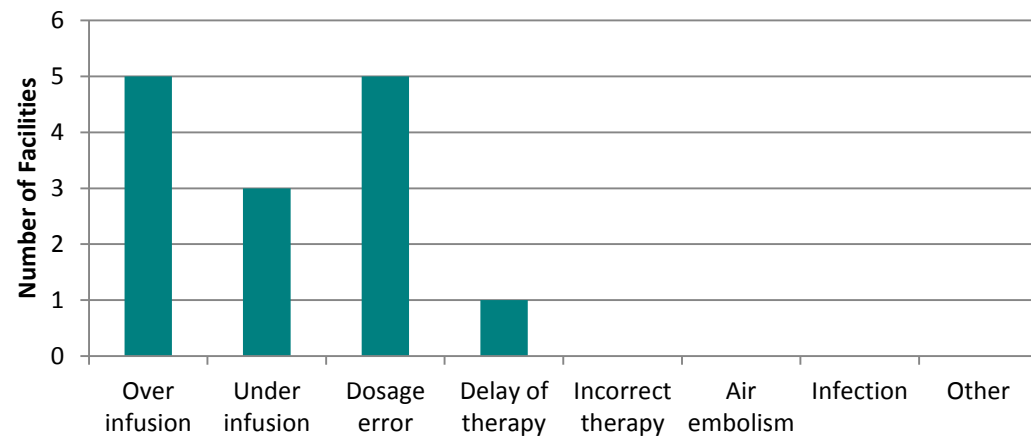
“Other” responses included: technicians licensed to administer meds (primarily cardiology technicians); anesthesiologists; anesthesia fellows; CRNA’s; licensed practical nurses; nuclear medicine technologists; respiratory therapists; pharmacists.

What are the three most frequent infusion pump failures or human errors that lead to adverse events?



“Human error” answers include: users circumventing or overriding warnings; incorrect programming; and, inability to verify the correct patient ID is entered into the pump. “Other” answers include: that smart infusion pumps are newly implemented and reliable event reporting data is not yet available.

What are the three most frequent outcomes of the adverse events?



Appendix D: Research Questions

Research Questions
<p>What brands of infusion pumps are currently in use at the facility?</p> <p>Are infusion pumps tracked and identified? If so, how?</p> <p>How many devices, types, and categories are used within the facility?</p> <p>What department is responsible and accountable for infusion pump management?</p> <p>Are other IV supplies (e.g., IV fluid bags, tubing) tracked and inventoried? If so, how?</p> <p>What data and messaging standards are used?</p> <p>For each brand, do the infusion pumps have alerts/alarms? If so, what activity activates an alert/alarm?</p> <p>Are there over-ride processes for alerts/alarms? If so, how are over-rides tracked?</p> <p>Who are the users of infusion pumps within the facility?</p>
<p>What types of adverse events are associated with infusion pumps?</p> <p>What are reasons for device failures?</p> <p>What types of failures occur?</p> <p>What types of patient safety measures related to infusion pumps would be important?</p> <p>Are any infusion pump safety measure concepts under development?</p>
<p>What types of data are gathered today to track adverse events and report quality related to infusion pumps?</p> <p>What types of data are transmitted and stored between the infusion pump, the electronic health record, and quality reporting solutions?</p> <p>What are the point-of-care processes related to data capture and documentation of infusion pump use?</p> <p>How are data currently captured used in care delivery, safety and quality reporting, and adverse event tracking?</p> <p>What data are available to be transmitted automatically from the infusion pump to other systems that include clinical data?</p> <p>What are existing examples of interoperability between electronic systems that enable safety and quality reporting?</p> <p>What value sets are needed in electronic systems to support infusion pump safety and quality measurement?</p>

Appendix E: Discussion Guide

Discussion Guide for Providers

ORGANIZATION INFORMATION _____	
Interviewee Name:	Title:
Primary Phone Number:	Email:
<hr/>	
DISCUSSION INFORMATION	
Date:	Time:

Booz Allen Hamilton is currently working with the National Quality Forum, to learn more about medical device safety, specifically the current electronic data capture processes involving infusion pumps. This work is part of NQFs “Critical Paths for Creating Data Platforms” project, set of initiatives around assessing electronic data readiness for quality and safety measurement and considering next steps to advance use of electronic data for quality and safety measurement. This particular initiative is focused on measuring and advancing infusion pump safety. Over the course of this interview, we will seek to understand common areas of adverse events related to infusion pumps (either due to human error or pump failure) and opportunities for infusion pump safety measurement, the current status of electronic data and data exchange in monitoring infusion pump safety, and ideas for where additional electronic data and data exchange could improve infusion pump safety measurement. The results of this and other interviews will be presented to NQF as a white paper that will be published for public comment later this summer. The white paper will also inform NQFs ongoing work on creating data platforms for infusion pump safety measurement and improvement.

Patient Safety Measurement

1. What types of patient safety measures related to infusion pumps would be important to address gaps in care, decrease adverse events and facilitate quality improvement?
2. Are you aware of any infusion pump safety measure concepts under development?

Device Use Characteristics

3. What types of systems that store electronic information about infusion pumps are used within the facility?
4. What types of data are transmitted and stored between the infusion pump, the electronic health record, and quality reporting systems?

5. What types of electronic data do you capture today to track adverse events and quality related to infusion pumps? How are those data used for adverse event tracking and quality reporting?
6. What data /value sets are needed in electronic systems to support infusion pump safety and quality measurement? What data are important to collect in order to have an effective quality reporting and improvement system?
7. What are the point-of-care processes for data capture and documentation of infusion pump use?
 - a. When the infusion pump is programmed?
 - b. When the IV bag is hung?
 - c. When the IV tubing and/or connector are engaged?
 - d. When IV is inserted into patient?
8. How are data that are currently captured used in care delivery?
9. How are alarm over-rides tracked? Are any data captured electronically when something is overridden? If so, what data?
10. Are any data captured electronically about infusion pump alarms? If so, what data?
11. If alert/alarm data are tracked electronically, are the data sent / shared with any other systems?
12. What data are available to be transmitted automatically from the infusion pump to other systems (to the pharmacy, to the EHR) that include clinical data, (e.g. patient name; dosage and frequency of administration programmed; amount actually administered)?
13. What are existing examples of interoperability between infusion pump systems that enable safety and quality reporting? What communication occurs between the infusion pump device and a hospital information management system or another device?

Discussion Guide for Suppliers

ORGANIZATION INFORMATION _____	
Interviewee Name:	Title:
Primary Phone Number:	Email:
<hr/>	
DISCUSSION INFORMATION	
Date:	Time:

Booz Allen Hamilton is currently working with the National Quality Forum, to learn more about medical device safety, specifically the current electronic data capture processes involving infusion pumps. This work is part of NQFs “Critical Paths for Creating Data Platforms” project, set of initiatives around assessing electronic data readiness for quality and safety measurement and considering next steps to advance use of electronic data for quality and safety measurement. This particular initiative is focused on measuring and advancing infusion pump safety. Over the course of this interview, we will seek to understand common areas of adverse events related to infusion pumps (either due to human error or pump failure) and opportunities for infusion pump safety measurement, the current status of electronic data and data exchange in monitoring infusion pump safety, and ideas for where additional electronic data and data exchange could improve infusion pump safety measurement. The results of this and other interviews will be presented to NQF as a white paper that will be published for public comment later this summer. The white paper will also inform NQFs ongoing work on creating data platforms for infusion pump safety measurement and improvement.

Patient Safety Measurement

1. What types of patient safety measures related to infusion pumps would be important to address gaps in care, decrease adverse events and facilitate quality improvement?
2. Are you aware of any infusion pump safety measure concepts under development?

Device Use Characteristics

3. In your experience with your customers, what types of systems that store electronic information about infusion pumps are used within the facilities?
4. What types of interoperability exists between your infusion pump products and the electronic health record or other hospital systems?
5. Based on your experience with your customers, what types of electronic data are captured today to track adverse events and quality related to infusion pumps? How are those data

used for adverse event tracking and quality reporting? What percent of those data are routinely present in the EHR?

6. From your experience with your customers and your own experience, what data /value sets are needed in electronic systems to support infusion pump safety and quality measurement? What data are important to collect in order to have an effective quality reporting and improvement system?
7. What are your customer's point-of-care processes for data capture and documentation of infusion pump use?
 - a. When infusion pump is programmed?
 - b. When IV bag is hung?
 - c. When the IV tubing and/or connector are engaged?
 - d. When IV is inserted into patient?

For example, what data are captured and documented regarding the 5 Rights of medication administration, as the IV is prepared, the pump is programmed, etc.

8. How are data that are currently captured used in care delivery from your experience with your clients?
9. Is there a procedure for tracking alarm over-rides and are any data captured electronically when something is overridden? If so, what data?
10. Are your products designed to have any data received/captured electronically regarding alarms? If so, how and what specific data? Are those data shared with other systems?
11. What data are available to be transmitted automatically from infusion pump products to other systems (e.g., to the pharmacy, to the EHR) that include clinical data, (e.g. patient name; dosage and frequency of administration programmed; amount actually administered)?
12. In your experience, what are existing examples of interoperability between infusion pump systems that enable safety and quality reporting? What communication occurs between the infusion pump device and a hospital information management system or another device?
13. What, if any, enhancements are you working on to expand interoperability with EHRs or other hospital systems?

Appendix F: Survey

Provider Survey

Organization Information

1. Facility size (# of beds)
2. Does the facility have an EHR? If so, is it certified for Meaningful Use?
3. Does the facility have CPOE? If so, in how many units?
4. Does the facility have an electronic medication administration system?
5. How many infusion pumps are used within the facility?
 - a. Traditional
 - b. Smart infusion pumps
6. For the smart infusion pumps, has dose error software been implemented?
7. Who are the users of infusion pumps within the facility? (Select all that apply)
 - a. Nurses
 - b. Physicians
 - c. Physician extenders (e.g., physician assistant)
 - d. Patients (e.g., self-administered analgesia)
 - e. Other – please describe

Infusion Pump Safety Information

8. What are the three most frequent infusion pump failures or human errors that lead to adverse events?
 - a. Alerts are not working as intended
 - b. Software malfunction
 - c. Human error – please describe
 - d. Failing power supply and batteries
 - e. Failure of physical set up of pump (e.g., tubing routed incorrectly; clamps not opened)
 - f. Other – please describe
9. What are the three most frequent outcomes of the adverse events?
 - a. Over infusion
 - b. Under infusion
 - c. Dosage error
 - d. Delay of therapy
 - e. Incorrect therapy
 - f. Air embolism
 - g. Infection
 - h. Other – please describe

Infusion Pump Data Capture

10. What brands of infusion pumps are currently in use at the facility?
11. What data are used to track and identify infusion pumps?
12. In which IT system(s) do infusion pump tracking data reside?
13. How do you identify for whom each pump is used?
14. Are the data tracked by the infusion pump reconciled against the placed order?
15. What data are captured regarding infusion pump maintenance?
16. In which IT system(s) do infusion pump maintenance data reside?
17. What department is responsible and accountable for infusion pump management?
18. Are other IV supplies (e.g., IV fluid bags, tubing, ports) tracked and inventoried?
19. What data are captured to track other IV supplies?
20. Where are tracking data for other IV supplies stored?
21. How do you identify which catheter (as a device) is used for which port?
22. In which IT systems are data stored regarding which catheter is used for which port?
23. What data and messaging standards are used with the infusion pumps back to the HER or other IT systems?
24. Are the users of specific pumps (e.g. the nurses) and the patients tracked electronically? If so, is that information sent to any IT systems within the facility? If so, which system(s)?

Survey for suppliers

Organization Information

1. Are your products interoperable with:
 - a. EHRs?
 - b. CPOE systems?
 - c. Pharmacy systems?
 - d. ADT systems?
 - e. Other hospital systems – please describe
2. What type of interface and what type of standard is available with your products (i.e., HL7, version 2, 3)
3. Do your smart infusion pumps products include dose error software?
4. How many hospitals do you serve?
5. How many hospitals use interfaces to exchange data between the infusion pump and other systems (CPOE, etc.)?

Infusion Pump Data

6. What tracking and identification methods do your products include:
 - a. UDI
 - b. GTIN
 - c. HibCC
 - d. RFID
 - e. Other – please describe
7. From your interaction with your customers,
 - a. In which IT system(s) do infusion pump tracking data reside?
 - b. What information about infusion pump maintenance is automatically captured by the pump?
 - c. What information is entered directly into the pump by users to enable tracking of maintenance?
 - d. In which IT system(s) do infusion pump maintenance data reside?
 - e. What department is primarily responsible and accountable for infusion pump management?
 - f. Are other IV supplies (e.g., IV fluid bags, tubing) tracked and identified (e.g., UDI, GTIN, or HibCC, RFID)? If so, what are the identification methods?
 - g. In which IT system(s) are tracking data on IV supplies captured?
8. Given your experience with your customers, who are the users of infusion pumps within the facility? (Select all that apply)
 - a. Nurses
 - b. Physicians
 - c. Physician extenders (e.g., nurse practitioners)

- d. Patients (e.g., self-administered analgesia)
 - e. Other – please describe
9. Are the users of specific pumps (e.g. the nurses) and the patients tracked electronically? If so, is that information sent to any systems within the facility? If so, which system(s)?

Patient Safety Information

10. Which are the three most frequent device failures or human errors that lead to adverse events?
- a. Alerts are not working as intended
 - b. Software malfunction
 - c. Human error – please describe
 - d. Failing power supply and batteries
 - e. Failure of physical set up of pump (e.g., tubing routed incorrectly; clamps not opened)
 - f. Other – please describe
11. What are the three most frequent outcomes of the adverse events?
- a. Over infusion
 - b. Under infusion
 - c. Dosage error
 - d. Delay of therapy
 - e. Incorrect therapy
 - f. Air embolism
 - g. Infection
 - h. Other – please describe

Appendix G: Infusion System Data Elements by QDM categories

TEP Data Required	QDM Elements (from Update June 2012)	Feasibility of specified QDM elements in currently implemented EHRs	Areas of Measurement
1. IV Fluid bag			
1. IV Bag UDI	Category: Device State: Applied, Ordered Attributes:	Yes but unsure if IV bag UDI information will be available	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
2. Contents a. Fluid i. Lot number ii. Expiration date b. Medication i. Lot number ii. Expiration date	Category: Medication, Substance State: Ordered, Administered Attributes: Dosage, Infusion Duration, Route	Yes (infusion duration may take additional work)	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
3. Ordinality: Bag order (1 st , 2 nd ,)	Category: Device, Medication, Substance, State: Applied, Ordered, Administered, Calculated, Attributes: Dosage, Infusion Duration, Reason, Route, Status	Yes (infusion duration, reason and status may take additional work)	Timeliness of drug administration Compliance with use of pump data gathering and/or safety features Rates of averted adverse events
4. Infusion rate setting	Category: Medication, Substance, States: Ordered, Administered, Calculated, Attributes: Actor, Dosage, Infusion Duration, Reason, Route	Yes (infusion duration, reason may take additional work)	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

TEP Data Required	QDM Elements (from Update June 2012)	Feasibility of specified QDM elements in currently implemented EHRs	Areas of Measurement
5. Order workflow status (administered, etc.)	Category: Device, Medication, Substance, State: Applied, Ordered, Administered, Calculated, Dispensed Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status	Yes (infusion duration, reason and status may take additional work)	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
6. Start-Stop date and time (Contents infused time: time bag is hung and taken down)	Category: Medication, Substance, State: Ordered, Administered, Calculated, Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status	Yes (infusion duration, reason and status may take additional work)	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
7. Rate, volume infused recorded a. Input/ Output record b. Medication administration record	Category: Health Record component, Medication, Substance, State: Documented, Ordered, Administered, Calculated, Reconciled Attributes: Actor, Dosage, Infusion Duration, Reason, Route, Status	Yes (infusion duration, reason and status may take additional work)	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
2. IV pole			
1. Cleaning date / time (frequency)	Category: System Resources (possible) State: Documented, transmitted Attribute:	Unsure: would have to be inter-operable with RFID tracking system or some other equipment management system	

TEP Data Required	QDM Elements (from Update June 2012)	Feasibility of specified QDM elements in currently implemented EHRs	Areas of Measurement
2. Cleaning method	Category: System Resources (possible) State: Documented, transmitted Attribute:	Unsure: would have to be inter-operable with RFID tracking system or some other equipment management system	
3. Location of IV pole 'home'	Category: Device, System Resources States: Applied, Ordered, Documented, Transmitted Attributes: Infusion Duration, Route, <i>environmental location, facility location*</i>	Unsure: would have to be inter-operable with RFID tracking system or some other equipment management system	
4. IV Pole Identifier	Category: Device, System Resources State: Applied, Ordered Attribute: Infusion Duration, Route	Unsure: would have to be inter-operable with RFID tracking system or some other equipment management system	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
5. IV Pole Location of Use	Category: Device, System Resources State: Applied, Ordered Attributes: Infusion Duration, Route, <i>environmental location, facility location*</i>	Unsure: would have to be inter-operable with RFID tracking system or some other equipment management system	
6. Patient to which IV Pole is assigned	Category: Device, System Resources State: Applied, Ordered Attribute: Infusion Duration, Route	Unsure: would have to be inter-operable with RFID tracking system or some other equipment management system	
7. Pump to which IV Pole is assigned	Category: System resources State: Documented, Transmitted Attribute:	Unsure: would have to be inter-operable with RFID tracking system or some other equipment management system	

TEP Data Required	QDM Elements (from Update June 2012)	Feasibility of specified QDM elements in currently implemented EHRs	Areas of Measurement
8. IV pole use locations	Category: Device, system resources State: Applied, Ordered, Documented, Transmitted Attribute: Infusion Duration, Route, <i>environmental location, facility location*</i>	Unsure: would have to be inter-operable with RFID tracking system or some other equipment management system	
3. Infusion Pump			
1. Pump UDI	Category: Device State: Applied, Ordered Attribute: Infusion Duration, Route	Unsure: would have to be inter-operable with RFID tracking system or some other equipment management system	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
2. Add-on pumps	Category: Device State: Applied, Ordered Attribute: Infusion Duration, Route	Unsure: would have to be inter-operable with RFID tracking system or some other equipment management system	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
3. Data that the pump has access to (either in cassette or through interface to EHR)	Category: System Resources State: Documented, Transmitted Attribute:	Unsure: would have to be inter-operable with RFID tracking system or some other equipment management system	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

TEP Data Required	QDM Elements (from Update June 2012)	Feasibility of specified QDM elements in currently implemented EHRs	Areas of Measurement
4. Pump Activity a. Start / stop b. Adjustments	Category: Device State: Applied, Ordered Attribute: Infusion Duration, Route	Yes	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
5. Rate of infusion	Category: Device, Medication, Substance, State: Applied, Ordered, Administered, Calculated, Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status	Yes (infusion duration, reason and status may take additional work)	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
6. Initial rate	Category: Device, Medication, Substance, State: Applied, Ordered, Administered, Calculated, Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status	Yes (infusion duration, reason and status may take additional work)	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
7. Thresholds (within limits / out of limits)	Category: Device, Medication, Substance, State: Applied, Ordered, Administered, Calculated, Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status	Yes (infusion duration, reason and status may take additional work)	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

TEP Data Required	QDM Elements (from Update June 2012)	Feasibility of specified QDM elements in currently implemented EHRs	Areas of Measurement
8. Over-ride	Category: Device, Medication, Substance, State: Applied, Ordered, Administered, Calculated, Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status	Yes (infusion duration, reason and status may take additional work)	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
9. Rate changes (increase / decrease) and violation of pre-prescribed limits	Category: Device, Medication, Substance, State: Applied, Ordered, Administered, Calculated, Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status	Yes (infusion duration, reason and status may take additional work)	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
10. Alarm / Alert Data a. Activate b. Terminate c. Over-ride d. Alert timing e. Alert Notification f. Alert data storage g. Fixed alerts h. Overridden alerts	Category: Device, Medication, Substance, State: Applied, Ordered, Administered, Calculated, Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status	Yes (infusion duration, reason and status may take additional work)	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

TEP Data Required	QDM Elements (from Update June 2012)	Feasibility of specified QDM elements in currently implemented EHRs	Areas of Measurement
11. Patient data and documentation in EHR	Category: Health Record component, Device, Medication, Substance, State: Applied, Administered, Calculated, Documented, Ordered, Reconciled Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status	Yes (infusion duration, reason and status may take additional work)	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
4. IV tubing			
1. Tubing UDI	Category: Health Record component, Medication, Substance, State: Documented, Ordered, Administered, Calculated, Reconciled Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status		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
2. Tubing and pump match documentation	Category: Health Record component, Medication, Substance, State: Documented, Ordered, Administered, Calculated, Reconciled Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status		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
3. Tubing data (date hung, etc.)	Category: Health Record component, Medication, Substance, State: Documented, Ordered, Administered, Calculated, Reconciled Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status		

TEP Data Required	QDM Elements (from Update June 2012)	Feasibility of specified QDM elements in currently implemented EHRs	Areas of Measurement
4. Type of tubing	Category: Health Record component, Medication, Substance, State: Documented, Ordered, Administered, Calculated, Reconciled Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status		
5. Connection data	Category: Health Record component, Medication, Substance, State: Documented, Ordered, Administered, Calculated, Reconciled Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status		
6. Medication/solution going through tubing – this is important for bolus doses administered outside the infusion pump	Category: Medication, Substance State: Administered Attribute: Route	Yes (infusion duration, reason and status may take additional work)	
5. IV connector			
1. Connector Type	Category: Health Record component, Medication, Substance, State: Documented, Ordered, Administered, Calculated, Reconciled Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status		
2. Connector UDI	Category: Device States: Applied, Ordered Attribute: Anatomical Structure, Dosage, Infusion Duration, Laterality, Route		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

TEP Data Required	QDM Elements (from Update June 2012)	Feasibility of specified QDM elements in currently implemented EHRs	Areas of Measurement
3. Port use and tracking use	Category: Health Record component, Medication, Substance, State: Documented, Ordered, Administered, Calculated, Reconciled Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status		
4. Cultures	Category: Lab test State: Ordered, Performed Attribute:		
6. IV infusion port/line			
1. Port UDI for device	Category: Device State: Ordered, Applied		
2. Port ID (with respect to the patient)	Category: Device State: Ordered, Applied		
3. Access date/time	Category: Health Record component, Medication, Substance, State: Documented, Ordered, Administered, Calculated, Reconciled Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status	Yes (infusion duration, reason and status may take additional work)	
4. Responsible party a. Inserting party b. Managing party	Category: Procedure State: Performed Attribute: Performer	Yes (performer may take additional work)	
5. Insertion date and time	Category: Procedure State: Performed Attribute: Performer, start datetime	Yes (performer may take additional work)	
6. Removal date and time	Category: Procedure State: Performed Attribute: Performer, stop datetime	Yes (performer may take additional work)	
7. Outcomes	Category: Care Goal	No	

TEP Data Required	QDM Elements (from Update June 2012)	Feasibility of specified QDM elements in currently implemented EHRs	Areas of Measurement
8. Fluid flush	Category: Health Record component, Medication, Substance, State: Documented, Ordered, Administered, Calculated, Reconciled Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status	Yes (infusion duration, reason and status may take additional work)	
9. Bolus Medication(s)	Category: Medication, Substance State: Administered	Yes	
10. Location	Category: Health Record component, Medication, Substance, State: Documented, Ordered, Administered, Calculated, Reconciled Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status Attribute:	Yes (infusion duration, reason and status may take additional work)	
11. Skin documentation	Category: Health Record component, State: Documented Attribute: Value Set: Skin documentation	Unsure	
12. catheter type	Category: Procedure State: Performed Value set: catheter type (ex. Peripheral, PICC, Central, Port)	Yes	
13. Catheter placement issues: a. # of insertion attempts b. # of lines	Category: State: Attribute:		
7. EHR			

TEP Data Required	QDM Elements (from Update June 2012)	Feasibility of specified QDM elements in currently implemented EHRs	Areas of Measurement
1. eMAR (medication administration record)	Category: Health Record component, Medication, Substance, State: Documented, Ordered, Administered, Calculated, Reconciled Attribute: Actor, Dosage, Infusion Duration, Reason, Route, Status	Yes (infusion duration, reason and status may take additional work)	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
2. Intake / Output record	Category: Health Record component, State: Documented Attribute: Value Set: I & O	Unsure	
3. IV record	Category: Health Record component, Medication State: Documented, Administered Attribute: Route Value Set: I & O	Unsure	
4. Site assessment	Category: Health Record component, State: Documented Attribute: Value Set: Skin documentation	Unsure	
5. Problems/ diagnoses	Category: Condition/ DX/ Problem State: Active, Inactive	Yes	
6. Orders, procedures	Category: Procedure State: Performed	Yes	
7. Labs – cultures	Category: Laboratory Test State: Performed, Ordered	Yes	
8. Supplies charge	Category: System Resources State: Documented Attribute:	No	
9. X-ray placement validation	Category: Diagnostic Study State: Performed Attribute:	Yes	

TEP Data Required	QDM Elements (from Update June 2012)	Feasibility of specified QDM elements in currently implemented EHRs	Areas of Measurement
10. Orders (prescriptions) linked to emerging infections (medications, including antibiotics)	Category: Medication, Laboratory Test State: Ordered, Administered Attribute:	Yes	

Appendix H: Sources List

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Appendix I. Glossary of Terms

<u>TERM</u>	<u>DEFINITION</u>
AAMI	Association for the Advancement of Medical Instrumentation
Acute Care	Providing or concerned with short-term medical care especially for serious acute disease or trauma. ⁹⁹
Adverse Drug Event (ADE)	An injury resulting from medication use
ASTER	Adverse Spontaneous Triggered Event Reporting
Alarm	Notification of an event that is not anticipated ¹⁰⁰
ACM	Alarm Communication Management
Alert	Programmed notification that occurs at specific points, such as the end of a programmed infusion ¹⁰¹
Bi-directional interface	Software that joins two different information systems
Bolus dosing	A single dose of a drug or other substance given over a short period of time. It is usually given by infusion or injection into a blood vessel. ¹⁰²
Catheter	A tubular medical device for insertion into canals, vessels, passageways, or body cavities usually to permit injection or withdrawal of fluids or to keep a passage open. ¹⁰³
CDISC	Clinical Data Interchange Standards Consortium
CDRH	Center for Devices and Radiological Health
Central Line	Intravascular catheters that terminate at or close to the heart or in one of the great vessels which is used for infusion, withdrawal of blood, or hemodynamic monitoring.
Central Line Bundle	A group of best practices including: hand hygiene, maximal barrier precautions, use of chlorhexidine as a skin antiseptic, optimal catheter site selection (i.e., avoidance of the femoral vein for central venous access), and daily assessment of line necessity with prompt removal of central lines when indicated. ¹⁰⁴

⁹⁹ Merriam-Webster. Available from: <http://www.merriam-webster.com/medical/acute%20care>.

¹⁰⁰ Care Fusion. Safety and Clinical Excellence. Perspectives. Available from: http://www.carefusion.com/safety-clinical-excellence/perspectives/medication_management.aspx

¹⁰¹ Ibid.

¹⁰² NCI Dictionary of Cancer Terms. Bolus dose definition. Available from: <http://www.cancer.gov/dictionary?cdrid=45620>.

¹⁰³ Merriam-Webster Online Dictionary. Catheters. Available from: <http://www.merriam-webster.com/dictionary/catheters>.

¹⁰⁴ Gabay M. Prevention of central-line associated bloodstream infections: central line bundles. Available from: http://www.proce.com/Prevention_of_CLABIs_Central_line_bundles.html.

<u>TERM</u>	<u>DEFINITION</u>
Central Line Insertion Checklist	A list that helps to ensure that all processes related to central line placement are executed for each line placement, thereby leading to a reliable process. This checklist includes a list of activities that are considered standard work before, during, and after the procedure, as well as a safety checklist. ¹⁰⁵
Central Line Associated Blood Stream Infections (CLABSIs)	A healthcare-associated primary bloodstream infection (BSI) in a patient that had a central line within the 48-hour period before the development of the BSI and that is not related to an infection at another site. NOTE: There is no minimum period of time that the central line must be in place in order for the BSI to be considered central line-associated. ¹⁰⁶
Clinical decision support (CDS)	A process for enhancing health-related decisions and actions with pertinent, organized clinical knowledge and patient information to improve health and healthcare delivery. The information delivered can include general clinical knowledge and guidance, intelligently processed patient data, or a mixture of both. Information delivery formats can include data and order entry facilitators, filtered data displays, reference information, alerts, and others. ¹⁰⁷
Common Formats	Common definitions and reporting formats that allow healthcare providers to collect and submit standardized information regarding patient safety events.
Connectathon	A weeklong interoperability-testing event. ¹⁰⁸
CPOE	Computerized Physician Order Entry
Critical Path	An algorithm for scheduling a set of project activities. It is an important tool for effective project management. ¹⁰⁹
Data Capture	Collecting and entering data in a computer, or the conversion of data into a form compatible with computers
Data Element	The atomic unit of data for which the definition, identification, representation and permissible values are specified by a set of attributes, or metadata. ¹¹⁰

¹⁰⁵ Institute for Healthcare Improvement. Central Line Insertion Checklist. Available at: <http://www.ihc.org/knowledge/Pages/Tools/CentralLineInsertionChecklist.aspx>

¹⁰⁶ Centers for Disease Control and Prevention. The National Healthcare Safety Network (NHSN) Manual: Patient Safety Component Protocol; 2012. Available from: http://www.cdc.gov/nhsn/PDFs/pscManual/16pscKeyTerms_current.pdf.

¹⁰⁷ Improving outcomes with clinical decision support: an implementer's guide. Second Edition. HIMSS. 2011 (in press). Available from: http://www.himss.org/asp/topics_clinicaldecision.asp.

¹⁰⁸ Connectathon. Available at: <http://www.ihe.net/connectathon/>.

¹⁰⁹ Kelley, J. Critical Path Planning and Scheduling: Mathematical Basis. Operations Research, Vol. 9, No. 3, May–June, 1961. Wikipedia. Available from: http://en.wikipedia.org/wiki/Critical_path_method.

<u>TERM</u>	<u>DEFINITION</u>
Data exchange	The process of sending and receiving data in such a manner that the information content or meaning assigned to the data is not altered during the transmission
Data Element Feasibility	The likelihood that data elements are available and a significant number of organizations can capture and access the data element in a consistent manner.
Data Infrastructure	Technology, processes, tools, and standards needed to promote data sharing and consumption
DEC	Device Enterprise Communication
DEC-PIB	Device Enterprise Communication Patient Identity Binding
DEC-SPD	Device Enterprise Communication Subscribe to Patient Data
Drug library	Database on drug dosing, drug interactions, and other clinical advisories
Electronic Health Record (EHR)	A longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. The EHR automates and streamlines the clinician's workflow. The EHR has the ability to generate a complete record of a clinical patient encounter - as well as supporting other care-related activities directly or indirectly via interface - including evidence-based decision support, quality management, and outcomes reporting. ¹¹¹
eMAR	Electronic Medication Administration Record
Electronic Measure (eMeasure)	Standardized performance measures in an electronic format ¹¹²
Extrinsic factors	Modifiable factors associated with central line insertion or maintenance or the patient care environment.
FDA	Federal Drug Administration
GMDN	Global Medical Device Nomenclature
Health Information Exchange (HIE)	A term used to describe both the sharing of health information electronically among two or more entities and also an organization which provides services that enable the sharing electronically of health information. ¹¹³

¹¹⁰ International Standards Organization. Information technology – Metadata registries (MDR) – Part 3: Registry metamodel and basic attributes. ISO/IEC 11179-3:2003(E). 2003. [3.3.36] Available from: <http://standards.iso.org/ittf/PubliclyAvailableStandards/index.html>. Accessed July 17, 2012.

¹¹¹ HIMSS EHR Definition. Available from: http://www.himss.org/asp/topics_ehr.asp.

¹¹² National Quality Forum. Electronic Quality Measures (eMeasures). Available from: http://www.qualityforum.org/Projects/e-g/eMeasures/Electronic_Quality_Measures.aspx

¹¹³ HIMSS Health Information Exchange Steering Committee August 2009. Overview of Health Information Exchange (HIE). Available from: http://www.himss.org/content/files/RHIO/RHIO_HIE_GeneralPresentation.pdf.

<u>TERM</u>	<u>DEFINITION</u>
Healthcare Quality Measure Format (HQMF)	A standard for representing a health quality measure as an electronic document.
Health Level 7 (HL7)	A not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. ¹¹⁴
HTSI	Healthcare Technology Safety Institute
Human factors	The study of how people use technology. It involves the interaction of human abilities, expectations, and limitations, with work environments and system design. ¹¹⁵
Infusion Pumps	Medical devices that deliver fluids, including medications and nutrients into a patient's body in a controlled manner
ICPS	International Classification for Patient Safety
IHE	Integrating the Healthcare Enterprise
IHE-PCD	Integrating the Healthcare Enterprise-Patient Care Device Domain
IHI	Institute for Healthcare Improvement
IHTSDO	International Health Terminology Standards Development Organization
Infection Control	Policies and procedures used to minimize the risk of spreading infections
Infusion Therapy	The administration of medication through a needle or catheter. It is prescribed when a patient's condition is so severe that it cannot be treated effectively by oral medications. Typically, "infusion therapy" means that a drug is administered intravenously, but the term also may refer to situations where drugs are provided through other non-oral routes, such as intramuscular injections and epidural routes. ¹¹⁶
Interoperability	The ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities. ¹¹⁷
Intrinsic factors	Non-Modifiable Patient Characteristics

¹¹⁴ HL7 International. About HL7. Available from: <http://www.hl7.org/about/index.cfm?ref=nav>.

¹¹⁵ US Food and Drug Administration (FDA). Medical Devices Glossary. Available from: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202502.htm>.

¹¹⁶ National Home Infusion Association. Infusion FAQs. Available from: <http://www.nhia.org/faqs.cfm#faq1>.

¹¹⁷ HIMSS. Interoperability Definition and Background. Available from: http://www.himss.org/content/files/interoperability_definition_background_060905.pdf.

<u>TERM</u>	<u>DEFINITION</u>
ISO	International Standards Organization
IV	Intravenous
IV Piggyback	A secondary IV solution that is given on top of the main IV solution, typically hung higher than the main IV solution, and connected to a port in the main tubing
Medical Administration Record (MAR)	The report that serves as a legal record of the drugs administered to a patient at a facility by a health care professional. The MAR is a part of a patient's permanent record in their medical chart. ¹¹⁸
MDEpiNet	The Medical Device Epidemiology Network Initiative
Meaningful Use	The American Recovery and Reinvestment Act of 2009 authorizes the Centers for Medicare & Medicaid Services (CMS) to provide incentive payments to eligible professionals (EPs) and hospitals who adopt, implement, upgrade, or demonstrate meaningful use of certified electronic health record (EHR) technology. ¹¹⁹
Medication Errors	An error occurring in the medication–use process and can occur at any stage in the medication use process, including prescribing, transcribing, dispensing, administering, or monitoring. Not all medication errors have the potential to harm a patient. ¹²⁰
Metadata	Data that provides information about other data. ¹²¹
National Healthcare Safety Network (NHSN) System	A secure, internet-based surveillance system that integrates and expands legacy patient and healthcare personnel safety surveillance systems managed by the CDC. ¹²²
NQF	National Quality Forum
NPSD	Network of Patient Safety Databases
NQF-endorsed measures	Standards that are evaluated through the Consensus Development Process for measuring and publicly reporting on the performance of different aspects of the healthcare system. Standards endorsed by NQF are widely viewed as the "gold standard" for the measurement of healthcare quality. ¹²³
NQS	National Quality Strategy

¹¹⁸ Wikipedia. Medication Administration Record. Available from:

http://en.wikipedia.org/wiki/Medication_Administration_Record.

¹¹⁹ HealthIT.Gov. EHR Incentives & Certification. What is Meaningful Use? Available from:

<http://www.healthit.gov/providers-professionals/ehr-incentives-certification>.

¹²⁰ Bates DW. A national study of intravenous medication errors: understanding how to improve intravenous safety with smart pumps. Healthcare Technology Safety Institute Infusion System Meeting. January 26, 2012.

¹²¹ Merriam-Webster Online Dictionary. Metadata. Available from: <http://mw1.merriam-webster.com/dictionary/metadata>.

¹²² Centers for Disease Control and Prevention. National Healthcare Safety Network (NHSN). Available from: <http://www.cdc.gov/nhsn/>.

¹²³ http://www.qualityforum.org/Measuring_Performance/Measuring_Performance.aspx

<u>TERM</u>	<u>DEFINITION</u>
Open source	A development method for software that harnesses the power of distributed peer review and transparency of process. The promise of open source is better quality, higher reliability, more flexibility, lower cost, and an end to predatory vendor lock-in. ¹²⁴
PIB	Patient Identity Binding
Patient Safety	A process or act of omission or commission that resulted in hazardous health care conditions and/or unintended harm to the patient. An event is identified by a generalized high-level, discrete, auditable term or group of terms. ¹²⁵
Patient Safety and Quality Improvement Act of 2005	Authorized the creation of PSOs to improve quality and safety by reducing the incidence of events that adversely affect patients. ¹²⁶
PCD	Patient care device domain
PSO	Patient safety organization
PIV	Point-of-care Infusion Verification
Port	A medical device implanted beneath the skin to provide access for infusion treatments
Post-market surveillance	The process by which a drug's safety is monitored on an ongoing basis after a drug is approved by FDA. ¹²⁷
Quality Data Model (QDM)	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.
Quality measures	A mechanism to assign a quantity to quality of care by comparison to a criterion. ¹²⁸
Recall	When a product is removed from the market or a correction is made to the product because it is either defective or potentially harmful. ¹²⁹
RFD	Retrieve Form for Data
RTM	Rosetta Terminology Mapping

¹²⁴ Open Source Initiative. Mission. Available from: <http://opensource.org/>.

¹²⁵ National Quality Forum (NQF). Serious Reportable Events in Healthcare 2006 Update: A Consensus Report, Washington, DC: NQF; 2009.

¹²⁶ US Department of Health and Human Services. Agency for Healthcare Research and Quality. Patient Safety Organizations (PSO) FAQs. Available from: <http://www.pso.ahrq.gov/psos/fastfacts.htm#ff01>.

¹²⁷ US Food and Drug Administration. An FDA guide to drug safety terms. Available from: <http://www.fda.gov/forconsumers/consumerupdates/ucm107970.htm>.

¹²⁸ Agency for Healthcare Research and Quality. Understanding Quality Measurement. Available from: <http://www.ahrq.gov/chttoolbx/understn.htm>.

¹²⁹ US Food and Drug Administration (FDA). Medical Devices Glossary. Available from: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202502.htm>.

<u>TERM</u>	<u>DEFINITION</u>
Smart Pumps	An infusion pump equipped with IV medication error-prevention software that alerts operators when a pump setting is programmed outside of pre-configured limits. ¹³⁰
Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT)	A comprehensive clinical terminology, owned, maintained, and distributed by the International Health Terminology Standards Development Organisation (IHTSDO) ¹³¹
Taxonomy	The study of the general principles of scientific classification. ¹³²
Unique Device Identifier (UDI)	A unique numeric or alphanumeric code that includes a device identifier, which is specific to a device model, and a production identifier, which includes the current production information for that specific device, such as the lot or batch number, the serial number and/or expiration date. ¹³³
Unique Device Identification (UDI) Database	A database that includes a standard set of basic identifying elements for each UDI, and is available to the public so that users of a medical device can easily look up information about the device. ¹³⁴
WHO	World Health Organization
Workflow	The sequence of clinical steps in care delivery
5-Rights of medication delivery	Right patient, right medication, right dose, right time and right route of medication administration.

¹³⁰ US Food and Drug Administration (FDA). Medical Devices Glossary. Available from: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202502.htm>.

¹³¹ US National Library of Medicine National Institutes of Health. Unified Medical Language System (UMLS). SNOMED Clinical Terms® (SNOMED CT®). Available from: http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html.

¹³² Merriam-Webster Online Dictionary. Taxonomy. Available from: <http://www.merriam-webster.com/dictionary/taxonomy>.

¹³³ US Food and Drug Administration (FDA). Medical Devices Unique Device Identification. Available from: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm>.

¹³⁴ Ibid.