Comments by the AAMI Foundation Healthcare Technology Safety Institute (HTSI)

The AAMI Foundation’s Healthcare Technology Safety Institute (HTSI) has had numerous projects in the past two years on infusion safety, and appreciates this opportunity to comment on the NQF report, “Critical Paths for Creating Data Platforms.”

The following comments were developed by experts in the HTSI community representing the voice of the provider-clinician, industry, and independent technology experts, always through the lens of patient safety and improving patient outcomes. We want to acknowledge the following members of the HTSI Infusion Systems Safety Steering Committee for their specific comments: Pat Baird, MBA, MS – Healthcare Quality and Patient Safety, Baxter Inc., Mary Logan, JD, AAMI, Nathaniel Sims, MD, Massachusetts General Hospital, Erin Sparnon, ECRI Institute, and Timothy Vanderveen, PharmD., Center for Safety and Clinical Excellence, CareFusion.

We commend the National Quality Forum (NQF) for undertaking this important initiative related to intravenous infusion safety and technology to reduce the frequency and severity of medication errors and other complications. We appreciate having had the opportunity to join with ECRI and AAMI in a presentation to the TEP. Furthermore, we strongly believe that the promulgation of quality metrics will energize provider organizations to fully engage with and collaborate with pump manufacturers and Clinical Information Systems providers to enhance interoperability between infusion pumps and electronic systems. Our overall visions are well aligned, and we are grateful that this NQF project at a high level supports HTSI’s mission and vision for infusion safety.

www.aami.org/htsi/infusion/mission.html

More specifically, what HTSI and its community of multi-disciplinary experts have spent close to two years defining and refining as the desired future state for infusion therapy is that:

→All pumps will be reliability connected to an information network and clinical information system that acquires all IV drug/concentration information without manual transcription (e.g., bar code; RFID tags; etc.);

→Automatic pump programming compared to the medication order (to ensure appropriate dose or rate);

→All infusion data will be automatically recorded in each patient’s EHR;

→Critical lab values and missing lab values immediately communicated to the appropriate caregiver in a timely manner requiring acknowledgement;

→Continuous monitoring with appropriate vital sign monitoring will be provided for all patients receiving high risk IV medications (e.g., heparin); and

→Critical infusion and physiological alarms associated with high risk IV infusions will be immediately presented to the appropriate caregiver.

In shorthand terms, the system needs auto-programming; auto-verification; and auto-documentation, along with the other checks and balances noted above. While these are our beliefs today about what is needed to make a significant improvement in infusion system safety, we continue to test and refine our
beliefs, and are testing them with research. To the extent that NQF can align itself around this mission and vision – or even select one of these key elements as the highest immediate priority (holding others for future projects), this important and well aligned work around patient safety will have the greatest opportunity for meaningful impact (i.e., change) in healthcare systems across the United States.

We have organized our comments by first providing general comments then by more specific comments identifying both the page number and the paragraph (if appropriate).

**General Comments:**

- While the paper focuses heavily on infusion systems safety, the title of the report does not mention “infusion” at all. It would be easy for a casual reader to overlook this report if that reader is particularly interested in infusion systems. In order that the NQF report be more widely read and appreciated, we strongly suggest amending the **TITLE** to be more specific, including at least the words (or equivalent): "Critical Paths for Creating Data Platforms for Patient Safety Improvement Through Quality Reporting Metrics for Intravenous Drug Therapy".

- It would be very helpful for NQF to describe the future state and where NQF envisions how this study and proposed metrics will be used.

- Many of the recommendations in this report rely on technological foundations that do not yet exist in most U.S. facilities (e.g., UDI, widespread use of integrated infusion pumps, patient and asset tracking systems). The ideas contained in this report could begin to make it into requirements or recommendations for many healthcare organizations starting in 5 to 7 years. This lead time will be needed to allow for a ‘test of reasonableness’ over the next several years as the following types of questions are resolved:

  1. Will UDI be available for individual (i.e., down to the unit of use) infusion accessories such as catheters, administration sets, and needle-free connectors?
  2. Will facilities be able to develop and maintain UDI for already-purchased capital equipment like infusion pumps and poles?
  3. Will U.S. facilities adopt integrated infusion pumps and bedside barcode scanning systems quickly enough to allow for a new, modified workflow that will collect this UDI at the point of care?
  4. Will U.S. facilities adopt location tracking systems (e.g., RFID) for capital equipment like infusion pumps and poles, and for patients?

If we were to poll AAMI members, this list of key, unresolved questions would be much longer. There are many system-level implications, workflow challenges, and policy issues that would need to be addressed as well. These four questions are the tip of the iceberg on the type of analysis that needs to be done prior to implementation of what NQF is considering.

HTSI's three-year study, "National Study on Intravenous Medication Errors," led by Dr. David Bates (and specifically referenced on page 21 of the NQF report), is an important project to address a knowledge gap about infusion safety. We recommend that the federal government and NQF wait until this study is completed before making any specific recommendations around infusion systems. Currently there is a significant knowledge gap regarding infusion pump safety and the National Study on IV Medication Errors is intended and designed to reveal why errors occur and how they can be intervened. It will test several interventions and compare the current state with the future state following the implementation of those interventions. The conclusion of this study will provide more in-depth and evidence-based knowledge of infusion system use than the environmental scan conducted by NQF in
connection with this report. Since this NQF report claims to establish a baseline and then desired future states, HTSI's national study is intended to do exactly that using scientific research, which will provide a stronger, evidence-based foundation than the environmental scan of 8 interviews. HTSI will have preliminary data in the next year. However, if this report must be published prior to the preliminary data from the National Study, we highly recommend that this report specifically acknowledge that scientific studies are in the process of being conducted and any final decisions regarding metrics should wait until this research is concluded.

We also strongly recommend that the following be incorporated in the report at the appropriate insertion points and cited from, “Sims N, Schneider D. Between Now and the ‘Big Bang’: Interim Technology Applications to Help Achieve IV-IT Interoperability. BI&T. 2012; 46(5):345-349

Sidebar on page 346, The ‘Big Bang’: Elements of Ideal IV-IT Interoperability
Sidebar on page 349, The Challenge of Associating A Pump Channel to a Patient

Specific Comments by Page:

Page 6, paragraph 3: The report states that "analysis is focused exclusively on medication error measurement. It goes on to say infusion pump data can be used for infection rate measurement. For the former comment, the analysis is focused on medication error prevention. This is described in the previous paragraph, but this sentence could be interpreted to imply that medication errors can be measured with current infusion pump technology. Unlike the NECMERP index which rates the severity of errors that have actually occurred, the data from Smart pumps typically is used to identify errors that were prevented. Working with Dr David Bates and other medication safety leaders, a unique index of prevented harm was created that hospitals can use to rate the severity of programming errors, had they not been prevented. (Am J Health-Syst Pharm—Vol 62 Mar 1, 2005) It is possible to also recreate some actual infusion pump errors utilizing a key press log integral to each infusion pump. This typically requires immediate sequestering of the infusion pump immediately after an error has been identified so that the key press log ( different from the Smart pump alert log) can be accessed. With respect to measuring infection rates with pump data, it is unclear how an infusion pump would provide data that could be used for infection rate determination (this is repeated at other places within the document.)

Also on page 6, 4th paragraph: Since very few infusion pumps have a bar code scanning capability, scanning barcode compliance seems like a future rather than current metric.

Page 7 and elsewhere in the draft: Reference is made to the sites that were involved in the environmental scan. While there was significant variability in the level of interoperability, the sample facilities selected seemed not to be representative of the current state of infusion pump integration, but rather a subset of more leading edge institutions that are what we would refer to as "early adopters."

Also on page 7: (Infusion Pump Data Capture) The draft mentions key data elements and taxonomies. It should be pointed out that the high degree of drug library variability including nomenclature, drug dosing units and concentrations, and dose limits along with the lack of denominators makes inter-hospital comparison of data from the current smart pumps very difficult. The smart pump alerts do provide a numerator of how often an alert is posted, but there is no context in terms of how often each individual drug is programmed. In addition, a hospital that uses very few hard dose limits and relies primarily on soft limits will have a totally different profile for alerts compared to one that uses primarily hard alerts and very few soft alerts. Without a standardized drug library including the alert limits, meaningful comparison will be very challenging. Later in the draft proposed metrics are presented. The hospital with
few soft limits would potentially look very good in terms of compliance as measured by overrides compared to one with mostly soft limits. In the work of the San Diego Patient Safety Council, representing most of the San Diego health systems, the high degree of variability in the doses that exceed limits complicated attempts to arrive at a common standard. Previous attempts to create a standardized drug library had proven very difficult, and the initial work of the SDPSC focused on only 34 high risk IV medications.

(http://www.carefusion.com/pdf/The_Center/Toolkit_Safe_Admin_of_High_Risk_IV_Meds%20revised%20Feb2011.pdf). A subsequent initiative (which is in draft form currently) selected a subset of 15 of the 34 drugs for creation of a community standard for soft and/or hard dose limits. This effort required 10 - three hour meetings to reach consensus on this short list.

Page 8: The draft suggests that IHE is the appropriate organization to develop alarm and alert standards. We suggest that two groups will need to be included in this activity. While IHE is an appropriate group for developing a standard integration message that carries data from one system to another (e.g. the structure and format of the message), AAMI is a more appropriate group to develop performance and safety standards for the use case, content, and clinical context of this message (e.g., minimum number or type of data elements transmitted in order to fill a clinical need). AAMI already has existing infusion pump and alarm standards committees at work.

Page 7 and 8: IEC/CD280001, Application of risk management for IT-networks incorporating medical devices is an existing standard that should be referenced under the category of "Infusion Pump Data Exchange between Systems (starting at the bottom of page 7) or under "Decision Support" on page 8. The goal of IEC 80001 is to apply appropriate risk management to address the key properties of safety, effectiveness, data and system security, and interoperability. Furthermore, AAMI and Underwriters Laboratories (UL) are jointly working on the development of a suite of interoperability standards to address patient safety aspects of device interoperability. We strongly recommend that this suite of standards be referenced in future reports and potential requirements for the EHR.

http://www.aami.org/standards/

The TEP's recommendations on the bottom of page 8 and other places in this report could be broadened to refer to infusion safety, and not infusion pump safety. The pump poles, connectors, infusions themselves - they are not the pump, but rather components of the infusion system. Many of the adverse events that are lumped under the infusion pump are not really caused by the pump or related to the pump itself, and therefore the infusion pumps themselves cannot prevent these errors. For example, connecting a syringe or an IV tubing to a contaminated port is not a pump complication. CLABSI's are not typically infusion pump related, except that pumps like IV poles are involved in the administration of the therapy. Installing drug A in channel B and drug B in channel A and infusing both at the wrong doses or rates is an operator error. Infusion pumps today cannot detect the actual fluid being infused. In addition, many infusions do not involve a pump; anesthesiologists frequently use gravity infusions, same is true of the ED, clinics, etc.

Page 10: Page 10: Under the Section, “Project Approach,” the first and second paragraphs mention briefly the TEP and what it has done. However, it does not describe the qualifications of the panel members so we were very surprised to see that based on titles in Appendix A, there was not one practicing clinician who uses infusion pumps, manages the drug libraries, interprets the pump data, etc. on the panel. The Intravenous Nursing Society, the AACN, ASHP, the AAMI Infusion Standards Committee, Anesthesia Patient Safety Foundation were not represented.
Page 13: Footnote 34 needs to be corrected and cite the publication, "Infusing Patients Safely: Priority Issues from the AAMI/FDA Infusion Device Summit," AAMI 2010, AAMI/FDA Summit on infusion system safety.

Page 14: It should be pointed out that Smart pump vendors have provided software, data analysis, assistance with creation of drug libraries using best practices, provided educational programs, consulting, etc. The NQF draft does not specifically point out that for most drugs, there are no recognized soft and hard limits, and individual hospitals have created their own, borrowed from other hospitals, set and then tweaked the limits based on the data. In addition, there is major work needed on standardization of dose, drug terminology, and the like. This alone could be the subject of an entire NQF project. As referenced above, several attempts have been made to develop a standardized drug library for at least some drugs, including an initiative within HTSI. However, unique clinical decisions at individual facilities have made such collaboration extremely difficult. NQF support of development of a standardized drug library may facilitate progress in this area. The lack of recognized standards has been a major issue and essentially every hospital has been forced to reinvent the drug library or attempt to force a borrowed one on its clinical staff. This has impact on safety, compliance, benchmarking, and other aspects of the smart pump use. Healthcare cannot continue to support a "one hospital at a time" approach to drug libraries. It is neither practical nor safe. While clinicians need some space to approach individual differences in patient needs, there is much room for improvement.


Page 17: Common data formats related to infusion therapy errors would be a huge step forward.

Page 17: Also introduces the Unique Device Identification system, which raises two main questions: 1) will UDI be available, and (2) will captured UDI provide meaningful data for harm prevention? For response to the first question, UDI won’t be difficult to implement on capital equipment, but may not be necessary in a hospital setting as most facilities already track serial number as well as a hospital-developed unique identifier. However, the picture is much different for infusion accessories, which include single-use devices like ports, tubing sets, catheters, etc. The difficulty of developing unit-specific UDI for these accessories (many of which are produced by the millions per day) is likely to result in these devices falling under a UDI exemption (page 40750 from the Federal Register / Vol. 77, No. 132 / Tuesday, July 10, 2012 / Proposed Rules):

Proposed § 801.30(c) provides an exception that would permit the labeler of a class I device to label it with a UDI that does not include any production identifiers; the UDI would only have to include the device identifier. Most Class I medical devices include a plain text version of relevant production identifiers (e.g., a lot number or an expiration date) somewhere on the device label. However, the cost of encoding production identifiers in dynamic barcodes for high-volume class I device production lines may outweigh the benefits of this enhanced identification. Furthermore, we believe that hospitals may be less likely to track or document individual class I device use in patient records, and are more likely to simply use a more-generic identifier; the device identifier portion of the UDI will adequately serve such needs. Labelers of class I devices are not prohibited from using a production identifier, but they would not be required to do so under this proposed rule.
Even if UDI for infusion accessories becomes available, documenting this in the EHR or manually on a paper record seems unlikely and of questionable value. A port, a tubing set, a catheter – these are components of care that start out as sterile components and only through use or misuse do they potentially contribute to infection or other complications. It is of limited use to track the exact identifier of a catheter when the real risks to a patient are whether the catheter site has been regularly cleaned, whether the catheter is checked regularly for patency, and whether the catheter is removed as soon as it’s not needed anymore. None of these important clinical questions will be enhanced through tracking UDI.

Page 21: The Husch research project was conducted prior to Smart infusion pumps. It was undertaken to evaluate the potential value of Smart pumps on reducing IV infusion errors. The Bates study discussed earlier will only include hospitals that have implemented Smart pumps. The Husch study is a great example of the complexity of IV therapy and why the safety advances must focus on the infusion system.

Page 21: The Healthcare Technology Safety Institute's (HTSI) vision and mission posted to the following website: [www.aami.org/htsi/infusion/mission.html](http://www.aami.org/htsi/infusion/mission.html). We believe that HTSI's strategic concepts that NQF is fleshing out through its work and this report are indeed following in the same direction. For example, our Vision and Mission describe the future state that NQF seeks to achieve, so that data can flow 'automatically' into quality metrics:

Page 24: Definition of Scope. Here is another example of where an infusion “system” is used rather than infusion “pump”. There seems to be an inconsistency between the definition of scope paragraph and the scope as described on the last paragraph on this page.

Page 28: If this table is to be used in future work, many of the “Business” items in the 2nd column should also be listed in the Content section. In general, the pattern in this table is that the only Environmental Analysis Questions are from the “Business” domain, and the only data requirements are from the “Content” domain. This seems incomplete. Finally, on page 28, in the 2nd column, item 11, and in the 3rd column, item 2, refer to the “Cassette process”. We recommend that this term is clarified. It is unclear what a Cassette process is in this context or how the process provides data to the pump.

Page 36: We highlight the phrase: "One facility discussed its ability to associate the pump and the medication order, but the facility does not routinely use the data" .... We believe that provider organizations have a strong 'long felt need' to constantly reconcile a patient specific medication order, with data flowing from the infusion pump that is administering that patient specific medication. The priority of this goal, for provider organizations, is articulated in the article "Between Now and the Big Bang - Interim Technology Applications to Help Achieve IV-IT Interoperability" BI&T, September/October 2012, pp. 345-349. This article concisely lists the "Elements of Ideal IV-IT Interoperability" in a table on page 346, as follows, with specific attributes listed for the following elements: (Software Versioning; Perfect Connectivity; No Latency; Seamless Digital Pathway; Standardized Terminology; Computerized Prescriber Order Entry; CPOE Personalized Decision Support; Automatic Identification Auto-Programming; Auto-Documentation). Additional components of the article list a "roadmap-sequence" for Smart Pump Integration with Clinical Systems, and discuss "Challenges of Associating a Pump Channel to a Patient". We encourage NQF to focus its advocacy for the adoption of better quality reporting metrics as a natural outcome of putting in place systems that assure data flows which satisfy the clinical need for such reconciliation.

Page 37: It is important to point out that with the exception of a small number of hospitals, the infusion pump data typically sent via a wireless network or manually downloaded is data captured around Smart pump alerts. For example, the infusion pump server will be tracking when an out-of-limit alert is triggered, and not necessarily full-disclosure infusion data. Generally, the only facilities capable of
collecting and tracking full-disclosure infusion performance, alert, and alarm data are those that have integrated their pumps to other information systems like EHR. Whether a facility has integrated their infusion pumps or not, maintenance data (if it is tracked electronically) will be present in a completely separate maintenance management information system.

Page 40: The maturity model is excellent. It could be enhanced with additional elements from the AAMI Infusion Safety Vision as noted under general comments above.

Page 46, Decision Support: In the discussion regarding alarm/alert priorities, initial work has already been performed by the 60601-2-24 committee in a soon-to-be-released update to the international infusion pump standard. Refinements to this prioritization have been drafted for inclusion in the update to the AAMI infusion pump standard. Regarding the discussion around standardization, this topic has also been researched by the Infusion Systems Steering Committee and the Standardization Working Group. Common Metrics: Assuming the metrics might be implemented at some point in the future, a metric that could be considered would be percentage of the hospital patients covered by smart pump/HIT interoperability. It would also be helpful to add patient scan to the nurse (or “caregiver” since not all users are nurses). Since compliance with use of all safety technology is variable, a metric on percentage of time the drug library should be considered.

The TEP considered areas where quality measures could advance infusion safety, not infusion pump safety. These additional metrics are beyond the pumps.

APPENDIX H: Sources List: We ask NQF to amend Appendix H: Sources List to include:

  

  NOTE: The 11th invitational conference at the CareFusion Center for Safety and Clinical Excellence in San Diego, held on June 2-3, 2011, brought together more than 40 experts and practitioners to share information, offer perspectives and address issues on the topic of infusion therapy and information technology. The day and a half of presentations and round-table discussions included individuals representing academic institutions, large health care systems, professional associations and industry. This conference report summarizes 17 presentations by nationally recognized experts.


- **Sims N, Schneider D.** *Between Now and the ‘Big Bang’: Interim Technology Applications to Help Achieve IV-IT Interoperability.* *BI&T.* 2012; 46(5):345-349

  NOTE: These two articles represent HTSI's latest thinking, not only on the benefits of what NQF is proposing, but on the challenges ahead along the road to get there.

- The Healthcare Technology Safety Institute's (HTSI) vision and mission:

Thank you again for the opportunity to submit these comments.

Respectfully Submitted on behalf of the AAMI Foundation’s Healthcare Technology Safety Institute,

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