HITRD RFI Responses, March 15, 2019

ACTION ON INTEROPERABILITY OF MEDICAL DEVICES, DATA, AND PLATFORMS TO ENHANCE PATIENT CARE

DISCLAIMER: The RFI public responses received and posted do not represent the views and/or opinions of the U.S. Government, NSTC Subcommittee on Networking and Information Technology Research and Development (NITRD), NITRD National Coordination Office, and/or any other Federal agencies and/or government entities. We bear no responsibility for the accuracy, legality or content of all external links included in this document.

Response to NSF document 2019-02519; Request for Information: Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care.

Submitted by:

Regenstrief Center for Healthcare Engineering
Purdue University
[redacted]

Primary contact:
Rich Zink
[redacted]

Contents

Summary of Comments

The Regenstrief Center for Healthcare Engineering (RCHE) at Purdue University brings unique resources, knowledge, and experience to the discussion on solving interoperability issues between medical devices, patient data, and platforms. RCHE's evidence-based community of practice, the Regenstrief National Center for Medical Device Informatics (REMEDI), is working with clinicians, vendors, national organizations, and researchers to improve infusion pump medication administration practices through sharing data, capturing best practices, and developing tools for visualization of data.

The innovative REMEDI crowd-sourced platform, takes a systems approach to improving patient safety. To resolve issues in the complex healthcare delivery space, one needs to look at hardware, software, data, people, and process. For this reason, the REMEDI collaborative is composed of hospital clinicians, industry leaders, third party integrators, medical device vendors, and others committed to improving care. Hospitals leverage REMEDI's HIPAA-aligned server built on HUBzero® technology, an open source software platform designed for collaboration and research. REMEDI's vendor-neutral approach, allows clinicians to use visualization tools to view their smart infusion pump data and those of other fully identifiable member hospitals'.

Since 2010, the REMEDI team has been addressing interoperability issues that span the entire system. As an example, software updates to smart infusion pumps may be delayed or incomplete if the hospital's wireless network lacks full facility coverage or if an infusion pump is turned off. When pump vendors change the format of their reports, the REMEDI development team needs to modify their code to properly handle another variation of data. Standards, and lack of standards, cause challenges when comparing care areas (e.g., Med-surg versus 5 West), benchmarking drugs (e.g., 253 variations for displaying intravenous potassium chloride), and confusion due to pump feature nomenclature (e.g., override and double confirmation used to describe the same clinical action).

RCHE's interoperability vision focuses on expanding its established, evidence-based community of practice model to other medical device technology in the medication use process and/or alarming devices in critical care areas. The next step is to link medical device data of multiple sources to show metrics like total patient alarm load (i.e., alarms generated from all medical devices being used by a patient). An ultimate vision is to connect the device data to patient data. This will allow for measuring impact (e.g., how the actions taken by clinicians on the medical devices result in improved patient care as measured by shorter length of stay (LOS), fewer readmissions and transfers to a higher level of care, and fewer adverse events).

RCHE is optimistic about achieving the federal vision for interoperability, although it may take a long time to get there as RCHE believes the primary issue is not one of technology, but of incentive.

Response

The Regenstrief Center for Healthcare Engineering (RCHE), an interdisciplinary research center located in Discovery Park at Purdue University, was established in 2005 by a gift from the Regenstrief Foundation. RCHE's sister organization, the Regenstrief Institute, is also funded by the Regenstrief Foundation. Simply stated, RCHE applies engineering and business principles to transform healthcare delivery. RCHE brings together researchers and practitioners from multiple disciplines to collaboratively improve healthcare delivery and empower individuals to live their highest quality of life. RCHE's mission is to pursue a proactive, patient-centered, and wellness-focused healthcare delivery system through conducting impactful research that leverages collaborative partnerships. RCHE's vision is to be a leading research institution that generates evidence for the effectiveness and successful adaptation of interventions and policies to improve the quality, accessibility, equity, and affordability of healthcare delivery. RCHE focuses on three strategic areas that include: Health Analytics, Capacity Management, and Rural/Global Health. The most relevant to this RFI is the Health Analytics objective which has the aim to develop data science-based approaches to personalized care.

Clinical and operational decisions should be based on the best available evidence, although this may depend on patient and context characteristics as well as judgement of the clinician. As the ability to collect and process large amounts of digital data continues to expand rapidly, it is becoming possible for healthcare organizations to develop an evidence base that links process activities to patient and population outcomes. RCHE is addressing this challenge by developing readily accessible databases containing medical device data and patient data into a structure that provides actionable information – bridging the gap between data and evidence generation for clinical knowledge translation.

In 2009, RCHE facilitated the development of an evidence-based community of practice for medical device informatics called the Regenstrief National Center for Medical Device Informatics (REMEDI). The REMEDI collaborative is a community of pharmacists, nurses, other clinicians, infusion pump vendors, researchers, and national organizations focused on smart pump technology and infusion therapy safety. The vision developed by the collaborative is "To be a vibrant, resourceful and collaborative community that advances and promotes infusion pump medication administration in the interest of patient safety and quality." The mission and primary objective of the collaborative is to conduct activities that improve patient safety and the quality of healthcare delivery with a focus on sharing infusion pump data and capturing the knowledge and best practices of the community.

REMEDI provides a vendor-neutral database of smart infusion pump data for hospitals with over 36 million alerts and compliance data representing almost 160 million infusions. REMEDI currently supports BD Alaris™, Baxter Sigma, ICU Medical Plum™, and Smiths Medical Medfusion™ pumps, with plans to support B. Braun. Leveraging the pump data, evidence-based decisions can be developed by clinicians, primarily pharmacists and nurses, to support hospital operations and improve patient safety. More than 150 clinicians have used REMEDI

analytics tools to generate over 50,000 reports since 2009. Sample reports are available in Appendix A.

Members have access to their own data and other hospitals' data including:

- Drug limit library details (e.g., concentrations, soft and hard limits, etc.),
- Alert data (i.e., those alerts occurring at the pump when the clinician is setting up the infusion)
- Operational alarm date (e.g., patient side occlusion and air-in-line alarms), and
- Compliance data (i.e., how well the hospital is using the smart pump features).

The data sharing process is manual and retrospective. Figure 1 shows how to capture, share and visualize data. The shared data is stored on RCHE's HIPAA-aligned research and collaboration portal, www.catalyzecare.org. This system, built on the open source HUBzero® software that hosts analytical tools, publishes data, and builds communities in a single ecosystem, allows users to conduct complex analyses via a point-and-click interface. These analyses conducted on both specific hospitals and groups of hospitals to enable comparative examinations and benchmarking. The system provides the ability to generate different reports for a clearer understanding of an organization's smart pump data and allows for drill down by drug, care area, alert type, resolution, date, time, etc. Examining clinician response to programming alerts is useful in addressing non-actionable alerts.

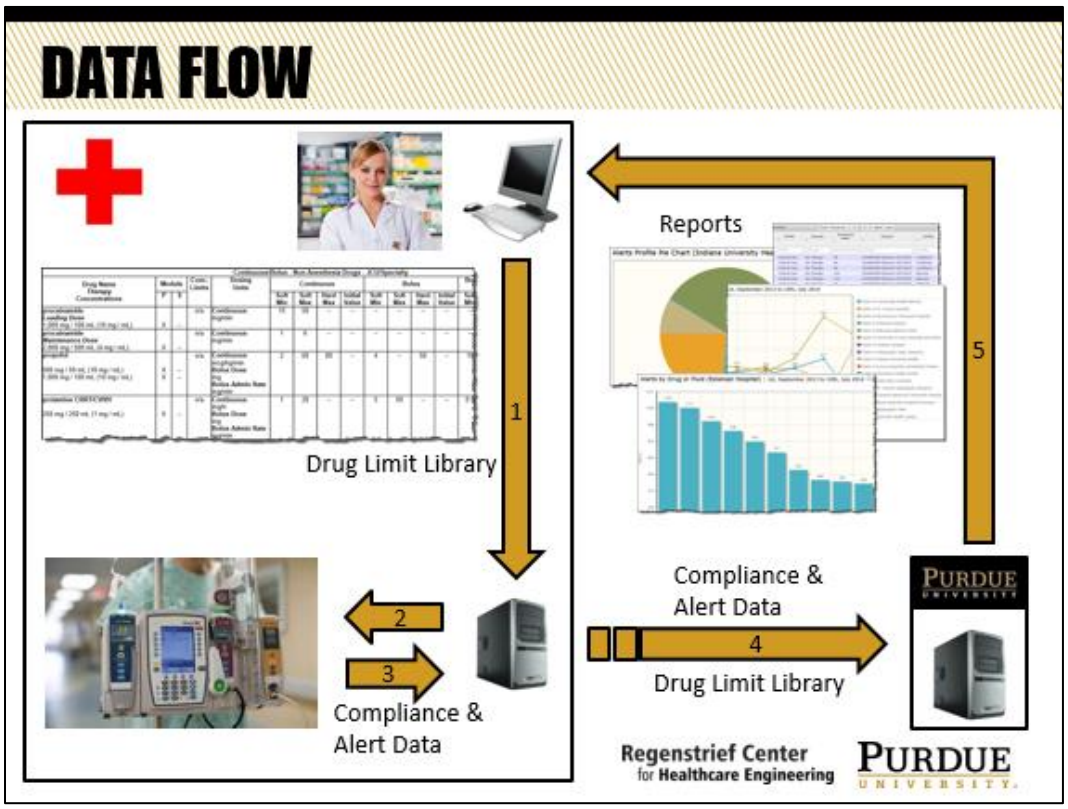


Figure 1: REMEDI Infusion Pump Data Flow.

The high-level data flow overview for infusion pump data:

Step 1. A hospital clinician, typically a pharmacist, uses the pump vendor's software to create a drug limit library and push it to a server for release.

Step 2. The server pushes the drug limit library to the pump fleet.

Step 3. Pump usage (or operations) data is captured and sent back to the server.

Step 4. A clinician at each hospital logs in to the pump vendor's software and runs standard vendor reports, saves the file(s) to a local drive in a preferred format, typically Comma-Separated Values (CSV). If PHI exists in the file (e.g., Patient ID), REMEDI provides a browser-side script to remove the data. Figure 2 shows the details for the required reports for one vendor. Next, the user logs in to REMEDI and uploads the file.

Step 5. After the REMEDI system processes the file(s) and maps the data to a standard data model, hospital users access REMEDI web-based reports and analytics.

Vendor Software	REMEDI Application	Vendor Report	Date Range Allowed	Export Format Selection	Actual Format Saved
CQI Reporter	Alerts	All Available Columns	Three (3) Months Allowed for Export	Excel (Data Only)	CSV
CQI Reporter	Compliance	Counters by Profile	Single Month Only	Excel (Data Only)	CSV
Guardrails Editor	Drug Library	Reports	N/A	MS Excel (v9.18 or greater) RTF (v9.17 or lower)	XLS/RTF
Infusion Knowledge Portal (IKP)	Alerts	All Available Columns Data Element	Three (3) Months Allowed for Export	CSV (Comma-Delimited)	CSV
Infusion Knowledge Portal (IKP)	Compliance	Guardrails® Suite MX Usage by Profiles	Single Month Only	Excel (Data Only)	CSV
Infusion Knowledge Portal (IKP)	Drug Library	Library Management Limit Details Report	Multiple Months Allowed for Export	Excel (Data Only)	CSV
Infusion Knowledge Portal (IKP)	Alarms	All Infusion Detail Report	Multiple Months Allowed for Export	Excel (Data Only)	CSV

Figure 2: Vendor Report Details in the Exchange of BD Alaris™ Data.

Hospitals can use the benchmarking reports to see how they compare to other hospitals. As an example, a member of the REMEDI collaborative, a Critical Access Hospital (CAH), used the compliance application to benchmark other hospitals and noted that their compliance rate was lower than other hospitals. Seeing that others were doing a better job of using the smart pump features gave the CAH confidence that they could improve their compliance rate. In response, the CAH put together a cross-functional team that defined and implemented a plan resulting in improving their compliance from the 70% range to greater than 90%. Since the foundation of the collaborative is to share knowledge and best practices, the CAH presented at the next REMEDI conference on how they improved their compliance allowing all member hospitals to learn from the CAH's journey. This is an example of change caused by social motivation or peer pressure, and the desire to achieve highest level of care quality/patient safety.

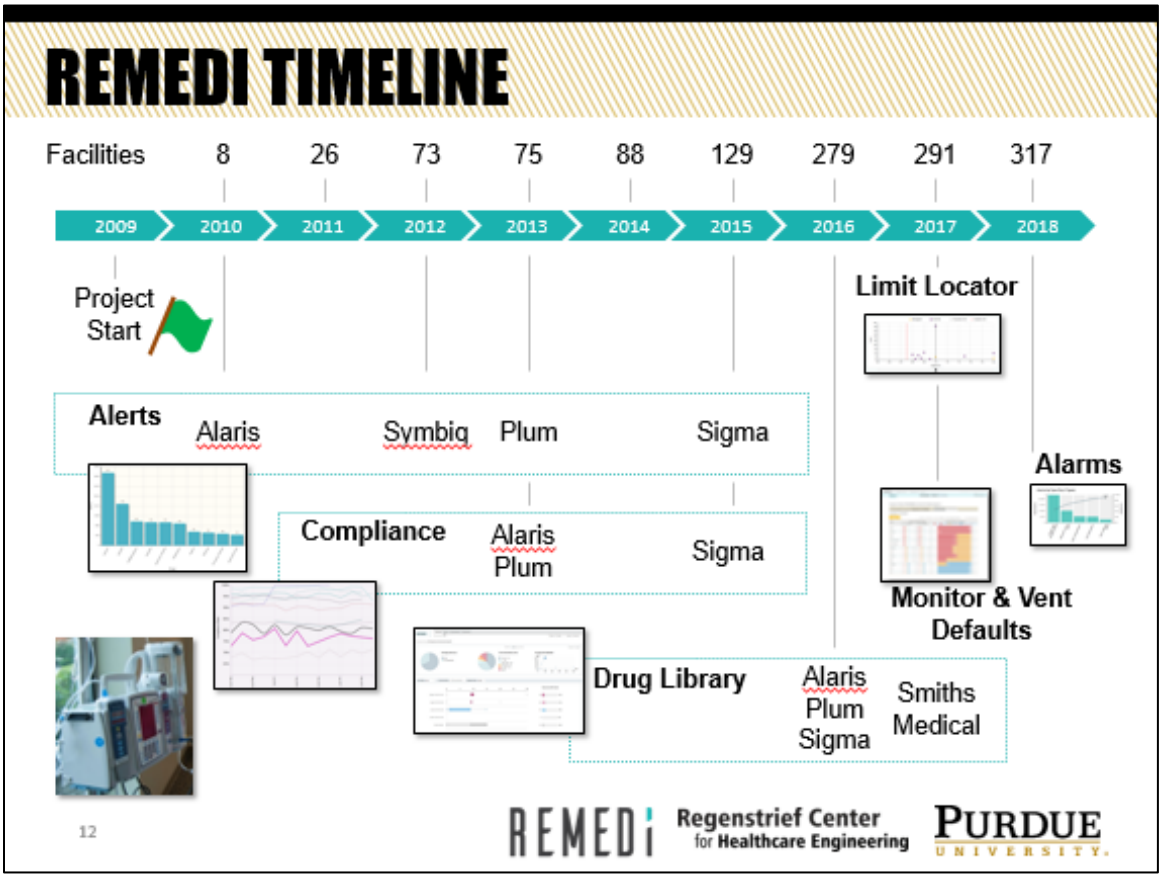


Figure 3: Timeline of REMEDI Features and Modules for Smart Infusion Pumps and the Expansion to Physiological Monitors and Ventilators.

Complementing the shared data, REMEDI highlights collaboration. Some members indicate that the community aspects of the collaborative are equally important, or more so, than the

shared data. Community activities focus on sharing information and best practices from one clinician to another via virtual and in-person conferences, a shared data repository, and discussion threads. Through regular meetings, representatives of the member hospitals share their knowledge in a collaborative environment, fostering knowledge development to advance medication administration practice and improve patient safety. The collaborative is led by a steering committee composed of members. A primary responsibility of the steering committee is to define relevant topics for meeting presentations and recruit presenters. Additionally, the steering committee, along with other members, provide suggestions for new tools and applications. The creation of the compliance module in 2013 came from a request by the community as the compliance percentage metric was of importance to them. Figure 3 provides a historical timeline for adding new vendors and features to the REMEDI application and tool suite.

Membership in the REMEDI Infusion Pump Collaborative includes hundreds of hospitals, numerous medical device vendors, and an assortment of national associations focused on improving healthcare delivery. Organizations that participate in REMEDI activities include the Institute for Safe Medication practices (ISMP), The Association for the Advancement of Medical Informatics (AAMI), The American Society of Health-System Pharmacists (ASHP), and others. Membership in REMEDI includes hospitals of many types (e.g., critical access hospitals, university teaching/research hospitals, safety net hospitals, etc.). Current membership includes approximately 65 systems, representing 400 hospitals in 33 states.

The REMEDI interoperability solution is vendor-neutral, has a human in the loop (manual), and the data shared is retrospective. The success of the collaborative has not come without overcoming challenges and gaining insight into healthcare interoperability. Challenges in the REMEDI model include:

- Gathering the required data (not all pump vendors expose all the data in their report options). For example, BD Alaris™ pumps record end-tidal CO2 readings, but the data is not available via reports or integrated with the EHR.
- It is common for the output of vendor standard reports to change after an upgrade to the vendor's medical device software. This requires modification of the REMEDI data processing code to properly capture the data and load it into the REMEDI database.
- Not all vendors provide tools for hospital clinicians to pull the data and, in some cases, the hospital has to pay the vendor to access their own data. The emergence of middleware providers to capture the device data using a black box is another trending showing progress in this space.
- The lack of standardized naming and nomenclature across various pump vendors is a challenge. For example, the vendors have different terms for describing a hospital unit or patient care subset including profile, care area, and critical care area. REMEDI minimizes this issue by having users map their care area names to a standard set. The common naming makes of easier benchmarking and comparison. Another example is

using a different term to define the same task (e.g. “double confirmation” and “override” are terms used to define the same response, administering the drug despite exceeding a soft limit). These differences required the REMEDI team to define a unique model for storing and sharing infusion pump data. Tools such as a vendor crosswalk documents are helpful in communicating across the infusion pump collaborative.

- Variation in drug naming is another interoperability issue. An examination of the shared smart infusion pump drug libraries shows that hospitals use different naming and nomenclature to match with their clinical practices. Figure 4 identifies the Top 10 drugs with naming variations found across the collaborative. The REMEDI team manually maps the provided drug names to a standard name. Again, this is done to make comparisons easier for end users.

Drug Name	Number of Naming Variations
Potassium Chloride	253
Amiodarone	230
Morphine	130
Magnesium Sulfate	130
Fentanyl	122
Dopamine	109
Piperacillin/Tazobactam	81
Vancomycin	77
Ampicillin	65
Fluconazole	59

Figure 4: Top 10 Alert Drugs by Naming Variations in REMEDI Infusion Pump Data.

- Pump update delays. Research by RCHE students and staff have identified that new drug libraries do not always reach the pump in a timely manner. RCHE analysis attributes half of this delay to hardware infrastructure (the hospital’s wireless network) and/or pumps being turned off and the other half due need a human to accept the new drug library and make it active on the pump.

The success of the REMEDI collaborative shows that this unique approach to integration is effective and can be expanded to other devices. In 2017, RCHE started to collect medical device parameters from hospitals for ventilators and physiological monitors. The RCHE vision, shown in Figure 5, is to build off the success of the REMEDI pump collaborative, expand to other medical devices (particularly those in the medication user process and/or generate patient alarms), connect the data collected from multiple devices, and integrate the network of medical device data to patient data.

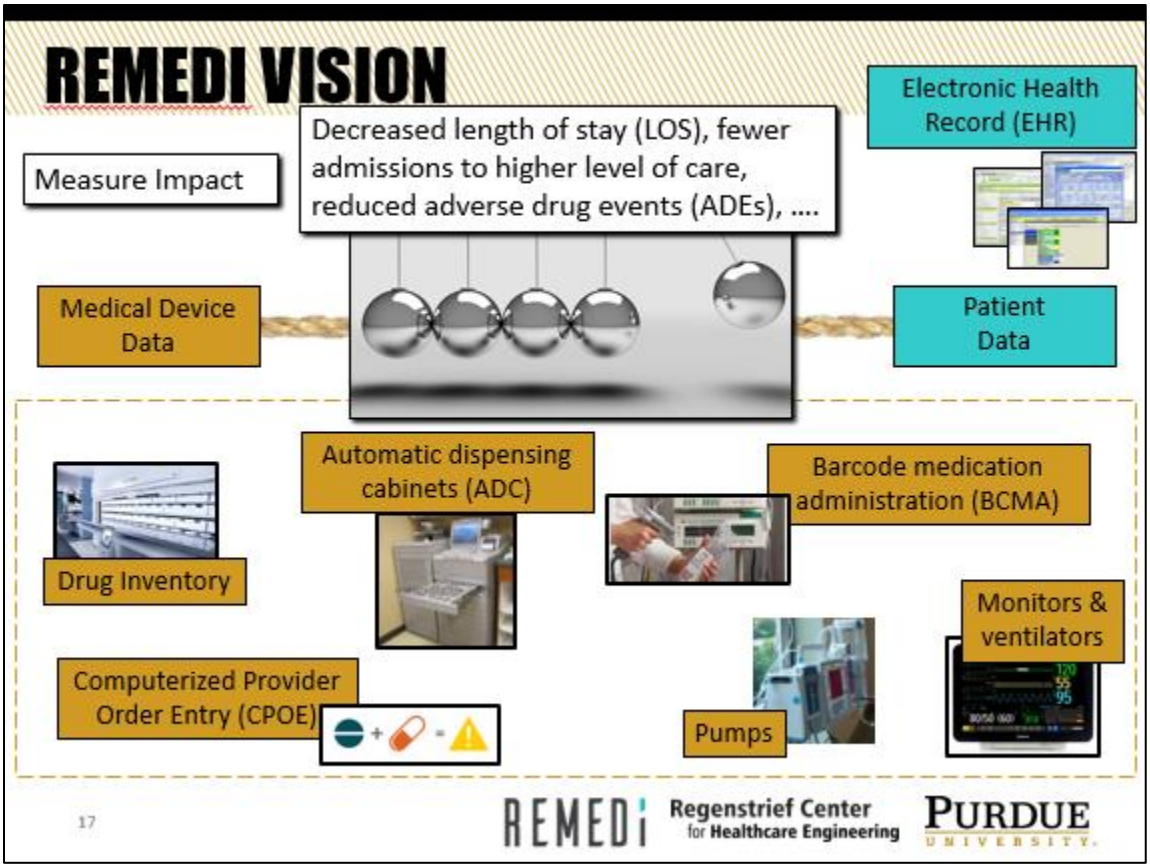


Figure 5: REMED Vision on a Slide.

An examination of the REMEDI database shows the use of smart infusion pump safe administering features has improved by an increase in the compliance percentage metric. With the improved device metric, it can be assumed patient safety has increased, but there is no direct evidence to support that patient outcomes have improved. The final step in the RCHE vision is to connect the device data to the patient data to be able to show impact on the patient (e.g., shorter length of stay or fewer ventilator days). RCHE had completed a small proof of concept project connecting medical device data to patient data using the patient ID as the key field.

To achieve interoperability for improved patient outcomes, a system approach looking at people, process, data, hardware, and software is required. Key roles in the drive for the interoperability vision outlined in the RFI included patients that interact with the devices, end users (clinicians that use the devices), and vendor human capital. REMEDI prioritizes the needs of patients through action. As a patient, the author has felt the pain first hand of the current gaps related to interoperability. During a visit to the ER, the author had to provide his medication list to the hospital. This should have been done automatically as the hospital and physicians belonged to the same healthcare system. Unfortunately, they used different EHR systems that did not communicate thus requiring the author to login to the physician's patient

accessible portal and hand the phone to the ER nurse for manually entering the medication record in the hospital's EHR.

Most members of the collaborative have had a loved one in the hospital and have experienced firsthand the consistent barrage of alarms that hospital patients endure. At the April 2016 in-person REMEDI pump conference, the conference was kicked off by [redacted] and raising the awareness of respiratory depression along with the need for continuous monitoring of patients on opioids.

Clinicians are needed to define the use cases and evaluate the technology. The medical device manufacturers and the middleware provides must take into account a human in the loop when designing their products. Knowledge from human factors engineering is important for engineers, programmers of firmware, software, and middleware, and others designing the system.

Additional roles in the interoperability discussion include medical device vendors, EHR vendors, middleware providers, federal and state government, universities & research centers, national & regional organizations, professional organizations, medication safety and patient safety, and standards organizations. The unique perspectives from all those involved allow for the balance of ideas and needs. The REMEDI community has data informaticists interacting with clinicians to understand how to solve system related problems. The Indianapolis Coalition for Patient Safety is an example of a regional group of hospitals working together to make Indianapolis the safest place for patient care and has workgroups examining pump data and the reports generated by from the vendor, REMEDI, and the EHR vendors to identify which reports and metrics should be used to monitor and improve for patient safety.

Experience gained from operating RCHE, an interdisciplinary research center, and facilitating REMEDI, a community of practice, highlights the need for aligning the incentives of diverse group of participants, to solve complex problems. The best solutions for achieving the federal vision for interoperability are likely to be a balance of the perspectives, needs, and views of academia (research-centric, vendor-neutral), clinicians (patient-centric), medical device manufacturers (feature-based, financially driven), patients, and other stakeholders. The REMEDI collaborative firmly believes that vendors must be involved in any discussions related to improving infusion pumps and patient safety, but that was not always the case. In the early years of the collaborative, there was resistance from some members of the community to have vendors participate as they felt that they would not be able to speak openly with their vendor in the room. By gradually increasing the interaction of the collaborative with the vendors, it became clear that having the vendors involved provided additional value to the members. Today, the vendors are active participants in REMEDI conferences where they are sharing their knowledge and interacting with their customers. This engagement provides clinicians the opportunity to learn from vendor presentations, get immediate answers to their questions, and

have access to vendor subject matter experts. Vendors benefit via receiving voice of the customer input from passionate, knowledgeable users.

RCHE is in alignment with the federal vision for medical device, data, and platform interoperability end state. RCHE's view is that the technology exists for accomplishing this goal, but, due to low incentives for change and adoption, it is likely it will not happen in the near future.

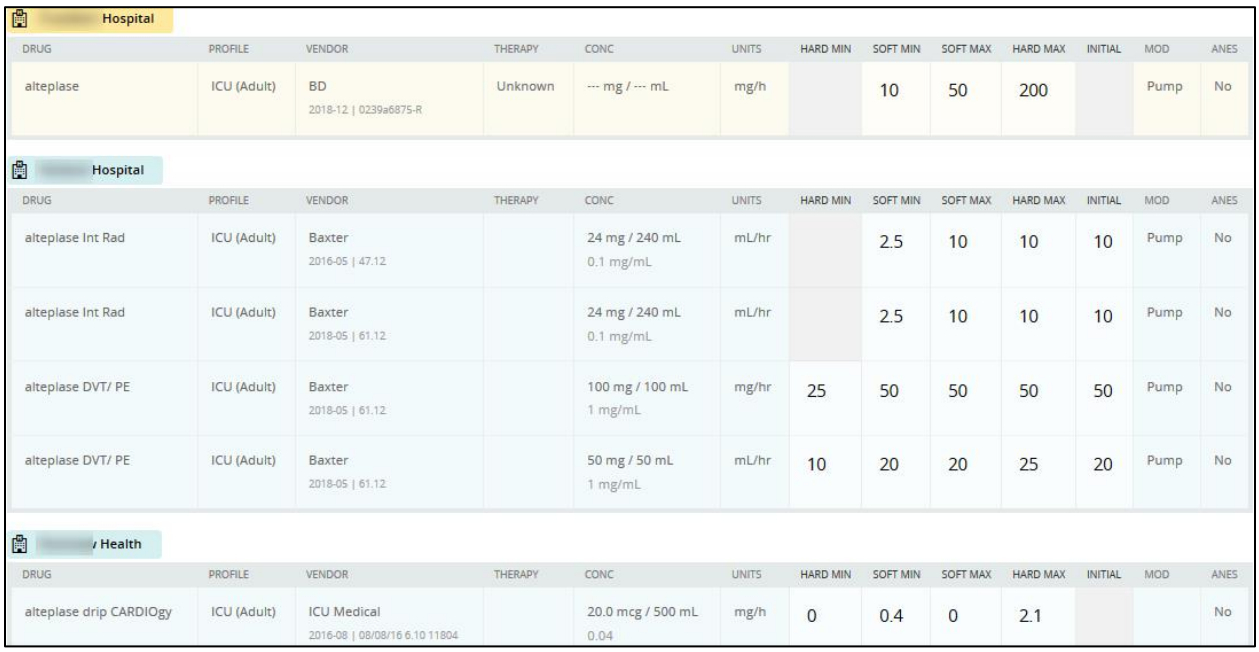
The challenges that face the visionaries include:

- Slow adoption of standards. The American Society of Health-System Pharmacist (ASHP) has an initiative called Standardize 4 Safety (S4S) that is focusing on standardizing medication concentrations to reduce medication errors and improve care. Despite published recommendations, hospitals continue to use non-standard concentrations. For example, for the medication Alteplase, S4S recommends use of a single concentration of 1 mg/mL. Data from the REMEDI database shows that only 45% of drug limit libraries use this concentration.
- Assignment of devices to patients. For the complete picture, devices may need to be assigned to patients to link the data. This may be a challenge when there are not enough devices to have one per patient or the cost to do so is prohibitive.
- Terminology and nomenclature. As mentioned above, medical device vendors do not always use the same terminology. The challenge here is how to achieve a balance between standardization and the need for vendors to differentiate their products.
- Risk and liability. Clinicians, payers, hospital legal teams, and others will likely express significant concern about an automated process with many actions performed automatically by technology without a human in the loop.
- The growing healthcare continuum. Other data sources not listed in the RFI include physician offices, retail pharmacies, community clinics, home, etc.
- Security and privacy. The challenges here are a given and will not get any easier in the future.

RCHE is in alignment with the federal vision for interoperability. With the experience and knowledge gained from the REMEDI infusion pump collaborative and other projects, RCHE can provide insight and share proven solutions appropriate for this discussion.

Further information on REMEDI is available on the Purdue University website; https://www.purdue.edu/discoverypark/rche/centers/remedi/remedi-overview.php.

Appendix A. Sample REMEDI Reports.



Hospital

DRUG	PROFILE	VENDOR	THERAPY	CONC	UNITS	HARD MIN	SOFT MIN	SOFT MAX	HARD MAX	INITIAL	MOD	ANES
alteplase	ICU (Adult)	BD 2018-12 | 0239a6875-R	Unknown	--- mg / --- mL	mg/h		10	50	200		Pump	No

Hospital

DRUG	PROFILE	VENDOR	THERAPY	CONC	UNITS	HARD MIN	SOFT MIN	SOFT MAX	HARD MAX	INITIAL	MOD	ANES
alteplase Int Rad	ICU (Adult)	Baxter 2016-05 | 47.12		24 mg / 240 mL 0.1 mg/mL	mL/hr		2.5	10	10	10	Pump	No
alteplase Int Rad	ICU (Adult)	Baxter 2018-05 | 61.12		24 mg / 240 mL 0.1 mg/mL	mL/hr		2.5	10	10	10	Pump	No
alteplase DVT/ PE	ICU (Adult)	Baxter 2018-05 | 61.12		100 mg / 100 mL 1 mg/mL	mg/hr	25	50	50	50	50	Pump	No
alteplase DVT/ PE	ICU (Adult)	Baxter 2018-05 | 61.12		50 mg / 50 mL 1 mg/mL	mL/hr	10	20	20	25	20	Pump	No

Health

DRUG	PROFILE	VENDOR	THERAPY	CONC	UNITS	HARD MIN	SOFT MIN	SOFT MAX	HARD MAX	INITIAL	MOD	ANES
alteplase drip CARDIOgy	ICU (Adult)	ICU Medical 2016-08 | 08/08/16 6.10 11804		20.0 mcg / 500 mL 0.04	mg/h	0	0.4	0	2.1			No

Figure 6: Sample report showing smart infusion pump medication administration parameters for three hospitals, each using a different pump vendor. Hospital names blurred for confidentiality.

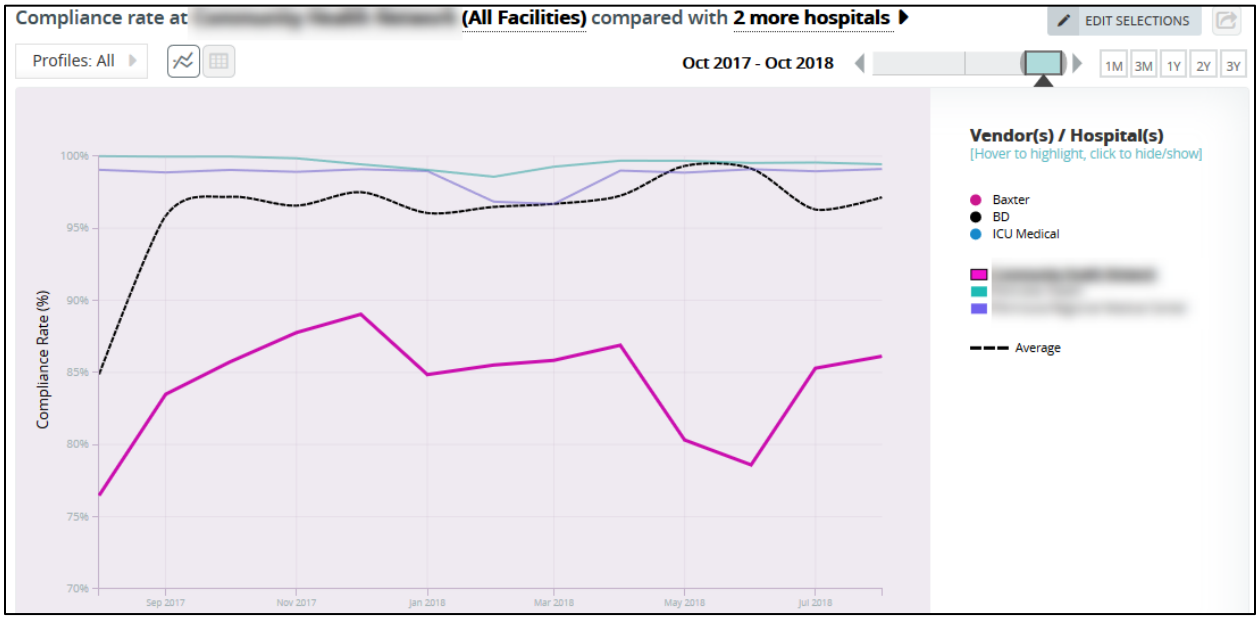


Figure 7: Sample report showing smart infusion pump compliance for three hospitals, each using a different pump vendor. Hospital names blurred for confidentiality.

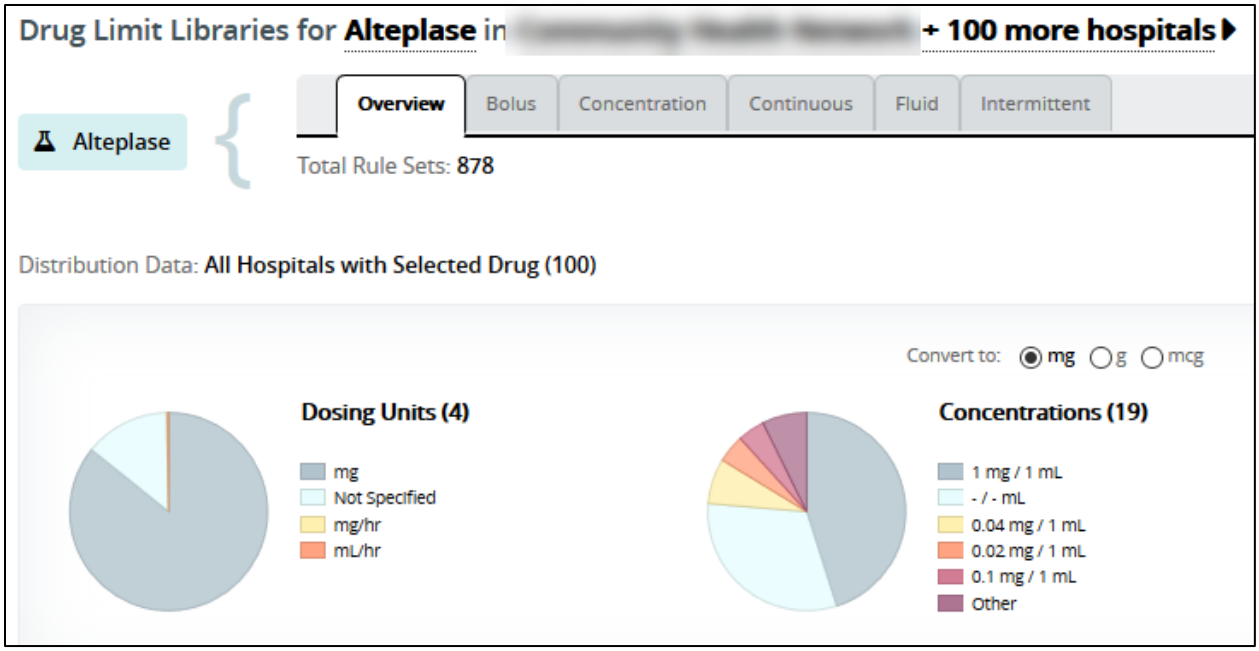


Figure 8: Sample report showing alteplase dosing units and concentrations found across 101 drug libraries, and three pump vendors, as shared by the REMEDI collaborative. Hospital names blurred for confidentiality.

Appendix B: Sample Quotes from REMEDI Members.

This is a great tool – I can't express how helpful this will be for developing our libraries!

But, honestly, the pump data made for a very easy PI project discussion, proactive approach to medication safety discussions, and evidence of how our organization identifies significant concerns and takes a "just do it" approach rather than waiting for approval through the corporate structure… 3 separate things that the surveyors asked us "how do you…" questions.

This is great! I currently abstract this type of information manually; using this website will be much better.

Nichole was singing the praises of the value of the Conference to Nursing at our Project Meeting.

It's not just that it is helpful… I'm hopeful.

Membership in the [REMEDI] Community allows us to develop realistic and obtainable goals that truly impact patient safety at our facility and help improve our nursing staff's working conditions through the reduction of unnecessary alarms.

REMEDI has greatly helped us identify areas for performance improvement with our Plum360 infusion pump drug library alerts.

Benchmarking against other like hospitals to determine whether we accomplished the current standard of care and it's not just a number. Relative value.

REMEDI has simplified the reporting and investigative process for our site. It takes away many of the challenges one is faced with in an attempt to interpret data from the vendor's standard reporting system.

Remedi is my first stop when entering a new drug into Alaris.

REMEDI is an invaluable network that challenges the status quo around smart pump technology and reporting capabilities.

The knowledge and resources provided through REMEDI provides health systems complimentary tools to optimize the use and programming of smart pump technology.

REMEDI has been awesome to make our program safer as well as give us a benchmark for our program.

Appendix C: Awards and Publications.

Awards received by REMEDI

IHI/NPSF Lucian Leape Institute Medtronic Safety Culture & Technology Innovator Award (2018)

AAMI Foundation & Institute for Technology in Health Care's Clinical Solution Award (2017)

ISMP Cheers Award (2017)

Sample publications featuring REMEDI Infusion Pump Collaborative data and research

Marwitz KK, Giuliano KK, Su W-T, Degnan DD, Zink RJ, DeLaurentis P. *High-Alert Medication Administration and Intravenous Smart Pumps: A Descriptive Analysis of Clinical Practice*, Research in Social and Administrative Pharmacy, accepted for publication, February 2019.

Hsu K-Y, DeLaurentis P, Yih Y, Bitan Y. *Tracking the Progress of Infusion Pump Drug Library Updates— a data-driven analysis of pump update delays*, Journal of Medical Systems, 43:75, 2019.

Hsu K-Y, DeLaurentis P, Bitan Y, Degnan DD, Yih Y. *Unintended Patient Safety Risks Due to Wireless Smart Infusion Pump Library Update Delays*, Journal of Patient Safety, 15(1):e8-e14, March 2019.

Giuliano KK, Su W-T, Degnan DD, Fitzgerald K, Zink RJ, DeLaurentis P. *Intravenous Smart Pump Drug Library Compliance: A Descriptive Study of 44 Hospitals*, Journal of Patient Safety, 14(4):e76-e82, December 2018.

DeLaurentis P, Hsu K-Y, Bitan Y. *Prevalence of wireless smart infusion pump drug library update delays*, American Journal of Health-System Pharmacy, 75(15), 2018