Gathering, Using, and Sharing Systems Data to Drive Safety Efforts
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Acknowledgments

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Introduction

The widespread adoption of electronic health records (EHRs) offers a significant opportunity to leverage the available digital information to improve patient safety. Organizations are using systems data, transactional data, or metadata to look at a variety of issues occurring in healthcare. Historically the approach to patient safety involves analysis of data based on voluntary reporting. However, it has been posited that voluntary reporting detects fewer than 10% of all safety events and that such reporting lacks real-time actionability. Thus, the desire to identify data generated within technology systems that can be broadly used to objectively detect safety-related events is a prominent area of focus for safety as data generation increases.

The data under discussion are the transactional data that reflect the routine actions taken to execute various healthcare activities. The “wrong-patient retract-and-reorder” (WP-RAR) measure is a recognized example of a systems-data-captured transaction. Capturing these data may uncover faulty design that can lead to harmful errors and can provide data for learnings that could be used for optimization or to evaluate patient safety activities. EHRs offer a significant opportunity to leverage the digital information they contain to improve safety management and to develop measures using near-real-time systems data.

Background

In August of 2018, ECRI Institute, in conjunction with the Bipartisan Policy Center (BPC), the Alliance for Quality Improvement and Patient Safety (AQIPS), and the Pew Charitable Trusts (PEW) brought together experts for two days of focused learning on data and their uses for driving safety. Meeting in Washington, D.C., the group focused their discussions on the many data sources used to drive safety. The group discussed and evaluated new data sources for safety and evaluated data infrastructure, data analysis, data governance, and confidentiality. Many of the data collected for patient safety activities are found in voluntarily reported retrospective data. These data are subjective. The question arose as to whether data could be obtained that were objective, closer to real time, and housed within the electronic systems themselves.

What Is Systems Data in Healthcare?

Health information technology (IT) generates a large volume of patient care and operational data. These data can be drawn from multiple sources, including EHRs; order entry, billing, and scheduling systems; and integrated medical device systems. When analyzed, these data have the potential to reveal information about healthcare delivery and the systems and processes associated with it (see Healthcare Systems Data Applications Relevant to Safety).

Health IT systems (hardware and software applications) record various levels and types of data in log/transactional files. Health IT developers, engineers, programmers, and others can access these files to enhance their understanding of a system (e.g., to verify that the system is operating as designed, to identify the causes of a behavior defect), to improve system performance, or to provide the insight needed to identify product or process variances, mitigate risks, improve processes, or optimize the use of the system overall.

The question remains, what can systems data tell us about safety?

Healthcare Systems Data Applications Relevant to Safety

- Measuring clinical practice behaviors
- Tracking compliance of processes and protocols
- Automating hazard detection
- Evaluating safety interventions
Several examples of systems data were provided by the experts in attendance on August 29th. Examples included data that addressed the functionality of systems, provided information about processes, or was focused on the specific concerns that a unit or organization may have. Systems data includes information about who logged in, when a system was accessed, from what location it was accessed, and what was viewed. It provides information about what activities occurred and the time spent on those activities. Much of this information is used to determine that systems are operating correctly. However, systems data have other uses; examples include data that are used to assess efficiencies (e.g., communications) or costs (e.g., power consumption) or to identify measures. Organizations have used systems data to assess and detect hazards or to evaluate or simplify processes (e.g., time from a medication order to administration). Another example of systems data is a measure endorsed by the National Quality Forum (NQF), the WP-RAR measure (NQF2723), an automated method for measuring wrong-patient electronic orders. This measure was developed and tested by Adelman and his study team and subsequently used at several locations using several different EHRs.

In response to the desire to identify new ways to gather information to drive safety and to expand the capture of a systems data measure, the Partnership for Health IT Patient Safety undertook a prototype project to determine not only whether the retract-and-reorder (RAR) measure could be more broadly applied but also whether safety learnings could be learned from aggregating systems data across organizations.

The Partnership and Its Mission

The Partnership for Health IT Patient Safety is a multi-stakeholder collaborative convened and operated by ECRI Institute and funded in part by the Gordon and Betty Moore Foundation. ECRI Institute is a 50-year-old nonprofit organization whose mission is advancing patient safety and quality through evidence-based healthcare and through analysis and learnings derived from information and events reported to ECRI Institute PSO. ECRI Institute convened the Partnership initially as a pilot program beginning in 2014.

The collaborative is composed of healthcare providers, health IT developers, academic researchers, patient safety organizations (PSOs), patient advocates, and professional societies. The Partnership has worked to identify safety issues for improvement and ways to implement safe technology practices. The collaborative brings together subject matter experts, evaluates data, looks at evidence from the current literature, and assimilates this information to identify safe practices. The Partnership’s goals include using a collaborative model for collecting and analyzing safety issues in a nonpunitive environment, identifying ways to improve the safety associated with technology’s use, and identifying ways to use technology for safety. Still more important is the ability to then share those evidence-based learnings with all stakeholders so that they are able to implement change.

What Data Drives Safety?

The data the Partnership have used to date for safety work include event reports submitted using standardized taxonomies, such as the Agency for Healthcare Research and Quality’s (AHRQ) Common Formats for Health IT5,6 and the HIT Hazard Manager, collected under the protections of ECRI Institute PSO. Other information that is used for learning about patient safety and is not collected using the Common Formats includes information from alerts, help desk encounters, root-cause analyses, malpractice insurer reports (e.g., closed-claims data), and information from the MAUDE (Manufacturer and User Facility Device Experience) and MedWatch databases. These data are collected in various forms, formats, and presentations (see also Appendix B) and identified and tagged using machine learning and natural language processing.

Informing a National Collaborative

ECRI Institute, the Bipartisan Policy Center, the Alliance for Quality Improvement and Patient Safety, and the Pew Charitable Trusts worked throughout 2018 to identify additional components of a national health IT safety collaborative needed to broadly drive safety and facilitate safety implementations. Gathering experts for the aforementioned meetings clarified and delineated areas for additional focus.

In advancing inquiries on data use, the Partnership undertook what became known as “the prototype project” to determine whether data directly recorded in health IT systems and available in various formats—“systems data”—could be gathered, deidentified, and aggregated outside of a PSO for shared safety learnings. Here, the term “data” refers to the facts or basic elements collected, and “information” reflects the knowledge communicated concerning those facts. The project’s goals reflect the identified scope.
Foundational to such learnings are the principles addressing data collection and data governance. These were also topics of discussion at the two days of expert data meetings, as were the various models of data collection, including centralized, federated, and hybrid models. The differences in these models are briefly summarized below:

- A centralized model houses data in a single location.
- A federated model combines information from multiple sources to provide a data set.
- A decentralized model looks to data obtained from other centralized sources.

Based on these discussions, the prototype project sought to determine whether organizations could retain their own data and share deidentified information to drive safety learnings using a federated model.

Additional data issues tackled by the project included whether it was possible to obtain information for analysis from a provider organization’s systems data outside of a PSO by gathering deidentified, nonidentifiable information from an organization’s analysis of its own data; whether it was possible to aggregate various systems’ data learnings; and whether it was possible to validate and harmonize information to drive safety.

The prototype project included these various objectives among its goals. Another independent project, occurring outside of the Partnership’s prototype project, looked at whether systems data could be gathered under the protections of a PSO.

Goals and Objectives of the Prototype Project

The goals and objectives for the Partnership’s prototype project included the following:

- Understanding the efforts required to obtain systems data
- Evaluating the ability of sites to identify, gather, and analyze systems data
- Evaluating whether sites could gather and retain their own data and whether they would be willing to share information about their learnings from those data
- Determining whether safety learnings could be derived from the information gathered
- Identifying whether this information could be aggregated in a transparent, searchable database that would provide value to other stakeholders

Methods

The Partnership invited members to join the project’s coordinating committee. Then, in conjunction with the coordinating committee, the Partnership identified volunteer participants for the project. Project volunteers included providers and their organizations, vendor/developers, and researchers. Originally, 13 provider organizations and four vendors volunteered to participate in the project. The project followed the process identified in Figure 1.

Figure 1. Partnership Prototype Project Process

<table>
<thead>
<tr>
<th>Coordinating committee</th>
<th>Recruitment</th>
<th>Workgroup kick-off</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB approval (as needed)</td>
<td>Install RAR query</td>
<td>Test query</td>
</tr>
<tr>
<td>Verify result data</td>
<td>Run query</td>
<td>Correlate RAR event with clinical context</td>
</tr>
<tr>
<td>Information submission</td>
<td>Identify challenges, barriers, and lessons learned (CBLL)</td>
<td>Document/share CBLL in ThinkTank</td>
</tr>
</tbody>
</table>
To achieve the goals and objectives outlined above, the prototype project adopted a recognized systems data measure, wrong-patient retract-and-reorder (WP-RAR) (NQF2723). This measure identifies events that occur “when an order is placed on a patient within an EHR, is retracted within 10 minutes, and then the same clinician places the same order on a different patient within the next 10 minutes.” These events are self-recognized (near misses), as reflected by the retraction, but most often they go unreported because the provider caught the error. However, the WP-RAR measure captures the information objectively within the systems data.

Project requirements and objectives were outlined for each of the provider participants; developer and researcher support was made available. The project sought to gather deidentified, nonidentifiable information using a blinded collection site. As such, each organization determined, based on its own requirements, as to whether they required institutional review board (IRB) approvals and data use agreements (examples of the project description for IRB submission as well as a sample data use agreement appear in Appendix C and Appendix D, respectively).

The Partnership team, coordinating committee, and project participants met in a virtual environment using collaboration software every six weeks from March through October 2019. Phone meetings with individual participants were held on an ad hoc basis. During the virtual and phone meetings, project participants were provided an opportunity to discuss the specific steps and status of the process, identify any challenges they were experiencing, share the information they had been able to gather, and request researcher or vendor support as needed. The allocation of responsibilities for each of the steps in this process is outlined in Table 1.

In some instances the vendor ran the query for the project participants. Other project participants obtained and installed the query on their systems. After installation, they tested and validated the query, and internally verified their results. Any issues that were identified when obtaining or running the query algorithm were addressed, as needed, with the originating researchers and with the applicable EHR developers.

### Table 1. Steps Allocated to Various Stakeholders

<table>
<thead>
<tr>
<th>Steps in the Process</th>
<th>Responsible Stakeholders</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Partnership Host</td>
</tr>
<tr>
<td>Identifying coordinating committee</td>
<td>X</td>
</tr>
<tr>
<td>Initial planning</td>
<td>X</td>
</tr>
<tr>
<td>Recruitment</td>
<td>X</td>
</tr>
<tr>
<td>IRB approval</td>
<td>X</td>
</tr>
<tr>
<td>Installing query</td>
<td>X</td>
</tr>
<tr>
<td>Validating data</td>
<td>X</td>
</tr>
<tr>
<td>Running query</td>
<td>X</td>
</tr>
<tr>
<td>Correlating clinical context*</td>
<td>X</td>
</tr>
<tr>
<td>Setting up anonymous credentials for submissions</td>
<td>X (IT)</td>
</tr>
<tr>
<td>Developing specs for submission of information</td>
<td>X</td>
</tr>
<tr>
<td>Establishing site for information submission</td>
<td>X</td>
</tr>
<tr>
<td>Identifying ways to make information accessible for outside analysis</td>
<td>X</td>
</tr>
<tr>
<td>Preparing data use agreements</td>
<td>X</td>
</tr>
<tr>
<td>Submitting information</td>
<td>X</td>
</tr>
<tr>
<td>Aggregation and information batching</td>
<td>X</td>
</tr>
<tr>
<td>Identifying safety learnings</td>
<td>X</td>
</tr>
</tbody>
</table>

* See “Project Limitations”. The ability to identify and follow up on the clinical correlations varied between organizations.
IRB, institutional review board; IT, information technology.
Data Collection

The prototype project looked at transactional information involving tasks performed to provide care to patients. In particular, this project examined orders (e.g., laboratory orders, medication orders) placed through the EHR system that were retracted within 10 minutes and then reordered within the next 10 minutes. These data were sourced from the participating organizations’ EHR data obtained during their regular operations. Due to the goals identified for this project, no identified data was submitted directly to the Partnership. All EHR data were deidentified, cleaned, and/or rolled up to a higher-level aggregation. The transactional information and instances were retained by the collecting organizations.

ECRI Institute’s Partnership team identified the information submission specifications for collection using a federated model. Once these specifications were determined, the team engaged ECRI Institute’s IT department to create a secure, credentialed SharePoint site to allow participating sites to anonymously upload their data.

Each participating organization was provided with anonymous credentials and access to the SharePoint site for the submission of information. Information-gathering specifications are listed Table 2, and the summary information is in Table 3. It was important that organizations identify the technical knowledge, expertise, and resources needed before beginning.

Table 2. Specifications for Information Gathering

<table>
<thead>
<tr>
<th>Element</th>
<th>Description</th>
<th>Data Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date/time of order</td>
<td>Date and time of original order</td>
<td>Localized date/time</td>
</tr>
<tr>
<td>Date/time of reorder</td>
<td>Date and time of reorder that followed the retraction</td>
<td>Localized date/time</td>
</tr>
<tr>
<td>Date/time RAR triggered</td>
<td>Date and time the retract-and-reorder event was captured by the algorithm</td>
<td>Localized date/time</td>
</tr>
<tr>
<td>User role</td>
<td>The role of the user/provider who entered the orders</td>
<td>Free text</td>
</tr>
<tr>
<td>Service</td>
<td>Service location for the orders (e.g., emergency department, intensive care unit, obstetrics, labor and delivery, medicine, perioperative suite)</td>
<td>Free text</td>
</tr>
<tr>
<td>Date/time RAR acknowledged</td>
<td>Date and time the designated person reviewed and interpreted the retract-and-reorder event</td>
<td>Localized date/time</td>
</tr>
<tr>
<td>Date/time follow-up completed</td>
<td>Date and time the designated person connected with the clinician who placed the order (to gather context for the event)</td>
<td>Localized date/time</td>
</tr>
<tr>
<td>RAR reason</td>
<td>Description of the clinical context/motivating factor for the retract-and-reorder event</td>
<td>Free text</td>
</tr>
</tbody>
</table>

Table 3. Monthly Summary of Information

<table>
<thead>
<tr>
<th>Element</th>
<th>Description</th>
<th>Data Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start date/time</td>
<td>The start date and time of the query—expected to be 12:00:00 a.m. the first day of the month</td>
<td>Localized date/time</td>
</tr>
<tr>
<td>End date/time</td>
<td>The end date and time of the query—expected to be 11:59:59 p.m. on the last day of the month</td>
<td>Localized date/time</td>
</tr>
<tr>
<td>Number of orders</td>
<td>The total number of orders placed between the start and end date and time</td>
<td>Integer ≥ 0</td>
</tr>
<tr>
<td>Number of RAR orders</td>
<td>The number of orders placed between the start and end date and time that met the retract-and-reorder definition</td>
<td>Integer ≥ 0</td>
</tr>
<tr>
<td>Number of order sessions</td>
<td>The total number of order sessions opened between the start and end date and time</td>
<td>Integer ≥ 0</td>
</tr>
<tr>
<td>Number of RAR order sessions</td>
<td>The number of order sessions opened between the start and end date and time containing at least one order that meets the retract-and-reorder definition</td>
<td>Integer ≥ 0</td>
</tr>
</tbody>
</table>

Note: Not all of the information originally identified was provided or received; several organizations reported that they found it difficult to obtain clinical correlations determining the reasons for the retractions that triggered the algorithm.
the project. While this project was facilitated by vendor intervention, any new project should also account for the supplemental resources that may be required from vendor/developers (e.g., accessibility of algorithms, report structure, automated file uploads).

Data security protocols were established for the transmission and storage of the data (see also Appendix E):
- In transit: Data are encrypted in transit using SHA-256 with RSA encryption with a key size of 4096 bits
- At rest: Data will be stored in an SQL Server database using TDE (transparent data encryption) compliant with FIPS 140-2
- Local machines: Local machines accessing the data are encrypted with BitLocker (Windows) or FileVault (Mac)

The Partnership team continues to monitor and track the progress of this project, and data gathering and aggregation are continuing.

Results

Four organizations submitted information to the prototype project, based on the parameters outlined above. However, responses for some of the fields were not standardized, and responses varied significantly by participant, particularly by user role and service line for each order. Submitted user role information was manually mapped to a standard set of user roles, to facilitate comparison among sites. Statistics for overall events by user role are shown in Figure 2. If these fields are standardized in the future, it would become possible to compare which users or departments have more RAR events as an aggregate over multiple participating sites.

Additionally, not all of the anonymized information contained clinical correlations clarifying the reasons for the retraction and reentry of information. The figures below provide a snapshot summary of the information obtained.

Figure 2. Participant Summary: Number of RAR Events by User Role (All Participants, N = 7,021)

![Figure 2](image-url)

Figure 3 shows events by user role (the role of the individual who retracted and reentered an order). Two of the organizations submitting data reported similar percentages of RAR events. However, the mix of providers in these categories at the different organizations is unclear, so it is difficult to generalize. This information may be useful within the organization itself. Those clinicians with the ability to enter orders may also differ by location because the participating sites were in different states, where prescribing status might differ.

Figure 4 depicts the average time to reorder based on the role of the user. Most often, the need to retract and reorder was quickly discovered. Recall that this project looked only at orders that were retracted and then reordered within 10 minutes.
Figure 3. Distribution of RAR Events by User Role at Participating Organizations

Figure 4. Average Time to Reorder by User Role

LPN, licensed practical nurse; PA/NP, physician assistant/nurse practitioner; RN, registered nurse
Figure 5 depicts the proportion (percentage) of RAR events that occurred in a given hour of the day. The question was whether RARs occur more often at certain times of day than others. Analysis revealed that events occurred throughout the workday but not necessarily during the overnight hours. However, because data on the timing of regular (i.e., not retracted) orders were not collected, it is difficult to extract meaningful inferences from these submissions. For example, most RARs seem to occur around 1 p.m., but that finding could reflect the fact that most orders are placed at 1 p.m. and the conclusion might be that when orders increase in general, the incidence of RARs also increases.

Figure 6 shows rates of RAR events by user role and time of day.

Figure 7 shows the RAR rate plotted by month for each participant. The total number of orders (bars) versus the RAR rate (lines) is calculated by the total number of RAR orders per 10,000 total orders for that month. The analysis aimed to determine whether the proportion of RARs was higher in months with more orders (e.g., whether a higher volume of orders results in more mistakes). The increases and decreases in the RAR rate do not appear to match any increase or decrease in total orders for a given month, suggesting that there is no strong relationship between these two factors.
An assumption could be that the total number of RARs increases with the total number of orders. Another assumption could be that an increase in the RAR rate could suggest that more monthly orders lead to overworked staff, who then make more errors. However, neither of these assumptions is borne out by the information obtained in this project.

Figure 8 displays the monthly RAR rate for the four participants, measured as the number of RAR events per 10,000 orders.

The trends vary by site, with participants B and D showing spikes in RAR rates for May and June. Overall, RAR rate appears to be lowest in the beginning of the calendar year (January–April 2019). Interestingly, three of the four sites showed a drop in RAR rate for July, a period in which many teaching hospitals take on new providers.
The scatterplots in Figure 9 show the correlation between average orders per session and the RAR rate. Each dot represents one month of aggregated data. This analysis sought to determine whether the number of orders processed in a single session correlated with RAR occurrences. The expectation is that more orders per session signals higher patient loads or frequent multitasking, both of which could lead to erroneous orders.

The scatterplots are separated by participant and feature a trend line to show the direction of the correlation. The $R^2$ score was also calculated to measure the statistical significance of the correlation. This score is a value between 0 and 1, with 1 being a perfect correlation and 0 meaning no correlation. Overall, these graphs show weak correlation between RAR rate and average orders per session. Site C had the highest correlation ($R^2 = 0.4$), but this still suggests a fairly weak relationship. However, given the low number of data points, it is difficult to draw a definitive conclusion.

**Figure 9. Monthly RAR Rate by Average Number of Orders per Session**

- **Participant A ($R^2 = 0.281$)**
- **Participant B ($R^2 = 0.069$)**
- **Participant C ($R^2 = 0.4$)**
- **Participant D ($R^2 = 0.01$)**
Reasons Identified for Retracting and Reordering

Not all organizations were able to follow up in a timely fashion with those doing the retracting and reordering of orders. However, some participants were able to provide situational circumstances related to retracting-and-reordering, including the following:

- Attempting to execute multiple tasks
- Working in a fast-paced environment
- Intending to enter information into a new record, but finding oneself in another chart
- Experiencing multiple interruptions
- Finding similarly complicated names, similar patient ages, allowing nothing to “stand out” to help distinguish the records
- Being tired

Organizations could identify any internal uses or learnings from the data they gathered. Organizations could choose to gather data surrounding the number of near-miss events, identify areas where events occurred most frequently, or identify processes to mitigate the events identified. No current information is available regarding changes that have occurred at the participating organizations.

Project Limitations

The prototype project relied on the availability of each organization’s participants to successfully execute the individual steps in the process. Dedicating the necessary resources was often challenging. Participants also discovered that some of the steps needed to execute the phases of the project were out of their control. For example, some organizations have IRBs that do not meet as frequently as others, causing project delay to accommodate IRB project review. Some organizations needed data use agreements as determined by their IRBs and legal review was required in those situations. Once the project was initiated, some participants found that their system did not provide the ability to download and run the algorithm; in these instances, organizations were expected to hire vendor consultants to execute the tool and provide the information they obtained. These limitations prolonged the time needed to complete the steps of the process, and inhibited at least one organization from participating in this project.

Other limitations participants encountered included the following:

1. **Available resources.** Some organizations found obtaining systems data to be a complex process, often requiring additional full-time employees or equivalents and other resources. Providers without the needed resources (e.g., small ambulatory care providers) were prohibited from readily obtaining the information.

2. **Vendor involvement.** The involvement or requirement of vendor/developer intervention varied. Some vendor/developers enabled organizations to revise the needed tool (WP-RAR algorithm and report). Those providing access to the tools also provided updates to those tools as they obtained them. In one system, vendor/developers tailored reporting formats to meet the needs of the provider organization systems.

3. **Consultants.** When one vendor/developer chose to run the algorithm for the provider organization, the process required involvement of a consultant. The involvement of a consultant was cost prohibitive for smaller organizations.

4. **Correlations.** Organizations found that obtaining clinical correlations to contextualize the systems data was not feasible when large volumes of data were obtained or when their own internal resources were limited.

5. **Measure use.** Several organizations applied the tool in a slightly different manner, not focused on wrong-patient errors, but on wrong orders. These organizations were not excluded from participating in the project. The group determined that the organization’s participation and the information obtained could inform the stated goals and objectives of the project.

6. **Data analysis.** Organizations conducted their own analysis before submission. Information obtained from data may not have been analyzed in the same or even in a similar way even though the organizations were using the same tool.

7. **Limited participant data.** Given the project delays, not all organizations could provide data in the time frame.
that was requested. Additionally, when information was obtained, this information was limited in its ability to drive technology-based safety changes because it was not robust enough to do so in the aggregate, or the information obtained by the organization was not robust enough to identify such issues.

8. **Standards.** Terminology for naming provider types and the clinical areas where issues were identified was not the same across organizations; thus trying to compare this information for safety learnings was limited.\(^\text{10}\)

9. **Participants.** The participants in this project were primarily large health systems with available resources. Smaller health systems and ambulatory care practices, while not excluded from the original participant solicitation, did not participate.

10. **Information for learnings.** Information obtained from the participants was not gathered as identified data. Also, limited numbers of participants submitted information. The information obtained varied by organization, and data differences encumbered graphical display. The information obtained and aggregated for learning from this project was found to be of limited use at present for determining national safety priorities; however, it may shed additional light on issues at the organizational level.

Analysts receiving data from the various participants found it difficult to “clean” or normalize the data in order to categorize it.\(^\text{10}\) When the specifications were created, a limited number of selections were provided; for example, the locations suggested (e.g., emergency department, intensive care unit, obstetrics, labor and delivery, medicine, perioperative suite) and those that participants identified often had varying names. In other cases, sites provided information with greater specificity to describe service locations.

It is also important to note that RAR events where the error remained unnoticed (and unretracted) for more than 10 minutes, or that were intercepted by a different clinician or individual, are not captured in this measure. Therefore, the overall RAR rate in any particular location may be underestimated. The information provides little insight into whether or not the same individual was involved in multiple near-miss episodes. This information may be clearer to the organizations themselves.

In looking to advance safety and safety activities, the data collected do not provide insight into potential harms at this level of study. The information received also provided little insight regarding the technology itself or about any role the technology may have played in the actions taken. Further investigation of clinical correlations may offer a subjective assessment of this potential.

Overall, given the limited number of participants for this project, the difficulty in standardizing user/department fields, and the lack of control data, it is difficult to extract an actionable focus from the information. However, such a focus was not the primary objective of this project.

### Lessons Learned

The prototype project was able to successfully achieve the majority of the goals identified. In so doing, several lessons were learned. First, active EHR monitoring using systems data and an algorithm that generates near-real-time alerting and subsequent follow-up clinical correlation is resource intensive. Not all organizations will have the resources available to readily and routinely use systems data for safety. Organizations may face challenges, for instance, executing the following:

- Installing algorithms
- Contracting with outside experts to run an algorithm and provide those data to the organization for analysis
- Following up with those creating events to identify why a transaction occurred
- Normalizing and analyzing the data obtained

The analysis of the information obtained, as depicted above, was insufficient to direct safety changes on a national level. Knowing the individual’s role, or locations or times when events occurred, provided little that is new regarding safety. It is unclear whether additional information from participant organizations regarding the reasons for near-miss incidents would provide additional actionable information to aggregate and prioritize safety recommendations.

What was clear is that those who participated did so enthusiastically. The measure provides insights into near-miss events that are not always reported to PSOs, vendors, or other event reporting systems. The transactional data objectively capture these actions. Organizations were willing to share that information with outside parties, but only with explicit
assurance that the appropriate safeguards were in place. Thus, positive outcomes were achieved for the first three objectives for this project (understanding the efforts required to obtain systems data; evaluating the ability of sites to identify, gather, and analyze systems data; and evaluating whether sites could gather and retain their own data and whether they would be willing to share information about the learning they gained from those data).

As to the fourth goal (determining whether safety learnings could be derived from the information gathered), it remains unclear whether a federated model, as envisioned and executed here, will provide a sufficient basis for safety priorities or whether the widespread use of systems data is scalable at this time given the resources needed versus the resources that are available, especially at smaller organizations. Finally, regarding the fifth goal, the project did not obtain the data with sufficient time to determine whether a transparent, searchable database could be made available to participants.

Discussion

The Partnership for Health IT Patient Safety has collaboratively focused on safe technology, safe use of technology, and the use of technology for safety following a multipronged approach in a number of structured efforts. In an effort to execute a broader sustainable focus, the Partnership worked with the Bipartisan Policy Center and subsequently with the Pew Charitable Trusts and the Alliance for Quality Improvement and Patient Safety to formally address the issues facing a national collaborative for health IT safety. As part of that investigation, the aforementioned organizations invited stakeholder experts to Washington, D.C., in August 2018 to participate in meetings focused on broadening the tools for the identification of safety issues; evaluating data and data analysis methods; discussing methods of maintaining data confidentiality; and evaluating the structures and processes for data governance. At the conclusion of these meetings, participants agreed that it was time for additional action to test the concepts discussed. Central to this query was the applicability of systems data for safety.

Systems data are collected routinely in the transactions populating EHRs. This data, which takes various forms, is objective and is captured via the keystrokes, exchanges, and activities being recorded in these transactions. Is it then possible to more broadly capture and use this information to drive safety?

Meeting participants looked at a number of examples of systems data that had been used for safety efforts at various organizations.10 One example of systems data had been tested in a number of facilities—the wrong-patient retract-and-reorder measure, or NQF-endorsed measure 2723—uses transactional information captured in various products. This measure provided a structured foundation for a prototype project, testing not the measure itself but the applicability of the measure and its use in a federated manner to aggregate deidentified, nonidentifiable anonymous information to derive safety learnings.

As the wrong-patient retract-and-reorder measure4 aims to identify wrong-patient errors that are captured when a provider enters an order using computerized provider order entry (CPOE), retracts that order within 10 minutes, and then executes the same order on a different patient within the next 10 minutes. This transaction (a near-miss event) is not captured by voluntary reporting, but instead is captured in the systems data itself. As with any near-miss event, such errors are useful in uncovering faulty system design and usability issues in efforts to improve safety strategies.2 The focus of the prototype project was to determine whether information derived from systems data, gathered in aggregate, could inform safety.

In order to better inform safety, the project which involved obtaining the systems data and then using that information to identify the clinical correlation (see Figure 10) attempted to retain this structure, but did vary somewhat depending on the participating location.

The data and the clinical correlations were obtained by the participant organizations. The summary information was then shared with the project host, in this instance the Partnership. As noted, volunteer participants encountered several challenges to executing the project as it was originally conceived. One challenge was conducting follow-up to obtain a clinical correlation. The reasons some participants found this difficult were multifold. First, some sites did not have the staff to timely follow up with the ordering provider to determine the reasons for the retracted orders once an algorithm was triggered. In other instances, the vendor rather than the project participant ran the algorithm, and too much time passed between the trigger and any communication that might occur to determine the reasons...
for a retraction. In yet another instance, the triggering event was related to a specific type of order, increasing the incidence of these orders. A review of this information by the organization allowed the organization to identify its own patterns and determine a focus for mitigation strategies.

Data for safety learnings, as discussed here and as outlined in Appendix B, have typically involved subjective assessments of issues that are submitted to a centralized repository (e.g., PSO, other event reporting repository). Obtaining these data often requires what may be seen as a cumbersome process relying on reporting and on the ability to recognize the issue as something to report. As such, near-miss events are not always reported, and self-recognized near-miss events are reported infrequently. Potentially, this lack of reporting, or delays in reporting of retrospective events, may cause organizations to overlook or delay action on such issues.

Event reporting primarily involves centralized data collection and analysis. While some PSOs using this centralized model of data collection have a national draw of submitted events, this is not universally the case. The prototype project sought to test a federated data collection model (combining information from multiple sources) and to identify barriers or issues that would need to be addressed in applying the model.

While the prototype project was based in the use of the wrong-patient retract-and-reorder measure (WP RAR), a measure that was chosen for its previously demonstrated validity and reliability, it did not address or evaluate the reliability of the measure for these sites or examine the mitigation strategies used in assessing wrong-patient orders executed using a CPOE system. That was not the intended purpose. Rather, the project focused on broad implementation of a systems data measure, testing a federated data collection model, and deriving shared safety learnings from the aggregated information.

While the systems data themselves are recorded and present, obtaining that systems data for evaluation requires additional work on the part of a variety of stakeholders including vendor/developers, clinical staff, informatics and IT staff, and others. This is especially true if this information is to be further exchanged and aggregated. Gathering aggregated information and ensuring that what was obtained was comparable was an additional responsibility placed on the host organizations. Normalizing this information was also a challenge for analysts reviewing and aggregating it. Additional standardization in vocabulary across healthcare organizations is needed in order to aggregate and scale learnings derived from such data. It is also important to recognize the unique character of populations served at different healthcare organizations. Such differences can inhibit ready normalization and standardization of nomenclature in some instances. Stakeholders may also have different needs or areas of focus. What may work at one organization may be an area for improvement at another organization.

The project was thus able to successfully achieve three of its five identified goals. However, the fifth goal—creating a searchable, transparent database—was never addressed because of the delay in obtaining information from participants. The fourth goal—determining whether safety learnings could be derived from the information submitted in a federated model—was inconclusive. These limitations may result from the limited data set; the broad categories of information that were requested versus the more specific information that participants provided; or the execution of the measure as intended.

What is clear is that obtaining systems data is not an abbreviated process. Multiple steps are required and multiple
stakeholders are involved. Participants were able to address and overcome initial barriers that they encountered. Moreover, organizations, including vendor/developer organizations, are willing to look at the role transactional data play in prioritizing safety events. It is yet to be determined whether such efforts are scalable. Expanding the prototype project, and studying additional measures similar to WP-RAR, have been discussed and at present the project remains active.

Conclusion

The prototype project was able to address the goals and objectives set forth specifically for this project. Recall that the project originally began with three high-level objectives and refined those goals and objectives as the project moved forward. The first objective was to determine whether safety information could be derived from systems data. The prototype project demonstrates that safety learnings can be derived from systems data across a number of sites.

Testing an alternative, noncentralized data collection model, the prototype project demonstrated that it is possible to share information using a federated model. Here, data ownership remains with the participants. Organizations obtained their own original data and shared information about those data for the project. However, despite this model and the submission of deidentified, nonidentifiable information, before sharing that information, most organizations needed to execute a data use agreement.

It is important to recognize the efforts required to obtain systems data. For this project, the team chose a recognized measure that had been tested and run on several EHR systems. This facilitated the use of this measure across sites with those same tested systems. While minor modifications were required, it was possible to obtain and run the algorithm at a number of locations. Other institutions may have their own safety measures that have not been applied, tested, or made available across various vendors’ products.

The prototype project met its original goals, identifying a working model for gathering and aggregating information from a systems data measure. This process will help to identify shared health IT safety issues in order to facilitate the collaborative identification and execution of solutions. It is now time to determine whether and how these learnings can be more broadly applied so that safety efforts become an inherent part of the daily workflow without increased burden.

References


Appendix A. Attendees at Data Meetings

Broadening the Tools for Safety: Using Systems Data Approaches, August 29, 2018

On August 29, 2018, the Bipartisan Policy Center, ECRI Institute, the Pew Charitable Trusts, and the Alliance for Quality Improvement and Patient Safety convened a meeting of experts and stakeholders at the offices of the Bipartisan Policy Center in Washington, D.C., to investigate a systems data approach to advance safety. The attendees at this day-long meeting included the following:

**Don Rucker, MD,** National Coordinator for Health Information Technology, Office of the National Coordinator for Health Information Technology, Department of Health and Human Services

**Jason Adelman, MD,** Columbia University Medical Center

**Daniel Barchi,** New York-Presbyterian Hospitals

**Geoff Caplea, MD,** Allscripts

**Gerry Castro, PhD,** Joint Commission

**David Classen, MD,** University of Utah, Pascal Metrics

**Christine Dymek, EdD,** Agency for Healthcare Research and Quality

**Scott Fraser,** ECRI Institute

**Gary Gartner, MD,** NextGen Healthcare

**Andrew Gettinger, MD,** Office of the National Coordinator for Health Information Technology, Department of Health and Human Services

**Cherie Holmes-Henry,** EHR Association, NextGen Healthcare

**David Hunt, MD,** Office of the National Coordinator for Health Information Technology, Department of Health and Human Services

**Eva Karp, RN, DHA,** Cerner Corporation

**Caroline Keogh, RN,** athenahealth

**Carol Keohane, RN,** CRICO

**Mitch Kost,** Office of the National Coordinator for Health Information Technology, Department of Health and Human Services

**Chris Lehmann, MD,** UT Southwestern Medical Center

**Jonathan Nebeker, MD,** Veterans Administration

**Olufemi A. Omitaomu, PhD,** Oak Ridge National Laboratory

**J. Marc Overhage, MD, PhD,** Cerner Corporation

**Mike Personett,** NextPlane Solutions

**Raj Ratwani, PhD,** MedStar

**Tracy Rausch,** DocBox

**Joe Schneider, MD,** Texas Medical Association

**Jeanie Scott, MS, CPHIMS,** Office of Health Informatics, Veterans Health Administration

**Jeff Wall, MD,** Cerner Corporation

**Merry Ward, PhD,** Veterans Administration

**Co-Hosts**

**Ronni Solomon, JD,** ECRI Institute

**Don Asmonga, MBA,** the Pew Charitable Trusts

**Peggy Binzer, JD,** Alliance for Quality Improvement and Safety

**Janet Marchibroda, MBA,** Bipartisan Policy Center

**Ben Moscovitch,** The Pew Charitable Trusts

**Lorraine Possanza, DPM, JD, MBE,** ECRI Institute
## Appendix B. Types of Data Available to Patient Safety Organizations and Others for Safety Analysis

<table>
<thead>
<tr>
<th>Data</th>
<th>Sources</th>
<th>Received Format</th>
<th>Sender</th>
<th>Receiver</th>
<th>Barriers</th>
<th>Comments Including Method of Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event reports (includes events with or without harm, near misses, and perhaps precursors to events, i.e., hazards)</td>
<td>Directly from organizations, Providers, Risk managers, Patient safety officers, Third-party vendor with mapping</td>
<td>Common Formats, Text fields, Excel files, Unique data fields—e.g., Hazard Manager, Mapped data fields</td>
<td>Healthcare organizations; risk, safety, or quality reporters, Vendor-intermediary, Other submitters</td>
<td>PSO, Event-reporting software vendors</td>
<td>Reports do not always come from the front line, but are transmitted through risk, safety, quality, or third-party vendor reporting systems, Reporting is not mandatory, Events may be reported well after they occurred, Association of event with any aspect of technology is not commonly recognized, Lack of common vocabulary for reporting events</td>
<td>Need to develop taxonomies for analysis, Need to use specialized tools such as text mining, Use of tagging methods and machine learning for continued reproducible analysis, Reports containing PHI are submitted through PSOs; any identifiable information is removed before the information is shared</td>
</tr>
<tr>
<td>Sentinel events</td>
<td>Healthcare organizations, Joint Commission reporting</td>
<td>Event reports</td>
<td>Healthcare organizations</td>
<td></td>
<td>Reporting is mandatory and may only report to that mandated site, Data are highly unstructured, with most fields usually not completed</td>
<td></td>
</tr>
<tr>
<td>Hazard reporting</td>
<td>Directly from healthcare organizations</td>
<td>Direct reporting using assigned fields and text, Excel files</td>
<td>Healthcare organizations; risk, safety, quality, IT</td>
<td>ECRI Institute PSO</td>
<td>Not all systems include specific hazard reporting</td>
<td>Unique set of fields that are more IT-related; information may not be completed by IT, and frontline providers or patient safety, risk, and quality personnel may not have all of the needed information to complete the appropriate fields</td>
</tr>
<tr>
<td>Root-cause analysis</td>
<td>Directly from healthcare organizations</td>
<td>Secure communications, Safe tables discussion summaries, Excel files or Word documents</td>
<td>Risk, patient safety, and/ or quality staff members</td>
<td>PSOs</td>
<td>Text mining required to evaluate</td>
<td>Information submitted to PSOs for protection of analysis of issues and mitigation strategies; solutions may be unique to the organization itself</td>
</tr>
<tr>
<td>Failure mode and effects analysis</td>
<td>Directly from healthcare organizations</td>
<td>Secure communications, Safe tables discussion summaries, Excel files or Word documents</td>
<td>Patient safety officers, IT</td>
<td>PSOs</td>
<td></td>
<td>Looks at information in a proactive manner; works best in closed system analysis as it is difficult to accommodate all aspects and external factors; is speculative and assumes logical progression</td>
</tr>
<tr>
<td>Data</td>
<td>Sources</td>
<td>Received Format</td>
<td>Sender</td>
<td>Receiver</td>
<td>Barriers</td>
<td>Comments Including Method of Analysis</td>
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</tr>
<tr>
<td>Help desk logs</td>
<td>Directly from healthcare organizations (IT, patient safety officers)</td>
<td>Excel files</td>
<td>IT, patient safety officers</td>
<td>PSOs</td>
<td>Often contain information that is organization specific and not generalizable</td>
<td>Contains only snapshots and not enough depth to evaluate an issue May contain proprietary information that vendors are unwilling to expose</td>
</tr>
<tr>
<td>Event data reporting apps</td>
<td>Healthcare organizations</td>
<td>Excel files</td>
<td>Frontline providers, Resident physicians</td>
<td>ECRI Institute PSO</td>
<td>Benefit is frontline reporting; additional step in workflow; need to protect screenshots through use of PSO reporting</td>
<td></td>
</tr>
<tr>
<td>Medical malpractice closed-claim files</td>
<td>Insurers (PIAA, Constellation, The Doctor’s Company, CRICO)</td>
<td>Excel files or Word documents</td>
<td>Insurers, PSOs</td>
<td></td>
<td>Provides a retrospective review that may be distant in time due to the pace of claim progression; information may be lacking in detail</td>
<td></td>
</tr>
<tr>
<td>MAUDE and other databases</td>
<td>Database</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>AHRQ databases</td>
<td>Database</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>System data (e.g., error logs, overrides)</td>
<td>Healthcare organizations, Vendor/developers</td>
<td>Excel files</td>
<td>Varies—IT, vendor, healthcare researchers</td>
<td>PSOs</td>
<td>Need to identify specific issues to investigate Appropriate personnel required to identify data Need to match with corresponding information</td>
<td></td>
</tr>
<tr>
<td>Vendor information</td>
<td>Vendor/developers</td>
<td>Varies (Word, Excel, structured reporting)</td>
<td>Vendor</td>
<td>PSOs, Vendors</td>
<td></td>
<td>Need for protections; considerations under the 21st Century Cures Act</td>
</tr>
<tr>
<td>Memos of issues corrected or outstanding</td>
<td>Provider organizations, Vendors</td>
<td>Word documents</td>
<td>Risk management, Risk management</td>
<td>PSOs, Healthcare organizations</td>
<td></td>
<td>Address specific issue that has generally been corrected by vendor</td>
</tr>
<tr>
<td>Reports from walkrounds or huddles</td>
<td>Healthcare organizations</td>
<td>Word documents</td>
<td>Providers, risk and patient safety officers, Providers, risk and patient safety officers, PSOs, Healthcare organizations</td>
<td>PSOs, Healthcare organizations</td>
<td></td>
<td>Communication of information</td>
</tr>
<tr>
<td>Log files</td>
<td>Healthcare organizations, Vendors</td>
<td></td>
<td>Risk management</td>
<td>PSOs, Healthcare organizations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Real-time data from EHRs</td>
<td>Provider systems, Vendor systems</td>
<td></td>
<td>Provider IT, Vendor</td>
<td>Healthcare organizations, Vendors</td>
<td></td>
<td>Access to information by outside analysts</td>
</tr>
<tr>
<td>Data</td>
<td>Sources</td>
<td>Received Format</td>
<td>Sender</td>
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<td>Barriers</td>
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<tr>
<td>EHR data warehouse</td>
<td>▪ Vendor systems</td>
<td>![Image]</td>
<td>▪ Provider, vendor</td>
<td>▪ Researchers, internally at organization</td>
<td>▪ Determine how difficult data are to obtain</td>
<td></td>
</tr>
<tr>
<td>Consumer groups</td>
<td>▪ MAME</td>
<td>![Image]</td>
<td>▪ Patient advocates</td>
<td>▪ Healthcare organizations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Empiric literature</td>
<td>▪ Peer-reviewed publications</td>
<td>![Image]</td>
<td>▪ Experts, medical-librarian-driven database searches (PubMed, MEDLINE, Embase, CINAHL, Scopus)</td>
<td>▪ Advocates</td>
<td>▪ Time for synthesis and analysis is great; delay in evaluation and publication</td>
<td></td>
</tr>
<tr>
<td>Gray literature</td>
<td>▪ Blog posts</td>
<td>![Image]</td>
<td>▪ Experts, medical-librarian-driven database searches (PubMed, MEDLINE, Embase, CINAHL, Scopus)</td>
<td>▪ Commentary</td>
<td>▪ Includes blog posts, commentary, and non-peer-reviewed results and analysis</td>
<td></td>
</tr>
<tr>
<td>Other data sources</td>
<td>▪ Wearables</td>
<td>![Image]</td>
<td>▪ Experts, medical-librarian-driven database searches (PubMed, MEDLINE, Embase, CINAHL, Scopus)</td>
<td>▪ Information not presently being submitted to this project</td>
<td>▪ ECRI Institute–developed</td>
<td></td>
</tr>
</tbody>
</table>

AHRQ, Agency for Healthcare Research and Quality; IT, information technology; MAME, Mothers Against Error Reporting; MAUDE, Manufacturer and User Facility Device Experience database; PHI, protected health information; PSO, patient safety organization.
Appendix C. IRB Sample Language to Customize

Assessing the Frequency of Wrong-Patient Orders Using the Wrong-Patient Retract-and-Reorder Measure

Background and Rationale

Policymakers have embraced health information technology (IT) as an essential component of high-quality healthcare; however, studies have demonstrated that the unintended consequences of health IT can include significant errors and patient harm.\(^{1-6}\) The danger of wrong-patient electronic orders was highlighted by one hospital’s report of more than 5,000 wrong-patient orders in one year.\(^7\) Additional hospitals with varying electronic health record (EHR) systems have each identified thousands of wrong-patient electronic orders per year; the mean rate is 111 per 100,000 orders.\(^7,11-13\)

The wrong-patient retract-and-reorder (WP-RAR) measure is an automated, validated, and reliable method developed by Adelman and colleagues to quantify wrong-patient electronic orders.\(^7\) The Wrong-Patient RAR measure identifies one or more orders placed for a patient that is retracted within 10 minutes and then placed by the same clinician for a different patient within the next 10 minutes. These are near-miss errors, self-caught by the clinician before they reach the patient. In the validation study, real-time confirmatory telephone interviews with clinicians who placed and retracted orders demonstrated that the RAR measure correctly identified wrong-patient orders in 170 of 223 cases, yielding a positive predictive value of 76.2%.\(^7\) The Wrong-patient RAR measure identified 5,246 orders placed on the wrong patient at a large academic medical center over a one-year period, translating to a rate of 58 errors per 100,000 orders. The wrong-patient RAR measure has been used as the primary outcome measure in several studies to quantify the frequency of wrong-patient electronic orders and evaluate strategies to prevent them.\(^7,10-13,14\) Based on this research, the Office of the National Coordinator for Health Information Technology (ONC) Patient identification SAFER guide recommends that hospitals and health systems use the wrong-patient RAR measure to routinely monitor patient identification errors.\(^15\)

The wrong-patient RAR measure is a fully automated electronic query that does not rely on voluntary reporting of errors or labor-intensive chart review. Voluntary reporting of errors has proven unreliable and significantly underestimates adverse event rates.\(^16,17\) A 2011 study by Classen et al. found that among 393 adverse events detected by various mechanisms, only 4 (1%) were identified through voluntary reporting.\(^16\) A 2010 study by the Department of Health and Human Services found similar results: of 120 adverse events examined, only 8 were voluntarily reported.\(^17\) Intensive chart review and trigger tools can identify more errors than voluntary reporting, but these methods are extremely labor intensive, which limits their usability. Automated surveillance, which uses electronic information systems to identify errors, has the potential to be a significantly more effective approach for identifying and monitoring errors.

Several health systems with different EHR systems have successfully employed the wrong-patient RAR measure and identified thousands of wrong-patient electronic orders per year. The RAR measure has made understanding the epidemiology of these errors and testing interventions aimed at preventing them both feasible and practicable. However, to date, health systems have not coordinated their efforts to standardize the measurement of wrong-patient orders in order to compare rates across systems and settings.

Methods

Design. Retrospective, cross-sectional, observational study.

- **Aim 1:** Internally observe the overall rate of wrong-patient orders over a [one-year]* measurement period, identified by the wrong-patient retract-and-reorder measure.
- **Aim 2:** Internally observe the rate of wrong-patient orders over a [one-year] measurement period in subgroup analyses by clinical setting, provider, patient, and order characteristics.
- **Aim 3:** Anonymously submit deidentified/nonidentifiable information as set forth in the prototype project.
- **Aim 4:** Learn whether the aggregated deidentified/nonidentifiable information provides robust patient safety learnings.
- **Aim 5:** Learn whether other steps are needed for data governance for a national patient safety collaborative.

*Highlighted areas are for each organization’s individual attention.*
Testing a model for information and data collection for a national patient safety collaborative. The Partnership for Health IT Patient Safety is a multi-stakeholder collaborative focused on health IT safety and is convened by ECRI Institute. The Partnership is conducting a proof-of-concept prototype project. This effort is being conducted in a separate format from the project conducted by the Alliance for Quality Improvement and Patient Safety so as to evaluate this proof-of-concept project in determining an ideal data governance structure. The prototype project is engaging provider organizations, subject matter experts, and vendor/developers in evaluating the use of systems information, specifically looking at an example of systems information identified by RAR. This project involves gathering data and reporting selected information to the prototype project to test whether this information is robust enough to identify health IT issues so as to develop safety solutions that can be universally applied across providers and healthcare organizations. Organizations participating in the prototype project retain their own data and share only deidentified and nonidentifiable information, as described below, with the Partnership’s prototype project.

### Data fields that will be submitted to the prototype project include:

**Primary outcome.** Organizations are looking at the rate of RAR events as detected by the wrong-patient RAR measure. The RAR measure is an electronic query run against every order to identify instances in which one or more orders is placed, then retracted within 10 minutes, and then placed by the same clinician for a different patient within 10 minutes of the retraction.

**Unit of analysis.** The units of analysis are (1) the order and (2) the order session.

If a clinician begins placing orders in the wrong patient’s record, there is the possibility that several such orders will be placed consecutively and then all retracted together. Therefore, individual orders do not represent independent opportunities for RAR events to occur. Rather, orders are clustered within order sessions. An order session is defined as a series of orders placed by a clinician for a single patient that begins with opening that patient’s order file and terminates when an order is placed for another patient or after 60 minutes, whichever occurs first.

### Inclusion Criteria

**Patient inclusion criteria.** All patients for whom an order is placed during the measurement period.

**Clinician inclusion criteria.** All clinicians who place an electronic order during the course of the measurement period.

**Data collection.** The wrong-patient RAR electronic query will be programmed into [EHR, data warehouse*] to retrospectively extract all orders for a [one-year period]. We will extract and analyze [one year] of retrospective data to describe the rate of wrong-patient order errors. We will also examine the rate of order errors stratified by [encounter characteristics, provider characteristics, patient characteristics, order characteristics, and in specific clinical settings].

We will extract the following attributes associated with each order:

- Encounter-level characteristics: clinical location (inpatient, emergency department, outpatient, and ambulatory surgery), department/unit (critical care, obstetrics, pediatrics)
- Provider-level characteristics: type of clinician ordering (attending, resident, medical student, physician assistant,

---

**Table. Specification for Information Gathering**

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date/time of order</td>
<td>Date and time order was placed</td>
</tr>
<tr>
<td>Date/time of reorder</td>
<td>Date and time order was placed for the second patient</td>
</tr>
<tr>
<td>Date/time RAR triggered</td>
<td>Date and time the query recognizes the RAR event</td>
</tr>
<tr>
<td>Date/time RAR acknowledged</td>
<td>Date and time designated person reviews and interprets the RAR query result</td>
</tr>
<tr>
<td>Date/time follow-up completed</td>
<td>Date and time ordering provider is contacted to discuss RAR event</td>
</tr>
<tr>
<td>Why the RAR?</td>
<td>Clinical context for RAR is explained/identified (e.g., ordered for wrong patient)</td>
</tr>
<tr>
<td>Total number of orders or order sessions within a specified time frame</td>
<td>Depends on what facility's EHR reporting system is capable of providing, for example: Total number of order sessions that occurred in a specified time frame</td>
</tr>
<tr>
<td>Data submission frequency</td>
<td>May be weekly, biweekly, bimonthly, or monthly</td>
</tr>
</tbody>
</table>

*Highlighted areas are for each organization’s individual attention.
nurse practitioner, nurse, pharmacist, or other), other provider characteristics as available (age, gender)

- [Patient-level characteristics: age, race, ethnicity, gender, insurance status, date and time of admission, date and time of discharge]
- Order-session-level characteristics: location of the order session (medical-surgical unit, intensive care unit, labor and delivery, pediatrics, other specialty floors)
- Order-level characteristics: type of order placed (medication, radiology, laboratory, nursing, other), date and time of the order, date and time of the retracted order

### Data Analysis

Using descriptive statistics, we will summarize characteristics of the orders, [patients], and clinicians included in the data set, overall and by clinician type, order type, and clinical setting. Then we will determine the rate of wrong-patient orders, calculated as the number of RAR events/total number of orders. We also will determine the rate of wrong-patient order sessions, calculated as the number of order sessions containing ≥1 RAR event/total number of order sessions. Rates will be presented as proportions per 100,000 orders or order sessions. In subgroup analyses, we will calculate rates of wrong-patient orders and wrong-patient order sessions stratified by type of encounter, clinician, order, and clinical setting.

### Protection of Human Subjects

#### Potential risk.
This study does not present more than minimal risk to either patients or clinicians, and does not involve any additional procedures for which verbal or written consent is normally required. Patients will be receiving clinical care in accordance with best practices and their clinicians’ discretion. To ensure confidentiality, the analytic data set will not include patient names or patient identifiers, and patient medical record numbers and account numbers will be replaced with pseudoidentifiers. In addition, all clinician identifiers will be removed from data sets prior to analysis to protect clinicians’ identities; a pseudoidentifier will be used instead.

#### Consent.
The proposed research project does not present more than minimal risk of harm to subjects and the research does not involve any procedures for which written consent is normally required. Data will be extracted retrospectively as it is collected as part of routine care. Additionally, large numbers of orders are needed for the analysis and this study cannot be practically carried out while requesting written consent for every order. Whenever appropriate, participants or legally authorized representatives will be provided with additional pertinent information. As such, per the Code of Federal Regulations Title 45, Part 46.116 (d), we ask the IRB to waive informed consent, and have completed the waiver-of-consent form.

#### Data security.
Identifying information, including patient medical record numbers and clinician identification numbers, will only be used for internal use. [Data will be stored in password-protected computers in locked offices, and all computers are encrypted to meet the security standards set forth by XXXX*.] Data files will be imported into the native format of the statistical program used for analysis. [Only the principal investigator and coinvestigators will have access to the data. Information as described above will be submitted to the prototype project; other information will not be released except as necessary for monitoring by the IRB. As such, per the Code of Federal Regulations Title 45, Parts 160 and 164 (a), we seek an exemption to the requirement for use of the Health Insurance Portability and Accountability (HIPAA) authorization form, and have completed the HIPAA waiver of authorization.

#### Data reporting.
Only summarized aggregate information will be shared with the Partnership’s prototype project. No protected health information or personal identifiable information will be transferred and no individual will be identified in any reports or publications.

#### Adverse events.
Any events that are brought to the investigators’ attention during the course of the study will be investigated and reviewed by the data safety monitoring committee (DSMC) and brought to the attention of the IRB.

#### Potential benefit.
There is no anticipated benefit of participation in this study for patients or clinicians. However, internally this study will provide data on the frequency of wrong-patient orders. These results will inform data collection and governance and interventions and safety practices related to aggregating information in a national collaborative.
References


11. Unpublished Quality Improvement Data from Brigham and Women’s Hospital.


Resources

Human Subject Regulations Decision Charts
Appendix D. Sample Usage Agreement

Usage Agreement

This USAGE AGREEMENT ("Agreement") is made, entered into, and effective on the date last signed below (the "Effective Date") by and between ______________________ ("Provider") a healthcare organization with its principal place of business located at ______________________, and ECRI Institute ("Recipient"), a nonprofit healthcare research organization, which convenes and operates the Partnership for Health IT Patient Safety, with its principal place of business at 5200 Butler Pike, Plymouth Meeting, PA 19462.

For purposes of this Agreement, Provider and Recipient may each be referred to herein collectively as a ("party") and collectively as the ("parties").

WHEREAS, Provider maintains certain provider data/information and wishes to provide Recipient with a limited set of this information so that the Recipient can conduct a prototype project, and create deliverables which can be shared with the healthcare community in support of patient safety (the "Prototype Project"). A more complete description of this Prototype Project is attached hereto as Exhibit A; and

WHEREAS, Recipient wishes to receive certain anonymized information derived from data/information collected and maintained by Provider as described more particularly below, for the sole purpose described herein; and

WHEREAS, the Provider’s Institutional Review Board determined that the provision of the anonymized information to the Recipient satisfies all specified criteria for a waiver of study subject authorization requirement. In addition the parties mutually acknowledge and agree that no PHI shall be provided from the Provider to the Recipient, nor does the Recipient want to receive any PHI from the Provider; and

NOW, THEREFORE, in consideration of the promises made herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

I. SCOPE AND PURPOSE

A. This Agreement sets forth the terms and conditions pursuant to which the Provider will disclose the de-identified, anonymized information ("Information") to the Recipient, as well as the purpose for which the Information may be used and the restrictions pertaining to Recipient’s use of the Information.

B. Provider agrees to provide Recipient the Information designated in Section II.

C. Recipient shall use or disclose the Information only for purposes necessary to conduct the Prototype Project and its associated activities as described. The Recipient shall be permitted to use the Information in order to support an ongoing safety collaborative, funded by a third party grant, and shall also be permitted to use such Information in order to develop and distribute certain patient safety publications and deliverables to the healthcare community.

II. LIMITED INFORMATIONAL SET

For purposes of this Agreement, Provider will provide the following limited Information to Recipient, which will be entered into a table with specifications to be established by the Recipient, with de-identified information submitted anonymously to Recipient and then analyzed:

A. Date/Time Order

B. Date/Time of Reorder

C. Date/Time RAR Triggered
D. User Role

E. Service

F. Date/Time RAR Acknowledged

G. Date/Time Follow-Up Completed

H. RAR Reason

I. Start date/time of the query

J. End date/time of the query

K. Number of orders

L. Number of RAR orders

M. Number of order sessions

N. Number of RAR order sessions

Provider represents that it owns, or has obtained the right to provide, all Information that it submits to Recipient. To the extent that Recipient develops aggregated, de-identified or similar informational analyses or works, Recipient shall own any such information and any derivative works created from it and may use such information for the purpose of improving safety and quality. Once Information is provided to the Recipient for analysis and reporting, this Information becomes part of the Recipient’s aggregate work product and cannot be retracted. Provider hereby agrees that the return of that information is not feasible as it has been integrated into the Recipient’s analyses and work product. Any display, publication or derivative work incorporating Provider’s Information by Recipient, and distributed to any third-party will be deidentified.

III. RECIPIENT’S OBLIGATIONS WITH RESPECT TO THE INFORMATION

A. Recipient shall use or disclose the Provider’s limited Information for the purpose of conducting the Prototype Project. The Project shall address: (1) how to obtain information from systems data that provider organizations gather, (2) determining if that information has value for patient safety activities, (3) looking at whether or not anonymized information can be made searchable and shared, and (4) determining if the learnings will help drive patient safety initiatives.

B. Recipient shall use appropriate safeguards to prevent use or disclosure of the Limited Information other than as provided for by this Agreement. Information will be stored on secure servers but will also be accessible by employees of the Recipient via their secured and encrypted laptops. The Information, will continue to be maintained by the Recipient in a confidential and secure manner after the expiration of the Project.

C. Recipient shall provide written notice to the Provider of any improper use or disclosure of the Information not provided for by this Agreement of which Recipient becomes aware within ten (10) calendar days of its discovery.

D. Recipient shall indemnify, defend and hold harmless the Provider, and its agents, officers, servants, and employees, and its respective successors, heirs, subcontractors and assigns (“Indemnitees”) from and against any claim, cause of action, liability, damage, cost or expense (including, without limitation, reasonable attorney’s fees and court costs) arising out of or in connection with any unauthorized or prohibited Use or Disclosure of the Information or any other breach of this Agreement by Recipient or any subcontractor, agent or person under Recipient’s control.

E. Recipient is not required to provide any compensation, deliverable or service to the Provider hereunder and exchange for the provision of the Provider’s Information.
IV. TERM AND TERMINATION

A. This Agreement shall be effective as of the Effective Date and shall terminate on or about August 1, 2020 unless Prototype Project is otherwise extended or terminated earlier.

B. Upon Provider’s knowledge of a material breach by Recipient, Provider shall have the right to take any or all of the following actions:
   a. Provide Recipient with written notice of the breach and an opportunity to cure the breach within ten (10) calendar days of receipt of such notice. If Recipient fails to cure the breach within the notice period, Provider may immediately terminate this Agreement; or
   b. Immediately terminate this Agreement (without an opportunity to cure) if Provider determines, in its sole discretion, that Recipient has breached a material term of this Agreement; or

V. MISCELLANEOUS

A. RECIPIENT ACKNOWLEDGES THAT THE INFORMATION PROVIDED BY THE PROVIDER IS PROVIDED ON AN “AS IS” BASIS WITH NO WARRANTY OR REPRESENTATION AS TO COMPLETENESS, ACCURACY, SAFETY, OR FITNESS FOR A PARTICULAR PURPOSE.

B. Recipient shall acknowledge Provider’s participant regardless of their ability to provide Information.

C. The parties agree to amend this Agreement from time to time as necessary by mutual, written agreement to comply with all applicable federal and state requirements regarding privacy and confidentiality of the Information.

D. Any ambiguity in this Agreement shall be resolved to permit Recipient to comply with all applicable federal and state requirements regarding privacy and confidentiality of the Information.

E. The waiver by either party of a breach or violation of any provision of this Agreement shall not operate as or be construed to be, a waiver of any subsequent breach of the same or any other provision hereof and shall not affect the right of either party to require performance at a later time.

F. Neither party may assign this Agreement without prior written consent of the other party. This Agreement will be binding upon and will be for the benefit of the parties hereto and their respective successors and assigns.

G. Each party agrees to be responsible to the other party (including its officers, employees, directors and agents) for any and all claims, damage, loss, expense, liability, obligation, action or cause of action resulting directly from its own negligent or wrongful acts or omissions. This paragraph shall survive the termination or expiration of this Agreement.

H. This Agreement shall be construed in accordance with and governed by the laws of the Commonwealth of Pennsylvania.

IN WITNESS WHEREOF, the parties have executed this Agreement effective upon the date last listed below.

ECRI Institute
By: ________________________________________________
Printed Name: _____________________________________
Title: _____________________________________________
Date: _____________________________________________

Provider
By: ________________________________________________
Printed Name: _____________________________________
Title: _____________________________________________
Date: _____________________________________________
Exhibit A

Project Description

The Recipient is conducting a Prototype Project, funded in part by a third party. The project shall involve both providers and vendors. The Recipient is gathering Information that has been submitted, collected and housed at multiple Provider locations. The information shall be gathered anonymously and blindly and will be aggregated for the purpose of promoting patient safety.

The objective of this Prototype Project is to determine:

- If provider organizations can identify and pull systems data (transactional information, in this instance a retract and reorder).
- If provider organizations could correlate the transactional information with a clinical circumstance, situation or event.
- If the Information providers obtain from looking at their data can then be shared in a de-identified and anonymous manner.
- If gathering information – from a provider’s Information/data which had already been analyzed by provider, would have a value for more generalizable safety activities.
- Can this Information be pooled for learnings?
- Ultimately can this analyzed aggregated de-identified anonymous information derivative from systems data be shared and used by others to improve patient safety?
Appendix E. Prototype Project Data Specification v2.1

1. Introduction

This document specifies the requirements for data extract uploads during the prototype stage of the data gathering project. There are two types of extracts expected: a list of retract-and-reorder events and a monthly count of orders and/or order sessions. Each upload should be composed of columns in the format described in this document.

1.1 Updates from Version 2

- Added information on data submission process (3)
- Added information on data security (Exhibit A)

2. Specification

2.1 Retract-and-Reorder Events

This extract represents the data for retract-and-reorder events. Each record represents one retract-and-reorder event, and the components related to that event. The column definitions are below, separated by systems data and manual entry data.

Table. Specification for Information Gathering

<table>
<thead>
<tr>
<th>Column</th>
<th>Description</th>
<th>Data Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systems data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1.1 Date/time of order</td>
<td>Date and time of original order</td>
<td>Localized date/time</td>
</tr>
<tr>
<td>2.1.2 Date/time of reorder</td>
<td>Date and time of reorder that followed the retraction</td>
<td>Localized date/time</td>
</tr>
<tr>
<td>2.1.3 Date/time RAR triggered</td>
<td>Date and time the retract-and-reorder event was captured by the algorithm</td>
<td>Localized date/time</td>
</tr>
<tr>
<td>2.1.4 User role</td>
<td>The role of the user/provider who entered the orders</td>
<td>Free text</td>
</tr>
<tr>
<td>2.1.5 Service</td>
<td>Service location for the orders (e.g., emergency department, intensive care unit, obstetrics, labor and delivery, medicine, perioperative suite)</td>
<td>Free text</td>
</tr>
<tr>
<td>Manual entry data</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1.6 Date/time RAR acknowledged</td>
<td>Date and time that the designated person reviewed and interpreted the retract-and-reorder event</td>
<td>Localized date/time</td>
</tr>
<tr>
<td>2.1.7 Date/time follow-up completed</td>
<td>Date and time the designated person connected with the clinician who placed the order to gather context for the event</td>
<td>Localized date/time</td>
</tr>
<tr>
<td>2.1.8 RAR reason</td>
<td>Description of the clinical context/motivating factor for the retract-and-reorder event</td>
<td>Free text</td>
</tr>
</tbody>
</table>

2.2 Monthly Order/Order Session Count

This extract will identify the total number of orders and order sessions placed over the period of a given month. The start and ending dates and times used in the retrieval query should be specified for each record.

Table. Monthly Summary of Information

<table>
<thead>
<tr>
<th>Column</th>
<th>Description</th>
<th>Data Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2.1 Start date/time</td>
<td>The start date and time of the query—expected to be 12:00:00 a.m. the first day of the month</td>
<td>Localized date/time</td>
</tr>
<tr>
<td>2.2.2 End date/time</td>
<td>The end date and time of the query—expected to be 11:59:59 p.m. on the last day of the month</td>
<td>Localized date/time</td>
</tr>
<tr>
<td>2.2.3 Number of orders</td>
<td>The total number of orders placed between the start and end dates and times</td>
<td>Integer ≥ 0</td>
</tr>
<tr>
<td>2.2.4 Number of RAR orders</td>
<td>The number of orders placed between the start and end dates and times that met the retract-and-reorder definition</td>
<td>Integer ≥ 0</td>
</tr>
<tr>
<td>2.2.5 Number of order sessions</td>
<td>The total number of order sessions opened between the start and end dates and times</td>
<td>Integer ≥ 0</td>
</tr>
<tr>
<td>2.2.6 Number of RAR order sessions</td>
<td>The number of order sessions opened between the start and end dates and times containing at least one order that meets the retract-and-reorder definition</td>
<td>Integer ≥ 0</td>
</tr>
</tbody>
</table>
3. Submission

3.1 Data Submission Overview

Data extracts will be submitted to the Partnership through an ECRI-Institute-owned SharePoint site. Project participants will receive credentials and instructions enabling them to access and upload their data to the site. Data should be submitted in CSV format and free of any identifying information. The instructions are included below again for clarity.

3.2 Data Submission Instructions

1. Using your web browser, go to the assigned URL and enter the credentials given (URL and credentials should have been received through email)

2. You will see a directory containing two folders:
   a. To submit retract-and-reorder data, click on the folder labeled “Retract_And_Reorder_Data” and then select “Upload” to choose and upload the file. You can also drag and drop the file from your file system.
   b. To submit monthly order/order session data, click on the folder labeled “Monthly_Order_Data” and then select “Upload” to choose and upload the file. You can also drag and drop the file from your file system.

Exhibit A

Data Security

The following information highlights the security protocols involved with transmitting and storing data submitted as a part of this Prototype project.

- **In transit:** Data are encrypted in transit using SHA-256 with RSA encryption with a key size of 4096 bits
- **At rest:** Data will be stored in an SQL Server database using TDE (transparent data encryption) compliant with FIPS 140-2
- **Local machines:** Local machines accessing the data are encrypted with BitLocker (Windows) or FileVault (Mac)