Ensuring Safe Performance of Electronic Health Records

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STRUCTURED ABSTRACT

**Purpose:** To refine and further develop the CPOE Evaluation Tool and assess hospital performance on the tool over time.

**Scope:** Although electronic health record (EHR) adoption is widespread, there are still concerns about the reliability of their medication-related clinical decision support. Due to the variability in how hospitals implement their EHRs, it is critical that hospitals regularly assess their operational EHR’s ability to aid prescribers in avoiding common and serious prescriber errors.

**Methods:** To further refine and develop the tool, we continuously updated the content by keeping up with the most recent care guidelines and we created three new testing modules that are ready to be implemented into the test.

**Results:** Overall hospital performance improved from 2014 to 2018 (58.7% to 65.6%). Hospitals excelled in areas concerning basic decision support but struggled with content related to advanced decision support. We found that hospitals which incorrectly alerted on more than one nuisance order (ones that test for alert fatigue), increased their overall scores by 3.19%, suggesting that some hospitals may achieve their high scores at the expense of over-alerting, which can cause alert fatigue. There was large variability in the performance of hospitals with the same vendor and medication database. We created two new modules that test an EHR’s ability to prevent CLABSI/DVT, and a Choosing Wisely category to prevent over-ordering unnecessary tests and procedures. A human factors survey was also created to assess alert design in EHRs.

**Key Words:** computerized physician order entry, electronic health record, medication safety, patient safety, quality of care
PURPOSE

In this study, we aimed to refine and further develop the Leapfrog CPOE/EHR test using the existing web-based testing approach. We updated the inpatient version of the test, so that the test is compatible with the latest versions of the leading EHR vendor products and the current hospital formularies. We also developed a new database that hosts and administers the test. Our specific aims were the following:

**Aim 1:** To measure the national progress on test performance by hospitals in inpatient EHRs in key domains, both in a cohort of hospitals which has taken the test serially, and then in hospitals overall.

**Aim 2:** To work to ensure that inpatient EHRs improve safety by updating a widely used existing test.

**Aim 3:** To iteratively improve the test in four test sites to cover additional new high impact safety clinical domains and iteratively refine them in four health systems, representing four of the leading EHR vendors.

- **SubAim 1:** To add EHR prevention capabilities for infection and deep vein thrombosis
- **SubAim 2:** To add capability to prevent overuse of laboratory and diagnostic tests, and procedures
- **SubAim 3:** To add testing for EHR enabled new errors or unintended consequences
- **SubAim 4:** To add testing of EHR usability relating to clinical decision support

SCOPE

Despite wide adoption of electronic health records (EHRs) in hospitals, inpatient safety problems persist. EHRs are currently adopted across multiple settings of care from hospitals to clinics and to a lesser extent, into long-term care and home care. In 2017, the Office of the National Coordinator for Health Information Technology reported that 96% of acute care hospitals had a certified EHR installed.\(^1\) Numerous studies have shown that EHRs with advanced functionality such as CPOE and clinical decision support can improve patient safety, especially in the area of medication safety.\(^2\) These safety benefits were one of the key major drivers helping to accelerate adoption.

Despite the success in terms of adoption, studies of patient safety problems in hospitals suggest that medication safety remains the leading category of adverse events.\(^3,4\) Other studies of
hospitals with advanced EHRs and CPOE have shown that high levels of medication safety problems can persist despite implementation of these systems and can even cause new problems. Reviews on safety and health IT from the IOM and others have suggested that adoption of EHR systems does not necessarily lead to significant improvements in patient safety. Instead, how systems implement and configure EHRs into their hospitals is far more important than just having one installed.

Health IT (HIT) supports a safety-critical system: its design, implementation, and use can provide substantial improvement in the quality and safety of patient care yet can also pose serious risks. In any sociotechnical system, consideration of the interactions of the people, processes, and technology form the basis for ensuring successful system performance. Evidence suggests that existing HIT products may not yet be consistently producing the anticipated benefits, suggesting that HIT products also have unintended risks of harm. Many of the adverse effects described above have been ameliorated by better design of workflow, alerting, and design of ordering processes and ongoing monitoring and improvement. HIT can be viewed as having two related but distinct lifecycles, one focused on the design and development of health IT traditionally vendor led, and the other associated with implementation and operation of HIT which is usually provider led. Traditionally, these have been separate silos, but a report by the IOM has suggested that these be a shared responsibility. We developed a method for testing EHR systems in actual operation that can support learning through linkage of these two lifecycles.

Integrating HIT within real-world clinical workflows requires attention to in situ use to ensure correct implementation and appropriate use of safety features. The safety of an EHR system will degrade over time if attention is not given to ensure the system’s safety on an ongoing basis. As there are changes in technology, fixes and upgrades must be continuously made to these applications. Organizations should continuously analyze how well they are using functions such as decision support, yet many do not. Given this, self-assessment tools are an important adjunct approach to assessing the functionalities of EHR such as clinical decision support. In prior work described below, we have developed a testing system that allows organizations to test the performance of their operating EHR systems on a frequent basis and use this information to improve the critical safety aspects of their EHR systems and feed it back for continuous improvement.
This testing system is a CPOE “flight simulator,” and it allows hospitals to evaluate the ability of their EHR to address high impact, high prevalence, EHR-related and impacted safety issues.\(^{11,12}\) This simulation was designed to work with all leading EHR vendor products and in a wide array of hospitals, from large academic teaching hospitals to medium sized community hospitals to critical access hospitals.\(^{11}\)

Designed as a self-assessment tool, hospitals are provided with a set of test patients they program into their EHR, and a list of associated test medication orders. These orders are distributed across specific areas of harm such as preventing serious drug-drug interactions, preventing the use of drugs contraindicated in pregnancy, preventing overdosing of medications for age or renal function, or administering a drug via a fatal route such as use of a contraindicated chemotherapeutic drug intrathecally.\(^{10}\) Hospitals receive immediate feedback in the form of an overall percentage score of medication orders appropriately alerted on, along with individual percentage scores for each order category.

There are also two subcategories within the test, fatal and nuisance orders. Fatal orders are ones that have killed patients in the past or caused a severe adverse drug event; these are included in the overall score. Nuisance orders test for alert fatigue in that they are inconsequential medication combinations that should not cause an alert to fire; these ones are not included in the overall score.

A past evaluation of the tool found that better scores on the test correlated with lower hospital mortality rates as well,\(^{13}\) while another evaluation found the rate of ADEs decreased by 43% for every 5% increase in overall score.\(^{14}\) These test results have also been used by hospitals to improve their EHR’s clinical decision support functionality and continually improve and optimize the safety performance of their EHR systems.\(^{8}\) This testing method has been included in the new HIT “Safer” Guides from the Office of the National Coordinator\(^{15}\) and has been used by US hospitals and UK hospitals since 2008. Most recently this testing has been used by 1,863 hospitals in the US in 2018.

**Settings**

Development of the content and testing methodologies were created through the collaboration between the University of Utah, The Leapfrog Group, and Brigham and Women’s Hospital. The Leapfrog Group is an organization formed in 2000, whose focus is making “great leaps forward” in the safety and quality of care,\(^{11}\) through publicly reporting on the safety of
hospitals. They have a set of national safety standards, and early on, CPOE was identified as one of them.16

The types of hospitals taking the tool varies greatly. Most are medium sized hospitals with 100-399 beds, some are smaller hospitals with fewer than 100 beds and others are large hospitals with more than 400 beds. Hospitals from all four regions of the US take our test, with most of them located in urban areas. Most hospitals are private, non-profit hospitals, and most belong to a healthcare system.

Participants

The development and assessment of the EHR post-deployment safety test only required the participation of individuals as part of their operational roles, not as subjects. In addition, only test patients that have been constructed to match specific test scenarios were used to test the safety of the EHR system design. Feedback about the medication tool was obtained from hospital personnel during their operational use of the implemented tool.

METHODS

Study Design

To update and further develop the tool, we used the existing software platform, and continuously updated the content throughout the study period, and designed new testing areas. When updating the content of the test, we analyzed the responses of hospitals from the previous year’s test and decide which medication orders to keep and which needed updating. Our research pharmacist also kept up with the most recent literature to ensure that the medication orders in the test followed the most recent care guidelines. In addition, we also made changes to the test in response to questions from hospitals about the type of alert an order would trigger. In terms of designing the new testing areas, we consulted experts at our organization, as well as our collaborators, to create test cases.

Data Sources/Collection

After hospitals take the test, their overall test results, demographic information, and responses to every medication order are collected by The Leapfrog Group. After each testing cycle, Leapfrog sends the results to our team, where we clean the data and run statistical analyses.
Interventions

The CPOE Evaluation Tool is a timed, online assessment that hospitals take through the Leapfrog Group’s annual hospital survey. Hospitals are provided with a list of test patients that they program into their EHR, and a list of associated test medication orders that they enter for each patient. Provided with every patient, are their demographics, diagnosis, allergies, and lab values. The test medication orders are distributed across ten order-checking categories that represent both basic and advanced decision support.\textsuperscript{17} While entering these orders, licensed prescribers record the decision support they receive (if any). Due to the variability in how CDS is implemented, this decision support can include pop-up alert messages as well as “hard stops” that prevent the order from being entered.

There are two subcategories within the test, fatal orders and nuisance orders. All these orders belong to pre-existing order categories. Fatal errors are ones that have killed a patient previously, and we include preferentially those which have resulted in multiple fatalities. These orders belong to the drug dosing (both daily and single), drug laboratory, drug route, and drug-drug interaction categories. Fatal orders are included in calculating the overall score. Nuisance orders are meant to test for alert fatigue and are medication combinations (drug-drug interaction and therapeutic duplication categories) that should not cause an alert to fire; such as those that were once thought to be potentially dangerous but have been shown to be safe. Nuisance orders are not included in the overall score.

After hospitals finish taking the test, they are provided with immediate feedback in the form an overall percentage score and individual order category scores. Both are calculated by taking the number of orders appropriately alerted on, divided the number of orders they were able to electronically order. For example, if a hospital does not have one of the drugs in their formulary, that test order is removed from the numerator and denominator. In addition, if a hospital is not able to electronically order two or more orders within an order category, that category receives an “insufficient” score. Also included on the results page is the fatal orders analysis and alert fatigue analysis. The fatal order analysis provides hospitals with the exact fatal orders they missed in test, and the alert fatigue analysis provides hospitals with the exact nuisance orders they incorrectly alerted on.

The new functionalities of the test we created include the Choosing Wisely initiatives,\textsuperscript{18} CLABSI/DVT prevention, and a clinical decision support human factors/usability survey. The
format of the Choosing Wisely and CLABSI/DVT material is similar to the medication test, where we provided hospitals with test patients, and orders that test the EHR’s ability to prevent the unnecessary ordering of labs or procedures, and their ability to address CLABSI/DVT in patients. For the human factors survey that is now ready for testing, hospitals would start with a “pre-test”, that contains questions about the configuration of the hospitals’ EHR (i.e. are alerts customizable by role, are providers able to submit feedback about the EHR, etc.). We would then provide hospitals with a list of high severity drug-drug interaction orders and ask them to enter one of them into their EHR. Once the alert appears, there are several questions that hospitals would answer, that assess how closely the design of alerts follow human factors guidelines.

Measures

The tool measures hospital performance by providing hospitals with an overall score and individual category scores. The order categories cover both basic and advanced decision support content\textsuperscript{17} as listed below (Figure 1)

<table>
<thead>
<tr>
<th>Basic Decision Support</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Allergy</td>
<td>Medication is one for which a patient allergy has been documented</td>
</tr>
<tr>
<td>Drug Dose (Single)</td>
<td>Specified dose of medication exceeds the safe range for a single dose</td>
</tr>
<tr>
<td>Therapeutic Duplication</td>
<td>Medication combinations overlap therapeutically (same agent or class)</td>
</tr>
<tr>
<td>Drug-Drug Interaction</td>
<td>Medication order pairs that result in a known harmful interaction when used in combination</td>
</tr>
<tr>
<td>Drug Route</td>
<td>Specified route of administration is inappropriate or potentially harmful</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Advanced Decision Support</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Dose (Daily)</td>
<td>Cumulative dose of medication exceeds the safe range for daily dose</td>
</tr>
<tr>
<td>Drug Age</td>
<td>Medication dose inappropriate/contraindicated based on patient’s age</td>
</tr>
<tr>
<td>Drug Laboratory</td>
<td>Medication dose inappropriate/contraindicated based on documented laboratory test results (includes renal status)</td>
</tr>
<tr>
<td>Drug Monitoring</td>
<td>Medication for which the standard of care includes subsequent monitoring of drug level or lab value to avoid harm</td>
</tr>
<tr>
<td>Drug Diagnosis</td>
<td>Medication dose inappropriate/contraindicated based on documented diagnosis</td>
</tr>
</tbody>
</table>

Figure 1: The order checking categories currently in the test, covering both basic and advanced decision support.

To take the test, hospitals are provided with PDF files of the patients and the Orders and Observation Sheet (Figure 2), where hospitals record the type of decision support they receive in response to a medication order (if any). Hospitals then record their responses in the Response
Form (Figure 3), which is used to calculate hospitals’ overall scores and individual category scores.

![Form Image]

Figure 2: The Orders and Observation Sheet, where hospitals record the decision support (i.e. alert) they received from their EHR, in response to the medication order.

![Sample Adult Inpatient Test Image]

Figure 3: The Response Form, where these responses are used to calculate the overall score and order category scores. The possible responses here indicate the type of alert we expect the order to trigger. In this example, we expected this order to trigger a drug-drug interaction alert, and this is reflected in the third and fourth response options.

On the results page, hospitals receive immediate feedback in the form of an overall percentage score of medication orders appropriately alerted on, along with individual order category scores (Figure 4). Also, on the results page, is the fatal order analysis and alert fatigue analysis. The fatal order analysis provides hospitals with the fatal orders they failed to alert on,
and the alert fatigue analysis provides hospitals with the nuisance orders they incorrectly alerted on.

![Test Results Table]

<table>
<thead>
<tr>
<th>Category</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Dose (Single)</td>
<td>33.33%</td>
</tr>
<tr>
<td>Drug Dose (Daily)</td>
<td>25%</td>
</tr>
<tr>
<td>Drug Route</td>
<td>100%</td>
</tr>
<tr>
<td>Drug-Drug Interaction</td>
<td>Insufficient responses to evaluate performance in this category</td>
</tr>
<tr>
<td>Therapeutic Duplication</td>
<td>0%</td>
</tr>
<tr>
<td>Drug-Allergy</td>
<td>50%</td>
</tr>
<tr>
<td>Drug Laboratory</td>
<td>50%</td>
</tr>
<tr>
<td>Drug Monitoring</td>
<td>25%</td>
</tr>
<tr>
<td>Drug Diagnosis</td>
<td>33.33%</td>
</tr>
<tr>
<td>Drug Age</td>
<td>25%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>84.29%</td>
</tr>
</tbody>
</table>

![Fatal Order Analysis]

You missed the following fatal orders:
- Hydromorphone 4 mg IV every two hours
- Diphenhydramine 250 mg po twice a day
- Promethazine 50 mg po once

![Alert Fatigue Analysis]

You missed the following Alert Fatigue orders:
- Morphine sulfate 4 mg intramuscular injection one time
- Codeine 30 mg po every four hours
- Omeprazole 20 mg po daily
- Diazepam 5 mg po once
- Glucocorticoids 6 mg po twice a day
- Diphenhydramine 25 mg po daily

Figure 4: The Test Results page, where hospitals are provided with their overall score and individual category scores. Also shown is the fatal order and alert fatigue analysis. The fatal order analysis provides hospitals with the fatal orders they failed to alert on. The alert fatigue analysis provides hospitals with the nuisance orders they incorrectly alerted on.

**Limitations**

The results of the tool only include hospitals who took the CPOE Evaluation Tool from 2014 to 2018. While this includes about a third of U.S. hospitals, it is not representative of all hospitals in the US. In addition, we did not assess patient outcomes or rates of reduction in harm, as the tool only uses test patients. Lastly, the fatal and nuisance orders are distributed across only a few order categories and may not be representative all the types of fatal and nuisance orders observed in hospital settings.
RESULTS

Principal Findings

The mean overall score on the tool increased from 58.7% in 2014 to 65.6% in 2018, showing that there have been some gains, but there is still opportunity for improvement. Areas of basic decision support are areas hospitals typically perform well in, while areas of advanced decision support are ones that hospitals still struggle with. We expected hospitals to perform better against fatal orders, given their high severity, but in 2018 only 83% of fatal orders were alerted on across all participating hospitals that year. This suggests that hospitals may not be targeting the most severe orders. Performance against nuisance orders steadily increased from 2014 to 2018 (65.7% to 89.7%) but remained stagnant from 2017 and 2018 (89.0% to 89.7%). We also found that hospitals who incorrectly alerted on more than one nuisance order, had slightly better overall performance compared to hospitals that did alert on as many nuisance orders. When testing our Choosing Wisely module with three pilot hospitals, we found that none of their EHRs prevented prescribers from ordering unnecessary tests and procedures.

Outcomes

Using the existing testing approach, we continuously updated the content of the test to keep up with changing care guidelines and changing formularies. We also created three new modules that (1) test EHRs on their ability to help prescribers avoid ordering unnecessary laboratory and diagnostic tests and procedures (The Choosing Wisely initiative),\(^\text{18}\) (2) test EHRs on their ability to help prescriber prevent CLABSI/DVT, and (3) we created a human factors survey about the design of CDS alerts. We were able to pilot the Choosing Wisely module at three pilot hospitals.

As noted above, the mean overall score in 2014 was 58.7% and increased to 65.6% in 2018 (Figure 5). In an analysis of hospitals who took the test repeatedly, we found that their overall scores were higher than hospitals taking the test for the first time.\(^\text{19}\) Drug allergy checking has consistently been the order category that hospitals always perform well in (Figure 6). Other categories that hospitals perform well in include drug dosing (both daily and single), therapeutic duplication (duplicate medication), and drug-drug interaction. Order categories that hospitals do not perform well in are drug age, drug diagnosis, drug monitoring, and drug
laboratory. Notably, the performance in the drug age, drug diagnosis, and therapeutic duplication categories improved greatly from 2017 to 2018.

Figure 5: A line graph showing the mean overall score on the tool from 2014 to 2018

Figure 6: Hospital performance in each order category from 2014 to 2018
We also found that overall performance varied greatly between hospitals who used the same EHR vendor and medication reference database (Figure 7). The combination of vendor and medication database with the largest range in score was “Vendor B/Med DB C” with a range of 86.1%. The combination with the smallest range was “Vendor A/Med DB A”, with a range of 64.9%.

Performance against fatal orders improved from 2017 to 2018 (75.7% to 83%). When we looked at hospitals who took the test in both 2017 and 2018, we found that hospitals who perform well against fatal orders, also tended to do well overall. In terms of nuisance orders, there was large improvement from 2014 to 2018 (65.7% to 89.7%). A high nuisance order percentage score indicates that not many nuisance orders were alerted on, while a low nuisance order percentage score means that most nuisance orders were alerted on. Even though there was
improvement over four years, in 2017 to 2018, the mean nuisance order score did not change (89.0% to 89.7%). For these two years, we also found that hospitals who alerted on more than one nuisance order, had a slight increase in their overall score, compared to hospitals that did not alert more than one nuisance order. This result suggests that hospitals may be achieving their high scores at the cost of over-alerting.

We were also able to pilot our Choosing Wisely content, which tested EHRs on their ability to prevent the over-ordering of laboratory and diagnostic tests, and procedures. In those three pilot sites, none of their systems had this capability. For the CLABSI/DVT modules, we consulted experts at our organization during its development, and is ready to be piloted.

Based off the I-MeDeSA instrument, we created a new human factors/usability survey that hospitals would use to assess the design of the alerts used in their EHR. We edited the content in I-MeDeSA to make questions more objective and created new section that asked prescribers to identify any irrelevant or unnecessary alerts or information that appeared along with the actual alert.

**Discussion**

We updated and further developed the inpatient version of the CPOE Evaluation Tool and assessed overall hospital performance, while creating three new testing areas. The mean score in the tool increased by 6.9% between 2014 and 2018, with fluctuations in performance during those four years. As expected, hospitals have basic decision support tools implemented, while advanced decision support tools have important room for improvement. We also found that very few hospitals’ EHR systems prevent prescribers from ordering unnecessary lab and diagnostic tests.

Our results have several implications. First, they show that hospitals’ overall performance minimally improved, and that most hospitals have basic decision support implemented. We also found that there is great variability in the performance of hospitals with the same combination of EHR vendor and medication reference database, suggesting that configuration of EHRs at the facility level varies greatly within vendors. This finding is consistent with an earlier evaluation of the tool, where the results from the first version of the tool were reported. In addition, hospitals who took the test repeatedly showed improvement in their overall performance. This suggests that repeated evaluations such as our tool provides hospitals with valuable information about the areas of CDS that their hospital can improve in.
For fatal orders, we expected that all hospitals would alert on all of them. From 2017 to 2018, the percentage of fatal orders alerted on only increased by 7% (75.7% to 83%). Although this does show improvement, these percentages should be much higher given the high safety risk of these orders. We also found that there is a positive linear relationship between overall scores and fatal order performance, where hospitals who perform well overall, also perform well against fatal orders. Given this, overall performance may be an indicator of how hospitals perform against fatal orders.

Performance for nuisance orders improved greatly from 2014 (66%) to 2018 (89%), however there was almost no change in performance from 2017 to 2018. Within these two years, we found that there is a negative relationship between overall score and nuisance order score, in that hospitals which perform well, also alert on all or most of the nuisance orders in the test. This result suggests that some of these hospitals have a low threshold for alerting, thus alerts of all severities fire. By doing this, it can cause alert fatigue which can have serious implications on safety, as prescribers can miss important alerts due to the number of alerts they receive and can cause alert fatigue.

Despite the widespread adoption of EHRs across hospitals in the US, there is still significant room for improvement in terms of their safety. Overall performance in our tool only minimally increased, and not many hospitals have advanced decision support tools implemented, and some hospitals are still struggling with some basic decision support functionalities such as alerting for fatal orders. The results of our tool provide hospitals with a general understanding of how their CPOE system performs against common and serious prescriber errors. With those results, hospitals can use them to make changes to their systems in order to improve upon quality and safety. With the future implementation of the new modules we created, hospitals will be able to test new areas of functionalities within their EHR.

**Conclusions**

The results from our study show that although there was overall improvement in hospital performance in the tool, there are still areas for improvement. Advanced decision support features are still not widely implemented across the hospitals in our study. In addition, fatal order performance is good overall, but the percentage correct should be higher especially given the high severity of these orders. In terms of nuisance order performance, we found that hospitals who perform well overall, may be achieving their high scores by and not all hospitals alert on all
the fatal orders. We also found that there is high variability in performance within EHR vendors, indicating that having an EHR is simply not enough, and how individual hospitals implement their EHR is far more important. The overall results in this tool provides hospitals with valuable insight on how their systems perform against common and serious prescriber errors and should take those results to further improve upon the quality and safety of their system.

Significance

The significance of this project is that it has demonstrated the value of ongoing testing of EHRs in operation to identify safety problems, vulnerabilities and areas for improvement. This test is the most widely used Health IT safety test in the United States and these data show that about 40% of hospitals are now taking this test, and better performance on it has been demonstrated to be associated with lower adverse drug event rates. Although performance is improving, the data shows that there is great variability even within vendors and that most hospitals do not yet have robust advanced medication-related decision support.

In contrast to EHR vendor claims, current operational commercial EHR systems still have significant safety vulnerabilities and so far, this is the only objective test available for hospitals to discover and address these vulnerabilities. Most high-risk industries have built safety oversight programs for mission critical software to ensure safe software. Healthcare has not built any oversight program to assure Health IT safety, which is why this program is critically important to maintain and further develop.

Implications

These data demonstrate the importance of tests like this which assess what decision support is in place and working. Tests like this should cover other sectors such as ambulatory care and pediatrics, and there would also be value in expanding scope to cover other domains of safety beyond medication safety.
List of Publications

Publications


Posters and Oral Presentations


Upcoming Publications

1. Submitted to Annals of Internal Medicine, awaiting review:
2. Ready for submission to The Journal of the American Medical Association:
References


