Payer Formulary Alerts as a Cause of Patient Harm and the Journey to Change Them

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ABSTRACT

BACKGROUND AND OBJECTIVES: A safety event drew attention to unsafe and inappropriate payer formulary alerts. These alerts display formulary, coverage, and eligibility data from the pharmacy benefits manager in response to an electronic prescription. They are intended to redirect prescribers to medications that are covered by insurance; however, these alerts were found to be inaccurate and contribute to potentially harmful alerts. Our objective was to reduce inappropriate payer formulary alerts by 30% within 1 year and to change the ePrescribing certification requirements to prevent future instances of harm.

METHODS: Using process mapping we identified the changes that were required both locally and nationally through our electronic health record (EHR) vendor and ePrescribing transaction broker. We partnered with vendors to show the safety risk and to suggest modifications to the payer formulary alert content and ePrescribing certification criteria. On the basis of the new criteria, we modified and deactivated inappropriate alerts. Rates were followed weekly for 13 months and a control chart was used to track progress.

RESULTS: From January 2014 to January 2015, we reviewed 59,325 payer formulary alerts from ambulatory care and 11,630 from the emergency department and inpatient wards. Both local and national modifications resulted in significant and sustained decreases in inappropriate alerts.

CONCLUSIONS: Enduring and meaningful change required partnership with multiple stakeholders, including EHR vendors, ePrescribing vendors, and pharmacy benefits managers. Improving drug alerts, reducing alert fatigue, and promoting value-based prescribing in the EHR will likely require similar partnerships.
A patient with known epilepsy presented to a pediatric emergency department at a large tertiary care pediatric hospital with the chief complaint of increased seizure frequency in the setting of a viral illness. The consulting neurologist recommended short-term therapy with clorazepate (Tranxene; Lundbeck Inc, Deerfield, IL), a long-acting benzodiazepine, to help with increased seizure frequency during this illness. After discharge, the prescription was filled at a commercial pharmacy. The patient’s caregivers adhered to the instructions on the bottle. Two days later, the same patient returned to the emergency department with complaints of altered mental status, slurred speech, and stumbling gait. During medication reconciliation, a review of the previous visit revealed that the patient was given a prescription for alprazolam (Xanax; Pfizer Inc, New York, NY), a short-acting benzodiazepine used for anxiety in adults in place of the recommended clorazepate (Tranxene), a long-acting benzodiazepine used as an antiepileptic.

Due to this error that resulted in patient harm, a root cause analysis was performed, which revealed that the provider misinterpreted a payer formulary alert displayed in the electronic health record (EHR), believing that alprazolam was the recommended alternative for clorazepate as depicted in Fig 1. Upon further review of this payer formulary alert, it was discovered that this medication safety event was a symptom of a much larger problem related to inappropriate payer formulary alerts. In the entire data set of >11,630 inpatient and emergency department payer formulary alerts that were reviewed, the alprazolam for clorazepate substitution only occurred once based on the unique combination of the patient’s insurance and prescription for clorazepate. However, there was a large alert burden caused by these inappropriate payer formulary alerts as well as 23 other instances of prescribing error attributed to these results, which could have resulted in harm. These errors included substitution of single-ingredient vitamins for over-the-counter (OTC) children’s multivitamins, substitution of

![FIGURE 1](https://example.com/figure1.png)

SCREENSHOT FROM EPIC TEST ENVIRONMENT SHOWING SUGGESTED SUBSTITUTION FOR CLORAZEPATE TO ALPRAZOLAM. REPRINTED WITH PERMISSION FROM EPIC SYSTEMS CORPORATION, 2015.
epidural clonidine for oral Tylenol, and substituting long-acting calcium channel blockers for short-acting ones. These errors were attributed to inappropriate payer formulary alerts caused by ePrescribing certification requirements. ePrescribing certification specifications required a local dictionary lookup for all medications that lacked a pharmacy benefits manager (PBM), creating unintended errors and a high alert burden. We set out to prevent future patient harm and to reduce alert fatigue by removing inappropriate payer formulary alerts required by Surescripts certification standards. Inappropriate payer formulary alerts were defined as those alerts that led to inaccurate medication or durable medical equipment (DME) substitutions.

A PBM acts as a third-party administrator of prescription drug programs, typically contracted by payers. PBMs are primarily responsible for maintaining the payer formulary and processing and paying prescription drug claims. They are intended to redirect prescribers to use covered medications. Therefore, payer formulary alerts do provide value to patients and payers. Patients pay out-of-pocket for medications not covered by their PBM. Previous research has shown that medication adherence can be a function of cost1 and that nonadherence to medications is related to increased health care use in children and adolescents.2 Prescribers have an ethical and professional responsibility to choose the medication that offers the highest value (the most effective clinical therapeutic at the lowest price), ideally suggested by the PBM formulary. However, the use of additional alerts also creates an alert burden that can lead to patient harm.3 Previous studies have shown that the best way to combat alert fatigue is to reduce low-utility alerts.4,5 Inappropriate payer formulary alerts are an example of low-utility alerts due to their high rate of inaccurate substitution recommendations with common medications, including albuterol and OTC medications.

In an effort to balance the utility of payer formulary alerts for cost savings and improved medication compliance with the concerns for both additional alert burden and, more importantly, possible patient harm, we initiated a quality-improvement project targeted at reducing inappropriate payer formulary alerts at our institution by 30% within 1 year through the removal of unsafe ePrescribing certification requirements.

METHODS Understanding a Complex Process

To effectively decrease inappropriate payer formulary alerts, we first engaged with key vendor stakeholders after the event previously described to review the logic and design of these alerts. Process mapping was used to understand each step (Fig 2). Payer formulary alerts are unique in that they require input from multiple external sources. These alerts are triggered when a provider places an order in a computerized provider order entry (CPOE) system, which in our institution is Epic (Epic Systems Corporation, Verona, WI). Electronic prescriptions are then passed to a national ePrescribing network, in this case, Surescripts (Minneapolis, MN). Surescripts passes an eligibility query to the patient’s PBM to determine the specific prescription

![FIGURE 2](https://example.com/figure2.png)

FIGURE 2 Formulary payer alert interrelationships between CPOE, national ePrescribing network, and PBM.
coverage. The PBM may optionally suggest a list of alternative medications on the basis of insurance coverage. If a patient is prescribed a medication that is not covered by his or her insurance, the PBM can return a list of alternate drugs in the same class or that represent a reasonable therapeutic alternative that are covered. If the PBM does not suggest an alternative, the ePrescribing certification specifications active in 2014 required that the CPOE system query a local drug database to find alternatives in the same therapeutic class that are covered. Our local drug database is provided by Medi-Span (Wolters Kluwer Health, Minneapolis, MN). In the alprazolam/clorazepate substitution, the patient’s PBM did not cover clorazepate but also did not suggest an alternative. Both medications are listed in the same therapeutic class (benzodiazepine) in the drug database, and alprazolam was covered by the patient’s insurance. As a result, the initial order for a long-acting benzodiazepine in the pediatric patient with epilepsy triggered a payer formulary alert that offered the short-acting benzodiazepine alprazolam as a possible formulary alternative. This substitution was an unintended consequence of the ePrescribing certification requirements of Surescripts, which generated the inaccurate payer formulary alert. The other 23 instances of possible harm found also were created by the same certification requirement. Therefore, disabling individual formulary alternatives would only rarely prevent harmful events because it might represent a relatively uncommon combination of medication, PBM, and formulary alternative. Instead, we concluded that the best way to reduce the burden of inappropriate payer formulary alternatives was to work with national vendors to change the ePrescribing certification requirements.

User Responses to Payer Formulary Alerts
When presented with the alert, the prescriber has the option to do the following: (1) continue with the original order (effectively overriding the alert), (2) cancel the ordering process, or (3) accept the alternate therapy and proceed to the next ordering screen. Even after accepting the alternate therapy, the prescriber may choose not to place the order, perhaps indicating that the user realized the payer formulary alert was not appropriate and aborted the process before signing the order. A prescriber’s decision to override or cancel an alert is a commonly used measurement of the perceived utility of the alert. We used prescribers’ decisions around these payer formulary alerts as well as investigating other possible errors caused by inaccurate payer formulary alerts to determine which types of payer formulary alerts were inappropriate or likely to cause harm. The payer formulary alert that was commonly overridden or canceled included OTC nonprescription medications. Because many OTC medications are not covered by PBMs in the pediatric population, essentially all payer formulary alerts for certain classes of common OTC medications in our setting triggered alerts, as was the case for OTC analgesics.

The generation of these inappropriate payer formulary alerts was clearly an unintended consequence of the ePrescribing certification specifications, which require a local dictionary lookup for all medications that lacked a PBM. In 1 common scenario, a prescription for oral acetaminophen would trigger a payer formulary alert, force a local drug dictionary lookup, attempt to match on the category of “analgesic, non-narcotic,” and finally suggest an alternative of epidural clonidine. Epidural clonidine is on the PBM formulary but is clearly an inappropriate therapeutic alternative for oral acetaminophen. Other categories that triggered many alerts included albuterol prescriptions, OTC medications, and orders for DME.

Implemented Changes
In discussion with both our EHR and ePrescribing network vendors, we identified that existing ePrescribing certification requirements that require CPOE systems to query a local drug database and select a covered alternative caused the initial event and led to 23 other possible instances of harm as previously outlined. Shortly after the initial medication error was noted, we convened a meeting of the clinical decision support committee on March 11, 2014. Concurrently, our medication safety committee escalated the issue to the Institute for Safe Medication Practices, which included a notice describing the error mode in their biweekly newsletter. We escalated the concern regarding the inappropriate payer formulary alerts to the attention of our Epic technical services representative who put us in touch with the clinical informaticist and ePrescribing team at Epic. Through this physician liaison, we were introduced to the vice president of clinical quality at Surescripts, who convened an alternative therapeutics forum to address this issue. In June 2014, Surescripts organized a therapeutics alternative forum that included representation from our institution, payers, PBMs, drug database vendors, and EHR vendors. The outcome of the meeting was a set of suggested updates to the certification requirements that would give PBMs and EHR vendors more latitude in filtering and displaying payer formulary alerts. Surescripts agreed to remove certification requirements for OTC medications and DME. They allowed local changes to be made as deemed appropriate by the clinical decision support team at an institution. These changes were implemented by Surescripts in August 2014. Furthermore, we continued to follow local payer formulary alert rates and identified targets for local improvement. Our first changes occurred in November 2014 in which we removed any remaining alerts for OTCs and DME (local change 1). Next, in December 2014 we identified further OTC medications that were missed with initial grouping in November and removed the alerts (local change 2). Last, in April 2015, we made changes to the alerts so that the payer formulary alerts would only suggest medications with the same route as the original order. For example, if an inhaled medication was ordered, the formulary alternative list would be restricted to those medications that also had an inhaled route (local change 3). Figure 3 summarizes the timeline of events.

Analysis
Control charts were used to track the percentage of payer formulary alerts
related to OTC medications, DME, and multivitamins that were canceled or overridden as a proxy for inappropriate alerts that the user found confusing (those that were cancelled) or of no additional value (those that were overridden), in addition to the alert types known to cause inaccurate substitutions. By using a custom structured query language query, we reviewed all occurrences of payer formulary alerts in the evaluation period. Data were obtained from the Epic Clarity reporting database. For each payer formulary alert, we obtained the date/time of the order, the location of the clinical encounter where the order was placed, the name and therapeutic class of the original medication, the action taken by the ordering provider in response to the alert ("cancel" the ordering session, "continue" with the original order, or "accept" the alternative), and whether the user placed the alternative order. If the user placed an alternative order from the therapeutic alternatives list, we were also able to obtain the name and therapeutic class of the alternate medication. Rates of inappropriate alerts were followed weekly for 13 months from January 2014 to January 2015. Our goal was to decrease inappropriate payer formulary alerts by 30% within 1 year through the removal of unsafe ePrescribing certification requirements.

RESULTS
For the time period of January 2014 to January 2015, we reviewed payer formulary alerts from all ambulatory visits (59,235 alerts) as well as payer formulary alerts from inpatient and emergency department encounters at the time of discharge (11,630 alerts). The changes after the Surescripts forum resulted in significant and sustained decreases in inappropriate alerts that may contribute to alert fatigue (see Fig 4). Initially overridden and cancelled orders (the marker for inappropriate alerts) for multivitamins, OTC medications, and DME compromised 27% of all override and cancel orders. Our goal was to decrease these inappropriate alerts to 19%, a 30% overall decrease. National changes by Surescripts that occurred between months 7 and 8 resulted in a significant decrease in alerts below the goal.
line, with sustained decreases of <5%. Local changes occurred in 3 parts and allowed for sustained decreases in goal categories of multivitamins, OTC medications, and DME. In addition, these changes led to the removal of the e Prescribing certification requirements that contributed to patient harm.

DISCUSSION
To our knowledge, the reports of the Institute for Safe Medication Practices submitted by our institution and this article are the first to describe this specific failure mode, which is attributable to misinterpretation of electronic data supplied by PBMs in the EHR. The introduction of the broader use of electronic medication prescribing promised to help decrease medication errors and studies after wide-scale implementation have supported this. However, the additional alert burden and risk of misinterpretation of these alerts leading to patient harm may outweigh the benefit when the alert suggests inappropriate and unsafe alternatives.

In our example, the identification and escalation of 1 adverse drug event led to a cascade of changes both within our own institution and nationally. Investigation into the root cause of this medication safety event revealed that the alprazolam/clorazepate substitution was the tip of the proverbial iceberg and suggested a much more complex cause for this error related to e Prescribing certification requirements. This situation was clearly an unintended consequence of the e Prescribing certification specifications, which required a local dictionary lookup for all medications that lacked a PBM.

In addition to the changes to the certification requirements to remove the types of substitutions that caused harm to our patient, we also sought to reduce the high frequency of these inappropriate payer formulary alerts. When clinicians are exposed to too many clinical decision support alerts they may eventually start to ignore them, a phenomenon described as alert fatigue. Alarm fatigue is generally thought to be attributable to 2 distinct factors. First, responsiveness to alerts decreases as the number of simultaneous alerts increases, a function of cognitive overload. Second, when clinicians are repeatedly exposed to the same low-utility alert over a period of time, they become desensitized to it, leading to a decline in clinician responsiveness to that category of alert, essentially a type of “alarm tachyphylaxis.” Due to the high number of these inappropriate payer formulary alerts, we believe they have the potential to contribute to alert fatigue and to cause harm through inappropriate substitutions. We hope that, through removal of these inappropriate payer formulary alerts, clinicians will be more likely to adhere to accurate payer formulary alerts that save money for their patients, because previous work has shown increased adherence to high-utility alerts with the removal of low-utility alerts.

By partnering with vendors to understand this error, we were able to decrease rates of payer formulary alerts locally and to effect changes in e Prescribing vendor certification criteria nationally. The national changes had the largest effect on decreasing the inappropriate payer formulary alerts to help combat alert fatigue; however, the local changes were also necessary to remove all of the inappropriate substitutions to prevent future patient harm. We have seen a sustained decrease in payer formulary alerts, with no additional reports of adverse events at our institution. Ongoing work regarding changes to payer formulary alerts to improve their substitution recommendations continues in an effort to balance the importance of cost savings for patients with possible harm created by inaccurate substitutions and alert fatigue.

CONCLUSIONS
A single event at our institution uncovered a host of inappropriate alerts caused by e Prescribing certification requirements developed to redirect prescribers to use covered medications. These alerts, which are part of e Prescribing certification requirements, created patient harm through inaccurate and unsafe substitutions as well as through high alert burden. To prevent future events of harm, we partnered with multiple stakeholders, including EHR vendors, e Prescribing vendors, payers, and PBMs, to make sustained local and national changes. Through tracking of inappropriate payer formulary alerts we were able to show an overall decrease in these unnecessary alerts, and we were able to change certification requirements to improve substitutions. We are grateful to the stakeholders who worked closely to improve the safety of all pediatric patients, and we hope this model of collaboration to improve the quality of care becomes the norm, not the exception.

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REFERENCES


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