Assessment of an Integrated Clinical Surveillance Alert System

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ABSTRACT

PURPOSE: To assess the changes in alert acknowledgement and intervention rate after integration of a clinical surveillance alert system with an electronic health record.

METHODS: This is a 60-day pre-post quasi-experimental study completed at a large academic medical center which assesses the utilization of eight medication alerts within a stand-alone clinical surveillance system before and after integration with the electronic health record. The primary outcome assessed is alert acknowledgement rate by clinical pharmacists.

RESULTS: 176 alerts were activated during the pre-assessment period and 230 alerts in the post-assessment period. Results will be described in higher detail including acknowledgement rate, alert accuracy, pharmacy consult rate, and pharmacy intervention related to alerts.

CONCLUSION: The use of clinical surveillance alerting systems can identify meaningful pharmacy led therapy interventions regardless of clinical pharmacy service model. Integration of such systems into the EHR improves their utilization and in our study was associated with a higher rate of alert identified therapy intervention.

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BACKGROUND

Utilization of clinical decision support (CDS) for pharmacotherapy orders at time of computerized provider order entry (CPOE) and pharmacist order verification is widely utilized in the hospital pharmacy setting. Historically, these tools have primarily utilized drug-drug interaction checkers, medication allergy precautions and contraindications, patient lab data, and other information as included in the Criteria for Meaningful Use Medicare and Medicaid EHR Incentive Program[1]. These systems are prioritized to make therapy interventions and provide enhanced monitoring near time of order entry, prior to medication administration to a patient. Many electronic health record (EHR) systems lack automated clinical surveillance capabilities or alerts to assess the ongoing monitoring requirements of medications. Standalone clinical surveillance systems, integrated with the existing EHR, can aid in ongoing pharmacotherapy monitoring, and utilization is growing in the hospital pharmacy environment[2]. There are many available programs that serve to provide ancillary clinical surveillance services for hospital pharmacy departments, including TheraDoc (Premier Inc., Charlotte, NC), Sentri7 (Pharmacy OneSource, Inc., Bellevue, WA), MedMined (CareFusion, San Diego, CA), and VigiLanz (VigiLanz Corporation, Minneapolis, MN). Historically, real-time clinical alerting systems have been challenging to implement due to inadequate assessment of often complex clinical situations resulting in high bypass rates and few meaningful actions. Successful implementation of alerting systems usually incorporates specific evaluation for possible clinical benefit predetermined high-risk medication intervention opportunities. For example, a rule-based alerting system was developed to address medications inappropriately ordered for naso-gastric tube administration[3]. A similar study assessed the associated reduction in medication errors with a rule-based alert for patients with hypokalemia[4].

Not exclusive to any clinical alert system, specific attention must be given to maximize the value and accuracy of alert identification and presentation. Burdensome alerts with little to no clinical relevance can foster to alert fatigue and desensitization. This could lead to an error if an alert is inappropriately dismissed, and especially relevant considering some studies have identified an average alert override rate of up to 90% or higher [5-7]. Alert fatigue is commonly attributed to a high alert volume and alert inaccuracy due to shortcomings in the logic of the alerting system. The alert timing and ease of accessibility has also been shown to contribute to clinician workflow interruption and inappropriate alert dismissal[8-10]. Additionally, regular review and revision of rule based clinical surveillance systems may not be completed due to the extensive time required and the often subjective data[11]. Positive end user perception, although challenging to maintain, may also improve alert responsiveness and adoption among pharmacists and is likely directly influenced by alert specificity[12].

These shortcomings must be addressed to effectively implement clinical surveillance programs utilizing electronic data analytic tools. New technology may improve the challenges that surround ease of use and clinical relevancy of alerts. This study adds to previous literature in assessing implementation of a novel technology to improve utilization of clinical surveillance alerts. The objective was to assess changes in clinical surveillance alert system utilization after the system was changed from a separate standalone window to an interfacing ribbon floating over the EHR window. The alert acknowledgement rate and resultant end action by the user was analyzed to determine the impact.

METHODS

Study design

This was a 60-day pre-post quasi-experimental study to assess the acknowledgement of alerts and subsequent interventions by clinical pharmacists with a new EHR interfacing clinical surveillance alert ribbon. The study was completed at Houston Methodist Hospital, a large tertiary academic medical center located in Houston Texas, and part of an eight-hospital health system. The hospital includes a clinical pharmacy team of approximately 50 clinical pharmacists who operate in primarily de-centralized consult-based roles providing daily review of medication orders, patient education, and other direct patient care services. Pharmacy consults may be ordered by a provider to allow a pharmacist to manage medications per hospital policy such as for anticoagulants or renal dose adjustments. Prior to the interfacing ribbon, alert acknowledgement was completed through a standalone web browser maintained independently, and in addition to the EHR. After a 60-day pre-assessment, eight rule-based alerts were added to the interface ribbon. This was accomplished by adding a floating pane on the

Table 1: Rule Based Alerts

Rule Based Alerts
Enoxaparin greater than one milligram per kilogram per day with creatinine clearance less than 30 mL/min
Enoxaparin dosed every 12 hours with creatinine clearance less than 30 mL/min
Rise of 0.3 mg/dL in serum creatinine in 48 hours while receiving IV vancomycin
Rise of 50% in serum creatinine within seven days while receiving IV vancomycin
Active orders for both metronidazole and piperacillin/tazobactam
Piperacillin/tazobactam dosed at an interval greater than every six hours with creatinine clearance greater than 40 mL/min
Warfarin ordered for at least three days with no INR results
Sotalol ordered with creatinine clearance less than 40 mL/min

EHR screen to interact with and acknowledge alerts without the need for a separate computer program open or additional login information. The eight rule-based alerts added to the interfacing ribbon are seen in table 1. Determination of included alerts were reviewed by a cohort of clinical, operational and medication safety pharmacists and were assessed based on the expected sensitivity and specificity of the rule, clinical value of the targeted intervention, actionable intervention rate of the alert, and expected alert volume. Rules included in the assessment were made up of both safety indicators such as anticoagulant overdosing, and quality indicators such as antibiotic underdosing.

Data and Endpoints

All patients for whom an alert triggers will be included in the assessment and all alerts will be included individually in the case of multiple alerts firing for the same patient during an individual hospital encounter. The pre-assessment period was from August 1st, 2021 to September 29th, 2021 and post assessment period from January 11th, 2022 to March 12th, 2022.

Clinical pharmacists were notified of the additional alerts in the interfacing ribbon by email and announcement prior to implementation, however no announcement of this assessment was made. Alert acknowledgement was encouraged in all communications but explicitly not required throughout the duration of the study. If a duplicate alert fired for the same patient for the same alert parameters within 24 hours, it was excluded from the study. Alerts which were unacknowledged but whose parameters were not met for at least 24 hours were also excluded due to lack of appropriate time for alert review prior to possible intervention. Alert acknowledgements were only included if acknowledged by a pharmacist, alerts acknowledged by another staff member such as a pharmacy student were excluded from the analysis.

The primary outcome assessed was alert acknowledgement rate by clinical pharmacists. Secondary endpoints included pharmacist intervention after acknowledgement, time to acknowledgement including within 24 hours and all duration, and specificity of alerts based on the associated rule parameters. Data regarding clinical surveillance alerts was collected through an online portal and exported to Microsoft Excel (Microsoft, Seattle, WA) for analysis. Retrospective chart review was completed to determine associated medication order actions resulting from an alert including medication dose change, retiming of a dose, and order discontinuation. Pharmacist intervention was defined as any medication order action related to the alert and included order modification, discontinuation, or additional lab order entry. Pharmacist interventions were attributed to alerts if completed within 10 minutes of alert acknowledgement or if alert acknowledgement documentation indicated cause of order action.

Statistical analysis with the chi square test and Fisher's exact test was utilized for the primary endpoint, and subgroup analyses of alert outcomes. Time-to-event analysis, Kaplan Meier curve with log rank test was utilized for time to alert acknowledgement. An alert acknowledgement

rate improvement from 20% to 50% was used to estimate a necessary sample size of 76 alerts in the assessment to be sufficiently powered with beta of 0.2 and alpha of 0.05. A p-value of less than 0.5 was determined for statistical significance. Statistical analyses were completed with RStudio (version 1.4.1106 © 2009-2021 Rstudio, PBC).

RESULTS

Primary Endpoint

A total of 406 total alerts were included in the study, 176 alerts in the pre-intervention period and 230 alerts in the post-intervention period. 12 alerts in the pre-intervention period and 26 alerts in the post-intervention period were excluded, most commonly due to alert acknowledgement by a pharmacy student, duplicate alerts and a single incident of laboratory result reporting system downtime in the post-intervention period which caused inappropriate alerts. Total alerts and acknowledgements for each rule during the pre- and post-intervention periods are listed in table 2. Alerts were acknowledged within 24 hours of activation for 11 alerts during the pre-intervention period and 50 alerts during the post-intervention period, an increase from 6.3% to 21.7% of total alerts (95% CI .109-0.488, $p<0.05$), as seen in table 3. The piperacillin/tazobactam renal dose adjustment alert had the highest incidence of alerts and alert acknowledgements in both study periods.

Table 2: Alert and Acknowledgement Activity

Rule	Alerts, n		Alerts acknowledged within 24 hours, n			Alerts acknowledged, no time restriction, n		
	Pre	Post	Pre	Post	P value	Pre	Post	P value
All rules	176	230	11	50	<0.01	35	97	<0.01
Pip/tazo dosed >Q6h interval and CrCl >40 mL/min	98	117	3	23	<0.01	6	38	<0.01
Enoxaparin dosed Q12h and CrCl<30 mL/min	22	38	3	9	0.51	19	27	0.21
Scr rise of 0.3 mg/dL in 48 hours while on IV Vancomycin	21	19	0	2	0.22	0	4	0.04
SCr rise of 50% in 7 days while on IV Vancomycin	15	21	0	2	0.5	0	2	0.5
Sotalol and CrCl<40 mL/min	7	15	0	3	0.54	0	7	0.05
Warfarin administered with no INR	5	10	5	9	1	5	9	1
Enoxaparin >1 mg/kg/day and CrCl<30 mL/min	5	7	0	1	1	5	7	1
Duplicate Anaerobic Therapy: Zosyn and Metronidazole	3	3	0	1	1	0	3	0.1

Secondary Endpoints

Total alert acknowledgement without time limitation was 19.9% in the pre-intervention period and 42.2% in the post-intervention period (95% CI 0.20 - 0.54. p<0.05). Alerts acknowledged within 24 hours of activation resulted in direct pharmacy intervention associated with the alert for 18.1%

Outcomes of alert acknowledgements in the pre-intervention period and 20% of post-intervention alert acknowledgements (95% CI 0.08 - 5.39, p=0.89). Concurrent pharmacy consultation orders were active for 6 (55%) pre-assessment medication alert acknowledgements and 26 (52%) post-assessment alert acknowledgements (95% CI 0.24 - 5.23, p=1). The alert was correct to its respective parameters for 91% of alerts in the pre-intervention and 90% in the post-intervention period (95% CI 0.02 - 9.47, p=1), seen in table 4.

Figure 1: Time to Alert Acknowledgement

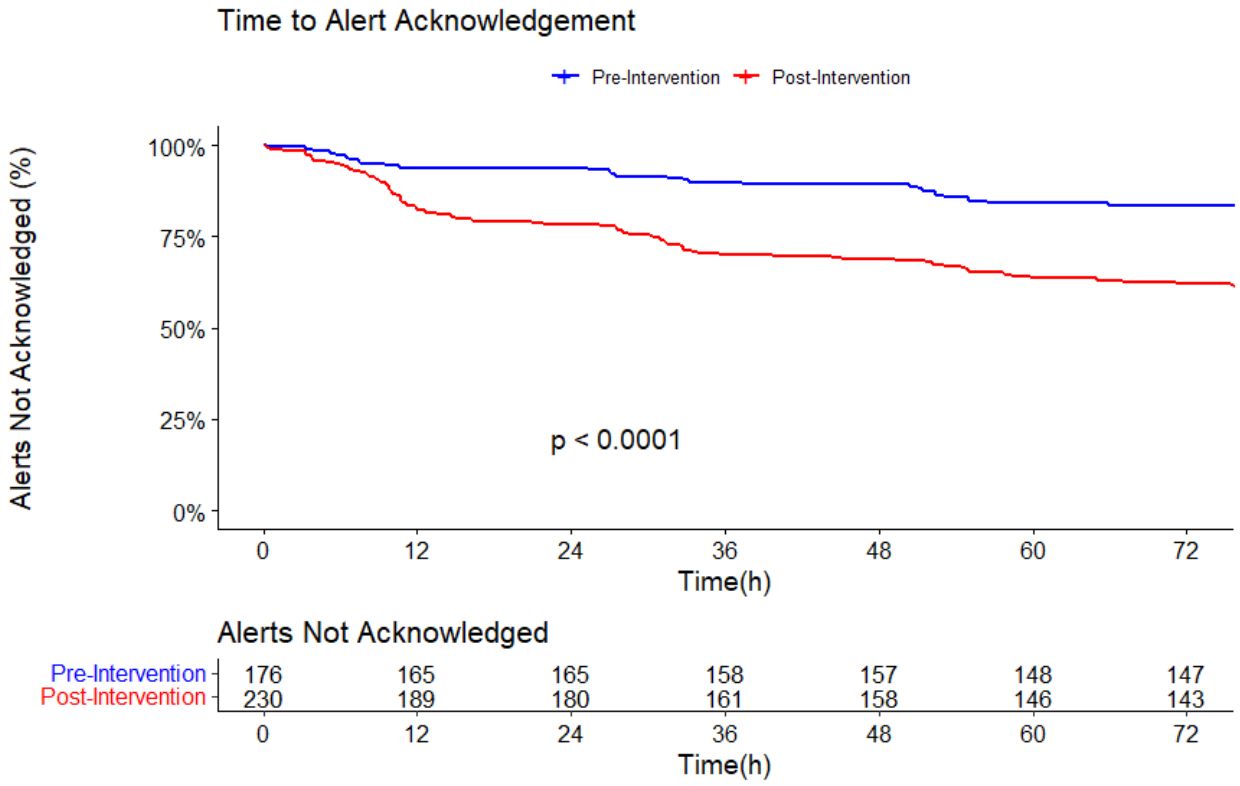

Table 3: Alert Acknowledgement

Primary Outcome	Pre-Intervention	Post-Intervention	p-value
Alert Acknowledgement within 24 hours, n (%)	11 (6.3)	50 (21.7)	p<0.01,
Secondary Outcomes			
Total Alert Acknowledgement, n (%)	35 (19.9)	97 (42.2)	p<0.01
Intervention action from alert, n (%)	2 (18.1)	10 (20.0)	p=0.89
Mean Time to Acknowledgement within 24 hours, h (median)	6.03 (6.39)	9.04 (9.67)	p=0.048
Mean Time to Acknowledgement for All Alerts, h (median)	68.99 (33.14)	30.89 (20.90)	p=0.051

As seen in figure 1, utilization of the interfacing ribbon reduced time to acknowledgement of all alerts and increased the proportion of alerts acknowledged within 24 hours and acknowledgement throughout the life of the alert, p<0.0001. Overall, mean acknowledgement time was reduced from 20.9 hours to 9.67 hours (p=0.051).

DISCUSSION

Outcomes

Our findings present multiple realized values from the integration of a clinical alerting system into an EHR, both in an increased awareness of clinical support tools and in pharmacist driven medication therapy interventions. After integration, alert acknowledgment increased significantly and resulted in a corresponding rise in pharmacy interventions. The proportion of alerts acknowledged within 24 hours was significantly increased with utilization of the interfacing ribbon

Table 4: Alert Pharmacy Consult and Incorrect Activation Incidence

Rule	Active Pharmacy Consult (acknowledged activations)			Inappropriate Alert Activation (acknowledged activations)		
	Pre n (%)	Post n (%)	p	Pre n (%)	Post n (%)	p
All rules	6 (55)	26 (52)	1	1 (9)	5 (10)	1
Pip/tazo dosed >Q6h interval and CrCl >40 mL/min	1 (33)	7 (30)	1	0 (0)	2 (9)	1
Enoxaparin dosed Q12h and CrCl<30 mL/min	0 (100)	4 (44)	0.49	1 (33)	1 (11)	0.45
Warfarin administered with no INR	5 (100)	8 (89)	1	0 (0)	0 (0)	1
SCr rise of 50% in 7 days while on IV Vancomycin	-	2 (100)	-	-	0 (0)	-
Scr rise of 0.3 mg/dL in 48 hours while on IV Vancomycin	-	2 (100)	-	-	1 (50)	-
Sotalol and CrCl<40 mL/min	-	3 (100)	-	-	1 (33)	-
Enoxaparin >1 mg/kg/day and CrCl<30 mL/min	-	0 (0)	-	-	0 (0)	-
Duplicate Anaerobic Therapy - Zosyn and Metronidazole	-	0 (0)	-	-	0 (0)	-

which reduced the time and number of steps necessary to interact with and acknowledge an alert. Time taken to acknowledge an alert was also reduced for the all alert acknowledgement group. While the rate of intervention action from alert did not change significantly, the absolute number of interventions did increase proportionately to alert acknowledgement. Considering the alerts parameters were the same throughout, a consistent rate of action could be expected regardless of alert acknowledgement volume. Alert acknowledgement and intervention persisted regardless of

any concurrent related pharmacy consult order, and without alert acknowledgement may not have been addressed appropriately resulting in an adverse drug event or suboptimal drug therapy. Alerts that coincided with a pharmacy consult order resulted in more timely review and order intervention in multiple instances. However, the cause of pharmacy intervention was highly dependent on the individual workflow of pharmacists and introduces the risk of duplicative review.

Alerts acknowledged and acted upon without a pharmacy consult order represent the most beneficial outcome of the system integration. These situations are the most likely to be overlooked or not immediately addressed due to human error including errors of omission, incomplete review, or distracting environmental factors. Although, these findings did not associate higher need for pharmacy intervention with provider orders for pharmacy consult services, 48% of alerts did not have an associated pharmacy consult. Even considering the pharmacy consult service model in this analysis, an alert for an already consulted encounter brought more timely attention to an actionable intervention then a daily consult review would have provided in multiple occurrences, demonstrating a value of patient review prioritization even in a pharmacy consult driven service model.

Improvements in alert acknowledgement and relatively high action rate in this analysis may be a result from the thorough alert selection. Careful attention was given to intervention rate from an alert as the clinical alert system value would likely decline substantially if alerts fail to correspond with actionable clinical interventions, due to alert fatigue and subsequent disregard. The review required to ensure each alert provided value to the clinical pharmacist was considerably time-intensive and did require ongoing assessment for alert quality assurance. Implementation and

utilization of such a system would likely require dedicated pharmacist support for successful operation.

Ultimately, integration of a clinical surveillance support system into the EHR improved utilization of clinical surveillance alerts and subsequent pharmacist intervention rate. A more formal integration of clinical surveillance alert system into pharmacist workflow may be beneficial for alert utilization and acknowledgement, especially considering the potential benefit to medication safety. Alternatively, a hybrid approach with required review of pre-determined high yield alerts and optional review for all other alerts based on individual's preference may be a more feasible and valuable implementation strategy. Future studies may address the specific needs for more advanced clinical surveillance alert systems such as the integration of artificial intelligence or improved specificity of alerts, and systems would certainly be expected to improve as the technology advances.

Limitations

There were several limitations in this analysis that affected the acknowledgment rate of alerts and assessment of pharmacy interventions. Most importantly, utilization of the alert system and alert acknowledgement was not required for pharmacists at any point. Whether an alert was acknowledged or not was dependent on the specific and unique review workflow performed by each individual pharmacist. There was also no information documented that differentiated whether an alert was seen or viewed, an alert could be viewed but not acknowledged. If a pharmacist viewed an alert but did not document acknowledgement, causation of any intervention taken could be misattributed. Only information documented in the alert and relevant order actions in close proximity of alert acknowledgement was used to identify resultant actions from an alert.

While pharmacists did not receive direct feedback for the alerts assessed during this study, information regarding a separate and concurrent alert response initiative was shared during this study period that may have contributed to an improved acknowledgement rate. However, this would not explain the absolute improvement in alert mediated pharmacy interventions.

The overall inappropriate alert rate was acceptable but was higher than expected and could contribute to alert fatigue and reduced perceived value of the alerting system. While inappropriate alert activation could be reported, determination of the false-negative alert rate would require thorough review of nearly all patient encounters with possible alert parameters present, not feasible for a study of this size. In a similar vein, the intervention rate for alerts was well below 50% indicating the majority of alerts were not clinically actionable. However, increasing this rate with the current technology would require much more stringent rule parameters and must be balanced with the risk of an actionable situation that doesn't meet the reduced alert sensitivity. Potentially duplicative review completed by pharmacists must also be considered if an alert brings attention to an intervention that has already been addressed as part of a pharmacist's independent review separate from the alerting system. In regard to this concern, the most frequent areas of occurrence were intensive care units which had a high rate of pharmacy consult services and increased clinical complexity, resulting in alerts with a much lower actionable intervention rate.

The variety of clinical pharmacy service structures in a hospital setting may challenge the implementation and use of an intricate or detailed clinical surveillance system due to risk of duplicative work and lack of clinical sophistication causing poor system utilization and perceived value from clinician users. However, even considering the consult based clinical pharmacy service model followed in this study, the value of ancillary clinical surveillance alert systems that are easy to use, readily accessible and specific to targeted meaningful interventions, cannot be understated.

CONCLUSION

The use of clinical surveillance alerting systems can identify meaningful pharmacy-led therapy interventions in a pharmacy consult service model. Integration of such systems into the EHR improved alert utilization and in our study was associated with a higher rate of pharmacist mediated therapy intervention identified by an alert.

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