Clinical Ophthalmology

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ORIGINAL RESEARCH

Reducing Injection-Related Safety Events in Retina Clinics

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Purpose: At the Kellogg Eye Center, we identified a series of injection-related patient safety events that led to a systematic review and redesign of our intravitreal injection protocol. The objective was to reduce injection-related patient safety events to zero.

Methods: A retroactive review, using the Healthcare Failure Mode and Effect Analysis model as a guide, was performed on our process for delivering intravitreal injections to identify potential failure modes and their impact.

Results: The total number of injection-related safety events was 1 in 2017 and 16 in 2018 at baseline. Potential vulnerabilities identified included errors in communication, patient identification, clinical documentation, and medication orders. The injection protocol was redesigned. After implementation, there were zero injection-related safety events in all Kellogg Eye Center Retina clinics for the subsequent 18-month follow-up period.

Conclusion: It is possible to redesign and implement an intravitreal injection protocol to reduce the rate of safety events in a large academic eye center.

Keywords: adverse event, healthcare failure mode and effect analysis, intravitreal injections, patient safety

Introduction

Intravitreal injections are one of the most common medical procedures performed in the United States,[1] and are performed in outpatient ophthalmology clinics to treat macular edema and choroidal neovascular membranes from various retinal diseases, including diabetic retinopathy, retinal vascular occlusions, posterior segment inflammation, endophthalmitis, age-related macular degeneration and myopic degeneration.[2] Commonly administered medications into the posterior segment include anti-vascular endothelial growth factor agents (bevacizumab, ranibizumab, aflibercept and brolucizumab), corticosteroids (triamcinolone and dexamethasone), and various anti-infective medications (vancomycin, ceftazidime, voriconazole, foscarnet).[3] These medications can be administered in one or both eyes, sometimes during the same visit. For many chronic retinal diseases, patients receive a series of intravitreal injections on a recurring schedule which necessitates having a safe injection protocol in place to prevent adverse events.

Despite the large number of intravitreal injections performed (estimated at 5.9 million injections in the United States in 2016),[2] ophthalmologists vary widely in terms of preferred safety techniques and protocols.[4] Intravitreal injection-related patient safety events can range in severity from causing no significant harm to the patient to having a severe adverse effect.[5] Much of the emphasis on safety in intravitreal injections centers around the risk of post-injection endophthalmitis.[1] At the Kellogg Eye Center (KEC), University of Michigan, we identified several injection-related safety events that led to a detailed systematic review of our entire injection process. The goal of this project was to reduce injection-related patient safety events to zero following implementation of a revised intravitreal injection protocol.

Materials and Methods

The objective of this Quality Improvement (QI) project was to (a) implement a practice to improve the quality of care, and (b) collect patient or provider data regarding the implementation of the practice for clinical, practical, or

Received: 15 February 2022
Accepted: 8 April 2022
Published: 22 April 2022

administrative purposes. Such activities do not satisfy the definition of "research" under 45 CFR 46.102(d), which is " … a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge … " Therefore, the Health and Human Services (HHS) regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an Institutional Review Board (IRB), or for these activities to be conducted with provider or patient informed consent. Exempt research is now codified at 45 CFR 46.104.

In March 2018, in response to safety events, Michigan Medicine's KEC organized a multidisciplinary task force consisting of faculty retinal specialists, ophthalmic technicians, medical assistants, photographers, clerical staff, clinic administrators and continuous improvement specialists to analyze the current state of intravitreal injection workflow at our institution. Initial meetings focused on educating the team on the continuous improvement tools that would be used for the analysis, which included Lean strategies and Healthcare Failure Mode and Effect Analysis (HFMEA).[6] The team met weekly or biweekly through the end of May 2018. During this time the team conducted observations and drafted process maps for all the key players/steps in the intravitreal injection process; status reports were submitted regularly to the department and hospital patient safety leadership. Injection-related risk reports were not rigorously reported prior to 2017, therefore the task force instituted a proactive risk assessment of the intravitreal injection process from 2017–18 using the HFMEA model developed by the Veterans Affairs National Center for patient safety in 2001 as a guide.[6] The aim was to determine the vulnerabilities that contributed to previous safety events and to also identify additional potential points of failure that could be curtailed before they resulted in a near-miss or unintended adverse outcome. The task force identified the following possible injection-related major safety events: wrong patient, wrong site, wrong medication, and expired medication.

The HFMEA necessitates analyzing and diagramming the primary process steps or tasks and the subprocess steps for the intended procedure. Each subprocess step is further dissected to identify what could prevent the step from being completed correctly (failure modes [FMs]) and why these FMs occur (failure mode causes).[7] Countermeasures are then proposed and implemented to address those vulnerabilities.

Results

Greater than 15,000 injections are performed annually at the four retina clinics that span the main KEC location. We have 20 faculty physicians and 42 ophthalmic technicians and medical assistants who administer and assist the physician with intravitreal injections, respectively. The total number of injection-related safety events was one in 2017 (wrong eye) and 16 in early 2018 (two wrong medication, 14 expired medication) prior to this project. These injection-related safety events were not isolated to a particular faculty member, staff member or clinical site.

Figure 1 outlines the process map for intravitreal injections performed at KEC retina clinics at baseline. In conducting this review, a total of 12 potential vulnerabilities leading to a safety event were identified for 5 of the 7 steps (the check-out process and the examination by the physician were felt to be low risk for contributing to an error and were excluded as a vulnerable steps). Of the 12 vulnerabilities identified, 5 were prioritized as high-value/high-impact and are included in Figure 1.

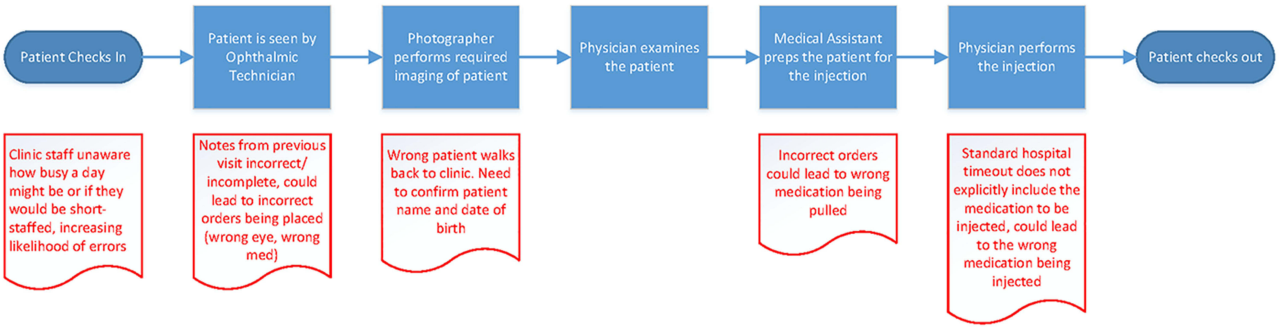

Figure 1 Intravitreal injection process map.

1. Verify patient's name
2. Verify patient's date of birth
3. Verify correct procedure, including name and expiration of injectable medication
4. Verify correct eye(s)
5. Physician initials the correct eye(s)
6. Previous chart's note pulled up and reviewed on the computer in the room

Figure 2 Kellogg Eye Center pre-procedure time-out.

The analysis of the process map led to several countermeasures and changes in how retina clinics perform intravitreal injections at KEC. The task force created an intravitreal injection Standard Operating Procedure (SOP) that was then applied to all KEC retina clinics and physicians. Notably, the SOP includes daily safety huddles focusing on team communication and identifying potential issues for the day, as well as mandating a 6-point standardized timeout process for every injection, specifically including laterality, medication name and expiration date (Figure 2).

The task force then introduced the new SOP to all four KEC retina clinics (including faculty, trainees, and staff). This educational effort spanned two months (September-November 2018). Subsequently, periodic audits of adherence to the SOP by a team of independent outside observers were instituted and their aggregate results shared regularly with the retina clinic workforce. In the 18-month follow-up period (December 2018-May 2020) after implementation of the SOP, there were zero patient safety events associated with intravitreal injections at KEC. This ultimately resulted in an institutional safety award being granted to the main KEC retina clinic, marking the first time an ambulatory clinic at the University of Michigan received this recognition.

Discussion

In 2018, 14 injection-related safety events were due to the use of expired medications. The cluster of expired medications came to one clinic together as one lot, and that lot was administered consecutively to different patients on the same day by the same team who did not realize the medications were expired.

Our task force's in-depth review of the baseline intravitreal injection process identified many potential vulnerabilities. Using a simple impact/effort analysis, 5 high-priority vulnerabilities which could lead to patient safety events were further examined to assess if barriers to error were already in place or needed modification. The following changes were then implemented:

Clinic Staff Unaware of Patient Volume or Staffing Shortages

Planning for daily retina clinic huddles, which included sharing metrics to monitor patient volume and encouraging open communication between all team members, began in June 2018. The huddles were formally initiated the following month.

Prior Notes are Incomplete or Incorrect

The retina service chief addressed the critical importance of complete and accurate notes at a meeting with retina faculty and staff. In addition, staff were actively encouraged and empowered to speak up if they encountered a note with missing information.

The Wrong Patient Walks from the Waiting Room to Clinic

The use of 2-point patient identifiers (full name and date of birth) at the start of each clinic encounter and at all handoffs between caregivers was reinforced.

Incorrect Orders Entered Into the Electronic Health Record

Identifying countermeasures and streamlining the injection process led to creation and implementation of an intravitreal injection SOP designed to prevent patient harm. The SOP mandates verification of the order placed in the electronic medical record against the written plan. Since poor communication is a root cause of many safety errors,[8] educating the

retina clinic teams about implementing this SOP was a key step in improving the safety culture in our department as our teams pursue the goal of clear and open dialogue among all members.

The Standard Hospital Time-Out Does Not Include the Medication to Be Injected

A pre-existing standard KEC 6-point clinic procedure time-out used in all KEC clinics was modified to be relevant to clinic-performed intravitreal injections, as part of the SOP. These modifications included the additions of verifying medication name and expiration date aloud during the pre-injection time-out.

After daily huddles were initiated in all four retina clinics as part of this project, similar huddles also spread to other sections in our department; now all KEC clinical areas perform daily huddles. In addition, having independent auditors from outside the department observe the injection process periodically affords us the opportunity to refine and adjust the SOP. Moreover, the auditor team can evaluate SOP adherence and then discretely give feedback regarding an individual's performance, which is a key factor in maintaining adherence.[9]

While auditing is helpful, positive feedback as well as the support of departmental and institutional leadership are key factors in the success of having zero harm events in the 18 months after implementation of the SOP. The main KEC retina clinic was awarded an institutional 365 Days of Safety Award in recognition of a full year without injection-related safety errors. Such recognition is a powerful tool to reward and incentivize the clinic team members in pursuit of the goal of patient safety. In addition, promoting an institutional approach of team-based systemic improvement rather than blaming specific individuals involved in safety errors contributes to the culture of safety that should be the goal of every healthcare delivery system.[10]

This project is potentially limited in that the workflow of KEC retina clinics may not be identical to other retina clinics. Thus, we would encourage tailoring of our intravitreal injection SOP to other sites and institutions as necessary. Also, follow-up longer than 18 months is needed to know if adherence to the SOP can be sustained with the goal of avoiding future adverse safety events.

Conclusion

This study demonstrated that it is possible to redesign and implement an intravitreal injection protocol to reduce the rate of safety events in a large academic eye center. It is important to engage clinical staff at all levels when creating and implementing a quality improvement plan. Promoting a culture of open communication, humility, and lack of individual blame can lead to continuous improvement in the safety of many tasks we perform daily as health care providers. Support and buy-in from leadership as well from every member of the clinical team is imperative towards the goal of achieving zero patient harm.

Acknowledgments

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Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Disclosure

The authors report no conflicts of interest in this work.

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