ABO SELF-DIRECTED IMPROVEMENT IN MEDICAL PRACTICE ACTIVITY (NON-CLINICAL)

Topic

Title of Project:	Avoiding Preventable Errors in Outpatient Intravitreal Injections

Project Description

Describe the quality gap or issued addressed by this activity. (Included in your response to this question should be a description of the resources that informed your decision to pursue this topic, a description of what the literature says about the issue you identified, and the rationale for choosing to address this clinical project	To avoid preventable errors in outpatient intravitreal injections, three interventions are proposed: . Time out performed and documented in EMR (EPIC) . Site Marking of eye to be injected with betadine swab (making "X" over brow of eye to be injected) . Identifying any injection errors or NEAR MISSES - Wrong Eye, Wrong Drug, Expired Drug, Wrong Route (i.e. - sub-Tenon's vs intravitreal injection)
Background Information: The month you pulled the baseline IRIS performance report and any additional information that me be pertinent:	The Institute of Medicine's 1999 landmark report "To Err is Human: Building a Safer Health System" highlighted the reality and impact of preventable medical errors. Important strategies applied to increase patient safety is the surgical time out and surgical site marking, now readily adopted as an Operating Room standard procedure. The simplicity and practicality of these strategies make them easily translatable to clinic procedures. Intravitreal injection therapy has revolutionized the management of patients with neovascular macular degeneration, Chordal neovascular membrane of other etiologies, diabetic macular edema, central and branch retinal vein occlusion macular edema, proliferative diabetic macular edema, and uveitis among others. The number of patients undergoing these procedures is considerable and continues to grow - more than 2 million per year since 2011. While this procedure carries with it risks of endophthalmitis, retinal tear or detachment, vitreous hemorrhage, lens injury, elevated intraocular pressure among others, there also exists the possibility of surgeon-related errors such as wrong site (wrong eye), wrong medication, expired medication, wrong route (e.g. sub-Tenon's vs intravitreal) - errors that should be preventable. Indeed, a review of Lucentis IND safety reports from 4/0/02 - 11/26/06 (in excess of 45,000 injections during this period) identified 22 operator (surgeon) related errors including wrong eye, wrong medication (confused lidocaine with ranibizumab), wrong dose, wrong route (subconjunctival vs intravitreal). These events occurred in patients who were involved in clinical trials, and treatment was administered under strict study-guided protocols. And yet, operator related errors - ideally preventable - did occur. Indeed, at that time, surgical site marking, and time outs had not been readily embraced by surgical culture. Additionally, safety experts the importance of identifying both errors and near misses to help improve safety. A NEAR MISS is defined as an unplanned event that did not result in injury, illness or damage - but had the potential to do so. An injection related NEAR MISS could include wrong eye, wrong medication (either incorrect or using medication to which patient has an allergy or sensitivity), expired mediation, wrong route of delivery, or other identifiable event that fits the NEAR MISS definition.

	This project aims to apply the strategy of using documented time out and site marking to prevent surgeon-related errors. With these relatively simple low-cost interventions in place, errors and near misses will be recorded, with a goal to look for opportunities to improve patient safety. I am unaware of any previous personal injection errors, but I do recall several previous near-misses. In fact, it was those occasions that inspired this project. In our institution, while near misses are discussed, this is the first project in the Department of Ophthalmology to systematically collect and review near misses. Near misses are thought to be valuable learning lessons for patient safety.
Project Setting: (Please select from options below): • Group Practice • Healthcare Network • Hospital • Multi-Specialty Group • Solo Practice • Surgical Center • Other	Other: • Academic setting - outpatient clinic
Study population: (describe the type of patient for whom the care process will be improved, e.g., all patients in your practice, patients with diabetes, patients presenting for emergency care:	All patients in my practice receiving intravitreal injections in clinic settings. Age range - 12 and up Both genders Diagnoses: neovascular macular degeneration, CNVM from other etiologies, Diabetic macular edema, proliferative diabetic retinopathy, central and branch retinal vein occlusion with macular edema, Uveitis CME

Quality Indicators / Performance Measures: It is important to carefully define outcome or performance measures that will be quantified at baseline (before the care process is changed) and at re-measurement (after you have implemented the proposed improvement) to quantify the impact of your care process change. There are two basic types of performance measures - process of care measures and outcomes of care measures. · Process of care measures (e.g. timely treatment of diabetic retinopathy) can influence outcome measure (e.g. decreased risk of severe vision loss); · Outcome measures can be linked to processes of care that can be improved. Generally, performance measures are expressed as rates, often as percentage rates. For example, if the intent of a project is to improve the quality of glaucoma care in your practice, you may choose to improve your rate of establishing a goal IOP in patients with newly diagnosed glaucoma, measured over a 3-month period. · The numerator of this process measure would be the number of newly diagnosed patients during this time who have a goal IOP recorded in the medical record. · The denominator would be the total number of patients diagnosed during that same time period. Continuous variables (e.g. the refracted spherical equivalent after cataract surgery) can often be simplified and transformed then into percentage rates by setting a quality threshold (within 0.5 diopters in the intended spherical equivalent) which, if attained, would qualify the patient to be in the numerator (e.g. number of patients within 0.5 diopters / total number of patients). It can be advantageous but not mandatory to have more than one quality measure in order to gauge the impact of your process change. In the example above, an additional outcome measure might be the percentage of patients in whom the goal IOP is attained within the first 6 months after diagnosis. If possible, measure quality indicators for at least 30 individual patients or data points during the baseline and again during the follow up period.	**Measure Type:** Process **Measure Name:** INJECTION ERRORS **Numerator Statement:** INJECTION ERRORS **Denominator Statement:** Total intravitreal injections performed in outpatient clinic **Measure Type:** Process **Measure Name:** NEAR MISSES **Numerator Statement:** NEAR MISSES **Denominator Statement:** Total intravitreal injections performed in outpatient clinic **Measure Type:** Process **Measure Name:** Time Out Performed **Numerator Statement:** Time Out Performed **Denominator Statement:** Total intravitreal injections performed in outpatient clinic **Measure Type:** Process **Measure Name:** Site (eye) marked **Numerator Statement:** Site (eye) marked **Denominator Statement:** Total intravitreal injections performed in outpatient clinic

We realize that this may not be feasible or appropriate for all projects. Please indicate at least one measure below; either a process or outcome measure: **Example Measure**: . Measure Type: Process Measure . Measure Name: Patient pain level during intravitreal injection . Numerator Statement: Number of patients in who pain levels decreased by 2 points on a 1-10 scale . Denominator Statement: 30 consecutive patients undergoing intravitreal injection.	

Project Interventions: Quality improvement requires that you analyze your care delivery processes and identify changes, which if implemented, will improve care and outcomes. Generally, educational interventions are thought to be weak and demonstrate little impact. The introduction of tools, strategies or systematic approaches to care delivery is more powerful. A tool is a thing, for example a preoperative checklist, or written standardized process or protocol. Strategies include changes in procedures or policies like the introduction of a surgical time out before surgery is initiated. Systematic approaches to care delivery involve a comprehensive analysis of care process and the introduction of a combination of tools and strategies designed as a complete process. Please describe the changes to your care processes you intend to introduce:	Introduction of strategies to prevent operator errors and to identify sources of errors. . Apply time out strategy to clinic intravitreal injections Confirm with patient and medical record the eye for treatment Confirm medication to be used Confirm medication has not expired . Apply site marking to confirmed eye undergoing treatment Use betadine swab to mark 'X' above brow of eye for treatment . Assess the effectiveness of this strategy and technique by recording: Injection Errors: Wrong Eye, Wrong Medication, Expired Medication, Wrong Route NEAR MISSES: Detected Wrong Eye, Wrong Medication, Expired Medication, Wrong Route prior to treatment. Error was corrected, but NEAR MISS is recorded and analyzed for patterns to further modify strategy to increase safety
Project Team: (include roles for yourself and all members of your team): List the individuals who will be involved in your quality improvement project (i.e., solo project, partners in practice, office staff, OR personnel, anesthesiologists) and the roles they will contribute.	Project team - I will collect and review data. I will share information with the crew of ophthalmic technicians that work with me including all members of my LEAN clinic team.
Will any other ophthalmologists be requesting MOC credit for participation in this SD-PIM?	No

Project Outcomes/Results

Project Summary	In the following sections, please prepare a brief summary of the project highlighting the data collected, effectiveness of your measurement approach, interventions, and the overall impact of the project.
Baseline Data: Quantify each of the quality indicators / performance measures described above for the baseline period (before interventions for improvement were introduced). Report the numerator, denominator and the calculated percentage rate for each measure.	METHODS: Prospectively, in the outpatient retina clinic setting, any errors or near misses were individually recorded in a log. These cases could be identified by technicians or injecting physician (TBC). Log was kept by TBC. Each such case was reviewed for source of ERROR or NEAR MISS. After a six-month period, clinic schedule and records were reviewed for total half day clinic sessions and injections performed during this time. If a patient had two injections done on the same day, this situation was considered as 2 injections. EMR Records were also reviewed for documentation of site marking and time out performed. Injections were performed in the clinic setting, often integrated into the daily course of clinic. One half day per week was set aside as an injection-only clinic. Typically, patients would receive initial check-in by front desk personnel and technicians who would review daily schedule, retrieve medication and place it in treatment room, talk to patient and prepare patient and patient's eye for treatment. An order for the medication and the eye for treatment would be place in the EMR in a pending state, awaiting signature of treating/injecting physician. When patient was prepared and ready, injecting physician (TBC) would speak to patient, examine patient, review medical record and perform time out, confirm eye and medication for injection, enter information into EMR and M.A.R. (Medication Administration Record), sign pending orders, prep and site mark eye, deliver injection, then complete EMR for visit. DATA: Mar 1, 2016 - Aug 31, 2016 1 provider (TBC) Half-day clinic sessions - 104 Injections reviewed - 509 TIME OUTS PERFORMED (as recorded in EMR) = 509 TIME OUTS PERFORMED/TOTAL INJECTIONS = 509/509 SITE MARKING PERFORMED (as recorded in EMR) = 508 SITE MARKING PERFORMED/TOTAL INJECTIONS = 508/509 TOTAL ERRORS (Wrong eye, wrong drug, wrong route, expired drug, etc.) = 0 TOTAL ERRORS/TOTAL INJECTIONS = 0/509 TOTAL NEAR MISSES (Wrong eye, wrong drug, wrong route, expired drug, etc.) = 8 TOTAL NEAR MISSES/TOTAL INJECTIONS = 8/509 = 1.6% NEAR MISSES - CATEGORIES WRONG EYE - 3 WRONG MEDICATION - 2 EXPIRED MEDICATION - 3

Follow-up Data: Quantify each of the quality indicators / performance measures described above for the re-measurement period (the period following implementation of the interventions for improvement).	**NEAR MISSES - CATEGORIES** WRONG EYE - 3 WRONG MEDICATION - 2 EXPIRED MEDICATION - 3 DESCRIPTIONS: WRONG EYE: 3 cases In each of the three cases, the patient was receiving intravitreal injection treatment to both eyes on staggered or sequential visits. The technician had looked at the daily schedule (which includes patient name and planned eye and medication for injection), had spoken to the patient, and had prepared medication and the eye for injection. It was the injecting surgeon's time out - which included review of medical record notes in EMR and discussion with the patient - that found the discrepancy. In each case, the patient was unsure of the eye for treatment, so one could not rely on patient's confirmation. Definitive confirmation came from review of medical record notes, and the proper eye was treated. It was later determined that the daily schedule had listed the incorrect eye for treatment. WRONG MEDICATION: 2 cases In each of the two cases, the patient had been receiving ranibizumab injections. The technician had looked at the daily schedule (which includes patient name and planned eye and medication for injection), had spoken to the patient, and had prepared bevacizumab as the medication for injection. It was the injecting surgeon's time out - which included review of medical record notes in EMR and discussion with the patient- that found the discrepancy. In each case, the patient was unsure of the medication for treatment, so one could not rely on patient's confirmation. Definitive confirmation came from review of medical record notes, and the proper medication was used. It was later determined that the daily schedule had listed the incorrect medication as bevacizumab for treatment. EXPIRED MEDICATION: 3 cases It is our custom for the surgeon to enter the information into the M.A.R - Medication Administration Record in the EMR- for each intravitreal injection. Technicians are not allowed access to this portion of the EMR. The information entered includes medication lot number, expiration date, and eye for injection. In each of the three cases of expired medication, that medication was bevacizumab. In our institution, bevacizumab is compounded by two of our hospital pharmacies, typically with an expiration date three weeks after sterile preparation into a pre-filled syringe. We order lots of 60 once to several times per week. The technician would typically place the medication in the room for treatment but would not always check expiration date. Entering data for the M.A.R. discovered these expired medications. These medications were discarded and replaced with unexpired proper medications.

Project Impact

Compare the baseline data to the re-measurement / follow-up data and quantify the impact of the process of care changes (your project interventions). The project hopefully resulted in improvement; however, some projects may result in a diminution in quality. If a lack of improvement or reduction in quality occurred, suggest other strategies that might be more effective.	DISCUSSION: The EMR medical record of visit notes/encounter note was the most definitive source of correct information. A time-out checking this information was essential to avoiding errors in 5 cases (3 wrong eyes and 2 wrong medications). This EMR medical record of visit note/encounter note had been completed by the injecting/treating physician. Other guides directing treatment (daily schedule, injection log) were not as reliable, as the data for these guides were entered by individuals separated from actual patient treatment. As such, unintended clerical errors could and did occur. Although such errors are infrequent, the consequences could be significant if they go unrecognized, Checking the expiration date on any medication prior to patient administration should be automatic. I have never seen an operating room circulating nurse hand a medication to a surgical scrub technician without verbally confirming the expiration date. Adding this same discipline to intravitreal medication is equally important. Patients undergoing ophthalmic surgery are asked to verbally confirm the eye/surgical site and surgical procedure as part of the day of surgery's pre-operative process. While such confirmation was sought from patients prior to intravitreal injection, patients were sometimes unsure as to the eye and medication for treatment, particularly when both eyes had received or are receiving treatment at different times. In each of the NEAR MISSES involving wrong eye or wrong medication, the patient's recollection would not have caught the potential error. Indeed, if a patient or accompanying family member calls into question the eye or medication for treatment, review of the medical record and discussion is warranted prior to treatment. After confirming the proper surgical site, patients undergoing ophthalmic surgery have that site marked by the surgeon or her/his designee. Employing this same idea, after confirming the eye for injection, at the time of preparation, I use a betadine swab, the same one used for treating lashes/lid margin and place an "X" above the brow of the eye to be treated. This "X" remains visible during the time of procedure, and it may be removed with an alcohol pad after the injection is performed. I apply the mark so that if I was called from the room after preparation but prior to injection, I would be reminded as to the eye for treatment. Indeed, if the person confirming the site for treatment is not continually present from the time of confirmation until the time of treatment, site marking may be useful. In an era of busy clinics with high volumes of intravitreal injections, efficiencies are understandably and appropriately sought. However, any steps that look to avoid preventable errors are steps worth taking. The practice of recording errors is long established to identify problems and prevent future errors. Collecting and analyzing NEAR MISSES is also a useful discipline to improve patient safety. I am one of 6 retinal specialists performing injections. Extrapolation from my experience to my entire group would translate to 48 Near Misses over 3000 injections. The recommendations below are implemented not just in my practice, but in the practice of all 6 of us. RECOMMENDATIONS IMPLEMENTED FROM THESES STRATEGIES: Use Medical Record as source to confirm proper eye and medication for treatment. Do not rely on daily schedule. Patient's memory may be useful, but not always reliable. Particular care should be made in the case of patients receiving treatment to both eyes on a staggered or sequential schedule.

	Impact- Over last 200 injections and since implementation - 2 wrong drug situations were identified and caught. Technicians used the medical record to confirm the drug rather than only using the daily schedule Impact- Over last 200 injections and since implementation - 2 wrong drug situations were identified and caught. Technicians used the medical record to confirm the drug rather than only using the daily schedule Expiration date should be checked on every medication prior to administration to a patient. Particular attention should be made to checking expiration dates on medications, especially compounded medications, in which the time between preparation and expiration is short. Impact- Over last 200 injections and since implementation - expiration dates checked on all medications before being brought to room for injection. Continue to monitor for ERRORS and NEAR MISSES to look for opportunities to improve patient safety. This exercise demonstrated such value. Site marking ("X" over brow with betadine swab) may be useful after site confirmation (as in no. 1 above), particularly if there is an interruption in personnel and procedure between the time of site confirmation and the actual injection. This project highlights the value of recording and evaluating Near Misses. Near Misses are thought of as learning opportunities, and this project was no exception. The information gained from reviewing these Near Miss cases has changed our clinic processes for intravitreal injection - among myself and my 5 partners. We are also implementing an easier way to capture Near Misses using the EMR. The project also highlights that operator-related intravitreal injection errors are uncommon, but the potential for such errors exists.

Project Reflection

Did you feel the project was worthwhile, effective?	Yes
How might you have performed the project differently?	Getting assistance from IT personnel to create an easier way to capture Near Misses - rather than using a hand-recorded log.
Please offer suggestions for other ophthalmologists undertaking a similar project.	Having large numbers is valuable; Using EMR/electronic database information is valuable. This often requires some preliminary work so that the EMR may be customized/adapted to more readily capture desired data. In that way, valuable features of the project may be carried forward.