**ABO IMPROVEMENT IN MEDICAL PRACTICE ACTIVITY**

**(CLINICAL)**

**Topic**

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| **Title of Project**: | Assess the Degree of Pain Experienced by Patients Undergoing an Intravitreal Injection at the Moment of Needle Insertion |

**Project Description**

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| 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 | Intravitreal injections evoke a sense of fear and anxiety in patients. Fear  of pain associated with the procedure is a primary concern for patients.  By assessing the amount of pain experienced and reducing that pain, the fear and anxiety may be reduced as well. This would improve the patient experience overall and potentially improve patient compliance with subsequent injections, which are often required for treatment of retinal disease. |
| **Background Information**:  The month you pulled the baseline IRIS performance report and any additional information that me be pertinent: | I perform between 15-30 intravitreal injections per clinic day. Our current protocol is to place a pledget of 4% lidocaine into the inferior fornix for  5-10 minutes prior to injection. I propose to assess the amount of pain experienced by each patient at the time of needle insertion on a 1-10 scale.  I will also assess how close we are adhering to the current practice of anesthesia in terms of average amount of time between anesthesia administration and procedure. We will then add a subconjunctival injection of 2% lidocaine immediately prior to ophthalmic sterile prep and assess the improvement in patient experience and pain scale. |
| **Project Setting**: (Please select from options below):   * Group Practice * Healthcare Network * Hospital * Multi-Specialty Group * Solo Practice * Surgical Center * Other | Group Practice |
| **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: | The study population will include all patients presenting for intravitreal injection in the office setting. |
| **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**: Patient pain level during intravitreal injection  **Numerator Statement**: Number of patients whose pain level decreased  by 2 points on a 1-10 scale  **Denominator Statement**: 30 consecutive patients undergoing intravitreal injection  **Measure Type**: Process  **Measure Name**: Frequency of subconjunctival hemorrhage occurring  during intravitreal injection  **Numerator Statement**: Number of patients who develop subconjunctival hemorrhage during intravitreal injection  **Denominator Statement**: 30 consecutive patients undergoing intravitreal injection |
| 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: | We will assess our current system of anesthesia prior to intravitreal injection by evaluating the time from anesthesia administration to procedure. We  will assess the patient pain level on a 1-10 scale under our current anesthesia protocol. We will assess these measures for 30 consecutive patients. We will identify changes to the care process including method  of anesthesia administration, for improvement. We will then use the same pain scale protocol for 30 consecutive patients to assess the reduction in pain with intravitreal injection. We will also assess the frequency of subconjunctival hemorrhage occurring between the two anesthesia methodologies. The improvement in care process is intended to reduce  pain experienced with intravitreal injection and improve patient overall experience. |
| **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. | I perform between 15-30 intravitreal injection procedures per clinic day.  My office administrator will identify patients presenting for intravitreal injection to be included in the assessment. I will employ 2 technicians  who will administer the initial pledget, document the time of anesthesia administration, and document pain scale by each patient in our EMR. |
| Will any other ophthalmologists be requesting MOC credit for participation in this SD-PIM? | NO |

**Project Outcomes/Results**

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| **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. | We collected initial data for 30 consecutive patients undergoing intravitreal injection in my practice using our standard anesthesia procedure which consisted of placing a pledget of 4% lidocaine in the inferior fornix for  5-10 minutes prior to injection. We recorded time at placement and  time of removal and injection. The average time of anesthesia was 6 minutes (range of 4-15 minutes). We assessed patient pain level on a 0-10 scale. The average numerical pain scale reported was 3 (range 1-5). The lowest pain scores were associated with longer pledget time. 75% of patients with pledget time of > 8 minutes reported a numerical pain score of 2 or less; 10 % of our patients experienced subconjunctival hemorrhage associated with the injection. |
| **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). | In our re-measurement period, we assessed a second set of 30 consecutive patients in my practice undergoing intravitreal injection. The anesthesia protocol was modified to include a subconjunctival injection of 2% lidocaine in addition to the previous pledget protocol. We again recorded time of pledget placement and time of injection. The average time of anesthesia treatment was 8 minutes ( range 5-15), which reflected the addition of the subconjunctival injection. We again assessed the patient pain level on a  0-10 scale. The average numerical pain score was 2 ( range 0-5). We again noted that the lower pain scores were associated with longer pledget times with 85% of patients with pledget times of >8 minutes reporting numerical pain scores of 2 or less. Our rate of subconjunctival hemorrhage increased to 30%. |

**Project Impact**

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| 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. | In our initial patient evaluation, we found that our anesthesia time was directly associated with patient pain scores with pledget times of < 8 minutes being associated with increased pain. The addition of the subconjunctival lidocaine injection in our re-measurement period did  result in a lower overall average pain score by 1 numeric point. However,  we again noted that the lower pain scores were associated with longer pledget times, so it is unclear whether the overall numeric reduction is a result of the subconjunctival lidocaine itself or the longer pledget time. Additionally, we found an increase in the rate of subconjunctival hemorrhage to 30% with addition of the subconjunctival lidocaine. After reviewing this data, we have revised our anesthesia protocol to increase  our pledget time to a minimum of 8 minutes as the association of increased anesthesia time with decreased patient pain was clear. We have not added subconjunctival lidocaine to our standard protocol as the pledget time had  a stronger association with patient comfort as well as a less frequent incidence of subconjunctival hemorrhage. Through this process, we have identified factors for improvement in our anesthesia process to both increase patient comfort  and reduce subconjunctival hemorrhage. |

**Project Reflection**

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| Did you feel the project was worthwhile, effective? | YES |
| How might you have performed the project differently? | For a more definitive assessment of the benefit of subconjunctival lidocaine, I would have standardized the pledget time in a separate data collection first. Once optimizing the anesthesia protocol from this standpoint, would have allowed a more accurate assessment of the potential additional benefit of subconjunctival lidocaine. |
| Please offer suggestions for other ophthalmologists undertaking a similar project. | I would recommend identifying an initial process for improvement that can be streamlined easily and can involve staff in a proactive way. The members of my team involved in this project have been energized by taking part in improving patient care and are now actively looking for other projects! |