

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

Topic

Title of Project:	Reduction in the Rate of Perioperative Incidents Related to the Intraoperative Time-Out Procedure
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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	<p>The quality concern of this project is the occurrence of perioperative incidents related to gaps in the current process of conducting sign in/time-out for surgical vitreoretinal procedures. If such gaps are addressed, potential incidents may be identified prior to initiating anesthesia and surgery, and also the occurrence of some intraoperative and postoperative complications maybe avoided or minimized. This in turn is conducive to better quality outcomes and more importantly, a safer medical practice environment for our patients.</p> <p>RESPONSE TO ADDITIONAL INFORMATION:</p> <p>Dear reviewer,</p> <p>Thank you for the email. Please find the clarifications needed regarding the 2 points raised:</p> <ul style="list-style-type: none">• "It is not clear whether or not the additional non-personal instance was part of the denominator of 96": Only the personal instances were part of all the calculations. The non-personal instance was not counted. It was used as an illustration to support the project idea.• "The proposed module suggests a using a denominator of 30. Would it make sense to adjust the denominator to a larger number so that the module would be likely to detect a reduction in instances of error?": The denominator of 30 is for the process measure. The outcome measure (the 2 personal instances are 2 outcomes rather than processes) denominator is 96 exactly like the denominator used for calculating the baseline rate as indicated in the proposal. <p>I hope this clears the confusion behind the 2 points above. Please advise how to proceed onwards.</p> <p>Best regards</p>
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Background Information:

The month you pulled the baseline IRIS performance report and any additional information that may be pertinent:

The idea of this project started with 2 personal experiences and 1 non-personal experience, all in the operating room. The 2 personal experiences occurred among the last 96 vitreous cases performed.

The first personal experience included an incident where the preoperative sign in procedure failed to recognize that the consent for the surgical procedure being conducted was not available on file. This was recognized late in the process after the patient was put under general anesthesia but luckily before the surgical procedure was started. After the circulating nurse discovered the lack of the consent, we were informed. The procedure had to be aborted according to institutional policy and the patient was awakened immediately without having the surgical procedure he was anesthetized for. The main question was the following: how did the patient make it through to the operating room with the consent lacking? He made it through all the checkpoints: from initial check-in by the preoperative nurse at the preoperative area, to the hand-off to the circulating OR nurse in the prep room, to the sign in/time out process inside the operating room. It turns out that the patient had received an intravitreal injection of anti-VEGF the day before surgery in preparation for the vitrectomy for his diabetic traction retinal detachment and vitreous hemorrhage. The consent for the preoperative intravitreal injection was thought to be the consent for the vitrectomy, thus allowing the patient to progress that far into the operative process through all the usual checkpoints. This case made me realize that the process of surgical consent identification requires some systematic modifications including strategy alterations as well as the introduction of further safety tools, especially that this incident has a high chance of recurrence knowing that diabetic traction retinal detachments constitute 60-70% of our retinal surgeries and that preoperative anti-VEGF injections are an integral part of the approach to such cases. The 2 systematic changes implemented included the following:

- A check performed the day before surgery where the surgeon reviews the charts of all the surgical cases for the following day looking for the availability of the appropriate consents. The findings are summarized in an email that is sent to a pool of recipients that includes all the nurses assisting in the cases as well as the ophthalmic OR manager. In that email, the surgeon alerts the nurses to the existence of the consent on file, its validity, and the need to obtain one on the day of surgery if needed.
- On the day of surgery, the consent is printed out from the electronic medical record and given to the surgeon by hand so the surgeon can follow what the nurse is saying at the time of sign-in/time-out just before anesthesia and surgery initiation to make sure the consent indicates the appropriate procedure (for example, vitrectomy with endolaser rather than intravitreal injection in the above case).

The second personal experience was related to a patient undergoing complex and long retina surgery with a previous history of LASIK surgery. During the procedure the cornea was getting hazy affecting the view to the back of the eye. Decision was to scrape the epithelium. At that point I had forgotten the old history of LASIK. Luckily enough for me, as I was scraping the epithelium in the usual quick way I noticed what seemed to me like the LASIK flap edge just lifting temporarily. I stopped immediately and asked the circulating nurse to review the record for prior surgical history.

	<p>Sure enough, LASIK was on the list. I then proceeded with scraping the epithelium but had to convert to a much more careful approach stroking the blade from the hinge area nasally towards the temporal periphery as gently as possible in order to avoid lifting the whole LASIK flap, as has been described in previously reported cases. The flap stayed in place nicely, a huge relief.</p> <p>The third experience, which was not personal, included a case that was presented during a vitreoretinal meeting of a patient that died postoperatively after a long procedure of internal resection of a large choroidal melanoma. The death was due to an air embolus. It was thought that the air made it to the blood stream during air fluid exchange through the large retinchoroidectomy that was performed and while some steps of the surgery were performed under air to control bleeding. Subsequently I became aware of similar cases in the literature that occurred in the absence of a large retinchoroidectomy where it was thought that the infusion cannula was partially embedded into the suprachoroidal space thus allowing air to pass into the suprachoroidal space and from there into the blood stream while performing air fluid exchange and thereafter.</p> <p>The second and third experiences above made me realize that a strategy modification implementing new tools as part of our surgical sign-in/time-out process is needed to avoid such occurrence in the future. This was further reinforced by a recent report from the American Society of Retina Specialists cautioning about such occurrences and the need to implement new systematic tools to avoid them (The Journal of Vitreoretinal Diseases 2017, Vol 1:79-80). The 2 systematic changes implemented included the following:</p> <ul style="list-style-type: none"> • Adding "history of previous LASIK" to the checklist of items we check for at the time of sign-in/time-out prior to anesthesia and surgery initiation. This must be confirmed from the beginning and checked off. The process is then repeated during surgery whenever the surgeon needs to perform corneal scrapings whereby we all stop and the surgeon confirms the lack or the presence of a prior history of LASIK. In the presence of a prior history of LASIK, corneal scraping when needed must be performed in a careful and gentle manner as described above. • Similarly, an additional time out is performed prior to air-fluid exchange where the surgeon confirms the presence of the tip of the infusion cannula in the vitreous cavity before switching to air. This must be verbalized loud and the check box indicating that this time out was performed should be checked on the time-out checklist. Switching to air is not allowed prior to doing this.
<p>Project Setting: (Please select from options below):</p> <ul style="list-style-type: none"> • Group Practice • Healthcare Network • Hospital • Multi-Specialty Group • Solo Practice • Surgical Center • Other 	<p>Hospital</p> <p>Other:</p> <ul style="list-style-type: none"> • The project will occur in a multispecialty hospital setting where I practice. We are a total of 3 vitreoretinal surgeons.
<p>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:</p>	<p>The patient population for whom the care process will be improved includes mainly patients undergoing eye surgery, particularly vitreoretinal surgery. However, some of the parameters described in this project, such as the presence of the appropriate consent on file and the history of prior LASIK surgery are also applicable to other ophthalmic and non-ophthalmic surgical procedures in general, and not only vitreoretinal procedures.</p>

	<p>Therefore, the impact of such a quality improvement initiative may include other medical disciplines.</p>
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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: rate of deficient time-out/sign-in procedure related to deficiency in either consent confirmation, or LASIK history check, or infusion cannula check
Numerator Statement: number of cases in which consent confirmation, LASIK history check, or infusion cannula check was not performed during the time-out/sign-in procedure as specified above
Denominator Statement: 30 patients undergoing vitreous surgery

Measure Type: Outcome

Measure Name: rate of consent error, LASIK flap damage, or post-operative death from air embolus
Numerator Statement: number of vitreous surgery cases with consent error, LASIK flap damage, or post-operative death from air embolus
Denominator Statement: 96 patients undergoing vitreous surgery (The 2 personal experiences occurred among the last 96 vitreous cases performed, hence the chosen denominator)

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.

<p>Project Interventions:</p> <p>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:</p>	<p>Please refer to the background information section above. The changes implemented, and the project interventions were described above rather than here so it is easier for the reader to understand the process and outcome measures described above also.</p>
<p>Project Team: (include roles for yourself and all members of your team):</p> <p>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.</p>	<p>We are 3 vitreoretinal surgeons in my institution, and all will be involved in this project. The role of the surgeon is to review the records at least a day before surgery and send an email to OR ophthalmology nurses and ophthalmic OR manager summarizing the surgical procedure for each posted case and indicating the existence in the record or lack of a valid, correct consent for the corresponding procedure. Also, on the day of surgery, the surgeon participates in the sign-in/time-out procedure for confirming that the correct consent is in the patient's record and that the patient does or does not have a history of prior LASIK surgery. Finally, the surgeon also participates in the time out for confirming the correct position of the infusion cannula in the vitreous cavity prior to switching to air when air-fluid exchange is necessary during surgery. The ophthalmic surgical nurses (scrub and circulating nurses) will also be involved in this project. On the day of surgery, the nurses participate in the sign-in/time-out procedure for confirming that the correct consent is in the patient's record, and that the patient does or does not have a history of prior LASIK surgery. The scrub nurse also participates in the time out for confirming the correct position of the infusion cannula by prompting the surgeon to confirm that the tip of the cannula is in the vitreous cavity prior to switching to air when air-fluid exchange is necessary during surgery. The circulating nurse will document that these 3 checks (consent confirmation, LASIK history check, and infusion cannula check) were performed.</p>
<p>Will any other ophthalmologists be requesting MOC credit for participation in this SD-PIM?</p>	<p>No</p>

Project Outcomes/Results

<p>Project Summary</p>	<p>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.</p>
<p>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.</p>	<p>Baseline Process measure:</p> <ul style="list-style-type: none"> • Numerator: 30 (number of cases in which consent confirmation, LASIK history check, or infusion cannula check was not performed during the time-out/sign-in procedure as described in part 1) • Denominator: 30 patients undergoing vitreous surgery <p>This baseline rate is 100% by default since none of these measures or tools were implemented previously.</p> <p>Baseline Outcome measure:</p> <ul style="list-style-type: none"> • Numerator: 2 (number of vitreous surgery cases with consent error, LASIK flap damage, or post-operative death from air embolus) • Denominator: 96 patients undergoing vitreous surgery <p>This baseline rate is 2.1%</p> <p>This baseline rate is already known: $2/96 = 2.1\%$ (the 2 personal experiences described above. This occurred among the last 96 vitreous cases performed, hence the chosen denominator).</p>
<p>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).</p>	<p>Follow-up Process measure:</p> <ul style="list-style-type: none"> • Numerator: 0 (number of cases in which consent confirmation, LASIK history check, or infusion cannula check was not performed during the time-out/sign-in procedure as described in part 1) • Denominator: 30 patients undergoing vitreous surgery <p>This follow-up rate is 0%</p> <p>Follow-up Outcome measure:</p> <ul style="list-style-type: none"> • Numerator: 0 (number of vitreous surgery cases with consent error, LASIK flap damage, or post-operative death from air embolus) • Denominator: 96 patients undergoing vitreous surgery <p>This follow-up rate is 0%</p>

Project Impact

<p>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.</p>	<p>The effectiveness of the interventions discussed in Part 1 was measured by comparing the baseline rates of the process and outcome measures with those at the end of the project period. A significant improvement was noted. Both rates dropped to the ideal target rates of zero. While it is acknowledged that these follow up rates obtained over the project review period may not reflect my future life time experience with this, I certainly hope that the rates remain zero for the rest of my carrier.</p> <p>The overall impact of this project is very significant. If surgical sign-in/time-out process failures as well as unfavorable outcomes related to that are avoided by strategy modifications as discussed in this project, a practice conducive to better patient safety will be created. The impact of this project may also be outreaching in that some of the parameters described, such as the presence of the appropriate consent on file and the history of prior LASIK surgery, are also applicable to other ophthalmic and surgical procedures in general, and not only vitreoretinal procedures. Therefore, the impact of such a quality improvement initiative may include other medical disciplines</p>
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Project Reflection

Did you feel the project was worthwhile, effective?	Yes
How might you have performed the project differently?	<p>The only thing one may have done differently is looking at a much larger number of cases over a much longer period of time. While this is a life time project as stated above, looking at a much larger number of cases is beyond the scope of this ABO recertification activity. Several options for increasing the sample size may be considered. For example, it would be nice to collect beeline data, introduce quality improvement measures and then reassess in 5 years after thousands of cases have been performed.</p> <p>Alternatively, a larger sample size may be achieved in the setting of a multicenter project involving numerous surgeons who agree for a specific set of quality improvement measures to the same end. Again, such projects are outside the scope of this activity.</p>
Please offer suggestions for other ophthalmologists undertaking a similar project.	<p>There are many other similar quality improvement projects one can think of. For example, one may consider looking at improving rates of intraocular lens (IOL) power errors (at time of implantation aside from IOL power calculation) by introducing similar process measures such as reviewing biometry before surgery, sending notifications (email or other) to all concerned people with a table including the cases and the respective IOL powers, including the table in the sign-in/time out procedure, and repeating the time out for lens power selection just as the surgeon asks for the implant during surgery (similar to what was done in my project to avoid LASIK flap damage at time of epithelial scraping for example). A check list including all these mentioned process steps may be also introduced for better documentation and ease of quality review checks. All these measures can lead to a better outcome and a lower rate of errors in IOL power at time of implantation, something that can easily happen to any of us during a busy surgery day</p>