**REGISTRY-BASED IMPROVEMENT IN MEDICAL PRACTICE ACTIVITY**

**(CLINICAL)**

**Topic**

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| **Title of Project**: | To Evaluate and Improve the Steps Involved in the Intraocular Lens Selection Process Across 5 Practices |

**Project Description**

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| Identify the exact measures from your monthly IRIS registry report you will focus on in 100 words or less. | A recent article, Human Error During Cataract Surgery: Right Patient, Wrong Lens, published in EyeNet Magazine, was a reminder to the industry that wrong-lens-wrong site, while statically uncommon, still remains a serious threat in cataract surgery across the country. I would like to chart the steps and implement a review, specific to the lens selection process and share the key steps, review findings, and the steps formulated to improve this safety process. |
| **Background Information**:  The month you pulled the baseline IRIS performance report and any additional information that may be pertinent). | None-Available |
| Project Setting: (Please select from options below):   * Group Practice * Healthcare Network * Hospital * Multi-Specialty Group * Solo Practice * Surgical Center * Other | Surgical Center |
| **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 includes reviewing the selection process of IOLs for all cataract patients spanning a 1-year period. We will look at the lens selection process through its entirety at; 1) wrong-site surgery. 2) correct-site-wrong lens. 3) near-miss incidents. |
| **Project Team**:  (describe the type of patient for whom the are process will be improved, e.g., all patients in your practice, patients with diabetes, patients presenting for emergency care). | As the administrator and Chief Medical Officer of an ophthalmology ASC, South Pointe Surgical Center, I promote a culture of safety in both the clinical and surgical environments. Working with consultants, I work to implement many safety and policy mechanisms in our systems in our ASC on a continuous basis. This project will also include the following participants:   * Nurse Manager * Surgical Tech and materials * Surgical Coordinator * All findings and recommendations will be shared with all ophthalmologists in the surgical center and policy change will be implemented. * We will also utilize a professional ophthalmology consulting   firm, to help offer further recommendations. |

**Quality Indicators / Performance Measures**

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| 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. For the registry-based improvement activity, you will use the monthly performance report generated on your IRIS registry dashboard. | We will implement changes based on a coordinated effort to identify, discuss, and put in place new policies relating to the steps of intraocular lens selection and preparation. For this project I will report on the following categories:   * Wrong lens request * Wrong site (eye) request * Wrong lens ordering * Improper IOL - Patient matching pre-operatively * Exact IOLs not available at the time of surgery, standard surgery * IOL not available following real-time surgery changes: ORA, sulcus selection. |

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| **Improvement Plan:**  State the improvement goal(s) you are aiming for and describe the change(s) to you intend to introduce to achieve the goal(s). 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. | Upon completion of the review, we anticipate a number of strategies will be employed to strengthen the process. These will include building in redundancy, or layering processes, checklists, time-outs, and checks-and-balances to strengthen the safety of IOL selection for the patients we serve here at the center. I will report on the systematic approaches and tools we implement organization wide, during this exercise. |

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| **Project Summary:**  In the following sections, please prepare a 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). | Introduction:  Cataract surgery carries a greater risk of inserting a wrong implant than any other procedure requiring an implant. This is due to a number of factors. Cataract surgery with intraocular lens (IOL) implantation is one of the most frequent operations in the US. These high number of procedures alone increase the numbers of a possible event. Additionally, for every IOL procedure, multiple elements of the data must be measured accurately by specifically trained surgeons. IOL planning and selection requires analysis of many factors about the patient, the eye, their refractive desires, and previous ocular history as well as the use of complex formulae. Correct IOL selection requires the clinician to check multiple biometry calculations and other data fields on different sheets of paper or screens as well as ensuring all pertain to the correct eye and often to transcribe such IOL selection. This, together with a huge number of permutations of available IOL types and dioptric powers, within a high-volume list, increases the risks far beyond that which one could expect with a hip replacement or similar implant. The evolving use of multi-focal, extended depth of field, and toric IOLs adds to the risk of error.  This complexity is expected to continue to rise in the future. The use of intraoperative aberrometry ORA-where the final IOL selection takes place moments before implantation-adds new complexity, significantly altering the traditional stops and safety mechanisms of traditional pre-surgical IOL selection.  Potential adverse events in cataract surgery include wrong patient, wrong eye, and wrong implant. In the safety literature from other industries, these errors fulfill the definition of what are termed, never events'. These are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented. Key in the discussion are also near misses: events that were recognized as an error but did not result in an actual adverse event.  There are safety principles from the business and technology industries that have important applications in a complete avoidance of lens surgery error. |
|  | The Cumulative Act Effect   * Also known as the Swiss cheese model of accident causation, cumulative act effect has direct application in thoughtful design of these lens surgery errors. The model used in risk analysis and risk management, including aviation safety, engineering, healthcare, emergency service organizations, and as the principle behind layered security, as used in computer security and defense in depth. It likens human systems to multiple slices of swiss cheese , stacked side by side, in which the risk of a threat becoming a reality is mitigated by the differing layers and types of defenses which are "layered" behind each other. Therefore, in theory, lapses and weaknesses in one defense do not allow a risk to materialize, since other defenses also exist, to prevent a single point of failure. * System produces failures when a hole in each slice momentarily aligns, permitting (in Reason's words) "a trajectory of accident opportunity", so that a hazard passes through holes in all of the slices, leading to a failure. * An organization's defenses against failure are modeled as a series of barriers, each alone may contain various inherent weaknesses in the individual parts of the system and are continually varying in size and position across the barriers. * Reason hypothesized that most accidents can be traced to one or more of four failure domains: organizational influences, supervision, preconditions and specific acts. * Preconditions for unsafe acts include lenses that are stored in an operating room, or reliance on lens inventories. Unsafe supervision encompasses for example, pairing inexperienced or per-diem OR staff, inconsistent time-outs. Organizational influences encompass such things as poor team training, poor communication culture, staff afraid of retribution if they speak-out. |
|  | Latent vs Active Failures   * We know any process, there may be both active and latent failures. Active failures encompass the unsafe acts that can be directly linked to an accident, such as (in the case of a surgeon), a surgical mistake or mishap. Latent failures include contributory factors that may lie dormant for days, weeks, or months until they contribute to the error. For example, a latent failure could be the similar packaging of two IOLs of differing powers that are then stored close to each other in a dark operating room. Such a failure would be a contributory factor in the administration of the wrong IOL to a patient. Such research led to the realization that medical errors can be the result of "system flaws, not character flaws" and that even with skill and sound judgment error may result.   Study Results   * After comparing 2-year historical data of 5 surgeons at South Pointe Surgical Center, 3 incorrect IOL to correct eye errors were identified. 2 differing axial lengths on LenStar resulted in mild myopia, 1 calibration issue of a-scan ultrasound in a dense, opaque crystalline lens resulted in a 3-diopter hyperopia outcome requiring a subsequent successful piggyback lens procedure. * No wrong eye surgery was performed. Despite the relative statistical safety, there were several near miss incidents and latent errors identified in discussions that create the conditions that may lead to error in the future. The surgical center has only been in operation for 2 years, so the statistical safety may be misleading, adding to the importance of conducting this review and making changes. As the chief medical officer, I have implemented changes based on this study. This, along with the literature review, particularly L R Steeples work as published in Eye and national safety guidelines constitute the categories below, and the system of measurement we are putting in place. The errors and near misses are categorized below by when the incident occurred within the cataract care pathway.   Preoperative issues:  Biometry error 3[a](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftn1)  Transcription error 6[b](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftn2) |
|  | Incorrect data for patient   * Wrong patient biometry data 2[c](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftn3) * Wrong patient medical notes 3[d](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftn4) * Patient identification issues 0   IOL selection errors   * Wrong IOL selected 5[e](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftn5) * Right/left eye confusion2[f](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftn6) * Plus/minus power error 1[g](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftn7)   Intraoperative  Changes in planned procedure   * Change in list order 0[h](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftn8) * Selected IOL not available 0[i](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftn9) * Complicated surgery 0   Perioperative/others   * Communication errors 2[j](applewebdata://0B4DF5D0-D342-4527-BE2E-5622D10074D6/#_ftn1) * Handwriting misinterpretations 0 * Wrong IOL brought into theatre 4[k](applewebdata://0B4DF5D0-D342-4527-BE2E-5622D10074D6/#_ftn2) * Wrong IOL in wrong box 0 |
|  | [a](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftnref1): 2 cases of axial lengths that differed significantly resulting in myopia, 1 case of a calibration issue of a-scan ultrasound, in a dense, opaque crystalline lens resulting in 3 diopter hyperopia and subsequent successful piggyback lens procedure.  [b](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftnref2): 2 instances of error of transcription from source data to a surgery cover sheet, and 4 instances were identified and corrected on pre-op time-out.  [c](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftnref3): 2 instances of the wrong target (0.00 rather than -1.75) printed source data. Both identified and printed correctly prior to case.  [d](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftnref4): 3 instances of the medical notes stating one IOL target, or lens type, and the order form stating another. Identified prior to case.  [e](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftnref5): 3 incidents of wrong eye selection in the ORA. 2 incidents pre-operative surgeon selection -choosing the right power but circling it on the wrong lens make on biometry. This was identified and corrected before surgery.  f: Patient arrived thinking they were having surgery on one eye but had signed consent for fellow eye. Identified prior to start of case.  g: Biometry needed to be re-printed from confusion about an unusual minus lens power in a long axial length. The error was identified preoperatively.  [h](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftnref8): No errors resulting, but we recognize that any change to patient order from late arrival, or necessary postponement may be a latent error.  [i](applewebdata://AA8FF647-FB82-4225-B6F0-203DA6E39852/#_ftnref9): This was not found in our data. However, I know this is a significant problem from prior practices I have worked at. We address this in our protocol  [j](applewebdata://0B4DF5D0-D342-4527-BE2E-5622D10074D6/#_ftnref1): Time-outs were not occurring a second time after ORA identified a new lens. We address this in our changes.  [k](applewebdata://0B4DF5D0-D342-4527-BE2E-5622D10074D6/#_ftnref2): We suspect this is very under-reported. This has not resulted in wrong lens, but we have employed bottlenecking and repeat time-out changes to eliminate this latent error entirely. |
| **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). | Preoperative issues:  Biometry error 0  Transcription error 0   * Incorrect data for patient * Wrong patient biometry data 0 * Wrong patient medical notes 0 * Patient identification issues 0   IOL selection errors   * Wrong IOL selected 0 * Right/left eye confusion 0 * Plus/minus power error 0   Intraoperative:  Changes in planned procedure   * Change in list order 0 * Selected IOL not available 0 * Complicated surgery 0   Perioperative/others:  Communication errors 2   * Handwriting misinterpretations 0 * Wrong IOL brought into theatre 0 * Wrong IOL in wrong box 0 |

**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. | The project has resulted in a number of policy changes involving the individual practices and at the time of surgery in the OR. These are summarized below. In addition, we meet regularly- quarterly with the owners, monthly with the quality control board and weekly with the staff, to discuss, identify problems and implement solutions. This collaboration is important to ongoing improvement and patient safety. This project was successful in identifying specific problems. It generated research and discussion to implement changes to correct these issues moving forward. These will be revisited regularly.  Preoperative Policy Solutions (IOL selection process in the individual clinics)  Biometry/imaging training Rather than using techs, we recommend super-users. Following the study, we now have 2 imaging technology experts who are super-users of our imaging technology. We invest in their education with user consultants from the manufacturers to recognize accurate imaging, errors, inaccuracies in biometry readings. We use several redundant latest-generation formulae to improve the selection accuracy.  **Avoidance of Transcription Errors**  The original biometry, Scheimpflug and Wavefront aberrometer print-outs now constitute the surgical packet.'. The surgeon  circles and initials the IOL lens selection in ink on the biometry page after carefully considering all data.  We have eliminated un-necessary transcription to 'surgical summary sheets' or 'boarding passes' from which we have found that errors in transcription may occur. For instance, if the surgeon is comparing the accuracy of data entered into the ORA from the summary sheet, there is a possibility for error if the summary sheet itself is in error. Only the original biometry, Scheimpflug and Wavefront aberrometer printouts are allowed for comparison.  **Avoid re-visiting the case for selection.**  One source of near miss, occurs from a surgeon re-visiting the surgical plan days after the consultation, necessitating re-visiting the patient notes, surgical plan, desired outcomes, etc. Lens selection now takes place same day during the actual pre-op patient encounter, where the individual details of the case are fresh in the surgeon's mind, and all necessary imaging, biometry and the patient are present to review the goals of surgery. No surgical plan is made outside the presence of the patient. Pre-operative surgical consent now includes the intended prescription target to be initialed by the patient during surgical counseling. |
|  | **Bottlenecking** is a powerful method of safety, where only one individual is involved. This avoids multiple steps of transcription where error may take place. Now, in our practice, IOL selection takes place, and the surgeon alone, enters the lens, make, eye, target into the master document directly, with the patient in the room. No other individual is authorized to adjust this field or entry. This master then becomes the source of lens ordering, and also constitutes the lens order sheet to the surgical center.  **Layering Review**  After the selection takes place, a second trained reviewer blindly selects the IOL independent of the surgeon, using a Lens Selection Checklist and then the two selections are compared. Any discrepancy in choice between the reviewer and the surgeon choice is flagged in a hard stop and the surgeon consulted.  Operative Policy Solutions(Surgical Center)  **Lens Submission Deadline**  Practices submitting lens lists for their upcoming surgery dates have a hard stop 1-week deadline. This ensures adequate time to order the IOLs.  **Avoidance of inventory**  Inventories are a common source of inaccuracies. "Doctor, we don't have that lens" whispered to a surgeon in a procedure is appalling and completely avoidable with zero tolerance. I have seen this scenario in other previous practice locations in my career. This happens from reliance on an inventory to produce the needed lenses on the day of surgery. With many surgeons operating at our ASC, this is a set-up for error for which we have zero tolerance. This is a precondition for unsafe acts. We require a hard-stop verification step 3-days prior to the surgery. Hard stop is defined here as a selection verification, that if not passed, stops the case until it is corrected.  **Rubber Band Policy**  The lens for the case as well as its back-up, are rubber-banded to the patient's boarding sheet and set-aside, out of the inventory, and never to be used by another surgeon, and are officially OUT of the inventory in a separate supply room.  **Avoidance of Transcription**  Just like in the pre-selection process, errors of transcription are known to occur in the OR. Transcribing IOL selection onto white boards, OR lists and paper notes and not checking intraoperatively with source documents or writing lens selection on whiteboard for the next case during an on-going operation. We entirely avoid these inherently problematic practices. |
|  | **Time outs and Team Briefs**  We always refer to source biometry and clinical documents during IOL checks at each stage listed above. We conduct a beginning of day team brief. Any unusual powers, medical conditions, similar names of patients or models or negative powers are voiced during the team brief and time out stages. Time-outs always check the selection is made using the correct formula, A-constant and pertains to correct eye.  **Change**  During the time-out process, the participants of the time out are in close proximity to one another. The circulator, the surgeon and anesthesiologist are not in different corners of the room. The actual IOL box is shown to the surgeon in plain view, while the verified eye and lens are confirmed visually.  If change in list order or procedure, the entire team pauses and repeats brief. If change in staffing during list/procedure: pause, repeat brief, and if new staff involved in IOL selection or collection repeat checks.  **One Lens in the Operating Room.**  Only one IOL in theatre with the patient and where the lens bank is in the theatre for a single lens to be selected and removed as suggested and be positioned in a selected place as per local protocol away from the lens bank. We absolutely have no stockpiling. In a bottleneck safety step, the only individual that brings the single lens into the room is the surgeon themselves.  In the case of a torn IOL, or where the back-up needs to be used, the room light is turned on overhead, the back-up lens is brought into the room and a new time-out takes place. Any time a new lens, or new product to be placed into the eye enters the room, a new time-out takes place, and the IOL box end showing the make and power are visually confirmed by the surgeon and team.  **ORA SYSTEMÂ® Intraoperative Wavefront Aberrometry**  While revolutionary in concept, ORA introduces changes at several steps in the safety steps.  If ORA is utilized, we require in our OR that three lens power steps both above and below the pre-operative selection, including their  back-ups are confirmed, rubber-banded and set-aside 1 week prior to surgery, should a final adjustment be made on the spot in surgery. In the case of multifocal toric, this requires the surgery center verifies the possession of a total of 18 lenses and their  back-ups, set-aside from inventory 1 week prior to surgery. There is a hard stop if they are not present, so there is never an instance of not having the correct lens present.  Following the ORA procedure, where a surgeon calls for a different lens than the pre-operative selection, we mandate the old lens be removed from the OR, and the new lens be brought into the OR. The lights are turned on, and new time-out ensues. |
|  | If change in list order or procedure, entire team pause and repeat time-out. If change in staffing during list/procedure: pause, repeat time-out, and if new staff involved in IOL selection or collection we repeat checks.  **Challenge and Check:**  Staff encouraged and allowed to challenge any issues, concerns or inconsistencies regarding IOL selection immediately. We instruct them to say the words "Doctor \_\_\_\_\_ stop. I need to consult with you." This allows the entire team to identify the hazard seen by one of the team members. |

**Project Reflection**

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| Did you feel the project was worthwhile, effective? | Yes |
| How might you have performed the project differently? | Discussion  The present data demonstrate the persistence of wrong IOL events in the USA. A recent analysis of wrong IOL incidents (44 cases) from the Veterans Health Administration confirm this. Analysis of the causal factors within our data and elsewhere suggests that non-technical errors (human factors) are the predominant cause of mistakes.  Checklists and policies alone are inadequate. The literature bears this out. The present analysis also adds to the view that checklist adoption is not enough. We find that multiple factors, such as staff engagement, constant communication and organizational support, influence checklist use and adherence. This may help explain variation in reported outcomes with checklists.  Human errors and team behavior provide actionable targets for improving safety and can be addressed positively by training and team simulation. The surgical safety process needs to be completed by teams who have trained together and had appropriate education in human factors in safe teamwork including communication, situation awareness, decision making, leadership and stress management.  How we might have performed the project differently?  I believe the project was well thought out. While the results and implementation are important, new 'policies' are never enough for a safe environment. Great organizations are defined by great communication. There MUST be carve-out time to collaborate. We can only build the best collaborative solutions when the best people collaborate. These round-table councils consistently allow a platform that puts team and patient safety over ego. In the future, future projects of this nature will be done also using Lucid Charts: a visual |
|  | productivity platform that helped in this project drive clarity, breaking down the complex and bringing to light unexplored insights. It also allows us to quickly share our pathways with consultants who can offer insights quickly. |
| Please offer suggestions for other ophthalmologists undertaking a similar project. | I highly recommend early buy-in from the key management and decision makers in the organization. Meeting to discuss the end-in-mind goals from the outset are critical to the success. I also recommend taking a data-driven approach - do the homework. There is no substitute to looking at the data, building the  dashboard metrics. Without them an organization is vulnerable to anecdotal ideas.  Chart the processes out on a map. Seeing the process helps every member of the team see their role within the bigger picture. It helps you see what your experience is like through the patient's eyes. Doing so reveals so much about safety.  Change and safety are not a fad diet or a project. There must be a regular system in place to drive safety and question the status  quo all the time. Fresh eyes on a system. Consulting. Set meetings to see the organization from a safety system perspective to eliminate the workarounds.  Identifying issues is not enough. Seeing needs must translate into new training, new policy, better communication. |