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

Topic

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| Title of Project: | Improvement in counseling patients and compliance of patients in the use of AREDS |
| | vitamin supplementation in advanced age related macular degeneration |

| Current recommendations for care include the use of antioxidant vitamin and mineral supplementation per the AREDS trials for patients with intermediate or advanced age-related macular degeneration. Treatment with AREDS2 supplements can reduce the progression to advanced AMD in the fellow eye (AMD PPP, 2015). The University of Colorado's Department of Ophthalmology has created a registry of patients seen at the clinic with age-related macular degeneration in order to better examine outcomes and practices at the University of Colorado. The goal of this project is to use the data collected for the registry to determine and increase the number of patients with advanced AMD taking AREDS. I am the principal investigator and lead the registry program for AMD. |
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| The Colorado Age-Related Macular Degeneration Registry (COMIRB #14-1470) was created in 2015. The overall objective of this protocol was to establish the first registry in Colorado of patients with Age-Related Macular Degeneration (AMD). The registry also includes patients without AMD to serve as controls for AMD patients involved in research projects. The clinical data in this registry is linked with a biobank, laboratory, and image data. |
| AMD who receive care at the UC Health Eye Center. Provide a state-of-the-art database and biorepository for research to support residents, fellows and faculty in the Department of Ophthalmology and across the Anschutz Medical Campus (AMC) to utilize in future eye-related research studies. This registry also investigates the relationship between epidemiological risk factors and biomarkers with AMD. |
| This registry and infrastructure were identified as a priority area for development by the Department of Ophthalmology's AMD Oversight Committee. The committee recognized the need to expand the knowledge of risk factors and biomarkers associated with AMD and to enhance information on the prediction, natural history, diagnosis and pathogenesis of AMD. |
| By creating this infrastructure, we hope to highlight the quality of ophthalmology research on this campus at a local, national, and international level. Over time, we expect to expand on this infrastructure and collect additional data and samples for additional eye-related research projects. |
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| Project Setting: (Please select from options below): Group Practice Healthcare Network Hospital Multi-Specialty Group Solo Practice Surgical Center Other Study population: (describe the type of patient for whom the care process will be improved, e.g., | neovascular AMD or geographic atrophy in at least one eye). Of those 176 patients, 89 (50.6%) reported that they were taking AREDS at enrollment into the registry. This data was self-reported to research assistant and abstracted from the medical record. The goal of this project is to increase the number of patients with advanced AMD that report using AREDS supplements Multi-Specialty Group Hospital Patients with Advanced Age related macular degeneration in at least one eye. Advanced age related macular degeneration includes patients with geographic atrophy or neovascular age related macular degeneration |
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| | A research blood draw of approximately 20 mLs of blood (serum and plasma). Collection of DNA from the plasma sample. Collection of information from image data which is collected as part of standard of care. Collection of data on the patient's medical, ocular, social and medication history. A review of the medical record at baseline and every 6 months to track progression of the eye disease and collect select medical data and data on images of the retina Using this registry, we identified 176 patients with advanced AMD (either neovascular AMD or geographic atrophy in at least one eye). Of those 176 patients, 89 (50.6%) reported that they were taking AREDS at enrollment into the registry. This |

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 remeasurement (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: Outcome

Measure Name: Self-reported use of AREDS2 supplementation **Numerator Statement:** Number of patients with advanced age related macular

degeneration in at least one eye self reporting use of AREDS2 supplementation **Denominator Statement:** Number of patients with advanced age related macular degeneration in at least one eye

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 intend to systematically call and counsel patients of mine who develop advanced age related macular degeneration in our registry (by imaging) who reportedly are not taking AREDS2 supplementation. We will call back patients in 3 months to assess whether the patient is compliant. In my practice we will notify patients who develop advanced AMD by imaging criteria every 3 months to take AREDS2 supplementation. The registry will serve as backup to the current practice model. |
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| 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 Leader – M.D. Research Coordinator |
| 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 |
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| | the data collected, effectiveness of your measurement approach, interventions, |
| | and the overall impact of the project. |
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| 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. | 87 of 176 (49.4%) patients with advanced age related macular degeneration reported not taking AREDS supplementation at enrollment in the macular degeneration registry while 89 of 176 (50.6%) patients reported taking AREDS 1 or AREDS2 at enrollment. 70 of 87 (80.5%) patients reporting not taking AREDS were either living or still attending our clinics. Of these 70 patients, we were able to reach 37 (52.9%) of them at baseline. On the baseline visit or phone call, these 37 patients were asked if they were taking an AREDS supplement and if not they were counseled to do so by the research coordinator who clearly stated this was the request of the treating physician. The coordinator also discussed the benefit of AREDS supplementation as evidence by the AREDS studies. At baseline, 15 of the 37 (40.5%) patients were already taking an AREDS supplement and 22 (59.5%) patients were not taking any supplement, were unsure, or were taking lutein alone or a different supplement. These 22 patients were counseled to take AREDS supplementation. |
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| 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). | After 90 days from the initial phone call or visit, we contacted the 22 patients who were not taking AREDS supplementation and we were able to reach 14 of 22 (63.6%) patients as some were not living or not reachable. Of these patients, 8 of 14 (57.1%) patients were now taking an AREDS supplement. 4 of 6 (66%) patients not taking AREDS supplementation indicated that they would start taking the supplement and that they just had not gotten to doing it. One patient requested a direct physician recommendation to take AREDS and one patient indicated that they would only take lutein and not AREDS. |

Project Impact

Compare the baseline data to the remeasurement / 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 summary, 57% of patients who were counseled to take AREDS began to take AREDS in a 90-day follow-up period. In addition, the majority of patients who were not taking AREDS at baseline reported that they were never counseled to do so. It is possible that these patients did not remember that they were counseled; however, it is more likely that the practice did not stress the importance of counseling patients with advanced AMD to take AREDS supplementation. The majority of patients who reported not taking AREDS in the 90-day follow-up period agreed to start taking AREDS as soon as possible. A few patients were resistant to the recommendation and one patient was amenable to beginning AREDS if the doctor counseled the patient directly. It is clear from this practice improvement project that it would be best to counsel patients directly in the office setting and on more than one occasion. It is possible that with repeated counseled the percentage of compliance will increase dramatically. It is also clear that counseling patients by phone can be effective but not in all circumstances. In fact, the time required to counsel by phone may be avoided by improving the counseling in the practice environment. This study did not assess the best mechanisms to counsel patients in the practice, but we will be attempting multiple strategies. These include improved physician and tech counseling in the office setting. All technicians have been reeducated with regard to the benefits of AREDS supplementation in advanced AMD. We also have instituted a handout for patients with pictures of AREDS products and the practice has begun to offer these supplements in the pharmacy dispensary area at the practice. It is clear that EMR documentation with the use of dot phrases or prepopulated text has improved the documentation of patient activities such as taking AREDS supplementation. Unfortunately, the workflow in our practices may not allow for proper counseling for our macular degeneration patients as evidenced in this study. We need to improve patient education in our practice. We are taking steps to do so.

Project Reflection

| Did you feel the project was worthwhile, effective? | Yes |
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| How might you have performed the project differently? | If time allowed, we could have had the doctor call patients directly. This may have increased compliance after the initial round of calls based upon direct physician recommendation. In addition, we could have had all the patients counseled live rather than by phone. This may not have been feasible, but it is likely the compliance would have been improved and would have allowed for increased patient contact rates as only 52.9% of patients were actually reachable by phone. |
| Please offer suggestions for other ophthalmologists undertaking a similar project. | It may be more effective to have a physician available when phone calls are made counseling patients. It is clear that several patients would have benefited from this approach. This may also decrease the amount of time it takes to complete a project similar to this one. |