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

Topic

Title of Project:	Reducing Extraneous Optical Coherence Tomography and Visual Field Testing of Plaquenil Patients

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	A decrease in extraneous patient testing for hydroxychloroquine toxicity decreases the utilization of organizational resources and manpower as well as risk to patients. Decreased testing would yield significant financial benefits to patients, the medical facility, and to medical insurers. It would save patients from the wasted time and inconvenience of performing such tests which can be frustrating and exertional. Moreover, testing of Plaquenil patients often involves testing patients that manifest severe arthritic conditions, and testing requires them to be chaperoned through various portions of the eye clinic. Thus, eliminating such superfluous testing would promote patient safety as well.

Background Information: The month you pulled the baseline IRIS performance report and any additional information that me be pertinent:	In our clinic, and at many ophthalmologic clinics across the country, every patient on Plaquenil (Hydroxychloroquine; "HCQ") that comes in for an eye exam undergoes repeat OCT and VF testing at each and every visit (at least annually). This is typically performed prior to the exam and most often without any scrutiny of dose, duration or the presence of underlying retinal pathology. However, this is *not* the recommendation of the American Academy of Ophthalmology, which recently released a statement in order to provide ophthalmologists with a clear guideline on such screening. Chloroquine/hydroxychloroquine toxicity was first described in Lancet in 1959. Moreover, since this retinopathy is not reversible, and there is no present therapy, early recognition of this rare event is vital in preventing patients from losing central. Therefore, since the early 1960s, patients who were treated with this widely employed medication have been routinely sent to ophthalmologists for dilated fundus exams to rule out toxicity. Even though there was little to no foundational evidence of efficacy, this screening modality was previously recommended as often as every 6 months in any patient using Plaquenil. However, with new and developing technologies, much has obviously changed since the 1960s. Accordingly, in 2016, the American Academy of Ophthalmology ("AAO") stated that "[m]odern screening should detect retinopathy *before* it is visible in the fundus." Thus, the primary screening tests, which are considered the mainstay presently, include automated visual fields plus spectral-domain optical coherence tomography (SD OCT), and dilated fundus exam is no longer considered a valid screening tool. Furthermore, in the recently published AAO statement entitled "Recommendations on Screening for Chloroquine and Hydroxychloroquine Retinopathy (2016 Revision)," the American Academy of Ophthalmology outlines a clear mandate for proper Plaquenil ("HCQ") testing. Within this statement, the AAO unequivocally clarifies that annual testing for every patient after initiation of Plaquenil is no longer suggested. In fact, within the abstract of the AAO's statement (*"the statement"*), "Recommendations on Screening for Chloroquine and Hydroxychloroquine Retinopathy," there is a sub-heading entitled "Screening Schedule" under which the AAO categorically clarifies that after a baseline study ophthalmologist should "[b]egin *annual* screening *after 5 years* for patients on acceptable doses and without major risk factors." (Emphasis added). Moreover, this mandate is reiterated and reinforced several times and in a few diverse articulations within the abstract. For example, in the body of *"the statement"* it is asserted that "[g]iven the initial low risk of HCQ or CQ retinopathy, with a proper dose and in the absence of major risk factors, annual screening can be deferred until there has been 5 years of exposure." Likewise, "Table 1" within *the statement* is also provided as evidence to support this mandate.

	Because chloroquine/hydroxychloroquine retinal toxicity was first described so long ago, many ophthalmologists and ophthalmology practices have developed a set pattern in their screening of patients who are taking this medication. These practices have become entrenched and often remain unquestioned and unchecked. On my arrival to my present institution of practice, I found that *all* patients taking Plaquenil, of *any* dose and of *any* duration, were routinely subjected to *at least* annual OCT and Visual field testing. Staff throughout the clinic, including the front desk and ophthalmic technician staff routinely routed every patient on Plaquenil toward this intensive annual screening including the costly and time consuming visual field and OCT studies without inquiry into any other parameters. Moreover, many of the optometrists and ophthalmologists appear to have been unaware of the new "[AAO] ... Recommendations on Screening." Noting the waste of resources, patient, staff, and physician time involved such testing, it seemed apparent that a decrease in the extraneous patient testing for hydroxychloroquine ("HCQ"/Plaquenil) toxicity while maintaining suggested and adequate monitoring under the American Academy of Ophthalmology guidelines was indicated. As is evidenced in the above observations, communication processes, behaviors of people, information processes, and infrastructure all appear to be playing a part in the perpetuation of unnecessary OCT and VF testing for patients on Plaquenil. Thus, this QI project was designed to inform and begin a productive change in these processes to advance patient safety as well as to yield significant financial benefits to patients, the medical facility, and to medical insurers.
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 entire population of patients seen at the clinic and patients scheduled to be seen in my clinic who are on Plaquenil therapy.

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:** Outcome **Measure Name:** The number of patients put through formal visual field testing and OCT testing for Plaquenil therapy that did not require testing under the new (2016) AAO recommendations will decline by 10 percent. **Numerator Statement:** Patients put through formal visual field testing and OCT testing for Plaquenil therapy that did not require testing under the new (2016) AAO recommendations. **Denominator Statement:** The total number of patients seen that were on Plaquenil therapy for an eye exam in my clinic at University of Kansas Eye Clinic **Notes:** *October 1st 2017 5:11 PM* This project involved a "PROCESS MEASURE," NOT an "outcome measure," as inadvertently stated above. To be more precise, the quality measure in this project is an "inverse process measure."

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:	**<u>Interventions/Tools:</u>** **Copies of the American Academy of Ophthalmology Statement; "Recommendations on Screening for Chloroquine and Hydroxychloroquine Retinopathy (2016 Revision)" were placed at each of the ophthalmic technician stations throughout KU Eye Clinic. Attention was drawn to their presence and content, and the ophthalmic technicians and ophthalmic technician coordinator were made aware of the new AAO recommendations as well as the suggested intervention protocol (below).** **A standardized protocol was established with the ophthalmic technician staff that all patients scheduled by the front staff for an appointment for Plaquenil screening or previously seen for Plaquenil screening will have their specific testing or *lack* of testing clearly pre-determined in writing on a printed copy of the schedule by the physician prior to their appointment work up.** **Under the protocol, at the beginning of each half day of clinic, patients known to be on Plaquenil (as noted by the appointment scheduler, technician staff, or the ophthalmologist) were highlighted (by any and all staff that became aware) on a printed copy of the schedule. The ophthalmologist (myself in this study) then indicated -in writing on the schedule- whether formal OCT and/or VF testing was to be performed. Under this intervention protocol, if not indicated in writing, the patient was not to have any of these tests performed. [If a patient was to have testing for another reason -but *not* solely for their Plaquenil therapy (such as in a patient with diabetic macular edema), the ophthalmologist would clearly clarify this in writing on the printed schedule in an effort to inform and educate staff]**

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.	As stated above, the participants in the QI effort/activity included all the appointment schedulers and ophthalmic technician staff that were involved in my clinic as well as and the ophthalmologist (myself in this study). Under the protocol, at the beginning of each half day of clinic, patients known to be on Plaquenil were to be noted by the appointment scheduler, technician staff, or the ophthalmologist and then were to be highlighted (by any and all staff that became aware) on a printed copy of the schedule. The ophthalmologist (myself in this study) then indicated -in writing on the schedule- whether formal OCT and/or VF testing was to be performed. Under this intervention protocol, if not indicated in writing, the patient was not to have any of these tests performed. For an individual to meaningfully participate in this QI effort/activity they were asked to apply all below mentioned "tools and interventions" to individual/team practice, reflect on impact of the initiative on their practice or organizational role, and attest to both meeting/working with others involved in the improve activities. This was accomplished verbally with the schedulers and ophthalmic technicians at the onset of the activity.
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.	Baseline data for this project was collected over the months of March through May 2017. This was done by way of a retrospective EMR review with some of the May baseline data being accumulated over the month of May while the project design was being fully "fleshed out." Over this period, approximately 13 "Plaquenil patients" presented and were examined per month in my clinic. "Plaquenil patients" for the purpose of this project were defined as any patient presenting to my clinic who was on Plaquenil for any reason and/or any duration. My title at the KU Eye Clinic was that of "Comprehensive Ophthalmologist and Clinical Instructor." As such, I was assigned many of the patients referred in to KU Eye Clinic for initial Plaquenil screening as well as those Plaquenil patients referred in, or being followed up for, any of a host of rheumatic conditions (with or without ophthalmic sequelae). The actual number of "Plaquenil patients" seen by me in March was 9 patients, in April it was 15 patients, and in May it was 14 patients. This is a total of 38 "Plaquenil patients" seen by me over the three months of baseline data collection. In addition, although not *specifically* vital to the parameters of this project as presented, but germane to some of the following discussions, approximately 504 patients were seen in my clinic monthly. Over the course of the three (3) months that the baseline data was collected, 100% (all 38) of the "Plaquenil patients" had Spectral Domain OCT of the macula and 10-2 central visual field testing performed by the technical staff before the patient was "roomed" for an exam by me.

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).	The follow up data for this project was collected over the three months following implementation of the project tools and strategies. To briefly re-cap; the "tools" included copies of the American Academy of Ophthalmology Statement; "Recommendations on Screening for Chloroquine and Hydroxychloroquine Retinopathy (2016 Revision)" which were placed at each of the ophthalmic technician stations throughout KU Eye Clinic. "Strategies and systematic approaches" implemented included drawing attention to the presence and content of the American Academy of Ophthalmology Statement; "Recommendations on Screening for Chloroquine and Hydroxychloroquine Retinopathy (2016 Revision)" as well as creating a standardized protocol with the ophthalmic technician staff that all patients scheduled by the front staff for an appointment for Plaquenil screening or previously seen for Plaquenil screening would have their specific testing *or lack of testing* clearly pre-determined in writing on a printed copy of the schedule by the physician (myself in this project) prior to their appointment work up. Over this re-measurement period, approximately 15 "Plaquenil patients" presented and were examined per month in my clinic. In June 2017, seventeen (17) "Plaquenil patients" presented and in July 2017, fourteen (14) "Plaquenil patients" presented. This represents a total of 31 "Plaquenil patients" that were scrutinized for the performance measure in the re-measurement period. (Due to my departure from the University of Kansas for a position in private practice, data for August 2017 was incomplete and is not included in this summary.) To be clear, in this project, an "inverse process measure" was what was *truly* addressed in that it was hoped that the process of care measure; superfluous ("inappropriate" or "extraneous") OCT and visual field testing, was to be eliminated. Thus, the numerator for this project was the number of "Plaquenil patients" that received "inappropriate" or "extraneous" OCT and/or visual field testing as determined under the American Academy of Ophthalmology Statement; "Recommendations on Screening for Chloroquine and Hydroxychloroquine Retinopathy (2016 Revision)." Thus, this numerator included the number of "Plaquenil patients" that received OCT and visual field testing even though they did not require testing under the AAO Guideline Statement and *merely* because they were on Plaquenil, but despite the fact that they had no other indication for such testing. As such, a patient with suspected choroidal neovascularization who had testing and just happened to be on Plaquenil would obviously not fall into this category of "extraneous," "superfluous," or "inappropriate" testing. The denominator in this project included the total number of "Plaquenil patients" who presented to my clinic over the "re-measurement period." To reiterate, for the purpose of this project, "Plaquenil patients" were defined as any and all patients presenting to my clinic who were on Plaquenil for any reason and/or any duration. The follow up data revealed that 27 of the 31 "Plaquenil patients" that presented over the "re-measurement period" were subjected to OCT and visual field testing. The four (4) "Plaquenil patients" that were not subjected to OCT and visual field testing had all been appropriately removed from testing by way of the tools and strategies in place. More specifically, all of these four (4) patients were "annual Plaquenil follow-up" patients that were on appropriate "real weight" doses of Plaquenil and who had had normal baseline studies with no other indication for testing. All of these patients had been on normal or lower risk doses (as adjusted for real weight calculations), had undergone baseline studies with normal results, and had been on Plaquenil less than five years. In addition, they had no other pathology indicating a need for OCT and/or VF testing.

	Of the 27 patients that had OCT and visual field testing, nine (9) were baseline exams for the institution of Plaquenil therapy which was considered an "appropriate" indication for these tests/studies under the AAO Guideline Statement. Twelve (12) of the "Plaquenil patients" that received OCT and visual field testing were greater than five years out from the initiation of Plaquenil therapy and were on a "weight appropriate dose," and thus, also were considered "appropriately" designated for annual administration of these tests/studies under the AAO Guideline Statement. Four (4) of the 27 "Plaquenil patients" who received OCT testing required this test due to a co-existing pathology including either macular degeneration or diabetic macular disease (or suspicion thereof). In sum, of the 27 "Plaquenil patients" that were subjected to OCT and visual field testing within the "re-measurement period", 25 of these patients had an appropriate indication for testing under the American Academy of Ophthalmology Statement; "Recommendations on Screening for Chloroquine and Hydroxychloroquine Retinopathy (2016 Revision). Whereas two of those tested were subjected to "inappropriate" testing under the guidelines. These two patients were tested merely because the technicians had noted upon workup that the patient was on Plaquenil and had performed the studies out of rote -previously learned- behaviors. Despite the fact that only two (2) patients were subjected to "extraneous" testing under the guidelines, the percentage of extraneous testing among all "Plaquenil patients" was 2/31 or 6.5%. On the other hand, of those "Plaquenil patients" *who received testing*, the percentage was even higher; 2/27, or 7.4%.

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.	Although there was a significant percentage of patients that received "extraneous testing" during the "re-measurement period," overall this intervention can be seen as a huge success. The fact that only 27 of the 31 "Plaquenil patients" that presented over the "re-measurement period" were subjected to OCT and visual field testing, means that 4 out of 31 "Plaquenil patients" were spared from "extraneous testing" due to the tools and strategies employed by the intervention. This can be seen as a 12.9% reduction in superfluous testing when all "Plaquenil patients" presenting to the clinic are examined. Given that prior to the intervention 100% of all Plaquenil patients were subjected to testing, the project undoubtedly had a significant and positive impact. This is even more significant when the impacts with regard to patient safety, as well as patient and healthcare facility time, energy, and money are examined. Considering the amount of wasted resources, as well as misplaced patient, staff, and physician time involved in such testing, these four patients (~13%) can be seen as a massive windfall when extrapolated to a larger population. Moreover, as mentioned in the project design discussion above, each time a patient is subjected to this testing there is a safety risk, and this safety risk is greater when the patients involved often manifest severe arthritic conditions such as in the Plaquenil patient population examined here. Thus, while eliminating such superfluous testing in approximately 13 % of any population would greatly promote patient safety, it likely has an even greater effect in this population. Therefore, this QI project has gone a long way to outline, inform, and begin a productive change in process measures that can decrease wasteful utilization of organizational resources and manpower as well as advance patient safety. As for the two (or 6.5% of) patients that had extraneous testing, this definitely begs for improvement. However, forensic investigation on my part (including informal interviews with the involved technicians), revealed that the technicians involved in the superfluous testing were ones who had been at the clinic for the longest periods of time and who had more engrained and more pre-conceived notions on how to approach Plaquenil patients. These "more seasoned" technicians also seemed to be less inclined to accept change constructively. With this in mind, it would follow that over a greater length of time, the communication and information process interventions applied here would eventually take hold and convert these "hold outs" to the benefit of all. Consequently, I suspect that the positive impact of this project would be even greater over time. In regard to impact over time, another tool and strategy addressing communication processes, behaviors of people, information processes, and infrastructure was employed in my practice to diminish future superfluous testing of Plaquenil patients. In order to relay the information and updated approach within the American Academy of Ophthalmology Statement to the medical community at large, I was careful to include a summary of my future screening thought process in the "assessment/plan" section of all my notes on Plaquenil patients over the re-measurement period. These notes are seen within the EMR by all caregivers in the KU system including those physicians referring Plaquenil patients for ophthalmologic screening. This summary of the "screening thought process," which I included in each evaluation of a Plaquenil patient, included a statement regarding the patient's "real weight" dose, duration of treatment, and prior testing with regard to Plaquenil screening as well as my plan for future testing (such as "re-test in 2018 after patient has been on HCQ therapy for 5 years"). I also explained my reasoning with reference to the American Academy of Ophthalmology Statement; "Recommendations on Screening for Chloroquine and Hydroxychloroquine Retinopathy (2016 Revision). In time, this additional QI intervention, it is hoped, will diminish the amount of Plaquenil patients referred in only for toxicity studies who do not require such testing. Although this particular intervention was not studied and/or quantified within this project, this process was also employed to help to diminish extraneous Plaquenil screening, and I feel it will likely have a positive impact and may be something worth a future QI study.

Project Reflection

Did you feel the project was worthwhile, effective?	Yes
How might you have performed the project differently?	As noted above, there was an adjunct intervention which I employed to inform the medical community at large via the EMR. That could be studied. In addition, if further clarification or quantification of the study's impact is desired, it may be of value for someone to do a more far-reaching study with a larger patient population and/or over a greater period of time.
Please offer suggestions for other ophthalmologists undertaking a similar project.	As noted above, there was an adjunct intervention which I employed to inform the medical community at large via the EMR. That could be studied. In addition, if further clarification or quantification of the study's impact is desired, it may be of value for someone to do a more far-reaching study with a larger patient population and/or over a greater period of time. Moreover, a more broad-reaching study on dogmatic clinical behaviors that become entrenched despite new information would be very enlightening. I fell that in Ophthalmology, where new technologies appear to regularly be changing the landscape, this would be particularly vital.