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Implementation of an Internal Quality Improvement Program: One Team's Journey

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The Model for Improvement, developed by Associates in Process Improvement, is a quality improvement framework that serves to promote sustainable changes in processes or workflow. This framework serves as a guide for quality improvement teams as they develop, test, and implement new processes (Institute for Healthcare Improvement, 2022). It encourages quality improvement teams to consider their goals for improvement, how to assess whether a change in practices and processes is an actual improvement, and what changes are achievable. Once these considerations are addressed, the model promotes a rapid cycle implementation of the Plan-Do-Study-Act (PDSA) cycle of performance improvement, originally developed by Edward Deming (The Deming Institute, 2022). Team members plan a quality improvement initiative, implement it, measure change, and act on the results of that change by cycling through the PDSA process repeatedly. The underlying premise is that quality improvement is constant.

Using this framework our clinical trials team at Kaiser Permanente Mid-Atlantic States (KPMAS) was able to develop an internal quality assurance program, which, while in its early stages of implementation, has already shown improvement in processes and workflows. This article provides a case study of our quality improvement journey.

KPMAS is a main member of NRG Oncology research cooperative group. There are approximately 15 NRG clinical trials open at any given time and eight clinical research nurses and coordinators across seven sites.

Through chart reviews and discussion of processes at bi-weekly meetings, our team realized that the current internal quality assurance (QA) program was not working well. Our original QA program was built around one individual conducting internal monitoring of our clinical trials, this same individual was assigned to other projects requiring more attention over time, so the internal QA program was not receiving the attention it needed. We wanted to ensure the accuracy of data collection and transcription, provide ongoing feedback to research investigators and staff, and keep our research charts thorough and organized. We wanted our program to accurately reflect our team's commitment to high quality clinical research.

After implementing the first phase of the Model for Improvement (goal assessment, how to assess whether a change is an improvement, and what change will result in improvement) our team was poised to engage in implementation of our revised internal QA program. Our goals were to standardize our processes and streamline our workflows and ensure new staff members were enrolling and following patients accurately in real time. Using the plan-do-

study-act method of rapid cycle improvement, we developed an action to achieve these goals.

As part of our planning phase, we conducted a review of the literature to gain insight into best practices for addressing our priority areas for improvement. From the literature and consensus among the team, we used the NCI Guidelines for Auditing Clinical Trials (Feb. 2021) to provide a roadmap for our quality improvement initiative. We also modified the NCI's audit worksheets to serve as checklists when reviewing charts and practices. Additionally, team members attended the SOCRA Quality Management Virtual Program. The three-day program provided valuable insight on best practices and tools for sustaining a quality improvement program.

From the literature review, we drafted a Standard Operating Procedure (SOP) manual, with the view that we would continue to update the SOP as we refined our understanding of what process worked versus those that did not. After implementing the new SOP, we began our internal quality review starting with patients' eligibility and enrollment. To facilitate this process, the clinical research nurses retrieved 2020 participant accrual list and split the research subject charts among the team and conducted their review. They met one on one with each other to provide feedback on strengths and areas needing improvement, before submitting the completed adapted NCI audit worksheets to the Director of Clinical Trials.

We learned a lot about our program and processes through this review. Most importantly, we learned that only eligible patients were enrolled in clinical trials. We also learned that the eligibility and enrollment processes differed from nurse to nurse. These differences included the consent process for non-English speakers, documentation in the EMR, and timing of eligibility checks and reviews. Thus, because of our review, inconsistencies were being corrected in real time and processes were being standardized. Our charts were becoming "audit ready".

The process is still ongoing as we move forward to review the treatment phase of research subject records. We finalized our SOP after much review including the eligibility and enrollment worksheets. We created clinical practice guidelines around the Non-English speaker consent process and timing of eligibility sign off, and we created protocol-specific EPIC smart phrases. These smart phrases will help standardize our documentation among the different clinical trials nurses.

Overall, the process has been very positive for our team.

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