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Best Practice when Caring for Patients on Oral Oncolytic Agents

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In 2022, 287,850 women in the United States were predicted to be diagnosed with invasive breast cancer, of whom 20,113 were likely to be in Texas (Texas Oncology, 2022). The breast medical oncology department of a local academic facility annually receives approximately 50,000 visits from patients with breast cancer. Reports conducted by the American Society of Clinical Oncology Quality Oncology Practice Initiative program found that only 51% to 59% of clinicians documented evaluation of laboratory monitoring for patients taking oral oncolytic agents (Redelico et al., 2018). Aware of this possible monitoring issue, the project lead and statistician at the local facility met to review patient electronic health records (EHRs). The review revealed from August 2022 through January 2023, only 29% of patients had documentation of compliance with lab monitoring and follow-up visits. In addition, 15.24% of patients taking oral oncolytic therapy were shown to have labs ordered on the day they started treatment. This demonstrated the need for improvement of lab monitoring and follow-up visits within the oncology facility.

Oral oncolytic use has increased in breast cancer over the last two years due to the expansion of use and convenience of these agents. Oral oncolytic use provides a less invasive alternative to intravenous chemotherapy with more manageable side effects (Thomas et al., 2019). These agents have shown to improve patient prognosis, quality of life, and treatment burden, but they also carry challenges for healthcare providers who manage this population (Thomas et al., 2019). Notably, the safety systems designed for IV chemotherapy cannot be translated into use for oral oncolytics. With IV chemotherapy, patients present to an ambulatory infusion center or clinical setting where providers review lab results and assess for therapy-related toxicities prior to administering treatment (Huff et al., 2022). Patients receiving oral

oncolytic therapy take the medication at home and are responsible for adhering to medication schedules, reporting symptoms, and attending laboratory appointments and follow-ups. New systems need to be in place to improve monitoring for patients taking oral oncolytic agents.

Safe self- administration of the oncolytic is heavily dependent on the patient's understanding of the treatment regimen. In addition to possible knowledge deficits, barriers which can affect monitoring patients' adherence to oral oncolytics include timely delivery of the drug and appropriate scheduling by providers (Doshi et al., 2018). In a breast medical oncology department within a Texas academic medical institution, there have been issues with providers not knowing when the patient received or started the oral oncolytic therapy, lack of communication between patient and provider, and inappropriate scheduling of lab work. Oral oncolytic monitoring requires observation visits at specific points in the patient's treatment cycle. Studies have shown when the appointments for laboratory monitoring and follow-ups are not scheduled by providers, patients continue to self-medicate with oral oncolytics despite missing these appointments, which places them at a higher risk for adverse drug reactions or toxicities (Huff et al., 2022).

To improve patient care, additional systems are needed to support shared decision-making between patient and provider, enhance patient understanding of procedures related to safe self-medication administration, improve provider notification of timely delivery and start of the oral oncolytic agent, and improve timely patient laboratory and follow-up appointments. Communication related to when patients receive and start the oral oncolytic can be done via the EHR, utilizing a *SmartPhrase.* The EHR is a tool used for documentation which is maintained by providers, and can be used to improve efficiency, quality, and safety of care (Ani et al., 2022). EPIC is one of the most used EHRs in the United States (Ani et al., 2022). The EPIC EHR

provides an avenue for patient and provider to communicate via MyChart. MyChart is a patient portal that is powered by EPIC to allow patients to access their medical records and communicate with their providers. Patient are notified via text message when there is a new result or message in their patient portal.

The SmartPhrase technology can provide a quick and easy method for providers to contact the patient, learn when a patient has a delay in care, and if clinic appointments and laboratory monitoring need to be adjusted. SmartPhrases, also known as “dot phrases,” allow commonly used texts to be easily inserted into the patient’s EHR messages (Jarou, 2021). The SmartPhrases can be created by an individual user and shared with others, allowing them to be available on a department or institutional level. SmartPhrases can include user prompts that allow users to customize the message based on a patient’s oral oncolytic. By helping patients prepare for their start dates, utilizing SmartPhrase technology to communicate with patients via the EHR about when they receive and start the medication, and aligning appointments to day one of their cycles, monitoring of toxicities can be improved to occur in the correct timeframe of each cycle, as advised by the individual drug manufacturer (Dana Farber Cancer Institute, 2022). Therefore, this quality improvement (QI) project was designed to help improve communication between the patient and provider with hopes to improve shared- decision making, administration of therapy, and toxicity and lab monitoring of oral oncolytic agents.

PICOT(S)

The PICOT(S) format (i.e. P: population, I= intervention, C= comparison, O= outcome, T= time, and S= setting) is utilized to describe a clinical issue and minimize the time spent searching for relevant data (Melnyk & Fineout-Overholt, 2019). The PICOT(S) for this proposal is P= adult female patients from the ages 18-85 with invasive breast cancer taking oral

oncolytics, I= an oral oncolytic care bundle (resources to provide individualized plans and improve shared decision making about treatment start and monitoring process, EHR SmartPhrase use to assess medication receipt and initiation, and aligning appointments and lab work with medication cycles), C= current process of scheduling patients every four weeks, O= improve monitoring of hematologic toxicity (labs on correct days after start of drug), use of provided resources, and shared decision making of starting treatment/ monitoring, T= 8 weeks, and S= an ambulatory breast medical oncology clinic. Utilizing this format, the PICOT(S) question for this proposal is, "Among adult female patients, aged 18-85 years, with invasive breast cancer in an ambulatory breast medical oncology clinic, does an oral oncolytic care bundle (resources to provide individualized plans and improve shared decision making about treatment start and monitoring process, EHR SmartPhrase use to assess medication receipt and initiation, and aligning appointments and lab work with medication cycles) compared to the current process of scheduling patients every four weeks without the bundle components improve monitoring of hematologic toxicity (labs on correct days after start of drug), use of provided resources, and shared decision making of starting treatment/ monitoring over a period of 8 weeks?"

Review of Literature

A literature search was preformed to identify systematic reviews, randomized controlled trials, research studies, and literature reviews related to the PICOT(S) question proposed for this quality improvement project. Databases that were searched include Cumulative Index to Nursing and Allied Health Literature, PubMed, Medline, and Education Resource Information Center. The filters used included data that was peer- reviewed and published in journal articles written in the last five to ten years. The disciplines included were medicine, nursing, and pharmacy. The subject terms included were oncology and cancer. The search terms utilized in each database

include oral chemotherapy OR oncolytics OR anti-neoplastics and lab monitoring OR assessing OR evaluating OR measuring.

The search yielded a total of 68 articles. Of these, 29 documents were eliminated because they did not evaluate oral chemotherapy only. Seven documents were removed because they did not address lab monitoring in the outcomes. 14 documents were eliminated because they did not contain subjects with breast cancer. One document was eliminated because it was only available in French. The remaining 17 document abstracts were reviewed to determine the aim of study, and relevance to PICOT(S) question, of these seven articles were eliminated. The remaining 10 pertinent articles were retrieved and critically appraised into an evidence table (see Appendix A).

The use of oral oncolytics comes with challenges due to the lack of design systems for patients self- administering treatment (Zerillo et al., 2018). The use of oral oncolytics, although more convenient, has many opportunities for error as the process includes multiple steps such as education, prescribing, dispensing, administering, assessing adherence, and monitoring for toxicity (Huff et al., 2022; Zerillo et al., 2018). The reviewed literature supports the creation of a structured process for monitoring patients taking oral oncolytics through improving shared decision making between the patient and provider (Huff 2020; Moran et al, 2023; Redelico et al., 2018; Zerillo et al., 2017), increasing early communication with the patient in the first few weeks of starting therapy (Huff et al., 2022; Moran et al., 2023, Zerillo et al., 2018), and rescheduling labs to align with treatment cycles (Heck & Null, 2020, Huff et al., 2022, and Redelico et al., 2018).

Patient Resources to Improve Shared Decision Making

Patients need to be active participants in their care to facilitate adequate monitoring of oral oncolytics. Barriers to complete care for patients on oral oncolytics include lack of patient

and provider understanding surrounding adherence, coordination of care, and monitoring (Huff, 2020; Moran et al., 2023) and lack of knowledge, preparation, and misconceptions about oral oncolytics (Huff 2020). Interventions geared towards counseling and improving shared decision making between the patient and provider (Moran et al., 2023), providing patients with resources that contain self- handling checklist and tips for home safety and administration (Huff et al., 2020, Kaler et al., 2022), and creating a calendar with the patient to schedule lab monitoring and follow up appointments showed a reduction in side effects, severe adverse events, and errors with monitoring (Huff, 2020; Moran et al, 2023). Providing resources about safe home administration and developing a plan for starting the treatment cycle and lab monitoring improves shared- decision making, encourages active participation, and increases understanding which improves patient adherence to medication regimen, monitoring parameters, and follow- up appointments (Huff 2020; Zerillo et al., 2018). In addition to collaborating with the patient to create a treatment plan, interventions that facilitate early communication in the first few weeks of starting treatment can increase accurate lab monitoring and patient safety (Huff, 2020; Huff et al., 2022; Zerillo et al., 2018).

Improving Communication Between Patient and Provider via the EHR

Several options exist for providers to communicate with patients regarding treatment such as utilizing the EHR, smartphone-based apps, electronic medication reminder systems, or telephone calls. However, no best practice has been established regarding what form of communication is superior in managing patients taking oral oncolytic agents (Huff et al., 2022; Zerillo et al., 2018). Huff et al., 2022, Moran et al., 2023, and Zerillo et al, 2018 conducted systematic reviews of studies regarding interventions to improve oral oncolytic laboratory and

follow-up monitoring. They found that communication with the patients within the first weeks of beginning a new oral oncolytic treatment should be included in a monitoring program.

Interventions designed for close patient monitoring early during therapy improve overall adherence rates with medication compliance, lab work, and follow-up visits (Moran et al., 2023). Studies utilizing clinicians to contact the patients at specific intervals and implement drug specific lab monitoring requirements demonstrated the significance of the clinician's role and the utilization of the EHR to decrease medication and lab errors (Finn et al, 2017; Sargent & Whalley, 2022). The use of EHR technology can streamline the oral oncolytic workflow making it easier and quicker for providers to review tests results, prevent medical errors, and improve patient- provider communication (Huff et al., 2022; Kaler et al., 2022). A study by Esper and Walker (2014) evaluated the use of SmartPhrases in documentation by nurse practitioners (NPs) in quality oncology practice initiatives and found there was an increase in efficiency of documentation. It also provided a method to expedite and improve quality of documentation. Patient and providers reported satisfaction with electronic communication (Huff et al., 2022). Early communication with patients can increase compliance with recommended laboratory tests and identify early signs of drug related toxicities.

Scheduling or Rescheduling Lab Monitoring to Align with Treatment

Each oral oncolytic has specific monitoring parameters at different intervals within a treatment cycle. Although clinicians may order treatment specific lab work for each patient when beginning treatment, patients may experience delays in care or adverse drug reactions resulting in need for adjustment of lab work. Studies conducted by Heck and Null (2020), Huff et al., 2022, and Redelico et al. (2018) to evaluate oral oncolytic lab monitoring found most treatment cycles were not fully complaint with the Food and Drug Administration (FDA) drug labeling for

lab monitoring. These researchers suggest the need for patients and providers to be active participants in upholding monitoring parameters. They also emphasize discussing frequency and importance of laboratory monitoring and follow- ups, closed- loop communication between patient and provider, and advocating for a standard oral oncolytic workflow to improve clinical outcomes and quality of life.

Thill and Schmidt (2018) and Watson et al. (2019) evaluated compliance with complete blood count monitoring of women with breast cancer taking oral oncolytic agents. Both research groups found that neutropenia was one of the most common side effects and could be managed appropriately with holding medication or dose reduction. Accurate patient monitoring and management of labs will improve management of dose reductions and dose interruptions (Thill & Schmidt, 2021; Watson et al., 2019). Suboptimal lab monitoring is a common factor in adverse patient events (Huff et al., 2022).

Summation

The use of oral oncolytics is becoming more common in breast cancer patients as they improve progression free survival and allows patients to have more flexibility in their treatment regimens (Huff, 2020). Several researchers have demonstrated the need for introducing a monitoring process to improve lab monitoring for patients taking oral oncolytics. The significance of these studies shows standardizing the management process of oral oncolytics by creating a monitoring program that includes patient resources about safe administration and personal contact with patients in the first few weeks of starting treatment can increase accurate lab monitoring and patient safety (Huff, 2020; Huff et al., 2022; Zerillo et al., 2018). By engaging in shared decision making and providing patients with resources to be successful with their treatment plans, contacting the patients via EHR by utilizing SmartPhrase technology, and

scheduling lab work to align with treatment cycles, providers can improve monitoring for common adverse side effects of oral oncolytic therapy.

Framework

The Plan- Do- Study- Act (PDSA) cycle was developed by W. Edward Deming based on the previous work of Andrew Shewart (Connelly, 2021). The PDSA is an effective method to test and learn about change on a small scale (Melnyk & Fineout-Overholt, 2019). The PDSA cycle is action oriented where a change is planned, implemented, studied, and action is taken on what is learned. This method is best for this QI project as it allows for testing on a small scale, is widely used and fits many interventions and settings, and helps quickly learn if an intervention works and where adjustments need to be made. There are four stages of PDSA.

The plan (P) stage is to plan the change and method of observation (Melynk & Fineout-Overholt). The do (D) stage is to implement the change on a small scale. The study (S) stage is to analyze the data from the implementation and to determine what has been learned. The act (A) stage is to adopt the change or refine the change based on what was learned and repeat the cycle (Melynk & Fineout-Overholt).

The plan stage included several steps that have been completed by this proposal. The problem was identified, the significance of the problem was researched and explained, the current process was explained, and a PICOT(S) question was developed. The EHR was utilized to determine how many patients were taking and were complaint with monitoring of oral oncolytic therapy within the breast center at an academic medical facility in Texas. The data was re-analyzed to evaluate patterns in lab work monitoring prior to the do phase. Additionally, resources were created to foster shared decision making about treatment and monitoring between

the patient and provider, and a SmartPhrase was created to contact patients with during the planning phase.

The do stage was the implementation of the action plan. This was done by presenting patients with resources on timely lab monitoring and follow- up and coordinating a follow-up and messaging schedule. Registered nurses, pharmacists, or NPs were able to utilize a SmartPhrase to send a message to the patient when the patient was seen in clinic. The first message was sent the day of the visit with FAQ handout. The second message was automated to delay sending to the patient until 3 days after her visit to determine if she has received her medication and when she started treatment. The NP evaluated the patient's response and when patient needs to return for monitoring. Appointments were moved or rescheduled as needed per care team instruction. The study phase included a review of patients and when they presented to clinic for lab monitoring and follow-up. This was completed by running a post- intervention report via EPIC. These results were later compared to the preliminary data. Lastly, in the act phase, the team reflected on the findings noted in the study phase. If needed, the interventions were refined, replaced, or adopted.

Project Questions & Objectives

Among adult female patients, aged 18-85 years, with invasive breast cancer in an ambulatory breast medical oncology clinic, does an oral oncolytic care bundle (resources to provide individualized plans and improve shared decision making about treatment start and monitoring process, EHR SmartPhrase use to assess medication receipt and initiation, and aligning appointments and lab work with medication cycles) compared to the current process of scheduling patients every four weeks without the bundle components improve monitoring of hematologic toxicity (labs on correct days after start of drug), use of provided resources, and

shared decision making of starting treatment/ monitoring over a period of 8 weeks? There were several objectives for this quality improvement (QI) project.

1. Implement shared decision making between the patient and provider by providing the patient with resources about oral oncolytic therapy and the lab monitoring/follow- up process, and by allowing the patient to decide when to start therapy.
2. Promote and increase utilization of SmartPhrase technology to improve communication between the patient and provider regarding obtaining and starting oral oncolytics and any barriers to starting treatment.
3. If a patient does not utilize the EHR for any reason, a RN will contact the individual by telephone. If the patient has not received their oral oncolytic within 7 days of prescription, the care team will provide any necessary intervention (e.g., contacting pharmacy, contacting insurance, filling out prior authorization) to assist with obtaining the medication as soon as possible.
4. Schedule blood work to align appropriately with the treatment cycle timeframes.

Setting

The project was conducted in an outpatient clinic setting within a 739- bed academic medical facility in Texas. The institution is a state facility that accepts over 80 different types of Texas insurances, including commercial, Medicare, Medicaid, and some plans outside of Texas. It, however, does not accept the Affordable Care Act. The project took place in the breast medical oncology department. The department consists of 32 provider- led clinics. The clinics are open from 8 AM to 5 PM Monday to Friday. Many clinics specialize in specific subsets of breast cancer within the department, all of which utilize oral oncolytic agents. Some subsets of clinics include hormone- receptor positive breast cancers, triple negative breast cancers, human

epidermal growth factor receptor 2 (HER-2) positive breast cancer, and BRCA positive breast cancer. Approximately 700 patients within the department take oral oncolytic therapy. The study was piloted within one of the provider- led clinic. The clinic team where this project took place consisted of a physician, nurse practitioner, pharmacist, registered nurse, and two medical assistants.

Population

The sample population was recruited using convenience sampling and included all females between 18-85 that had been diagnosed with breast cancer. The population came from one provider-led clinic. The inclusion criteria were that they must be on an oral oncolytic for breast cancer only. This included patients with metastatic and non-metastatic breast cancer. This also included patients who were currently on oral oncolytic agents and those starting new oral oncolytic regimens. Included patients already had to be using the facility for treatment and follow- up. Participates had to be females between the ages 18-85. The exclusion criteria included pregnant patients or if patients were getting oral oncolytic agents from a different oncologist at an outside facility.

Team Roles & Procedures

The team consisted of an NP, pharmacist, and RN who were in clinic daily. The role of the NP, who was the project lead, and pharmacist was to give the drug information and obtain consent for the oral oncolytic agent. The NP's role included providing the patient with a folder of information regarding oral oncolytic therapy. The folder contained a handout about oral oncolytics in English at an 8th grade reading level. Additionally, the NP explained lab monitoring parameters and follow up schedule for the medication (see Appendix B). The NP met with the patient and filled out dates for lab monitoring, when to return for follow-up visits, and when to

repeat scans, if needed. Another handout addressing frequently asked questions (FAQs) about oral oncolytics was sent to the patient via EHR message (see Appendix C). The NP notified the patient that she would receive a MyChart message asking if she received her medication and when she started treatment.

The NP utilized SmartPhrase technology to contact the patient via MyChart and ensure the patient received their medication and started their treatment. The RN notified the NP of the patient's response or lack of response within seven days from the original clinic appointment. The NP reviewed the messages with the patient and moved labs and follow-up as needed to meet drug monitoring compliance as outlined by each drug manufacturer.

Team Education

The NP and pharmacist were already familiar with the most common oral oncolytic agents used in breast cancer, drug monitoring parameters, and importance of monitoring, but a pre-implementation meeting occurred to educate the pharmacist and RN on the project's purpose (see Appendix D). The RN was educated on importance of lab monitoring and follow- up parameters. All incoming patient messages go to the RN first per institutional policy, therefore, the RN assisted with directing the messages from patients to the NP. The RN and pharmacist were educated on how to utilize the SmartPhrase. By typing ".OOFUSMARTPHRASE," the message would populate (see Appendix E). The RN and pharmacist were also educated on how to set the message to deliver three business days in the future after the clinic visit and how to set notifications in the EHR to be notified if the patient does not read or respond to the message after receiving it. If there was no response within 24 hours of the patient receiving the message, the RN was educated to notify the NP. The NP completed a follow up telephone call for patients who did not respond to the message within 24 hours after receiving it. The NP reviewed

medication guidelines for monitoring and adjusted lab work and follow up to be compliant with monitoring guidelines for the specific agent.

Implementation

In the pre-implementation phase, approval for the project was obtained by the site manager and the Quality Improvement Advisory Board (QIAB) (see Appendix F). A retrospective chart review was completed from 8/1/22-2/1/23 to evaluate length of time before patients received the medication and started oral oncolytic therapy, the number of patients who had labs ordered on day one of their cycles, and compliance with follow- up visits demonstrating the value of the project. The retrospective chart review was part of the information gathering phase to determine that a gap existed. The retrospective chart review was completed on the entire breast center patient population, but the project was conducted in one clinic only. Therefore, data was collected for the 90 days prior to the intervention in the one clinic where the project was implemented.

Prior to implementation, the *Oral Oncolytic Tips Sheet* (see Appendix B) and *Frequently Asked Questions (FAQs) for Oral Oncolytic Agents* (see Appendix C) were shared, edited, and reviewed with the team. In addition to the initial education, subsequent team meetings were held every other Wednesday or Friday at the end of the clinic day to evaluate the implementation phase, provider burden, and to determine if changes needed to be made. The implementation phase was eight weeks long.

Patients newly starting oral oncolytic therapy were provided the resources created for oral oncolytic agents. Patients who were already taking an oral oncolytic were offered educational handouts if they were within their first six cycles of therapy. The care team reviewed the contents of the handouts and filled out the section in the tips sheet explaining how often the

patient would have labs, follow-ups, and scans. If current patients refused the resources due to comfortability with their regimen, they were verbally advised when labs, follow-ups, and scans would need to take place. All these interventions were a part of the patient's care and covered by insurance. Patients were informed that they should see their providers and have lab monitoring completed before starting each new cycle. Each patient was asked if they had any personal life activities that might cause them to delay starting therapy. If so, the patient was allowed to ask questions and delay the start of medications as part of shared decision making. The patient was also informed about importance of notifying the team if they were unable to obtain their medication once the script had been provided.

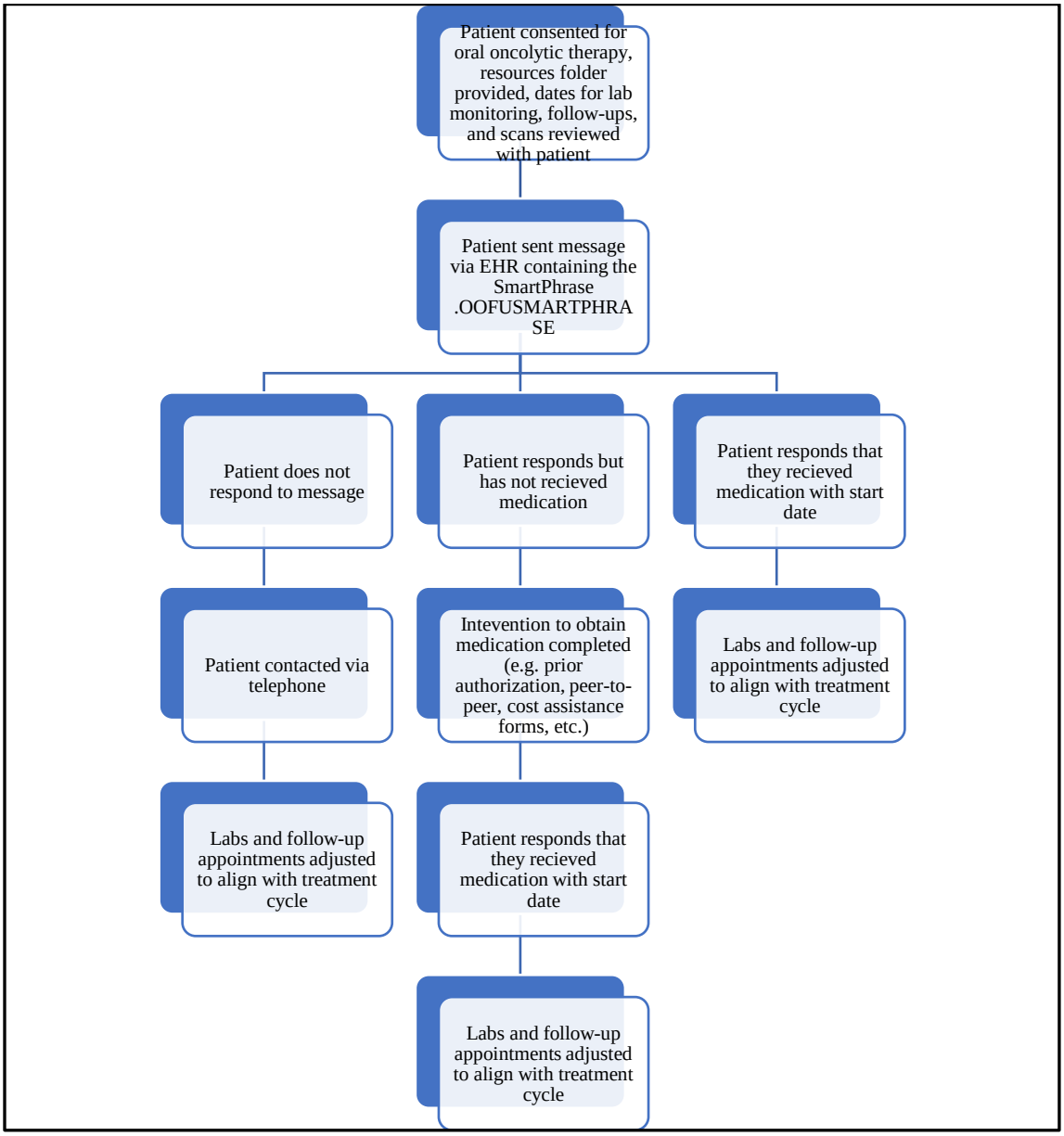
Once monitoring parameters for treatment had been established, the NP constructed a message to send to the patient (see Appendix E) to assess for delays in treatment. The SmartPhrase OOFUSMARTPHRASE was utilized and the SmartLinks were filled out to be specific to each patient's regimen. The message was delayed sending three business days from when the patient was seen in clinic and to notify the provider if not read within four business days from when the patient was seen. If the patient did not speak English, an institutional translation service was used to assist with sending a message.

Once the patient responded by telling the RN the start date, the RN forwarded the message to the providers. If the patient did not respond, the NP or pharmacist called the patient. If the patient responded and was unable to obtain her medication, the RN notified the providers to further explore the cause. The NP and pharmacist were responsible for ensuring that the patient was able to obtain the oral oncolytic therapy. Once the start date was obtained, the NP contacted the scheduling department to adjust labs and follow-up based on the patient's medication start date. If patients did not have access to MyChart, they were advised on how to

obtain access and provided with the institutional document for how to obtain access. If patient did not own a smart device or computer, additional contact was conducted via telephone only (see figure for flow chart). If a patient's therapy was discontinued and a new oral oncolytic was started, the process was restarted.

Figure

Workflow map for the implementation phase



Data Collection

The data collection was completed by the project lead. The data measurements dashboard was configured into an Excel file (see Appendix G) and data collected over eight weeks was entered. The Excel file with these data collected was stored on a password protected institutional computer in the DNP student's locked office. Patient confidentiality was maintained by utilizing a de-identifier code. The patient de-identifier code was a reverse alphabet numerical system (see Appendix H) for their first, middle, and last name initial, followed by the participant number. The patient data was utilized to identify possible outliers and assess for further information. Thus, it was very important to use coding so that patients will not be identifiable. The Excel file contained a legend leaf bar with the variable name and variable information column for de-coding (See Appendix G).

Measurement Tool

Spreadsheets allow a compact method to collect large amounts of data accurately and in a timely manner (Staziaki et al., 2016). This results in the tools producing internal consistency and reliability (Phelan & Wren, 2006). Spreadsheets as data collection tools possess key functions which can result in error-free spreadsheets that can be directly importing into a statistical software package for easy data analysis (Statziaki et al., 2016). The data collection Microsoft Excel measurement tool is specific to the data being measured and is a good representation for what is being tested, therefore, the tool has high face validity (Phelan & Wren, 2006). Microsoft Excel was provided by the medical institution at which the project was conducted.

The areas of measurement for the project included (a) patient received the resources, (b) patient was contacted by team, (c) patient response was sent to the provider by the RN, (d) further intervention was needed for patient to obtain medication, (e) provider adjusted labs and

follow-up appointments, and (f) patients came to appointment and labs at correct timeframe within a cycle. The oral oncolytic used in breast cancer and type of breast cancer were assigned a numerical identifier. The remaining measurements utilized a dichotomous value of yes or no, and were also assigned a numerical identifier, as this aligned with determinations of the intervention taking place and if the intervention was successful in achieving the desired outcome. The measurement tool for data collection was a spreadsheet tool using Microsoft Excel. To assure consistency, the data values were input by the project lead No formal statistical test was completed to determine the validity and reliability of the measurement tools created for this project. The tool used did not have statistical reliability testing, nor did it have statistical validity testing. It was created according to the reviewed literature and the need in the clinic to improve patient health.

Statistical analysis

A statistician was consulted to discuss the best statistical methods for the QI project on March 30th, 2023 and on June 12th, 2023. Another meeting was completed on January 29th, 2024, to complete the statistical analysis. The measurement of the proposal question was measured on a nominal level, as a yes or no question. The project compared retrospective pre-intervention data to post- intervention data. The data was compared using a chi-squared test. For this QI project, it assisted with comparing lab monitoring and follow-up data for patients who do not receive the intervention with those who do receive the intervention. Descriptive statistics was performed on the demographic and represented in a table. Participants were also asked if they used the resources provided and that data was recorded. The data analysis was done by using the Statistical Package for the Social Sciences (SPSS).

Ethics

This DNP project strived to maintain ethical standards. The proposal was be submitted to the Graduate Nursing Review Committee (GNRC) to conduct a review process. As this is a QI project, Institutional Review Board (IRB) approval was not needed but QIAB approval was granted. Data collection was done in a systematic way to avoid error and maintain integrity of the QI project (Resnik, 2020). Honesty and consistency were maintained in reporting data results, method of data collection, and procedures for data collection. The data implementation and collection methods, materials, and analysis to evaluate the QI project were disclosed. Bias was avoided in the collection and interpretation of the data. The project lead practiced with integrity and carefulness to prevent errors. Caution was taken to store patient data and QI project data to maintain patient confidentiality. The data was kept in a locked office on a password protected computer. Special care was taken to conduct QI project in compliance with Human Subjects Protection Training (see Appendix I).

Results & Interpretation

The purpose of this 8-week QI project was to improve shared decision making among the patient and provider and improve timely lab monitoring and follow-ups for patients who are receiving oral oncolytic therapy. The pre-intervention data showed that over a period of eight weeks, 40 patient encounters were for patients taking oral oncolytic therapy. The mean age was 60, ranging from 30-82 (see Appendix J). Of these 40 encounters, roughly half (45%) were Caucasian, followed by Black or African America, Hispanic or Latino, and Asian, respectively. Most patients had a hormone positive breast cancer (72.5%), followed by triple negative, BRCA positive, and HER-2 positive. The most common oral oncolytic therapy was Palbociclib (39%), followed by Abemaciclib, Capecitabine, Olaparib, Everolimus, and Tucatinib. Of those 40, 24 had labs and follow-up at the correct time within the treatment cycle (60%).

The intervention data showed that over a period of eight weeks, 18 patient encounters were for patients taking oral oncolytic therapy. The mean age was 59, ranging from 28-82. Of these 18 encounters, roughly three-fourths (72.2%) were Caucasian, followed by a small portion of patients who were Hispanic or Latino and Asian. Most patients had a hormone positive breast cancer (94.4%) followed by triple negative. There were no patients who had triple negative or HER-2 positive breast cancer in the intervention data. The most common oral oncolytic therapy was Palbociclib (77.8%), followed by Abemaciclib and Capecitabine. With the implementation of the QI project, of those 18, 17 had labs and follow-up at the correct time within the treatment cycle (94.5%).

Only two encounters in the intervention phase were for patients starting new a medication. Both patients were provided shared- decision making regarding start date and were given the *Oral Oncolytic Tips Sheet* and *Frequently Asked Questions (FAQs) for Oral Oncolytic Agents*. Both patients reported they did not utilize it due to the amount of information given on the first visit. All the patients in the intervention phase were contacted via EHR to ensure they have the oral therapy and they have started treatment. All replies were sent by RN to NP for review. Three encounters required NP or pharmacist intervention for the patient to obtain medication. All patient appointments were adjusted to the correct date based on their treatment start date. Of the 18 encounters, one patient refused to move her labs and follow-up due to a conflict with work, resulting in her labs and follow-up being at the incorrect time.

Discussion

The findings of this QI project establish the positive impact of the clinical interventions on improving lab monitoring and timely assessments for patients taking oral oncolytic agents. The QI project improved efficiency in healthcare delivery within the department. A chi-squared

test was utilized to evaluate the difference between the pre-intervention encounters and the intervention encounters and yielded a p-value of .008, which is statistically significant. Although patients reported they did not use the handouts provided to them, they did maintain contact with the care team via EHR, and most patients attended laboratory appointments and follow-ups as directed. This establishes that the oral oncolytic care bundle was effective in improving monitoring of patients on oral oncolytic therapy.

A noteworthy and unexpected benefit of the QI project was an improved patient-provider relationship. This is an important aspect of the oral oncolytic care bundle as it influences patient's adherence to treatment plans, confidence in their provider, and overall satisfaction. Patient feedback, both verbal and written, suggested expressions of gratitude for the care and attention they received. This implies a positive impact on the patient experience beyond the primary objectives of the project. I received responses from patients stating, "thank you for caring" and, "thank you for checking on me" in several messages followed by how they were doing on treatment. Based on the feedback, the interaction via MyChart message may have reinforced the feeling of connection patients experience with their oncology providers.

A study by Soloman et al. (2019) found that patients received their oral chemotherapy in an average of eight days from prescription. The EPIC report conducted by a statistician within the breast center of the local organization showed that only 13% of patients in the breast department had their oral oncolytic within 10 days of prescription. This is a delay in care and below the average median time which further demonstrates the need for early communication with the patient. Although this QI project did not measure the time from prescription to when patients received their oral therapy, this can be included in future QI projects to further prevent delays in care.

The sustainability and replicability of this project is an important aspect. The use of available technology and existing SmartPhrase capabilities allows the care team to take advantage of the EHR to easily send scheduled messages to the patient. Although interventions were primarily conducted by a NP, the messages sent to patients can be delegated to a RN. Similarly to the project, the RN will forward the patient responses to the care team and instruction to adjust labs, follow-ups, and scans can be provided by the NP, pharmacist, or physician. It is sustainable as it requires very little effort to carry out the interventions when a multidisciplinary collaborative approach is applied. Scalability is an essential aspect to achieve a broader impact on a larger population of patient with breast cancer (Zamboni et al., 2019). The ease with which the interventions can be replicated suggest a straightforward method to scalability. The interventions are adaptable to meet the needs of similar outpatient departments and can also be easily adopted by those utilizing oral oncolytic agents requiring laboratory follow up.

Limitations

It is important to recognize that the interventions implemented in this project are specific to this population and facility and may not be generalizable to other patient populations or healthcare facilities. Factors such as demographic variations, patient preferences, and EHR type may impact the applicability of the interventions in different settings. While all participants in the QI project had access to a patient portal, it is important to acknowledge that there is a small subset of patients who may not be able to utilize this technology. This limitation was not directly addressed during the project but should be considered in future research.

The sample size of the QI project was relatively small, which may affect the generalizability and robustness of the results. A larger sample size would provide more reliable

statistical power and increase the external validity of the findings. The pre-intervention data group included six different oral oncolytic therapies, whereas the interventions group only included three medications. This limitation may decrease the applicability of the findings to other breast cancer patients on oral oncolytic agents.

Since the development of the QI project, two new oral oncolytic agents, Elacestrant and Capivasertib, have received FDA approval for use in patients with metastatic breast cancer. This development is significant as it increases the number of medications being used to treat breast cancer, and further signifies the importance of the QI project interventions. Subsequent studies should include these therapies to maintain relevance and comprehensiveness.

Implications

The success of this project shows opportunities for improvement in monitoring patients taking oral oncolytic agents. The interventions developed through this QI project demonstrate potential for integration into standard practice and is currently being adopted by the clinic in which this QI project took place. The utilization of SmartPhrase technology provides an easy method to contact patients while minimally disrupting the existing workflow. Implementation of an oral oncolytic monitoring program will result in better management of oral oncolytic therapy, reduce adverse events, and improve patient outcomes. Enhanced communication and proactive monitoring guidelines will further support the patient through their oral oncolytic journey. These interventions will lead to a more positive patient experience resulting in higher patient satisfaction scores.

Conclusion

Oral oncolytic therapy is advantageous for patients as it results in a better quality of life through less clinic visits, more flexibility, and ability to receive treatment outside of a hospital

(Huff et al., 2022). The current literature supports the need for introducing a monitoring process for patients taking oral oncolytic therapy that includes contact with the patient within the first week of treatment (Heck & Null, 2018; Huff, 2020). The QI project introduced a monitoring program that showed improvements in clinical outcomes measured with the potential for widespread implementation. In addition to the improvement of laboratory monitoring, there was a broader positive impact on patient care. Implementing an oral oncolytic monitoring program into standard practice holds a high potential for enhancing the monitoring process for patients taking oral therapy and improving patient outcomes.

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Appendix A

Evidence Table

Evidence Table for Improving Lab Monitoring of Patients Taking Oral Oncolytics

#	Author Citation	Design & Aim or Hypothesis & Major Variable	Population & Setting & Sample Size	Intervention	Measurement (e.g. tool to assess outcome)	Results &/OR Recommendations	Strengths & Limitations	Evidence Level & Quality Rating
1	Zerillo, J. A., Goldenberg, B. A., Kotecha, R. R., Tewari, A. K., Jacobson, J. O., & Krzyzanowska, M. K. (2018). Interventions to improve oral chemotherapy safety and quality: A systematic review. *JAMA oncology*, *4*(1), 105–117. https://doi.org/10.1001/jamao	Design: SR Aim: To summarize the peer-reviewed and gray literature on interventions to improve OC care delivery toward describing best practices and identifying current gaps IV: OC management process DV: Adequate management of OC	Population: Patients with cancer taking OC. Setting: Hospitals in United States, Canada, United Kingdom, Indonesia, Germany, India, and Spain Sample Size: 16 full-text articles met inclusion criteria representing 3612 patients	Perform a systematic review of PubMed, EMBASE, and CINAHL from January 1995 to May 24, 2016, using search terms pertaining to OC, cancer, and interventions and outcomes. Interventions in articles focused on prescribing (n = 1), preparation/ dispensing (n = 2), education (n = 11),	N/A	Existing data suggest that a monitoring program should include contacting patients within the first few days after treatment initiation, and standardized toxic effects management protocols	Strengths: Good sample size. Utilized gray literature, as some management programs may not be represented in peer- reviewed articles Limitations: Gray literature is evaluated less systematically than peer-reviewed, therefore could have missed relevant data. Excluded hormonal agents.	Level III, Good Quality

	ncol.2017.0625			administration (n = 5), monitoring (n = 14), and storage/disposal (n = 1)				
2	Huff, C., Thakkar, N., & Westlake, C. (2022). Oral chemotherapy laboratory monitoring and follow-up: A review of the literature. *Clinical Journal of Oncology Nursing*, *26*(5), 487–494. https://doi.org/10.1188/22.CJON.487-494	Design: SR Aim: Improve OC laboratory monitoring by identifying potential barriers and opportunities for reliable communication between patients and providers. IV: Monitoring process for OC DV: improved clinical outcomes secondary to appropriate lab monitoring	Population: Patient with cancer prescribed OC Setting: Outpatient clinical setting Sample Size: A literature review found 76 articles, of which 15 were selected for review	Review literature of conducted using Nursing/Academic Edition, OpenAccess Journal Finder, Scopus®, and SocINDEX® using the search terms oral chemotherapy, safety standards, and lab monitoring	N/A	Improvement solutions needed to strengthen workflow for appropriate OC laboratory monitoring and follow-up by discussing with patients and how these impact clinical outcomes and quality of life, appropriately monitor laboratory results, and advocate for standard oral	Strengths: Four databases searched. Included all types of studies that reported failure in laboratory testing. Limitations: Size of patient population in studies included and generalizability of ambulatory care practice settings	Level III, Good quality

						chemotherapy workflows that improve communication.		
3	Heck, J., & Null, A. (2020). Frequency of appropriate lab monitoring of oral chemotherapy in an outpatient setting. *Journal of Oncology Pharmacy Practice: Official Publication of the International Society of Oncology Pharmacy Practitioners*, *26*(5), 1097–1102. https://doi.org/	Design: Retrospective, observational chart review Aim: Understand the frequency of appropriate laboratory monitoring of oral chemotherapy IV: VHA guidelines DV: Complete, partial, or incomplete monitoring	Population: Patients with cancer who have received a subset of OC drugs, mean age 67 Setting: Eastern Colorado Health Care System Sample Size: 172 patients	Chart review on initial and subsequent prescription fill dates, appropriate labs as defined by VHA guidance and baseline and follow-up lab monitoring dates, and appropriate labs as defined by VHA guidance were collected for up to 12 cycles of chemotherapy per patient.	VHA Guidance on Dispensing and Monitoring of Oral Chemotherapy	Baseline monitoring was 100%. Post-guidelines, there was an increase in frequency of laboratory monitoring. 40% no attempt at monitoring pre-guidelines. 33% no attempt at monitoring post guidelines.	Strengths: Good sample size, used specific guidelines for measurements Limitations: Lack of advertisement of VHA guidelines to providers, not controlled for selection bias, morbidity may also impact ability for patients to follow up	Level IV, Good quality

	10.1177/10781552198820 77							
4	Watson, G. A., Deac, O., Aslam, R., O'Dwyer, R., Tierney, A., Sukor, S., & Kennedy, J. (2019). Real-world experience of Palbociclib-induced adverse events and compliance with complete blood count monitoring in women with hormone receptor-positive/HER2-negative metastatic breast cancer. *Clinical Breast Cancer*, *19*(1), e186–e194. https://doi.org/	Design: retrospective single-center analysis Aim: provide a real-world experience of the toxicities associated with 33albociclib therapy and to evaluate compliance with complete blood count (CBC) monitoring IV: CBC monitoring DV: Detection of hematologic toxicities and rationale for dose modifications	Population: Hormone receptor positive, HER2 negative metastatic breast cancer patients Setting: Ambulatory oncology clinics Sample: 64 patients, median age 62.5	CBC monitoring Day 1 and 14 of the cycle. CBC monitoring day 21 of cycle if day 14 counts showed absolute neutrophil count (ANC) <1000.	Blood laboratory monitoring	57 patients returned for blood work on Day 14, 7 did not. 67% of patients had ANC > 1000 on day 14. 25% had Grade 3 and 4 neutropenia. Most common adverse event was neutropenia in 95% of patients	Strengths: provides information on dosing patterns, CBC monitoring, and Aes during therapy. Showed that neutropenic events are often uncomplicated. Similar data found in this trial when compared to the drug trials Limitations: Small sample size	Level IV, good quality

	10.1016/j.clbc.2018.09.002							
5	Thill, M., & Schmidt, M. (2018). Management of adverse events during cyclin-dependent kinase 4/6 (CDK4/6) inhibitor-based treatment in breast cancer. *Therapeutic Advances in Medical Oncology, 10*, 1758835918793326. https://doi.org/10.1177/1758835918793326	Design: Meta-analysis Aim: overview of the efficacy data and to describe the CDK4/6 inhibitor-based treatment-associated adverse events, including hematological and nonhematological adverse events IV: Different CDK 4/6 inhibitors for treatment of breast cancer DV: Toxicities with use of CDK 4/6	Population: Patients with metastatic breast cancer Setting: Outpatient oncology clinic Sample Size: 2,561	Compare hematologic and non-hematologic toxicities as seen in eight clinical trials for 3 different CDK 4/6 inhibitors	Measures symptoms occurring in >30% of patients	The main side effects associated with a CDK4/6-inhibitor are similar, including neutropenia and gastrointestinal side effects. Early and sufficient monitoring is the key to treating patients successfully, minimizing side effects and treatment interruptions, and avoiding a lack of confidence for this innovative treatment	Strength: Evaluated RCTs only. Large sample size. Limitations: There are additional trials on these medications which could have been included for a more comprehensive analysis	Level I, High quality
6	Huff C. (2020). Oral	Design: SR	Population: Patients with	OC home safety education	OC home safety	Comprehensive patient	Strengths: Excluding	Level III,

	chemotherapy: A home safety educational framework for healthcare providers, patients, and caregivers. *Clinical Journal of Oncology Nursing*, *24*(1), 22–30. https://doi.org/10.1188/20.CJON.22-30	Aim: Education for healthcare providers, patients, and caregivers using a checklist and teach-back tool focused on OC IV: Providing education for patients to manage OC at home DV: Enhance patient safety by improving knowledge about adherence and monitoring process	cancer taking OC Setting: Home setting Sample Size: 7 selected articles for review	provided by nurses	education checklist	education is key to improving adherence and deterring potential health and safety hazards with exposure	Search strategy included, literature review searched 3 databases, journal articles that included intravenous chemotherapy were excluded Limitations: Smaller sample size. Gaps in knowledge, further research needed on barriers to safety of patients taking OC	Good quality
7	Moran, A., Elwell, J., Holle, L., & Hook, K. (2023) Development, implementation, and evaluation of an oral	Design: Quality Improvement Aim: Develop, implement, and evaluate a standardized program to improve safety for patients	Population: Patients taking oral oncolytic therapy Setting: Academic medical center	Establishing an oral oncolytic management program to mitigate errors in prescribing, improve adherence, and improve monitoring by	Dose verification checklist, informed consent, completion of adherence and	The use of standardized order templates and dual-nurse dose verification improved from 0% to 91%	Strengths: Completed a review of literature to demonstrate areas needed for oral oncolytic program, created a workflow map	Level IV, good quality

	anticancer management program. The Journal for Nurse Practitioners, 19(4). https://doi.org/10.1016/j.nurpra.2022.10.019	newly prescribed oral oncolytic agents IV: Oral agent program development DV: Improved compliance, Completion of adherance and tolerance checks	Sample size: 119 patients reviewed, 12 met inclusion criteria	developing a new workflow, develop medication specific electronic templates, update institutional policies and procedures	tolerance check	($P < .05$), the completion of informed consent improved from 25% to 67% ($P < .05$), and the completion of an adherence/tolerance check improved from 8.3% to 75% ($P < .05$). In both the pre- and postimplementation data collection, documentation of medication-specific patient education was lacking or completely absent.	Limitations: Small sample size, short term follow up period for the study so not sure for how long the compliance will last	

8	Finn, A., Bondarenka, C., Edwards, K., Hartwell, R., Letton, C., & Perez, A. (2017). Evaluation of electronic health record implementation on pharmacist interventions related to oral chemotherapy management. *Journal of Oncology Pharmacy Practice: Official Publication of the International Society of Oncology Pharmacy Practitioners*, *23*(8), 563–574. https://doi.org/	Design: Retrospective study Aim: pharmacist-managed oral chemotherapy program and evaluate pharmacist interventions before and after implementation of an oral chemotherapy program IV: Pharmacist assist with beacon plans and labs and follow up orders placed DV: Improved monitoring of hematologic toxicity and adverse drug reactions	Population: Patients taking OC, median age 58, central nervous system, colorectal, kidney, breast, pancreas, gastroesophageal, myeloma, skin, sarcoma, and other types of cancers included Setting: Medical University of South Carolina Hollings Cancer Center Sample: 240 patients	Utilization of EPIC for lab parameters, treatment instructions, pre-medications, laboratory orders, and chemotherapy medication orders	Measurement tool was based on categories examined included intervention categories, value of significance, severity of error	Use of an electronic system decreased errors with patient education, labs monitored, coordination of care, and medication dosing	Strengths: Study demonstrated pharmacist role with OC, practitioners stated pharmacist involvement improved safety, demonstrated utilization of EPIC decreased lab errors and medication errors. Limitations: retrospective design in a single center, which may limit the generalizability, orders placed outside of EPIC plans were not captured, documentation being different electronically when done in plans	Level III, Good quality

	10.1177/10781552166652 47							
9	Redelico, T. J., Walton, S. M., LaFollette, J., Adams Curry, M., & Bernal-Mizrachi, L. (2018). Assessment of provider adherence to recommended monitoring parameters for oral anticancer medications. *Journal of Oncology practice, 14*(7), e446–e450. https://doi.org/10.1200/JOP.17.00018	Design: Retrospective chart review Aim: Evaluate provider compliance with US Food and Drug Administration (FDA) drug labeling-specified monitoring parameters for commonly dispensed OC Variables	Population: Patients taking OC, median age 55 Setting: Grady Health System, Atlanta Sample: 77 patients	Review patient charts to determine if lab monitoring adhered to the FDA guidelines	Monitoring tool was developed for each OC that described dosing, dosage adjustments, toxicities, and FDA-specified lab monitoring parameters.	36.1% met monitoring parameters as recommended by the FDA.	Strengths: Determined need for improved monitoring in ambulatory setting, 349 treatment cycles were evaluated despite small sample size Limitations: Clinical significance of lab monitoring not occurring was not reviewed, all labs ordered were captured, therefore some people may have been marked as compliant if labs were not ordered for monitoring purpose, resulting in overestimation	Level III, Good quality
10	Kaler, A., McClosky, V., Raghavendra,	Design: Quality improvement	Population: Breast cancer patients	Intervention: Improve EHR functionality for	Measurement tools: Productivity	Ordering labs went from 23 mouse clicks	Strengths: Utilized a multi-disciplinary team	Level IV, good quality

	A., & Tripathy, D.(2022). Oral oncolytics: Using remote technology to improve access, operational efficiency, and satisfaction. Clinical Journal of Oncology Nursing, 26(3), 308-312. https://doi.org/10.1188/22.CJON.308-312	Aim: streamline process for monitoring oral oncolytic patient reported outcomes, improve safety, operational productivity, and care team satisfaction IV: Lab monitoring orders sent through EHR, symptom monitoring application DV: improve productivity, improve patient reporting of symptoms	taking oral oncolytic therapy Setting: Oncology Facility in Texas Sample: 732 patients taking oral oncolytics. 30 patients enrolled in using application	lab monitoring orders, implementation of application for patient-reported outcomes and symptoms monitoring. Resources for how to take medication and reminder for blood work. Virtual support groups	enhancement measured by number of clicks it takes to order lab work. Changing for fax to electronic fax for results. Remote symptoms monitoring measured by number of patient reported outcomes were received and answered. Provider satisfaction survey	to 5, results changed to electronic fax decreasing time to distribute by 95.8 minutes daily. 30 patients enrolled, 92 symptoms reported and answered by application	to address barriers to care during the pandemic, demonstrated the ability to utilize technology in patient care Limitations: Patient satisfaction data was not collected, protection of patient data when using applications to interface with the EHR can be a timely process	

Note. DV= Dependent variable, IV= Independent Variable, OC= oral chemotherapy, QI= Quality improvement, RCT= Randomized controlled trials, SR= Systematic Review

Appendix B

Oral Oncolytic Tips Sheet

When taking oral oncolytics at home, patients must understand instructions, precautions, and side effects of medications.

What should I know before beginning oral oncolytic agent?

- The *dose and frequency* of the drug. Always double check the strength of the dose before taking, as it may take several pills of different strengths to make up the total dose prescribed.
- When is the best time to take the medication, and whether to take the medication *before, with,* or *after* a meal or snack.
- Review all medications or supplements you are taking with a member of your oncology team, as some may impact/ interfere with the effectiveness of the oral chemotherapy. When starting a new medication, please consult your oncologist for concerns of interaction with other drugs.
- Know what to do if you miss a dose, vomit, or take an extra dose by mistake.
- Understand the side effects of the medication

How do I handle my oral oncolytic safely at home?

Storage

- Keep medicine in its original container.
- Keep out of reach of children or pets.
- Do not store oral chemotherapy pills in a bathroom with a shower or on your windowsill.

Handling

- Wash your hands thoroughly before and after you take the pills.
- Do not crush, break, or chew your pills.
- If caregivers are administrating the drug, they should avoid handling the medication with their bare hands. Caregivers should use gloves when emptying the pill(s) in the lid or plastic cup to give to the patient that is receiving the medication.

Disposal

- If you have oral chemotherapy pills left over, please return them to the pharmacy where the prescription was filled.
- Do not flush them down the toilet, pour them in the sink, or throw them away in the trash.

What do I do if I am having side effects?

- Depending on the type of oral chemotherapy you are taking, you may experience a variety of side effects. If side effects are impacting your everyday functions, you should contact your oncology team to let them know.
- Keep contact information for your oncology team readily available in a prominent place.
- If you need to contact your team, you may contact them via MyChart message or you may call the triage line at XXX-XXX-XXXX.

Tips to Consider

- Try to take your pill at the same time and under the same circumstances every day.
- Use the reminder features on your smart devices, such as alarms or a reminder app, to prompt you to take the drug as prescribed. You may also use other reminder devices if you so choose.
- If you travel, make sure you have enough pills on hand for unexpected delays.
- Keep a diary of the time you took the medication and the symptoms you experienced that day to monitor patterns

Will I still need to see my doctor?

- Even though you are taking oral chemotherapy at home, you will still need to see your cancer care team. They will need to monitor if the treatment is working to treat your cancer and how you are tolerating your medication. Follow-up visits, blood tests, and scans will be scheduled by your oncology team. It is very important that these be completed on certain dates after starting the chemotherapy. If you experience a delay in obtaining your medicine, notify your oncology team so they can update due dates for blood tests and other needed follow- up care.

Frequency of blood tests: _____

Frequency of follow- ups: _____

Frequency of staging scans: _____

Appendix C

Frequently Asked Questions (FAQs) for Oral Oncolytic Agents

Q: How do I reach my clinical team if I have questions or concerns about my treatment plan
A: Use MyChart to send a message to your doctor with the specific question. You should expect a response within 2 business days. If you do not have access to MyChart, call the Breast Center at (XXX) XXX-XXX, and press 4 to speak to the nurse

Q: What should I do if my pharmacy says I need a prior authorization?
A: The medication the doctor is prescribing may require a prior authorization. A Prior authorization is when insurance needs more information about why you need this medication. Somebody from your medical team contacts your insurance to complete a prior authorization. Please notify your provider if a prior authorization is required.

Q: What do I do if I cannot afford my medication?
A: You can contact our specialty pharmacy at XXX-XXX-XXXX, option #2 to speak with a financial representative or contact the dispensing pharmacy.

Q: What if I cannot swallow my medication?
A: Do NOT crush or chew this medication without approval from your provider. Do not mix this into your pill box with your other medication. Contact your provider if you are having trouble swallowing the medication.

Q: Who should I contact if I am experiencing a side-effect from my treatment?
A: For any urgent issues, call the Breast Center at (XXX) XXX-XXXX, and speak to the nurse (press option 4). If you are calling after-hours (after 5 PM), on holidays or on a weekend, you can call (XXX)-XXX-XXXX and ask for the Breast Medical Oncologist "On Call."

For any non-urgent issues, *send a message to your clinical team through MyChart. If you do not have access to MyChart, call the Breast Center at (XXX) XXX-XXXX, and press 4 to speak to the nurse.*

Appendix D

Team/ RN Education

What is the purpose of this project?

- Improve monitoring of patients on oral oncolytics by obtaining required blood work and completing follow-up visits in a timely manner
- Improve patient safety/ safety events related to inadequate lab monitoring.

Why is lab monitoring important for patients who are on oral oncolytic agents?

- Evaluates if there is drug toxicity related to medication such as neutropenia, anemia, thrombocytopenia, increased liver enzymes, increased serum creatinine.
- Prevents long- term complications, such as kidney damage or liver failure.
- Allows providers to intervene prior to emergent or fatal event.
- Prevent hospitalizations related to drug toxicities.

How do I contact the patient and when?

- RN is expected to contact the patient within 3 days of clinic visit to ensure patient has received their medication and obtain treatment start date.
- RN will send a message to the patient on the day they are seen in clinic by utilizing a smartphrase. The smartphrase will populate when RN types .OOFUSMARTPHRASE.
- The RN will click the correct pre-set smartlinks pertaining to the patient's treatment and set the message to send to the patient 3 days after the visit.
- RN will notify NP with the patient's response.
- If patient does not respond in 24 hours, RN will call the patient.
- If RN is unable to reach the patient, they will notify the NP

Appendix E

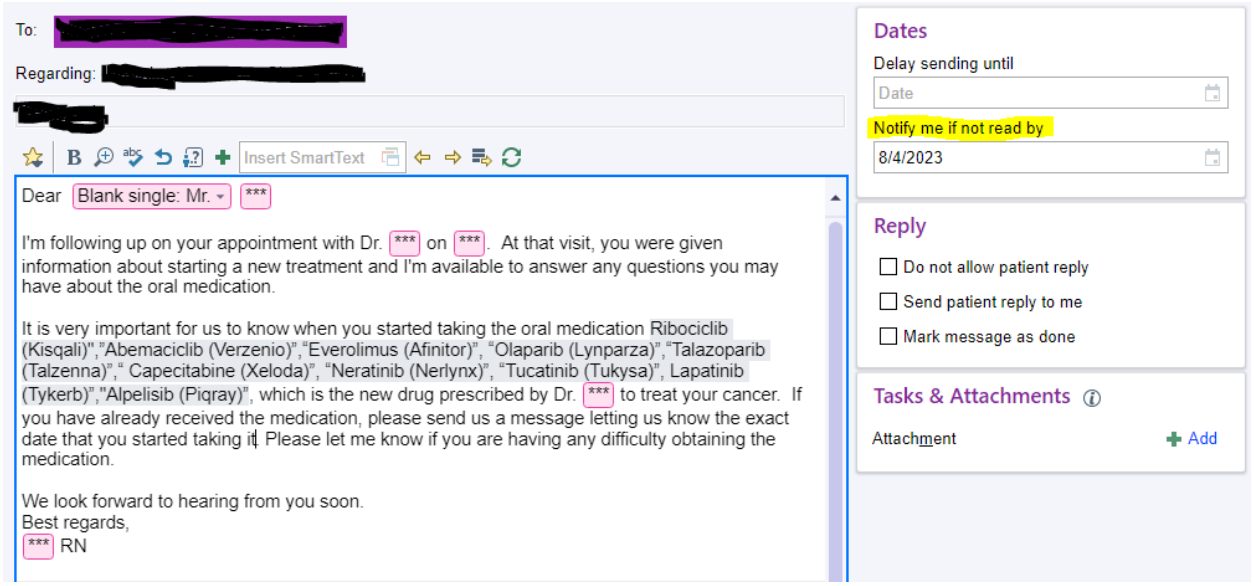
Patient Messages

Dear {Blank single:19197::"Ms.","Mrs.","Mr."} ***

I have attached a tip sheet and frequently asked questions about oral therapy to this message. Please review this and the oral therapy educational material provided to you at your visit prior to starting therapy.

We will message you in approximately 3 days to ensure that you have started treatment and to answer any further questions you may have.

We look forward to hearing from you soon.
Best regards,
***



Appendix F

Approval Letter

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

To Whom It May Concern,
Dharusal Patel has permission to continue with the lab monitoring QI project for patients taking oral oncolytics in the outpatient Breast Medical Oncology department.

Michelle Butaud

Michelle Butaud, APRN, ANP-BC, AOCNP, CBCN
Manager, Advanced Practice Providers

MD Anderson Cancer Center

Breast Medical Oncology

QIAB Approval

Workflow Notification

The QIAB has reviewed and approved your QI project titled: Improving Lab Monitoring of Oral Oncolytics

Project Registration ID: 1083

−Your project is now part of MD Anderson's Quality Improvement Project Registry.

−Click this *Link to access your project in the Registry, where – among other things – you can add/update/change the names of your Project Team Lead(s), Team Members, and/or Facilitator(s).

***Please save this email with the link to your project, or copy the url link and save it in your Contacts.**

FROM THE OFFICE OF PERFORMANCE IMPROVEMENT:

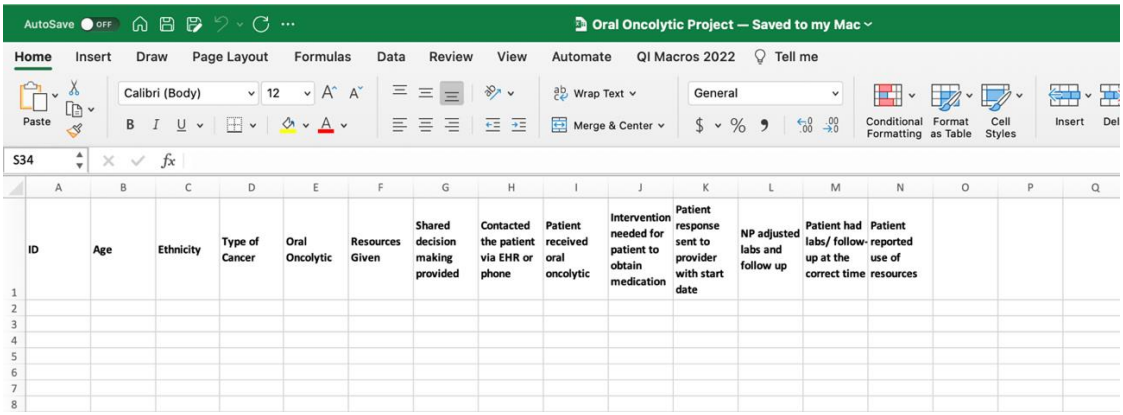
Patient Experience: Incorporate patient perspectives into your decision-making process or your quality improvement project.

Patient Satisfaction Report/PGSurveys: If surveying patients (patient satisfaction) as part of your project, closely review Press Ganey survey questions to determine if they are applicable to your project.

Quality College: An MD Anderson resource for quality education and tools.

Appendix G

Data Collection Dashboard



Coding Legend for Excel Data Collection Sheet

ID	Study ID number
Age	Age
Ethnicity	1=Hispanic or Latino; 2=Asian, 3=Black or African American, 4=White, 5=Native Hawaiian or other Pacific Islander 6= American Indian or Alaskan Native
Type of cancer	1=Triple negative; 2=Hormone positive; 3=HER-2 positive; 4=BRCA positive
Oral oncolytic	1= Palbociclib; 2=Abemaciclib; 3=Ribociclib; 4=Everolimus; 5=Olaparib; 6=Talazoparib; 7=Capecitabine; 8=Neratinib; 9=Tucatinib; 10=Lapatinib; 11=Alpelisib
Resources given	1=Yes; 0=No
Shared decision making provided	1=Yes; 0=No
Contacted the patient via EHR or phone	1=Yes; 0=No
Patient received oral oncolytic	1=Yes; 0=No
Intervention needed for patient to obtain medication	1=Yes; 0=No
Patient response sent to provider with start date	1= Yes; 0=No
NP adjusted labs and follow-ups	1=Yes; 0=No
Patient got labs/ follow-up at the correct time in cycle	1=Yes; 0=No
Patient reported use of resources	1=Yes; 0=No

Appendix H

Coding System for the Participants

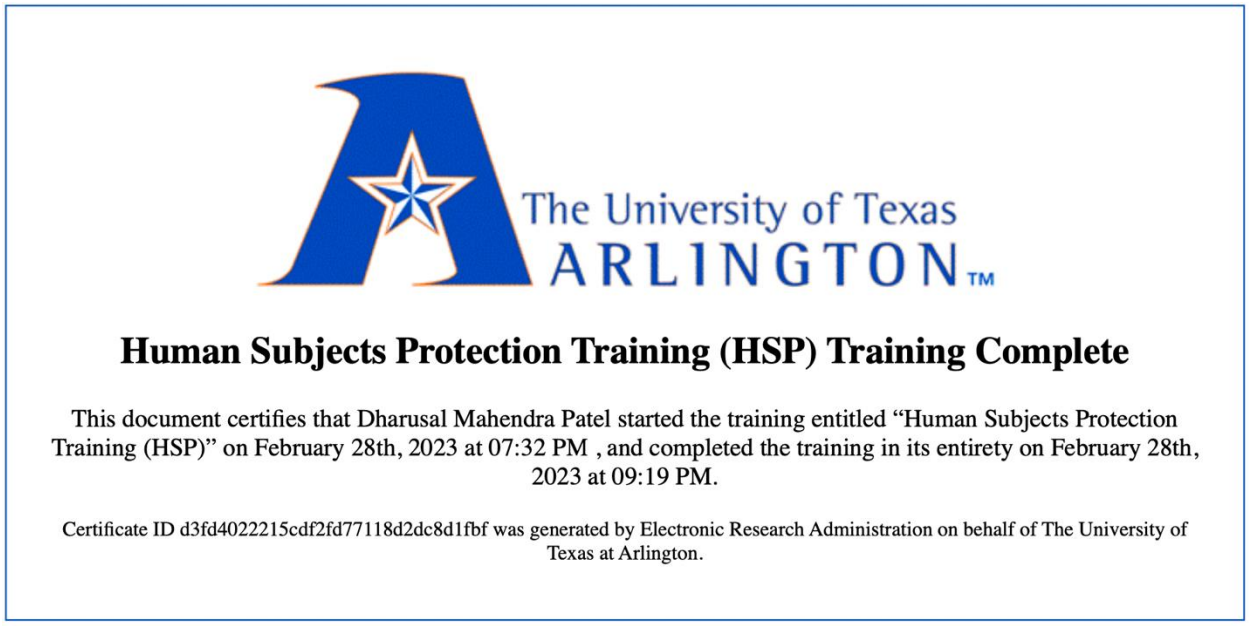
A= 26	N= 13
B= 25	O= 12
C= 24	P= 11
D= 23	Q= 10
E= 22	R= 9
F= 21	S= 8
G= 20	T= 7
H= 19	U= 6
I= 18	V= 5
J= 17	W= 4
K= 16	X= 3
L= 15	Y= 2
M= 14	Z= 1

Initial First Name- Initial Middle Name- Initial Last Name- Participant Number

If John Fitzgerald Kennedy was a participant, his code would be 17-21-16-001

Appendix I

Human Subjects Protection Training



The University of Texas ARLINGTON™

Human Subjects Protection Training (HSP) Training Complete

This document certifies that Dharusal Mahendra Patel started the training entitled "Human Subjects Protection Training (HSP)" on February 28th, 2023 at 07:32 PM , and completed the training in its entirety on February 28th, 2023 at 09:19 PM.

Certificate ID d3fd4022215cdf2fd77118d2dc8d1fbf was generated by Electronic Research Administration on behalf of The University of Texas at Arlington.

Appendix J

Patient Demographics

Patient Demographics

Demographics or baseline characteristic	Pre-intervention encounters (n=40)	Post- intervention encounters (n=18)
Mean age, years	60 (30-82)	59 (28-82)
Race, n (%)		
Hispanic or Latino	10 (25)	4 (22.2)
Asian	3 (7.5)	1 (5.6)
Black or African American	9 (22.5)	0 (0)
Caucasian	18 (45)	13 (72.2)
Cancer type, n (%)		
Triple negative	6 (15)	1 (5.6)
Hormone positive	29 (72.5)	17 (94.4)
HER-2 positive	1 (2.5)	0 (0)
BRCA positive	4 (10)	0 (0)
Oral Oncolytic Agent, n (%)		
Palbociclib	16 (39)	14 (77.8)
Abemaciclib	10 (24.4)	3 (16.7)
Everolimus	1 (2.4)	0 (0)
Olaparib	4 (9.8)	0 (0)
Capecitabine	9 (22)	1 (5.6)
Tucatinib	1 (2.4)	0 (0)