

## Pharmacist Driven Oral Oncolytic Medication Education and Consent

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### Abstract

**Background:** The number and type of oral oncolytic therapy in oncology is expanding rapidly. Oral oncolytics have serious side effect potential and patient education has been shown to reduce adverse events. Pharmacist driven interventions have been shown to improve safety and adherence. The University of New Mexico Comprehensive Cancer Center (UNM CCC) initiated a pharmacist driven patient education and consent process for oral oncolytic therapy.

**Methods:** A pharmacist driven education process was initiated at UNM CCC from August 2016 to October 2018. The metric measured was the percent of patients on oral oncolytic therapy who were educated and consented. We used a statistical process control chart method to examine the delays in chemotherapy between the baseline and postintervention periods. The interventions included Electronic Medical Record (EMR) generated orders, physician education, pharmacy staff notifications and hospital discharge planning.

**Results:** The initial monthly education and consent rate was 17.9% followed by 45.5% the following month. This quickly grew to an average of 87.0% (95% CI 55.7-118.2) for the subsequent 15 months which achieved control. Additional changes were made as part of the PDSA cycle which increased the education rate to 95.7% (95% CI 84.4-107.1). These two periods were statistically significantly different ( $p = 0.0025$ ).

**Conclusion:** A pharmacist driven program for education and consent upon initiation of oral oncolytics is possible and can successfully educate the majority of patients. Future expansions of this program will include ensuring patient adherence and educating patients who fill oral oncolytics outside UNM CCC.

Word Counts:

(1500 max manuscript)

(250 max abstract)

## **Introduction**

The number and type of oral oncolytic therapy in oncology is expanding rapidly<sup>1</sup>. There are established patient safety standard practices for chemotherapy education administered in infusion centers, however, with the increasing number of oral chemotherapy agents, there is a need to apply the same patient safety practices to oral chemotherapy education<sup>2</sup>. Oral oncolytics have serious side effect potential and patient education has been shown to reduce adverse events<sup>2,3</sup>. Patients are often unaware or hesitant to report serious side effects<sup>4</sup>. There is wide variability across cancer centers regarding education and safety of oral oncolytics<sup>5</sup>. Pharmacist driven interventions have been shown to improve safety and adherence<sup>6,7</sup>. The ASCO Quality Oncology Practice Initiative (QOPI) suggests four defined domains of responsibility: (1) creating a safe environment-staffing and general policy, (2) treatment planning, patient consent, and education, (3) ordering, preparing, dispensing and administering chemotherapy and (4) monitoring after chemotherapy is given, including adherence, toxicity and complications<sup>8</sup>. Our project focuses on the second intervention; treatment planning, patient consent, and education.

The University of New Mexico Comprehensive Cancer Center (UNM CCC) initiated and then improved upon a pharmacist driven patient education and consent process for oral oncolytic therapy. The goal was to achieve greater than 80% education and consent rate among patients filling oral oncolytic therapies at UNM CCC pharmacy.

## **Methods**

To begin establishing standards of practice for oral chemotherapy education, we developed a pharmacist driven quality improvement project focusing on patients filling oral chemotherapy prescriptions at the University of UNM CCC outpatient pharmacy. Per QOPI guidelines, chemotherapy is defined as agents used to treat cancer, given through oral and parenteral routes or other routes as specified in the standard. Types of oral oncolytics included targeted agents, alkylating agents, antimetabolites, plant alkaloids and terpenoids, topoisomerase inhibitors, antitumor antibiotics, monoclonal antibodies, biologics and related agents. Hormonal therapies were not included in the definition of chemotherapy or in this project. Unique circumstances of UNMCCC include the very rural nature of New Mexican patients, distance required to travel for healthcare, and the higher prevalence of Hispanics and Native Americans with disproportionately low socioeconomic status<sup>9,10</sup>. Members of the team included clinic based pharmacy staff, oncology providers, nurses, nurse navigators, outpatient pharmacy staff and administration. This quality improvement project was selected as the programmatic clinical goal for the UNMCCC Cancer Committee as part of the requirements of the Commission on Cancer. QI methodology using the Plan-Do-Study-Act (PDSA) cycle was used for this project. Institutional review board exempt status was granted for this quality improvement project.

The pharmacist driven education and consent process was initiated at UNM CCC and monitored from August 2017 to October 2018. Beginning August 1<sup>st</sup> 2017 patients filling new prescriptions at the UNMCC outpatient pharmacy would receive a 30 minute education session with a pharmacist,

scheduled at the patient's convenience to provide focused medication review, consent and an opportunity for patients and their caregivers to ask questions before starting treatment. Each of the education sessions would be documented in the patients' medical record for all members of the treatment team to view.

The intervention initially used a message generated by an order in the Electronic Medical Record (EMR) to alert the pharmacist of new oral oncolytic prescriptions (Figure 1). Initial uptake by providers was low so education regarding this order was presented to providers as part of PDSA cycle #1. Provider adherence to this order increased but patients were able to obtain the new prescription before the pharmacist educator could intervene with consent and education. PDSA cycle #2 consisted of outpatient pharmacy staff being instructed not to release the first fill of an oral oncolytic prescription without notifying the pharmacist educator beforehand. The pharmacist educator would then come to the outpatient pharmacy to consent and educate the patient regarding the oral oncolytic therapy. Also part of PDSA cycle #2, some patients were started on new oral oncolytic therapy while in the hospital due to progression, side effects of previous therapy or new diagnosis. These patients were bypassing the above framework so inpatient hematology and oncology fellows were instructed to notify the pharmacist educator of patients discharged directly from the hospital with a new oncolytic prescription. The pharmacist educator could then contact the patient and set up an appropriate time for consent and education. The goal was for 80% of all patients filling a prescription for oral chemotherapy at the UNM CCC Outpatient Pharmacy to undergo a 30-minute teaching that will be documented in the pharmacy note.

We used a statistical process control chart method to examine the delays in chemotherapy between the baseline and post intervention periods. QI macros software was used to create figures and analyze data. Statistical analysis included run charts with 95% Confidence Intervals and t-tests with two tails, assuming unequal variation between groups and an alpha of 0.05.

## **Results**

From August 1<sup>st</sup> 2017 to October 31<sup>st</sup> 2018, 229 patients filled new oral chemotherapy prescriptions at the UNMCC outpatient pharmacy. Out of these, 210 patients participated in a 30 minute education and consent session with the pharmacist that was documented in the patient's medical record. The initial monthly education and consent rate was 17.9% followed by 45.5% the following month. This quickly grew to an average of 87.0% (95% CI 55.7-118.2) for the subsequent 15 months which achieved control (Figure 2). Additional changes were made as part of the PDSA cycle #2 which increased the education rate to 95.7% (95% CI 84.4-107.1). These two periods were statistically significantly different ( $p = 0.0025$ ) showing additional cycles of PDSA led to additional improvement. For the entire QI period, 91.7% of all patients filling a new prescription for oral chemotherapy at the UNMCC outpatient pharmacy received a 30-minute education session with a pharmacist documented in the medical record. This exceeded the target goal set by the UNMCCC Cancer Committee for 2018 of 80%.

## **Conclusion**

This project built a pharmacist driven consent and education system for oral oncolytic therapy de novo and initially achieved an 87% capture rate. Continued PDSA cycles resulted in further improvement to 95.7% capture rate. The interventions used had various levels of success and

alternative strategies were implemented as needed. Building the new orders through the EMR to alert the pharmacist educator of new oral oncolytic prescriptions took time and Information Technology (IT) manpower. Once built, provider use of this order was low. Subsequent education regarding the importance of this project and the effect on patients improved rates of providers ordering pharmacy education and consent. However, too many patients continued receiving the prescriptions without consent or education. Discussions with outpatient pharmacy staff lead to the decision that all patients receiving new oral oncolytic prescriptions must receive consent and education from the pharmacist educator before receiving the medication. This led to outpatient pharmacy staff verifying through the EMR that education and consent had been done, and if not, contacting the pharmacist educator to intervene. The last group of patients that were being missed were individuals started on new oral oncolytics in the inpatient setting when admitted for progression, side effects of previous therapy or new diagnosis. These patients would fill their prescription at the hospital discharge pharmacy circumventing the above framework. All hematology and oncology fellows were then instructed to alert the pharmacist educator regarding new starts of oral oncolytics. The pharmacist educator could then contact the patient and meet for consent and education when convenient for the patient.

This data shows a pharmacist driven program for education and consent upon initiation of oral oncolytic therapy is possible and can successfully reach the majority of patients. To maintain this intervention, the above framework remains in place and increased support for the outpatient pharmacy has been implemented. Future expansions of this program will include ensuring patient adherence, educating patients who fill oral oncolytics outside UNM CCC and education and adherence for hormonal therapy. Given proper support, the likelihood of success outside of oral oncolytics filled at UNM CCC pharmacy is high.

**Figure 1.**

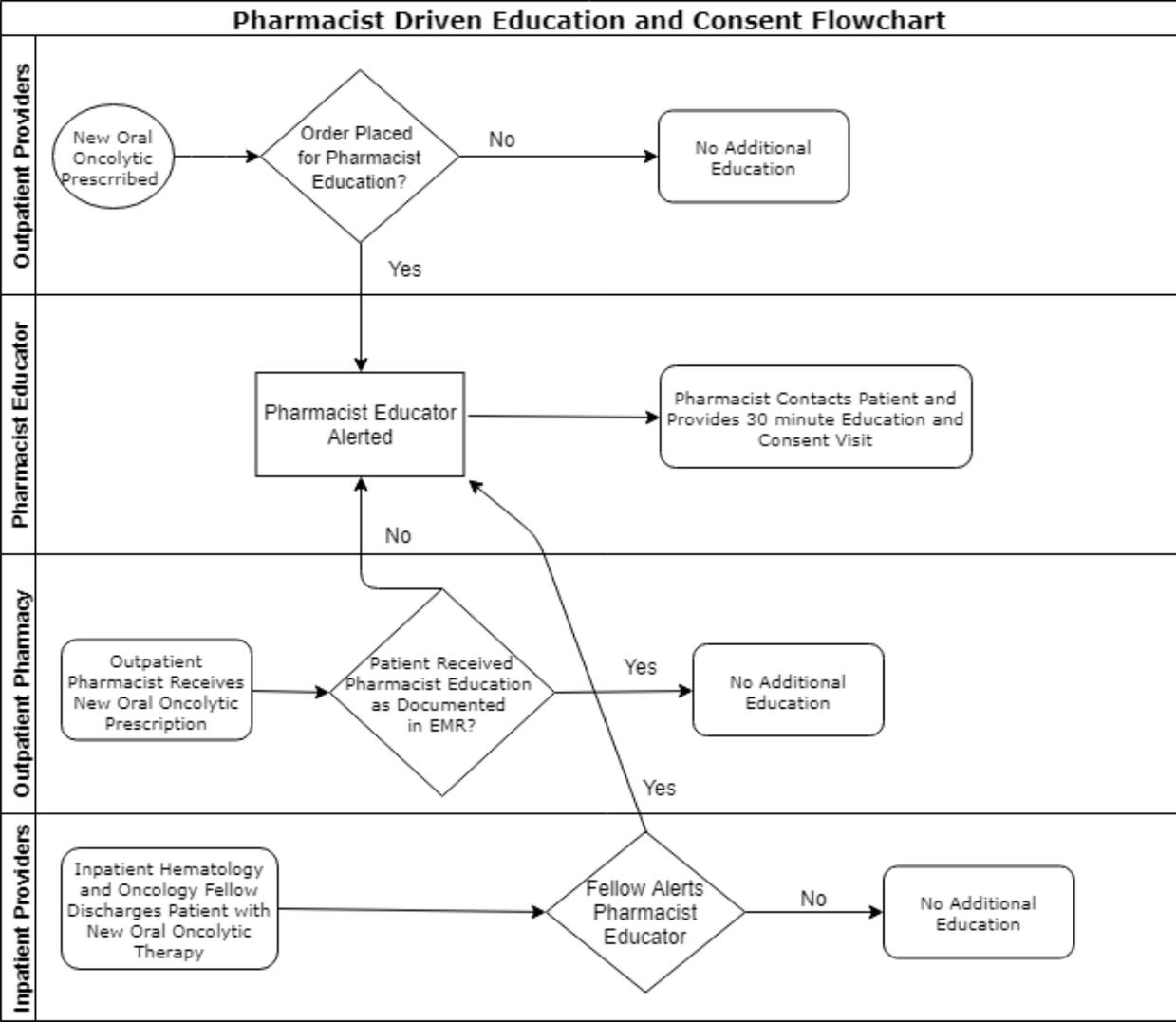
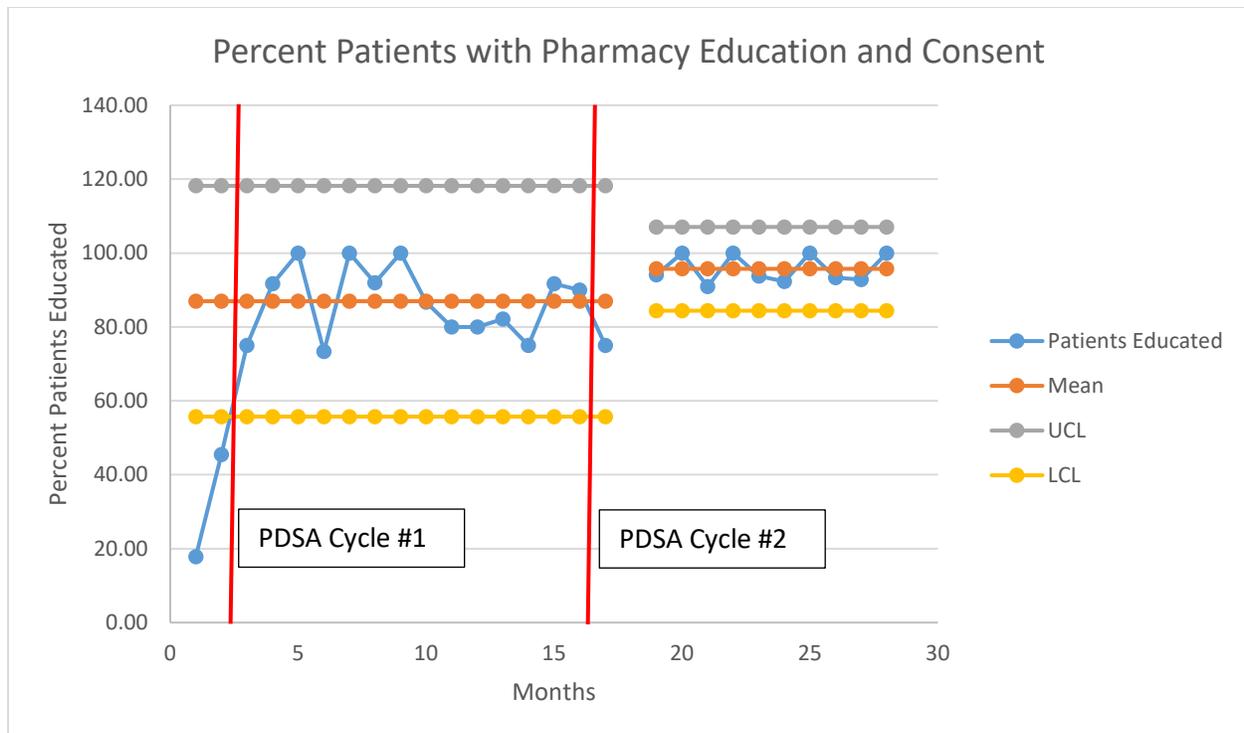


Figure 2.



\*Gap shown only to visually separate two segments compared to each other

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With increasing recognition of the need to improve the quality and efficiency of oncology care delivery, practices are taking note of the science of improvement. Various techniques are in use to identify and analyze problems, intervene, and then measure the effects of the intervention. Many of the insights and schemes that inform improvement science have been gained and adopted from other industries.

The editors of *Journal of Oncology Practice (JOP)*, with guidance gained from ASCO's Quality of Care Committee, publish articles demonstrating the application of improvement science techniques in oncology practice. These papers provide examples of implementing QI strategies and, in composite, provide a library of these efforts. We believe a collection of QI projects provides actionable lessons and resources that inform and inspire oncologists to measure and improve.

*JOP* Quality in Action manuscripts are brief, structured reports of quality improvement (QI) projects. These will be subject to peer review and, if accepted, published as Medline-indexed online articles, under the series title, Quality in Action. *JOP* editors are seeking:

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Required manuscript sections are summarized below:

- Title
- Abstract: Limit to 250 words.
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aims); the theory or framework used to guide the project; and brief context from published literature. A detailed literature review is not required.

- **Methods:** Describe the local context of the project; the selected change or intervention and why it was selected; methods used for implementation and evaluation; and qualitative and/or quantitative analytic methods. Studies utilizing standard QI methodology (e.g., PDSA, Lean, Six-Sigma DMAIC) are encouraged.
- **Results:** Describe the relevant diagnostic data and the results of the intervention, preferably using standard QI tools (e.g., cause-and-effect diagram, Pareto chart, histogram, run chart, statistical process control chart). Results of the intervention might include changes to the system, care processes, and/or outcomes. It is not necessary to demonstrate improvement if results are informative.
- **Discussion:** Summarize the key successes and challenges of the project; if no improvement was demonstrated to the health care system, care processes, or patient outcomes, explain why. Comment on the impact of local context on the intervention and outcome, and on the likelihood of successful uptake beyond the test setting. If appropriate, include a plan for sustaining and disseminating the intervention.
- **Acknowledgments:** If appropriate, acknowledge funding and non-author contributions (e.g., research assistance, manuscript editing).

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