

# Leveraging Technology to Achieve Excellence in Oral Oncolytic Management





A confirmed cancer diagnosis can be an emotional, all-consuming, and devastating circumstance for patients and their families. While this is a too frequent occurrence in the United States, cancer survival rates are improving due to early diagnosis through screening and the increased availability of new anti-cancer treatments and targeted therapies.<sup>1</sup> According to the American Cancer Society’s 2022 statistics,<sup>2</sup> the impact of cancer is profound and continues to grow with last year’s projections being forecast as:

- 1,918,030 new cancer cases
- 609,260 cancer deaths
- Approximately 5,250 individuals newly diagnosed with cancer per day
- Lifetime invasive cancer probability of 38.5 percent in women and an even higher rate of 40.2 percent in men, based on life expectancy and risk.

For these patients, access to state-of-the-art anti-cancer treatment and services is integral to their survival and quality of life.

### The Landscape of Oral Oncolytics

Oral oncolytic treatment is the fastest growing form of anti-cancer therapy in newly approved clinical trials. In the U.S., the prevalence of oral anti-cancer agents ranges from 25 percent to 35 percent of all antineoplastic agents on the market, and approval by the U.S. Food and Drug Administration has exploded exponentially over the last three to four years.<sup>1,3,4</sup> According to 2019-2020 ACCC President Dr. Ali McBride, “More than 3,500 novel approaches have been evaluated

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clinically or pre-clinically in the last decade. Currently, more than 10,000 clinical trials with novel and approved agents, alone or in combination, are ongoing, with over 12 percent having entered Phase III status...Of the more than 800 new oncology therapies currently in the pipeline, 25 [percent] to 35 percent are oral agents.”<sup>1</sup>

Oral oncolytics are often preferred by patients and clinicians for their comparative administration ease, convenience, flexibility, and reduced burden of care.<sup>1,3,4</sup> Specific advantages of oral oncolytics over standard chemotherapy infusions include:<sup>3-6</sup>

- Fewer oncology clinic or office visits
- Less patient monitoring
- Increased patient convenience
- Fewer expended healthcare resources and lower administration and management costs
- Patients’ ability to maintain a quality of life that closely resembles their life before cancer

- Reduction in financial burden on patients due to frequent transportation, childcare, and other out-of-pocket costs that are not usually covered by insurance.

Conversely, there are also disadvantages to oral oncolytic therapy, including:<sup>3-6</sup>

- Increased knowledge burden on patients, who must understand how to self-administer their medications, which can challenge even highly educated patients
- Side effect management and treatment adherence, particularly when patients may experience forgetfulness as a side effect of their anti-cancer treatment
- The high costs of oral oncolytics
- The safe handling and storage of these medications.

To address these factors and harness the potential of oral oncolytics to transform cancer care, oncology programs and practices must build systems to support patients through all phases of oral oncolytic management—from prescription to adherence. A multifactorial, multidisciplinary approach is needed to educate, support, and improve patient adherence and outcomes when taking an oral oncolytic. According to Dr. McBride, “Developing an oral chemotherapy workflow that includes financial assistance, high-quality patient education, side effect self-management support, and monitoring and follow-up is critical. This complex workflow involves many members of the cancer care team, including pharmacists, pharmacy technicians, financial navigators, physicians, advance practitioners, and nurses.”<sup>1</sup>

### Getting Started

In early 2021, Baptist Health’s Miami Cancer Institute entered its survey window for the American Society of Clinical Oncology’s (ASCO) Quality Oncology Practice Initiative (QOPI®) re-certification. This was a critical re-certification for the cancer institute because our 2018 survey highlighted a few opportunities for improvement, including oral oncolytic patient education and consent. Miami Cancer Institute implemented several improvements after the 2018 survey; however, an understanding of our current performance could not be assessed due to staff and leadership turnover. The 2020 QOPI standards<sup>7</sup> set forth strict criteria for education, consent, documentation, and management of any form of anti-cancer therapy, including oral oncolytics (Table 1, below).

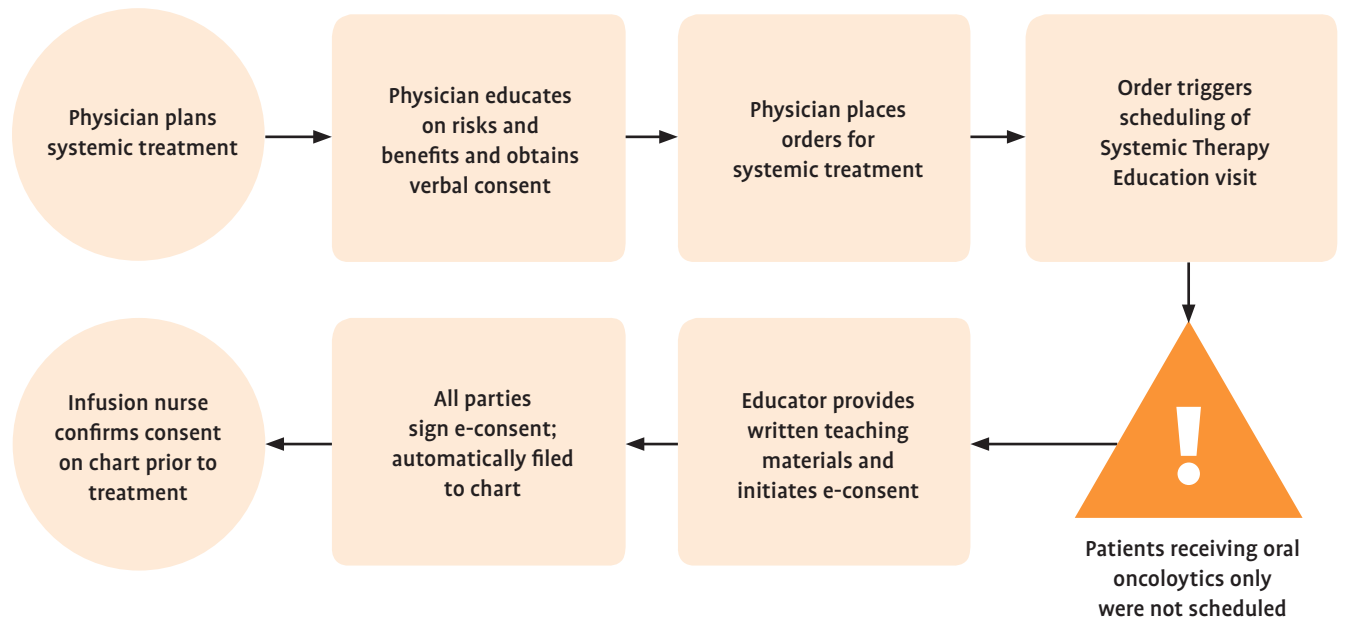
To understand our then baseline performance, our pharmacy team completed an initial consent audit, which demonstrated that only 26 percent of our oncology patients had evidence of documented and signed consent for oral oncolytic treatment in the electronic health record (EHR) prior to April 2021. At the time, the process relied on provider teams, who would provide informed consent and comprehensive patient education. Following this, Miami Cancer Institute pharmacists would provide additional follow-up education and adherence monitoring. These results were a call to action that our process needed to be fixed, and immediate interventions were needed to improve our performance to ensure patients were educated on and consented to their oral oncolytic treatment appropriately. Our assessment showed that patients on an oral-oncolytic-only

**Table 1. 2020 QOPI Standards for Education & Consent Documentation of Chemotherapy Initiation<sup>7</sup>**

STANDARD NUMBER	2020 STANDARD DEFINITION	REQUIREMENTS
2.1	Domain 2. Treatment Planning, Patient Consent, and Education: This domain describes the requirements for obtaining and documenting patient consent or assent for chemotherapy, and patient and family education prior to the initiation of treatment.	<p>The healthcare setting has a policy that documents a standardized process for obtaining and documenting chemotherapy consent or assent. Informed consent and assent (optional) is documented prior to initiation of each chemotherapy regimen. The consent process should follow appropriate professional and legal guidelines.</p> <p>The content of informed consent is the discussion with the patients; it is the education and understanding of the patient. The documentation is evidence that the legal obligation of obtaining informed consent has been fulfilled; it is evidence that the discussion occurred, the patient was educated, and the patient understood. Informed consent for chemotherapy is an essential prerequisite to the administration of a chemotherapy agent by any route in any healthcare setting. Informed consent needs to be documented.</p>

QOPI = Quality Oncology Practice Initiative

**Figure 1. Simplified Systemic Therapy Education and Consent Process with Observed Failure Mode in Oral Oncolytic Regimens**



regimen were not being referred to a standard systemic chemotherapy education visit, which was the norm for parenteral and combination therapies. Hence, there was no education being provided, and the subsequent consent process did not occur. There were no referral orders in our EHR to trigger an oral oncolytic education referral and consent initiation (Figure 1, above).

In April 2021, we created an “Oral Oncolytics Patient Education Referral” order to be placed by the oncologist, which would trigger a task to schedule patients for a comprehensive systemic therapy education session and close the loop on the consent process. After educating the patient on their oral oncolytic therapy, the systemic therapy educator would also enter a “Consult to Pharmacy Order: New Oral Oncolytic Education” order in the EHR to trigger follow-up pharmacy education and adherence monitoring. Providers and staff were educated on the workflow, and the new referral orders for May 2021 went live.

We monitored the workflow for the next three months (May 2021 to July 2021), seeing improvements in patient education, consent documentation in the EHR, and referral order use. Figure 2, page 9, compares the pharmacy teams’ oral oncolytic consent documentation in the EHR prior to April 2021 to post-implementation, using the new workflow for clinical and medical staff and referral orders to the systemic education and pharmacy teams. Over the following three months, we saw an improvement of 33 percent in overall consent compliance. In addition, our audit demonstrated 60 percent compliance with

referral order usage, 59 percent compliance with patient education documentation, and 60 percent compliance with signed patient consent. Figure 3, page 9, illustrates our audit’s results, demonstrating utilization of the provider’s referral order for comprehensive systemic therapy patient education, documented and informed consent, and patient education in the EHR. These results suggest that when the referral order is used as intended, patients are educated and their consent is obtained.

### **From Good to Great: A Call to Action and Multidisciplinary Approach**

In August 2021, despite these initial improvements, Miami Cancer Institute executive and operational leaders remained unsatisfied with these results. Not only did 59 percent consent compliance fall far below our internal benchmarks, but the complexity of prescribing, authorizing, and fulfilling an oral oncolytic—combined with patients’ ability to independently start oral medications—meant that we could not ensure patients were properly educated and provided consent prior to starting treatment. Our team was strongly aligned on the belief that our patients deserved a higher standard of oncology care that better met the 2020 QOPI standards. Further improvements would require a multifaceted, collaborative, and interdisciplinary team approach, patient-centered education, and use of intensive and creative non-reimbursable resources, including technology, to meet the needs of our diverse patient population.<sup>1,3-6,8</sup>

To that end, we assembled executive and operational leaders,  
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Figure 2. Percentage of Oral Oncolytics Consent Compliance

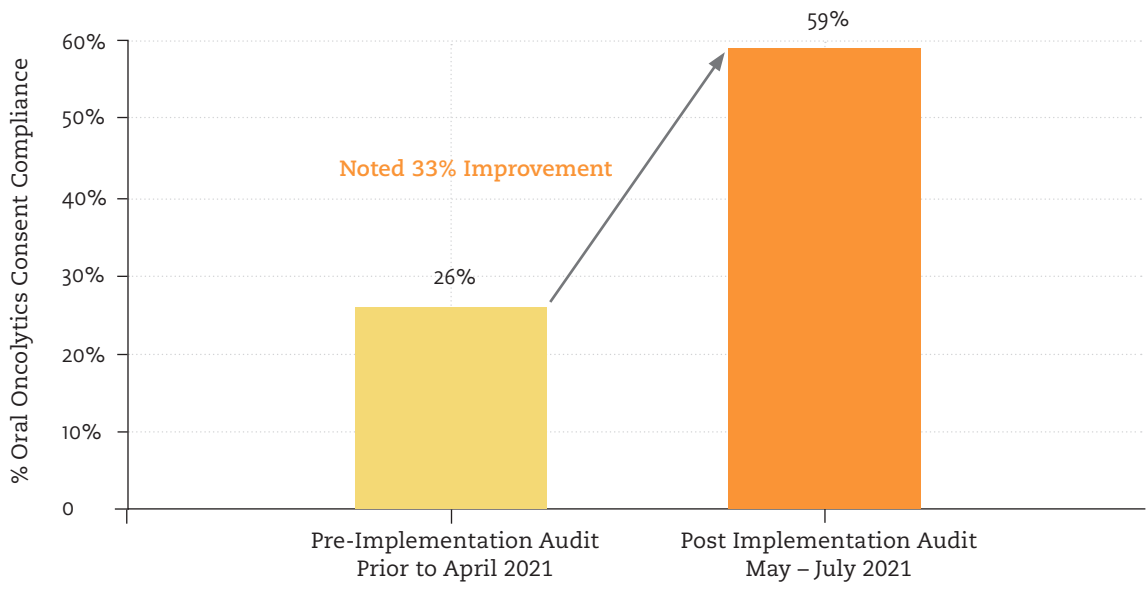
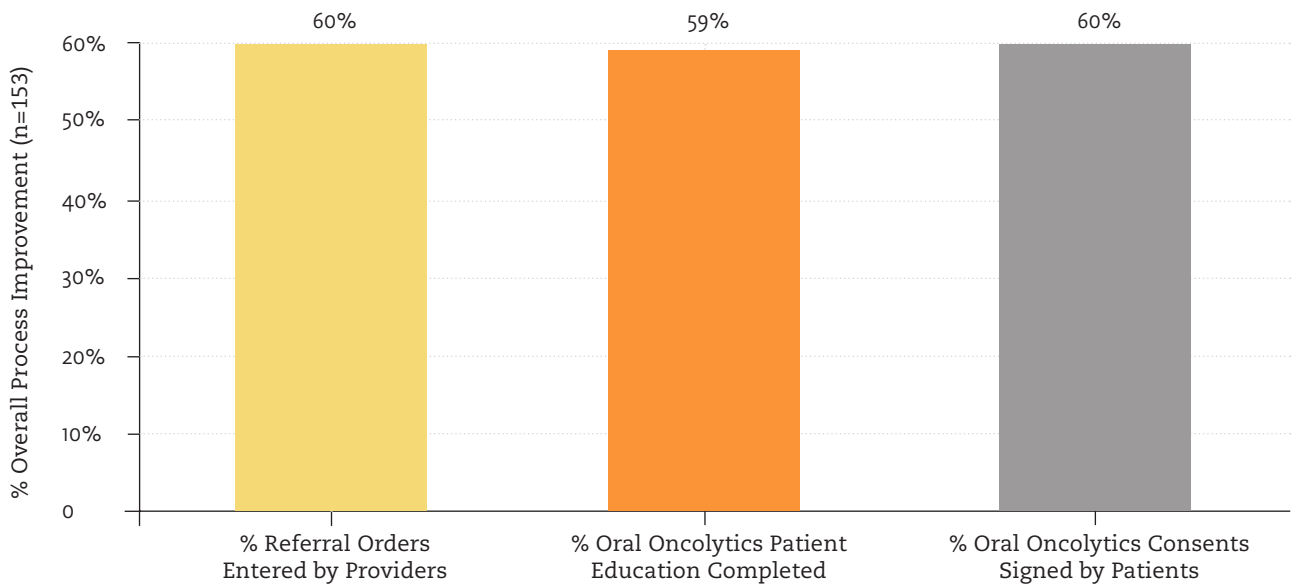


Figure 3. Percentage of Overall Process Improvement



**Table 2. Provider and Pharmacist Oral Oncolytic Responsibilities by Role**

PHYSICIANS AND ADVANCED PRACTICE PROVIDERS	PHARMACISTS
Identify patients, who are appropriate for treatment with oral oncolytics	Review prescribed oral oncolytics for appropriateness of therapy and missing lab work or clearances
Provide initial patient education regarding oral oncolytic treatment, including risks, benefits, and side effects	Obtain insurance authorization
Obtain verbal, informed consent	Submit insurance appeals and coordinate application for co-pay assistance
Order lab work and clearances, as well as coordinate start of oral oncolytic regimen	Perform patient education and counseling on treatment initiation
Manage patient symptoms	Track adherence at key intervals
Prescribe refills	

*(Continued from page 8)*

who have oversight of key areas that would impact oral oncolytic management. The team transparently evaluated initial and ongoing data and outcomes associated with the oral oncolytic workflow at the cancer institute.

### Reviewing Our Existing Workflow

We found that the initial, patient-facing tasks performed by providers in the clinic and the downstream education and coordination provided by pharmacists worked well (Table 2, above). However, these two expert groups operated in siloes, communicating through messages within the EHR. The cohesiveness of the overall workflow hinged on the systemic therapy education session and support provided by nurse educators. Unfortunately, this visit often occurred too late to capture patients’ education and informed consent needs prior to treatment initiation. In addition, patients receiving oral oncolytics did not benefit from an infusion nurse’s final check for documented consent and education prior to treatment administration (see Figure 1, page 8). When this process failed, there was no mechanism to identify missing care or evaluate quality on an ongoing basis.

The COVID-19 pandemic introduced additional challenges in the form of decentralized teams, staffing shortages, and remote platforms. Providers and clinic support staff rotated between on-site and remote work, adding complexity to interdisciplinary communication. Technology solutions designed to work in on-site applications did not translate to webinars, video calls, and phone consultations. Many clinics continued to rely on paper consents and written education that were delivered in-person by providers during a routine medical oncology visit. It quickly became clear that our workflow needed to evolve.

### Revising Our Workflow

Over the next month, our team set out to revise and optimize our oral oncolytic workflow to overcome these observed challenges and make best use of our existing resources. The team crafted a new workflow that included three key innovations:

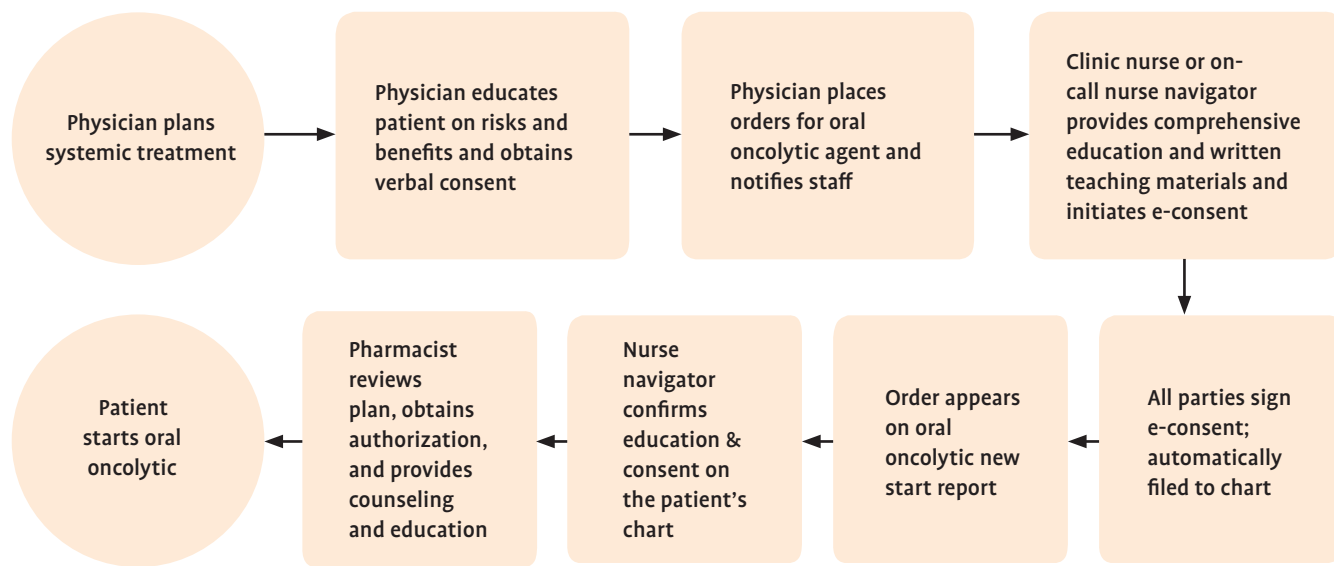
1. Support of local clinic nurses or an on-call oncology nurse navigator to improve overall compliance and ensure quality
2. Technological changes, including expansion of e-consenting, web- or phone-based patient education, and informed consent during telehealth visits
3. Quality oversight and care coordination that is provided by the oncology navigation team (Figure 4, page 11).

These changes ensure patients receive the same quality of care whether they are being seen in-person or via telehealth.

### Training Our Staff and Providers

We began implementation by hosting training sessions for our physicians, advanced practice providers (APPs), registered nurses, nurse navigators, and medical assistants. These sessions were led by informatics educators, clinical educators, team champions, and leaders. Training focused on changes to the workflow and technology support. For medical oncology teams, these changes represented minor revisions to the existing process and added resources. For others, most notably nurse navigators, the new workflow involved increased partnership with clinical teams and tasks that were not traditionally considered in scope for their role. On-call nurse navigators were included in the process to address gaps in nursing support in some clinics. This necessitated more detailed education on the workflow, familiarity with patient education materials, and a

**Figure 4. Revised Oral Oncolytic Workflow**



learning curve as nurse navigators adjusted to the new process. Staff and providers alike voiced that, when possible, patient education and care coordination should be performed by local clinic nurses.

During this phase, stakeholders contributed key observations and potential challenges based on their expertise. For instance, the revised workflow originally included a final check performed by the pharmacy team prior to dispensing to ensure each step of the process was documented appropriately. Pharmacists noted that many payers mandated the use of off-site, third-party pharmacies, which would make a quality check at this step impractical. It became clear that nurses must play a crucial role in ensuring compliance and quality—both during the patient’s treatment planning visit and subsequent auditing.

**Technology & Tools**

Prior to this implementation, Miami Cancer Institute relied on e-consent software embedded within the EHR. Clinicians would initiate and sign an English or Spanish version of the e-consent using a digital tablet. This consent, when completed and signed, would be automatically filed in a designated consent folder within the EHR. Unfortunately, although the pandemic made remote e-consenting a priority request, our EHR is still working to implement this function. As a result, some medical oncology clinics reverted to paper consents, which were emailed or faxed during telehealth visits and eventually scanned into patients’ health record. This approach was highly manual and prone to failure.

Instead, our team promoted the use of an approved third-party software to allow remote e-signatures. Project leaders partnered

with the cancer institute’s technology and digital team to build new, digital consent templates. These templates could be initiated during a telehealth visit, sent to patients or caregivers via a secure email, and automatically returned to the clinic once completed. This new process required additional staff training and minor revision of our health records process. More importantly, it necessitated a recommitment by medical oncology teams to perform all patient consents electronically.

Oncology informaticists also collaborated with clinicians and our technology and digital partners to build a real-time report of all new oral oncolytic regimens that Miami Cancer Institute providers prescribed. This report supported nursing efforts to capture education and consent needs throughout the day within individual clinics and perform an institute-wide daily audit.

**Evaluating the Impact of Our Innovation**

Our quality improvement efforts continued at the executive and operational leadership levels. Stakeholders met weekly to evaluate the success of the revised workflow. The team established initial measures of overall compliance with clinic education and consent standards.

Initial data demonstrated a rapid improvement in overall education and consent compliance (90 percent, n=146) over the course of two months versus the 60 percent audit benchmark. Despite these data, leaders identified a persistent gap between our performance and aspirational goal of 100 percent compliance. To address this gap, we reviewed several key factors, including the prescribing physician, clinic specialty, type of visit, timing of prescription order, and nurse roles within the clinic. We identified

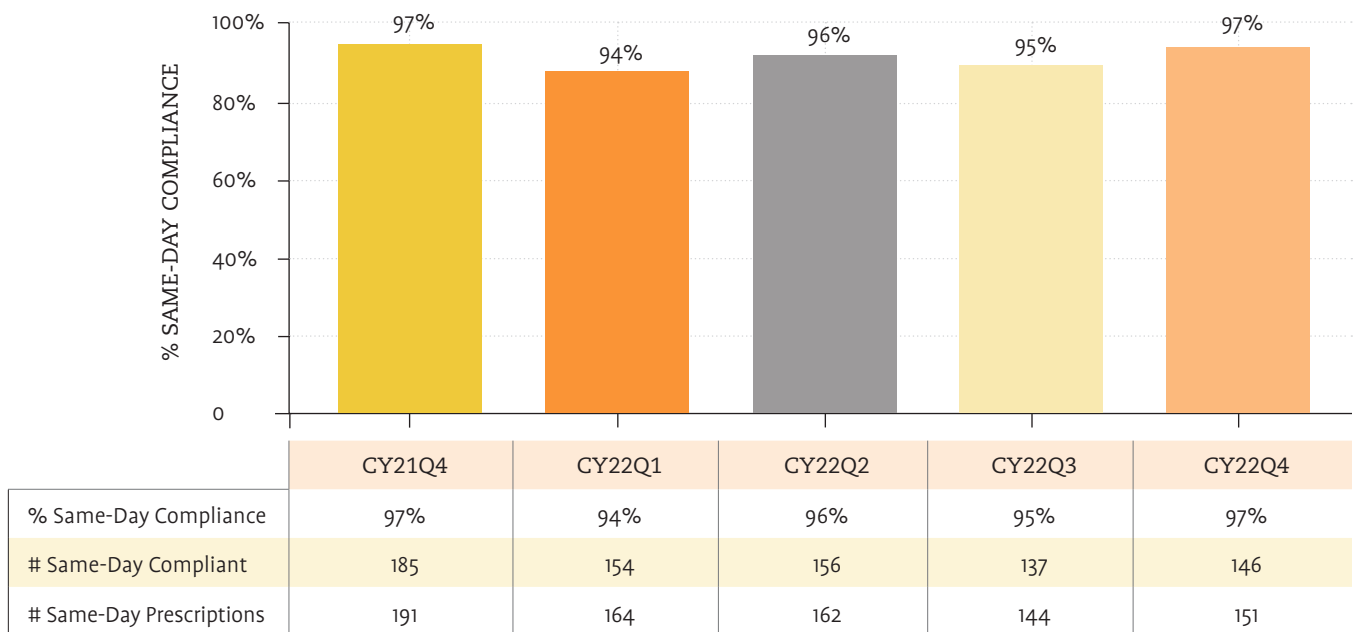
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**Table 3. Reasons for Non-Same-Day Compliance for Patients Prescribed Oral Oncolytics**

REASONS FOR NON-SAME-DAY COMPLIANCE	NUMBER OF CASES
No provider notification	251
Infusion and oral oncolytic	218
Virtual consult	95
Scheduled APP consent/education visit	49
Rx written on the weekend/after hours	32
Rx written in the inpatient setting	30
Other	18
<b>TOTAL</b>	<b>693</b>

APP = advanced practice provider; Rx = prescription

**Figure 5. Same-Day Compliance with Oral Oncolytic Standards**



CY = calendar year; Q = quarter



(Continued from page 11)

several operational and clinical challenges (see Table 3, page 12) with one common theme: non-compliance was more likely to occur when patients did not receive their oral oncolytic prescription and required education and consent at the same time. Consequently, we modified our key performance indicator to reflect same-day compliance—a measure that better ensures all requirements, including education, consent, and prescription order, occur during the same clinic visit.

We included additional process metrics to measure key steps in our revised workflow, particularly those deemed potentially prone to failure in busy clinic settings. We measured provider documentation of the informed consent discussion, nurse-led review of patient education materials, and all parties' signatures on the completed consent form. These measures captured related requirements and provided some redundancies in case of process failure. These process metrics allowed us to identify and address specific opportunities.

Fortuitously, Miami Cancer Institute had previously migrated to a suite of web-based applications and reporting tools. This technology allows providers, staff, and leaders to share data in real time. Teams met weekly to review the audit dashboard and transparently discuss performance, opportunities, and recommended actions needed for improvement. Overall and same-day compliance quickly improved to 90 percent (n=1,614) and 96 percent (n=867), respectively (Figure 5, page 12). Patients who were not targeted for same-day compliance were monitored daily by nurse navigators, who were reviewing the oral oncolytic dashboard, until compliance was achieved. These nurse navigators

also facilitated communication and care coordination with clinics to ensure patients received education and consent before starting their treatment.

In February 2022, Miami Cancer Institute successfully completed QOPI re-accreditation with zero deficiencies cited and a perfect survey score. Members of our oral oncolytic process improvement team, including a prescribing provider, nurse educator, nurse navigator, clinic nurse, and pharmacist, were on-hand to present our new workflow to QOPI surveyors. Operational leaders shared our project outcomes and ongoing efforts to improve clinical quality for patients receiving oral oncolytics. The surveyors complemented the team's interdisciplinary collaboration and patient education materials, noting that Miami Cancer Institute was unique in achieving the same high-quality care for patients on infusion and oral oncolytic treatments alike.

### Challenges & Solutions

Our team faced many challenges during this project. To address these, we employed a key tenet of quality improvement: resisting the tendency to oversimplify. During our weekly meetings, we identified several reasons clinical teams could not reasonably achieve same-day compliance (Table 3, page 12). We tracked these reasons and measured non-same-day cases by examining overall compliance. This allowed us to respond to operational challenges within individual clinics and further refine our workflow.

Most often, same-day compliance was not feasible because the ordering physician did not notify the clinical team of the new oral oncolytic start. This occurred during clinic peak times, when



physicians were covering for one another or when an unusual regimen was ordered. Team members reviewed outcomes at the individual, physician level, and leaders sought physician buy-in through rounds and provider education.

Some oral oncolytic medications were ordered in combination with an infusion. When this occurred, comprehensive education included patient teaching on all prescribed agents. This task was deemed best handled by our expert systemic therapy educators, and the visit was scheduled prior to the patient's intended treatment start date.

Although remote e-consent signatures played a key role in this project, the entire process of obtaining and scanning signed consents into patients' chart could not practically be achieved during a single telehealth visit. Instead, remote consent was initiated during the virtual treatment decision-making visit, and patients' consent was subsequently scanned into their health record once complete.

One medical oncology clinic employed a unique approach to physician and APP collaboration. The physician planned and ordered all new treatment regimens, and the APP scheduled a subsequent follow-up visit to complete a detailed assessment, additional work-up, patient education, and informed consent. These providers felt that this was the best approach for their patient population and consistently delivered education and consent prior to treatment. Our project team acknowledged this practice preference and audited new prescriptions to ensure that the follow-up education and consent visit was scheduled and that compliance was achieved before treatment.

Not all oral oncolytic prescriptions were written during operating hours. Some were written after hours by physicians managing busy clinics or those working ahead in anticipation of authorization delays. In some cases, oral oncolytic regimens were planned during an inpatient hospitalization; when this occurred, the inpatient team or APP was responsible for providing written education and initiating the consent process. However, inpatient units often used paper consents and retained them for scanning at a later time. The assigned nurse navigator monitored these orders to ensure compliance was achieved once the clinic opened or the patient was discharged from the hospital.

Many other challenges impacted our oral oncolytic workflow. Clinical teams partnered to address unique circumstances as they arose; these included sudden Wi-Fi outages, the absence of a patient proxy or legal decision-maker, and many other unique patient- and clinic-specific challenges. The key ingredients to resolving project challenges were the multidisciplinary team's commitment to best practice and their willingness to transparently examine and learn from failures.

### **Sustaining the Change: Updates in Staffing, Roles, & Responsibilities**

As we transitioned to project maintenance, we needed to build in mechanisms to sustain our progress. Clinic staffing gradually recovered as COVID-19 numbers improved. Nurses within each clinic now provide adequate support during treatment

decision-making visits without leveraging on-call nurse navigators. Instead, nurse navigators use their increased familiarity with oral oncolytic regimens to proactively identify symptoms and adherence issues during routine navigation follow-up encounters. Designated nurse navigators are now assigned to perform the daily house-wide audit and quality review of the oral oncolytic workflow. Ongoing leadership review transitioned from the executive and operational leadership level to the manager level, and outcome measurement shifted from weekly to monthly intervals.

### **Sustaining the Change: Identifying Next Steps**

During this phase, stakeholders shifted their attention to potential next steps for further improvement. This includes optimization of oral oncolytic reporting tools, e-consent software, and an improved e-signature workflow between physicians and APPs. Leaders and staff defined requirements for an automated audit tool and oral oncolytic reporting dashboard. The oncology informatics team worked with our technology and digital, as well as EHR specialists to provide customer feedback and request updates to the embedded e-consent functionality.

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### **Practice Implications**

Oral oncolytic treatment regimens pose unique challenges to cancer programs and practices and require an interprofessional approach to ensure optimal patient outcomes. In our innovation project, each team member contributed disciplinary and specialty expertise to our combined efforts. Physician buy-in was an especially crucial factor in each clinic's success since our revised workflow began with the prescribing physician. Clinic nurses played a key role in breaking down siloes between providers, pharmacists, and patients to ensure compliance with quality care standards. Nurse navigators provided on-call support, care coordination, and quality oversight to the process. Pharmacists bridged gaps between patients and their insurance companies, assistance programs, and dispensing pharmacies. APPs efficiently addressed urgent symptoms, follow-up visits, and refills. Educators, informaticists, and leaders provided critical support and guidance to the clinical team. In short, the successful management of patients on oral oncolytic regimens is a team sport. Cancer programs and

practices interested in improving oral oncolytic management should build upon interprofessional team members' specialty knowledge, top-of-license practice, and opportunities for increased collaboration between team members.

Great teamwork can be further enhanced with the right technology. Seamless integration of smart tools, such as automated EHR tasks and alerts, can help clinicians deliver the best possible patient outcomes. Although our team faced many challenges, we continually sought better approaches to work via innovative technology solutions. Often, this required us to partner with informaticists, our technology and digital team, as well as our EHR vendors to articulate clinical goals and propose future digital enhancements. This ongoing partnership is key to furthering oncology innovation.

Finally, our team is committed to continuous improvement and includes several stakeholders with formal quality improvement experience. These individuals help us approach process changes in a systemic manner, strive for standardization, and maintain transparency and exacting standards. Cancer programs and practices can leverage well-established quality improvement methods and resources to continually improve the quality of their care delivery.

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## Our Program At-a-Glance

Miami Cancer Institute, a community-based ambulatory cancer center in Miami, Fla, opened its doors in January 2017. The institute is a 405,000-square-foot, next-generation, anti-cancer treatment center built with one goal: that no patient with cancer in south Florida would ever have to leave home to receive innovative, comprehensive, and lifesaving treatments.

Miami Cancer Institute is an alliance partner with Memorial Sloan Kettering Cancer Center, which allows for the expansion of clinical trials and knowledge-sharing with some of the most prominent and pre-eminent oncology/hematology experts in the world, benefiting patients in south Florida, Latin America, and the Caribbean.<sup>9</sup>

In six short years, Miami Cancer Institute has grown exponentially and is now recognized for its leading clinical care, research, compassionate patient experience, and state-of-the-art technology. The institute treats more than 9,000 new patients with cancer annually, with approximately 1,000 patients accessing care and services daily. The cancer institute is a renowned center of excellence and part of the Baptist Health South Florida system—the region's largest healthcare provider. In its 2022 to 2023 report, *U.S. News & World Report* ranked Miami Cancer Institute's oncology program in the top 10 percent of all high-performing cancer centers in America.<sup>9</sup>

Miami Cancer Institute is a hybrid academic center accredited and certified by the American Society of Clinical Oncology Quality Oncology Practice Initiative, Commission on Cancer, and Foundation for the Accreditation of Cellular Therapy. The institute offers a wide range of specialized clinical care and patient services to patients and their families, including radiation oncology, proton therapy, blood and marrow transplant, clinical trials and research, medical and surgical oncology, prevention and multidisciplinary specialty clinics, support services, and a well-known oncology patient navigation program.

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