

ROSALIND FRANKLIN UNIVERSITY OF MEDICINE AND SCIENCE SCHOOL OF PHARMACY STUDENT WRITING CLUB:

Specialty Pharmacy: Challenging Oncolytic Waste

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Abstract

Oral oncolytic waste is an expensive issue that burdens patients and the healthcare system. Waste is preventable through specialty pharmacy prevention and intervention in the form of specialized treatment plans, adherence follow-up, and technology designed to monitor treatment regimens, etc. Specialty pharmacies approaching waste management has resulted in the creation of a wide variety of tools and methods of prevention and intervention. Using these methods to manage waste can significantly improve the financial burdens associated with such waste.

Specialty pharmacy and pharmacists play many unique roles in patient care, the most notable of which is the management of treatment regimens for patients taking oral oncolytic medications. These approaches to treatment practice often include education, monitoring, and waste management. While sometimes unavoidable, prevention and oversight of potential and current waste are central goals of specialty pharmacy practice. Oncolytic treatments are not only expensive but also have extensive side effect profiles. Both of these factors directly affect patient compliance and may contribute to waste.

Unlike in the generalized community setting, the methods used by specialty pharmacists in order to address oral

oncolytic waste are often individualized to specific patients. These methods include, but are not limited to, technology designed to monitor adherence, drug repository programs, pharmacy-based compliance protocols, and intervention assessment. In order to gauge the effectiveness of specialty pharmacy in the mitigation of this waste it is important to examine the impacts of waste on finances and patient care. In this article, the authors attempt to provide an overview of the financial impact of oncolytic waste and the steps taken by specialty pharmacies for waste mitigation.

Financial Effects of Oncolytic Waste

With the increasing availability of oral formulations, oncolytic treatment for malignancy has increasingly shifted from managed care to an at-home setting where patients have more control over their treatment outcomes. With 25% to 35% of oncolytic drugs being formulated for oral use, eligible patients are no longer required to visit ambulatory settings in order to receive treatment.^{1,2} A large part of this transition is due to the FDA approval of oral oncolytic medications within the past decade. Oral formulations provide unique advantages in that they circumvent the inefficiencies of IV formulations as well as indirect medical costs such as driveline issues, infusion monitoring, setting up appointments, travel time, etc. Mitigation of these issues facing patients is a positive step forward in supplying proper treatment; however, new challenges arise. Oral formulations bring concern for compliance, transitions of care, prescription cost, side effect management, and the responsibility of the patient and their treatment goals. The process of treatment is complex, highly individualized, and involves multiple

disciplines which potentially results in patient fatigue and confusion. This leads to treatment complications, insufficient knowledge, and ultimately waste.

To examine the financial impact of waste, a 2019 study conducted by Monga and colleagues analyzed treatment regimens using four oral oncolytics (sunitinib, everolimus, axitinib, and vemurafenib). Over a period of three years, researchers found a 41% occurrence of waste in a population of 88 patients.³ The estimated monetary total of this waste accounted for approximately \$250,000 with the disposal of 1,179 unusable tablets and capsules. With an average yearly incidence rate of 461 new cases of malignancy per 100,000 people per year, the financial impact of potential waste is massive.⁴ Waste of this scale places an unnecessary burden on patients and the healthcare system and requires both prevention and intervention. In this instance, specialty pharmacy holds a unique role. Utilizing their expertise, specialty pharmacies have developed tactics to drastically reduce these instances of waste and improve patient treatment outcomes simultaneously.

Patient Impact

To examine how specialty pharmacies provide meaningful prevention and intervention, one must examine the waste production process. In the case of oncolytics, waste manifests specifically as gaps in maintenance (or discontinuation) of therapy, nonadherence, poor side effect management, and improper use. In the transition of care between hospital and home, patients are especially at risk for gaps in treatment and therapy maintenance. Examinations of the instances of waste reveal multiple separate contributing factors. The major factor for waste is attributed to drug cost and coverage. Most

patients who are treated with IV oncolytics, for example, pay bills resulting from medical coverage during an outpatient visit whereas those treated with oral oncolytics pay through pharmacy benefits. Although the difference in treatment is simply the setting, patients paying out of pocket typically spend between 25% to 33% of the drug price for an oral formulation.⁵

For individuals without private insurance, the financial burdens increase and health outcomes decline. Patients with Medicare as primary insurance were found to be more likely to abandon their prescriptions for oral oncolytics compared to those with private insurance.^{1,2,6,7} This abandonment is primarily attributed to treatment alterations where patients who were previously taking IV formulations of oncolytic drugs now take oral formulations. The coverage change from Part B to Part D causes patient burden by forcing them to engage in higher values of cost sharing with the primary insurance while foregoing the coinsurance assistance provided by Medigap.² While the monetary cost can be lower for private insurance, those on Medicare pay cost sharing values in specific tiers that can exceed values in excess of \$500 per 30 day supply. This amount does not include prescriptions for other health conditions. In most cases, Medicare patients are required to pay between 25% and 50% of the cost of the drug before benefit assistance. As cost sharing amounts increase patient persistence and adherence will decrease, but at values of greater than \$500 per month, almost one in four patients will abandon their therapy altogether. In addition, patients are significantly more likely to abandon or discontinue their regimens if they are picking up more than one prescription every month.^{1,6,7} This indicates a higher likelihood of nonadherence for patients with comorbidities or strict finances. Furthermore, patients who pick up more than five prescriptions that are unrelated to oral oncolytic therapy are 50% more likely to abandon their oral oncolytic therapy.¹ While Medicare patients are eligible to receive copayment assistance through specific foundations, the available funding depletes over time. In addition, many manufacturer coupon cards are not eligible for use with Medicare Part D

and so patients cannot use them for their monthly bills.⁵ With no means of paying the monthly cost of treatment, the trend is that one in ten patients will abandon or discontinue their therapy altogether.^{6,7}

Waste Reduction Scenarios

Aside from financial issues, education must be supplemented. Because oral oncolytics reduce the total time spent by patients in the presence of healthcare professionals, it becomes important to ensure that patients understand how treatment for malignancy impacts their individualized health outcomes. This is where specialty pharmacies employ their expertise as the overall goal of specialty pharmacies includes the improvement of adherence, implementation of cost savings, and improvement of treatment outcomes. To highlight the impact of specialty pharmacies, a 2017 study by Stokes and colleagues, aimed to compare the abandonment and adherence rates of patients taking oral oncolytics who visit retail and specialized pharmacies.⁸ The preliminary difference was that specialty pharmacies were employing custom therapy management programs tailored to individual patient needs. Researchers set out to determine the impact of specialty pharmacies on therapy regimens. Abandonment was defined by an initial rejection of a claim for an oral oncolytic (based on prior authorization or step therapy) and a subsequent unpaid claim. Adherence was measured by checking total days supply values and recording gaps in therapy. Treatment lengths were characterized as persistence: the duration of continuous use of an oral oncolytic. At the end of the study, researchers found that patients were less likely to abandon their regimen in specialty pharmacies compared to retail pharmacies (0.8% vs. 2.0%, $p < 0.001$). Patients were also more likely to be adherent when filling at specialty pharmacies (71.6% vs. 56.4%, $p < 0.001$) and had a longer average duration of persistence by 16 days (235.2 vs. 218.5, $p < 0.001$). The data revealed that there was a higher impact on adherence and therapy regimen when a specialty pharmacy was involved.⁸

In a separate analysis conducted by the University of New Mexico Comprehensive

Cancer Center (UNM CCC), a quality improvement program was used to assess the impact of pharmacist intervention of oral oncolytic prescriptions in new patients.⁹ The methods employed the Plan-Do-Study-Act tool whose purpose is to test the effectiveness of changes in their current system. Using this tool, UNM CCC desired to improve a 30-minute focused medication review counseling session with a goal of at least 80% of their patients undergoing counseling. Patients targeted by this program included those newly prescribed or already taking an oral oncolytic medication who had also not yet received counseling as indicated by the electronic medical record. At the end of the first month, UNM CCC delivered focused medication reviews to 17.9% of their patient population, 45.5% at month two, and 87% by month fifteen. In a repeated Plan-Do-Study-Act cycle UNM CCC was able to educate 95.7% of the total patient population. This study emphasizes the importance of proper patient counseling for strengthening a patient's awareness of proper medication use and adherence.

Separate from these specific instances is one common approach that specialty pharmacies employ to mitigate oncolytic waste: limiting the amount of medication that a patient receives on their first fill. Referred to as partial filling, the aim of this act is to reduce waste by ensuring that patients who are prescribed an oral oncolytic are responding appropriately to the prescribed dose and route.^{10,11} Monitoring these factors not only improves side effect management but also reduces patient costs and costs associated with inventory resupply for the pharmacy. In addition, these partial fills allow for adherence assessment whereby specialty pharmacists can gauge any errors in use without processing the entire claim. Analysis of the total cost savings showed that patients save an average of \$440 per month which can be equivalent to the cost sharing values associated with Medicare coverage tiers.¹¹

Another factor through which specialty pharmacy improves outcomes, specifically in regard to adherence, is the use of the postal service in drug distribution. The main benefit of a mail order service is that the patient receives a prescription in a

timely manner without a gap in therapy, especially in the case of oral formulations that do not require a provider visit for administration.¹² As seen with the UNM CCC program, comprehensive medication consultations are being utilized by specialty pharmacies to fully educate patients on their prescribed oral oncolytics. After discussing standard consultation points, these pharmacists go into great depth to discuss all relevant information for an individual patient. In terms of waste, patients learn the importance of storage, proper use, disposing of hazardous packaging material, what to do in the instance that an adverse drug reaction occurs, and further individualized lifestyle modifications.¹³ These are a few items among a long list of education points conveyed in such a counseling session.

Technologies employed by specialty pharmacies have also made large impacts on waste prevention. One such example is the use of oncology service lines which bring together every relevant health care service that a patient needs for proper treatment. With Fairview Health Services in Minnesota for example, oncology service lines allow pharmacists to independently follow-up with patients via portal technology as well as reduce variation in clinical care policies among health systems, thereby improving the safety of therapy management.¹⁴ Similarly, Accredo Pharmacies utilize text messaging as a reminder for patients of upcoming refills, citing an 8% increase in adherence.¹⁵ Avella Specialty Pharmacies have taken a different approach. Armed with a wireless medication bottle that uses light and sound, patients of Avella are reminded to take their medication at the timed dosing interval.¹⁶ In the event that a dose is missed, the bottle coordinates an intervention for the patient via phone call and live support in order to manage appropriate medication use.

Drug Repository Programs

The methods of prevention and intervention outlined above can be used by any specialty pharmacy in challenging the ongoing waste of oral oncolytics. In addition to these services, eligible specialty pharmacies can further improve waste reduction by acting as drug repositories.

Wisconsin, one of twenty-one participating states in the union, uses a drug repository program to allow specialty pharmacies to collect and redistribute medications that are donated by patients.¹⁷ While this may seem alarming at first, there are strict requirements in allowing the redistribution of a medication. Under Wis. Stat. § 255.056, donated medications must comply with the following safety standards: a drug must be sealed in the original packaging, the expiration date must be greater than 90 days from the time of donation, and the drug which is redistributed must be provided to an eligible individual as determined by a practicing physician. In addition, a pharmacist must review these safety standards and approve the release of the medication for patient use. As donated drug products cannot be resold for compensation per Wisconsin's repository law, this program provides free medication for patients without insurance coverage or patients with inadequate insurance.¹⁸

One complication with this system however is evaluating storage conditions. Though a medication may be sealed and untampered, the condition in which the bottle or single-unit container was stored by donors may vary. Currently there is no existing method of identification for improperly stored medications in this program. To address this specific issue, Wisconsin repositories require a signed testament by donors of the proper storage standards as outlined by the medication manufacturer.¹⁹ Donors of these medications are then held responsible in the event that an adverse event related to medication condition occurs.

Conclusion

With an increased availability and use of oral oncolytic medications, there becomes a potential of increased waste and associated healthcare dollars. Specialty pharmacies around the country have established efficient and effective methods to help mitigate this waste. In addition to such direct measures, pharmacies of certain states hold a unique position in that they can act as repositories for donated medications with an intent for redistribution to those who cannot otherwise afford therapy. Specialty

pharmacists and pharmacies play a key role in preventing waste by utilizing skills, knowledge, and technology to properly educate patients on their medication side effects, provide the opportunity for follow-up patient meetings, ease the process of medication management, improve adherence, and decrease cost. Such methods and examples can be utilized to help curtail expensive medication waste in other therapeutic areas in order to lower healthcare spending.

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