Published in final edited form as:

J Oncol Pharm Pract. 2021 September ; 27(6): 1409–1421. doi:10.1177/1078155220960800.

Enhancing patients' understanding of and adherence to oral anticancer medication: Results of a longitudinal pilot intervention

Mingqian Lin^{1,*}, Douglas Hackenyo^{1,*}, Nicole Savidge¹, Ruth Ann Weidner¹, Rachel Murphy-Banks¹, Tara Fleckner², Susan K Parsons¹, Angie Mae Rodday¹

¹Tufts Medical Center, Boston, USA

²Tufts Clinical and Translational Science Institute, Tufts University, Boston, USA

Abstract

Background: Oral anticancer medications (OAM) make administration more convenient for patients, but shifts the responsibility of care from clinical providers to the patients themselves. Following an institutional pilot study showing inadequate understanding and adherence among vulnerable patients taking OAM, a longitudinal intervention was developed using an oncology specialty pharmacist and medication navigators to enhance OAM understanding and adherence.

Methods: Patients initiating OAM were approached for four formalized teaching and check-in sessions, supplemented with medication information sheets and individualized calendars. At each session, participants were assessed on their OAM understanding and adherence using teach-back and validated measures. A study evaluation elicited feedback from participants on the usefulness of the intervention.

Results: Of 80 eligible patients, 58 (72.5%) received formal OAM teaching from the specialty pharmacist. Of those, 54 (93.1%) enrolled in the study with 39 (72%) completing the intervention for final analysis. At study completion, all participants adequately understood OAM taking, but 41.0% had inadequate understanding of OAM handling. Throughout the study, participants reported issues that were addressed by the intervention team (28.2% to 31.6%) as well as those requiring additional assistance from the treatment team (26.3% to 38.5%). Most participants found the intervention to be very beneficial (initial evaluation, 86.5%; final evaluation, 76.9%).

Conclusions: This pilot intervention addressed gaps identified by our institutional assessment through formalized OAM teaching and follow-up. Improved understanding of taking and handling OAM through this subsequent study illustrated the enhanced effect of a multidisciplinary and multicomponent intervention to better educate and support patients on OAM.

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Corresponding author: Angie Mae Rodday, Tufts Medical Center, 800 Washington St #345, Boston, MA 02111, USA., arodday@tuftsmedicalcenter.org.

*These authors are co-first authors of this work.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Keywords

Oral anti-cancer medication; adherence; intervention; patient navigation; patient education

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Introduction

Advances in oral anti-neoplastic therapeutics in recent years have broadened treatment delivery options across cancer types. These oral anticancer medications (OAM) have transformed clinical practice for providers and care delivery for patients. In contrast to infusion-based therapies, OAM is taken at home instead of under direct surveillance of clinical providers, making it more convenient for patients.^{1,2} As the responsibility of medication delivery shifts from the clinical providers to the patients and their caregivers, concerns have arisen regarding how well patients understand taking and handling OAM, and the extent to which they are taking them correctly (adherence) and for the indicated duration (persistence).³ The consequences of inadequate adherence can be severe and clinically significant. Ruddy and colleagues showed that poor and incorrect intake of OAM may cause more side effects and lower drug effectiveness, and lead to higher rates of hospitalization and morbidity.³ Inadequate adherence and/or early discontinuation of treatment can also lead to poorer disease outcomes and have been associated with greater risk of cancer recurrence and mortality.⁴⁻⁶

Factors contributing to suboptimal adherence are multifaceted. Patient-level factors include simply forgetting to take medications⁷; having cognitive challenges that impede medication taking; being unable to read label instructions due to language or literacy; and feeling overwhelmed by treatment factors.⁸ Poor patient-provider communication in which clinicians do not sufficiently explain details about the prescribed medications nor ask about potential socioeconomic barriers to obtaining them has been shown to contribute to lower adherence.⁹ Complex treatment regimens, such as those with multiple medications and/or multiple routes of administration, have been associated with poorer adherence.¹⁰ Patients with chronic or comorbid conditions are more likely to be non-adherent or discontinue OAM early.¹¹ High medication costs, such as co-pay amounts, and pharmacy access issues, such as refill frequency, are additional system-level barriers that disproportionately impact vulnerable patients.^{12,13}

A number of interventions have investigated how to improve or ensure sufficient OAM adherence, utilizing tools and educational resources, and have engaged healthcare workers across disciplines with varying degrees of success.¹⁴ Institutional programs have been implemented to monitor medication prescriptions more accurately, improve patient-doctor communication, and expand patient follow-up and toxicity management.¹⁵ Organizational tools, such as calendars and treatment schedules, have been provided to patients to remind them to take their OAM on time.⁸ Initiatives in both outpatient and inpatient oncology settings that more actively involve pharmacists and nurses to promote better patient education, symptom management, and regular follow-up have demonstrated promising improvements in patient satisfaction, medication management, patient knowledge, and adherence.¹⁶⁻²⁰ Patient navigators have also been deployed to improve treatment adherence

and routine follow-up particularly among vulnerable patient populations. A study using navigators with underserved populations in breast oncology showed improvements in adherence with adjuvant therapy and timeliness to care.²¹

A Patient Navigation Program was created in 2014 in the Tufts Medical Center (Tufts MC) Cancer Center to reduce barriers to cancer care by providing linguistically and culturally congruent care for patients of Chinese origin and/or of lower socioeconomic status. A programmatic review in 2016 revealed that over 30% of 996 patient navigator visits across 158 patients involved assistance with medication-related issues. To address these challenges we designed a pilot cross-sectional assessment of medication adherence among vulnerable patients already on an OAM, who filled their medications at Tufts MC Cancer Center pharmacy (to allow for tracking of refill times).²² We found that in the absence of standardized OAM education only 15% of patients had both adequate understanding of OAM taking and handling, despite self-reports of high adherence. Herein we present the subsequent pilot longitudinal intervention study among patients starting a new OAM. We utilized a multidisciplinary team-based approach led by a specialty pharmacist and medication navigators to enhance patient understanding and adherence, leveraging validated measures and evidence-based educational methods.

Methods

Research Setting, Eligibility, and Study Team

Study participants were enrolled at the Tufts MC Cancer Center, a large urban academic hospital in Boston, MA. The cancer center houses a specialty pharmacy that dispenses oncologic agents, such as OAMs, and other medications. Located in Boston's Chinatown, Tufts MC serves a large number of non-English, Chinese-speaking patients, as well as patients of lower socio-economic status. As part of standard of care, patients starting on an OAM received information and/or teaching about their OAM on an *ad hoc* basis from the specialty pharmacist and/or their oncology team. The intervention, detailed below, sought to augment the standard of care through standardized teaching and the addition of formalized check-ins.

The study was approved by the Tufts Health Sciences Institutional Review Board (IRB). Patients were eligible to participate if they were newly prescribed at least one OAM (excluding hormonal therapy for breast and prostate cancers), had an active diagnosis of a solid tumor or hematologic malignancy, were at least 18 years of age, were proficient in English or Chinese, and were receiving their cancer care at Tufts MC. Patients who had been taking newly prescribed OAM for more than seven days at the time of screening were excluded. To accommodate Chinese-speaking participants, all study materials, including full-length informed consent documents were professionally translated into written Traditional and Simplified Chinese and approved by the Tufts IRB.

Study team members represented diverse clinical and research disciplines. The specialty pharmacist had an extensive clinical oncology role in managing and teaching about OAMs. Prior to the study, two medication navigators received formal training in medication education and triaging of medication-related issues with the oncology team and oncology

specialty pharmacist. Their prior experience in patient navigation in assisting patients with medication-related issues further augmented their preparation for the study. One medication navigator was fluent in two dialects of Chinese, Cantonese and Mandarin, and conversed and reviewed informed consent and all study forms with Chinese-speaking participants. An oncologist was available to provide clinical insight. Biostatisticians assisted with data analytics and a data manager created and managed the study database. Also, a patient stakeholder assisted with the development of the intervention.

Intervention Procedure

At the time of a regularly scheduled clinic visit, the specialty pharmacist and the medication navigator met with patients starting on a new OAM for an in-person teaching session, based on material from the validated Multinational Association of Supportive Care in Cancer (MASCC) Oral Agent Teaching Tool (MOATT).²³ The MOATT aims to enhance the patient's knowledge of his/her medication(s); their understanding of taking and handling the medication; and understanding about drug-specific information such as dose and schedule, side effects, and interactions with foods and drugs. The teaching was supplemented with study tools: information sheets about the OAM(s), adapted from Oral Chemotherapy Education resources through the National Community Oncology Dispensing Association,²⁴ as well as individualized medication calendars. Following the MOATT teaching and prior to the teach-back portion, patients were invited to participate in the study, and informed consent was obtained. Among participants, responses to the MOATT teach-back were documented (time point 1, T1), after which participants completed study forms that gathered demographic and clinical information, and baseline symptom burden using the MD Anderson Symptom Inventory (MDASI), a validated symptom scale.²⁵

The longitudinal intervention consisted of four points of contact: two teaching meetings to coincide with the new OAM start and Cycle 2 refill, and two check-ins in the interim (Figure 1). Meetings were conducted either in person or over the phone. In-person check-ins were typically coordinated with the patient's scheduled clinic visits and took place in clinic. If scheduled clinic visits were not anticipated within the study windows or if the patients expressed preference, the study participants were contacted by phone for any time points subsequent to the initial meeting.

The medication navigator checked in with study participants for a booster check-in (time point 2, T2) 7–10 days after the initial pharmacist-led teaching session, again, utilizing the MOATT teach-back to reinforce understanding and identify issues. At the time of the first refill, the pharmacist and navigator checked in with participants for an education “refresher” (T3). At T3, a medication calendar updated for the new refill was provided as well. The study concluded with the medication navigator checking in with participants for a fourth and final time (T4) at any point between T3 and the start of the 2nd refill, within typically a 30-day period.

Study Measures

The MOATT teach-back and other study forms are described below. The teach-back took approximately 5 minutes for English-speaking patients and 10 minutes for Chinese-speaking

patients (with translation) to complete. Other study measures required no longer than 10 minutes to complete in total.

MOATT Teach-back.—The specialty pharmacist and/or the medication navigator documented responses to the teach-back, evaluating them as “correctly answered,” “correctly answered with use of tools/required prompting,” and “incorrectly answered.” Any issues or concerns identified during the teach-back were also recorded.

Demographics and Clinical Data.—Participants provided their year of birth, gender, race/ethnicity, education, employment, and financial impact due to cancer. Trained study staff abstracted clinical information from the electronic medical chart, which was reviewed by the study oncologist. Comorbidities were collected and defined based on conditions that required long-term management with medications (e.g., hypertension), which would potentially add to overall medication burden. As part of the participant’s cancer treatment history, we determined whether the OAM was part of frontline or subsequent-line therapy. The specialty pharmacist also collected information about the OAM class and whether the participant received additional financial assistance paying for their OAM through subsidized prescription coverage or drug assistance program.

Patient-Reported Adherence to and Understanding of OAM Measure.—This patient-reported measure included a set of questions about the participant’s adherence to the OAM as well as questions about patient understanding of how to take the OAM (i.e., daily, how many times per day, with food) and special handling instructions (i.e., wash hands, storage, disposal). Two self-adherence questions were adapted from a 3-item medication adherence measure, previously validated for patients with HIV.²⁶ Other questions that assessed understanding of taking and handling were created by members of the study team who had prior experience in survey development. This measure was assessed at T2-T4; the final assessment included additional questions about potential insurance issues, handling, storing, and proper disposal. One specialty pharmacist reviewed and validated patient-reported responses to the understanding questions for accuracy. Patient-reported responses on understanding of OAM taking (i.e., daily, how many times per day, with food) and OAM handling (i.e., wash hands, storage, disposal) were compared to the prescribing instructions for that OAM and classified as adequate or inadequate. Adequate responses were those describing behaviors that avoided compromising medication safety or efficacy. All of the patient responses and pharmacist classifications were reviewed by the study oncologist, who had not participated in the ordering of the OAM or in the *ad hoc* education

MD Anderson Symptom Inventory (MDASI).—The MDASI is a validated, multi-symptom patient-reported outcome measure that assesses symptoms caused by the cancer or treatment. It included 13 core items that encompassed symptoms presented with the highest frequency and/or severity in patients with various cancers on different treatments. Symptoms included pain, fatigue, nausea, emotional distress, and lack of appetite. Six other items asked about how the symptoms interfered with how the patient felt and functioned (general activity, mood, walking ability, normal work, relationships, enjoyment of life). All items referred to the prior 24 hours of symptom report and were rated on a 0–10 scale (0 being not

existent, 10 being most severe). This tool is also available in written Chinese. According to the MDASI User Guide,²⁷ subscale scores for core symptom severity and interference were calculated for patients who completed at least half of the items in the subscale using the arithmetic mean of items in the subscale. The measure was given at all study time points, but only administered to participants who attended meetings in person. For participants who were reached out over the phone, the MDASI was not administered; however, any clinical issues raised by the participant during the session, including symptoms, were still documented. Any symptoms reported were also relayed to the clinical team to be addressed.

Study Evaluation.—The study evaluation forms were designed specifically for this study to obtain participant feedback on the usefulness of the check-ins and study tools (i.e., medication information sheets and the calendar). An initial evaluation of nine questions was given at T2 to align with completion of the participant's first OAM cycle. A second and final evaluation composed of 14 questions was given to gather their feedback on the check-ins during Cycle 2, their usage of the tools during Cycle 2, as well as the study overall.

Data Analysis

Study participants were divided into analytic and nonanalytic cohorts based on their completion of study time points. The analytic cohort included participants who had completed all time points (T1-T4) or who were missing a single time point due to a non-medical reason (e.g., logistical). This reduced potential bias when comparing outcomes over time in the presence of data that are missing not at random (i.e., patients withdrawing from the study early due to medical reasons).²⁸ Participants who were prescribed more than one OAM, had a change in regimen or asynchronous start were excluded from the analytic cohort because they did not fit into the framework of our pilot intervention. To understand potential differences in the analytic and non-analytic cohort that could impact the generalizability of our findings, baseline demographic, clinical characteristics and patient-reported measures were summarized separately for the two groups.

The remaining analyses were restricted to the analytic cohort. Teach-back responses, self-assessment of OAM adherence, specialty pharmacist validation of patient-reported understanding, issues expressed by participants related to OAM, and study evaluations were described using summary statistics. As part of the teach-back, participants were asked if they had any questions or concerns related to their OAM (e.g., side effects, missed doses, food-drug interactions, and disease response). These issues were subsequently classified as directly related to the intervention (and addressed by a member of the intervention team) or beyond the scope of the intervention and therefore requiring input from the clinical team. Participants also reported on whether they had any intermittent issues between study visits and whether they reached out to the medication navigator, specialty pharmacist, or the treatment team. While some participants reported multiple issues, concerns were analyzed at the individual level.

Results

Study Participation

Ninety-seven patients prescribed a new OAM at the cancer center were identified, during the study period September 2018 to July 2019. Upon further screening, 17 were found to be ineligible. Of the remaining eligible patients (n = 80), 58 met with the specialty pharmacist for formal OAM teaching (72.5%) after which 54 (93.1%) enrolled in the study (Figure 2). Of the 26 patients who were not enrolled, 22 of them could not be approached, principally for logistical reasons (e.g., pharmacist unavailability [n = 13] or workflow barriers in clinic [n = 6], such as delayed or prolonged clinic visits, patients needing to go to other scheduled appointments). Among the 54 enrolled, 39 (72%) participants met criteria for inclusion in the analytic cohort. For T2-T4, 59.0% of the analytic cohort had at least one visit by phone.

The non-analytic cohort (n = 15) was primarily withdrawn from the study due to medical reasons (n = 7), such as OAM intolerance and progression of disease within the first treatment cycle leading to discontinuation of the drug.

Participant Characteristics

There were few differences between the analytic (n = 39) and nonanalytic (n = 15) cohorts at study entry (Table 1). Participants in the analytic cohort had a mean age of 64.5 years and 51.3% were female. The majority identified as non-Hispanic White (61.5%) with 23.1% identifying as Asian or Chinese ethnicity. Nearly a quarter of the participants (23.1%) had less than a high school education. Two-thirds of participants had any private insurance (including a private insurance supplement to Medicare). Only 33.3% were employed.

The majority of participants had advanced disease at the time of study enrollment (stage IV, 60.0%). Most indications for OAM were for subsequent-line treatment (69.2%) and were not for curative intent (56.4%). Most patients (69.2%) had at least one comorbid condition. MDASI scores at study entry revealed relatively low severity of symptom burden with median Core and Interference scores of 1.8 and 1.5 out of 10, respectively.

Patient Adherence to and Understanding of OAM

As reported on the teach-back, improvements in correctly recalling the OAM name, when to take their OAM, how to take them, and how to store them, were observed and sustained throughout the study with or without referring to study tools (i.e., medication calendar, medication information sheet) (Table 2).

Most participants reported doing a “Very Good” or “Excellent” job (T2, 83.8%; T3, 81.1%; T4, 82.4%) at taking their OAM in the way they were supposed to, and most participants reported that they “Almost Always” or “Always” (T2, 94.6%; T3, 97.3%; T4, 97.1%) took their OAM in the way they were supposed to. Validation by the specialty pharmacist of patient-reported understanding similarly found that by T4, all participants adequately understood how to take their OAM. However, 41.0% of participants had inadequate understanding of handling their OAM at T4. For example, one patient had mentioned “throwing away” any leftover OAM (inappropriate disposal), while another patient was able

to describe proper hand-washing while handling OAM, but inadequately explained how to properly store it.

Issues Identified through the Intervention

Questions or concerns were consistently raised by the participants or identified by the intervention team that required additional assistance (Table 3). A number of these issues (T1-T4 range 28.2% to 40.5%) pertained to the scope of the intervention and were resolved by the specialty pharmacist and/or medication navigator. Some examples were: food-drug interactions for the prescribed OAM; how to dispose of leftover pills; and financial concerns due to drug cost. However, issues that were beyond the scope of the intervention (T1-T4 range 26.3%–54.1%) were referred to the clinical team. Examples of these include: managing side effects; questions regarding the efficacy of the OAM compared with other cancer therapies; disease response to treatment; and obtaining prescriptions for OAM refills and other medications. Additionally, in between study check-ins, participants were found to have contacted either the intervention team and/or the treatment team to address intermittent concerns.

Study Evaluation

Most participants (initial evaluation, 86.5%; final evaluation, 76.9%) reported that the check-ins with the specialty pharmacist and/or medication navigator were very beneficial (Table 4). At T2, the majority of participants found the intervention tools “Very Helpful” (medication information sheet, 75.7%; medication calendar, 73.0%), although this decreased slightly by T4 (medication information sheet, 63.2%; medication calendar, 52.6%). As part of the final evaluation, 97.4% of participants thought that the number of check-ins was just right and 60.4% perceived it to be helpful to continue the intervention outside this study’s scope. Evaluations at both time points revealed that participants reviewed side effects in their medication information sheets the most (T2, 80.7%; T4, 84.6%), and that they used the check-boxes on their medication calendars to mark off when they took their OAM most frequently (T2, 84.6%; T4, 83.3%).

Discussion

In response to suboptimal OAM adherence and understanding of vulnerable patients at our institution, we undertook this pilot intervention to enhance education and support for patients taking OAM. Results demonstrated improved and sustained understanding of OAM taking. The intervention expanded support by identifying and resolving issues related to OAM during and between check-ins, thereby extending the clinical care capacity of the oncology team. Feedback about the intervention from participants was positive and reflected that patients were invested and engaged.

Our intervention illustrates that a comprehensive and multifaceted approach to education is essential in helping patients better understand how to take and manage their oral cancer therapies. These findings are consistent with similar successes of other monitoring programs that extend beyond only providing educational information^{29–32} or feature more intensive follow-up by pharmacists, nurses, or specialized monitoring programs.^{16,17,19,33}

Although patient navigators have been utilized to improve timeliness to care and treatment adherence,²¹ this study adds promise to deploying navigators to provide OAM monitoring and ongoing support.

While study participants showed adequate understanding of OAM taking by the end of the intervention, aspects related to handling OAM and recalling their name remained as areas for further improvement. Proper handling (e.g., washing hands, wearing gloves) and appropriate disposal (i.e. returning leftovers to a pharmacy instead of throwing them away) of OAM are important as they present safety concerns unique to these types of medications and the need for programs to address them.^{34,35} While some participants struggled to correctly name their OAM and often confused it with other non-OAM medications, the reasons pertained primarily to patients' understanding of their cancer care. This may be more challenging for patients who are on multiagent therapies (i.e., combined intra-venous and OAM); on several other medications for supportive care or management of comorbid conditions; or prescribed multiple OAMs that have different dosing schedules and handling instructions. This is consistent with other literature findings that increased medication burden and higher complexity of treatment regimens could create more confusion for patients and present added barriers to adherence, emphasizing the need for interventions to help patients better understand their treatment(s), including OAM.¹⁰

The persistence of emergent clinical issues throughout the intervention period highlights the usefulness of periodic check-ins with patients. While study participants (26.3% to 54.1%) continued to raise questions beyond the scope of the OAM intervention throughout the duration of the pilot study, the medication navigator and specialty pharmacist brought them to the attention of the other oncology team members and resolved them promptly. Effective communication and a close working dynamic between these multiple providers facilitated this process, which are crucial within an increasingly multidisciplinary approach to OAM management.³⁶ This structured care would allow patients to better navigate their questions and concerns. Cancer care teams will need to continue exploring ways to maintain or extend their capacities to continually support patients on OAM in order to mitigate potential gaps in care.

The MDASI results at baseline indicated low symptom burden. However, symptoms and symptom burden likely change throughout the course of treatment, or in the setting of disease progression. Studies have indicated that symptom burden and poor symptom management may result in discontinuation of OAM, including hormonal therapies, through the use of various symptoms evaluations.^{37,38} Information about the symptom burden as well as the extent to which the symptoms interfered with patients' quality of life—both of which are measured by the MDASI—could be useful throughout the intervention to identify any correlations between symptoms reported and OAM adherence. Although we intended to collect serial symptom assessments, our data at follow-up time points were incomplete, due to the proportion of participants that chose to complete check-ins by phone.

This study was feasible to deliver, and featured a high enrollment rate (93%) and positive evaluations, which suggest that patients are interested in and appreciative of additional education and support for OAM. The inclusion of language-congruent forms and tools

ensured appropriate materials were available to our Chinese-speaking patients and promoted their study participation.

This pilot intervention study capitalized on several strengths. A multidisciplinary team representing clinical and patient perspectives allowed the tailoring of the intervention and the use of tools to be cognizant of clinic processes and sensitive to patient needs. The specialty pharmacist's unique background in providing patient education and the medication navigators' prior experience working in the cancer center as medical liaisons were additional assets to the intervention. The timing of the check-ins, completion of study measures, and conduct of OAM education were designed to be as congruent with clinic workflow as possible and not disruptive to clinician or patient schedules. The intervention utilized study measures and teaching tools (MOATT, medication information sheets) that have been previously validated. These materials were adapted with awareness of potentially lower health literacy and language barriers within our study population. This intervention standardized a practice model that previously was delivered on an *ad hoc* basis to a larger population in need.

There are limitations to this study. Since this pilot intervention was conducted at a single institution, it should be evaluated in other settings and patient populations for generalizability. Another limitation of this study is the use of patient self-report measures for OAM adherence. Other methods of assessing adherence could be explored to supplement patient self-reports, such as electronic monitoring tools (e.g., the Medication Events Monitoring System [MEMS]), determining the Medication Possession Ratio (MPR), and pill counts.³⁹ Although the accuracy of patient-reported responses about OAM understanding were validated by the oncology specialty pharmacist at the conclusion of the study, this could be done at earlier time points to help address inadequacies in OAM taking and handling earlier on in the treatment course. The exclusion of participants with multiple OAM from final analysis due to asynchronous starts highlights the need to address this clinical reality in future studies.

There are a number of considerations for future intervention design. Although most participants completed the study once enrolled, a number of potential participants were not approached for participation due to logistical reasons. One potential solution to this would be to schedule a set time for initial teaching, rather than trying to more informally add this session to the clinic visit. This approach recently has been instituted at our cancer center before the start of new infusion therapy with good acceptance. Further, several participants discontinued the study after the first cycle of OAM (i.e., the non-analytic cohort), due to either disease status and/or toxicity, but their outcomes through T2 were not significantly different from those of the analytic cohort (results upon request). This suggests that these individuals might have derived benefit from follow-up. For example, given the persistent suboptimal understanding of proper OAM disposal, drop-outs due to early drug discontinuation could benefit from enhanced knowledge of properly discarding their discontinued medications. Additionally, while we included patients of vulnerable (lower socioeconomic status, non-English speaking) and non-vulnerable status, future studies could consider stratifying the sample and targeting recruitment to these two patient populations.

Furthermore, we plan to proceed with a randomized control trial for more rigorous testing. Since this intervention focused on the first two cycles of OAM, one aspect for future study could be longer-term follow-up of these patients. Extending the length of follow-up could further explore trends over time in adherence and issues pertaining to OAM. As OAM presents a different care delivery model than that of infusion-based therapies, factors such as patient expectations towards treatment, communication preferences, and patient quality of life might also impact adherence.^{40,41} These can be further explored in future studies.

In summary, this pilot intervention was designed to address an urgent need for improved education and support for patients prescribed OAM, as well as new strategies to address gaps in patient care. It demonstrated the enhanced effect of integrated multidisciplinary follow-up with supplemental informational tools for patients. It is imperative to consider what the standard of care should be in response to these novel therapies, and how to best utilize the appropriate expertise to deliver high quality patient care.

Acknowledgements

We would like to thank Fengqing Wang, BA for her assistance in the design of this study. We would also like to thank John Erban, MD for his ongoing support of this work.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the Moore/Moreau Cancer Research Project Funding Opportunity (Roddan, A.); Yawkey Foundation (Parsons, S.); National Center for Advancing Translational Sciences, National Institutes of Health, Award Number 1KL2TR002545 (Roddan, A.); National Center for Advancing Translational Sciences, National Institutes of Health, Award Number UL1TR002544 (Fleckner, T.)

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Medication start (T1)	Cycle 1 check-in (T2)	First refill (T3)	Cycle 2 check-in (T4)
<i>(Pharmacist + Navigator) In-Person</i> Pharmacist conducts formal educational session about OAM Provide medication calendar and drug information sheet (English/Chinese)	<i>(Navigator) In-Person/Phone</i> Navigator checks in ~1 week after OAM start to reinforce understanding and review issues	<i>(Pharmacist + Navigator) In-Person/Phone</i> Re-teaching (~1 month after start) by pharmacist on new refill or new cycle of treatment Provide updated medication calendar for cycle 2	<i>(Navigator) In-Person/Phone</i> Final check-in by Navigator before start of 3rd cycle or 2nd refill
Study Measures: • MOATT* Teach-back • Demographics form • MDASI**	Study Measures: • MOATT Teach-back • Self-adherence • Initial study feedback	Study Measures: • MOATT Teach-back • Self-adherence	Study Measures: • MOATT Teach-back • Self-adherence • Final study feedback
*MOATT: "MASCC Oral Agent Teaching Tool"; **MDASI: MD Anderson Symptom Inventory			

Figure 1.
Study schema.

Figure 2.
Study enrollment and completion.

Table 1.

Patient and disease characteristics.

Overall Cohort, n = 54					Analytic Cohort, n = 39		Non-analytic Cohort, n = 15	
Patient Characteristics								
Age in years (yrs), mean (SD)								
Female, n (%)								
Race/Ethnicity, n (%)								
White, Non-Hispanic								
Asian								
Other								
Highest Level of Education, n (%)								
Less than High School								
High School or More								
Employed, n (%)								
Insurance Type, n (%)								
Any Medicaid								
Medicare Only								
Any Private								
Financial Assistance Program, n (%)								
Yes, Any Program								
No								
Financial Problems Due to Cancer, n (%)								
No								
Yes								
Don't Know								
Any Comorbidity, n (%)								
Disease Characteristics								
Cancer type, n (%)								
Solid								
Hematologic								
Stage of Diagnosis, n (%)								

	Overall Cohort, n = 54	Analytic Cohort, n = 39	Non-analytic Cohort, n = 15
Less Than Stage IV	6 (33.3%)	4 (40.0%)	2 (25.0%)
Stage IV	11 (61.1%)	6 (60.0%)	5 (62.5%)
Unknown/Unspecified	1 (5.6%)	0 (0.0%)	1 (12.5%)
Yrs Since Diagnosis, median (Q1, Q3)	2 (0, 10)	2 (1, 10)	1 (0, 11)
MDASI Core Items Total, median (Q1, Q3)	1.5 (0.5, 3)	1.8 (0.5, 3.5)	0.7 (0.2, 1.5)
MDASI Interference Items Total, median (Q1, Q3)	1.4 (0.5, 4)	1.5 (0.7, 4.3)	1.3 (0, 3)
<i>OAM Characteristics</i>			
Medication Class, n (%)			
TKI	33 (61.1%)	25 (64.1%)	8 (53.3%)
Other	21 (38.9%)	14 (35.9%)	7 (46.7%)
Frontline or Subsequent-line Treatment, n (%)			
Frontline	16 (29.7%)	12 (30.8%)	4 (26.7%)
Subsequent-line	38 (70.3%)	27 (69.2%)	11 (73.3%)
Curative Intent, n (%)			
Yes	22 (40.7%)	15 (38.5%)	7 (46.7%)
No	29 (53.7%)	22 (56.4%)	7 (46.7%)
Not indicated/Not documented	3 (5.6%)	2 (5.1%)	1 (6.7%)

Abbreviations: MDASI = MD Anderson Symptom Inventory, OAM = oral anticancer medication, Q1 = Quartile 1, Q3 = Quartile 3, SD = standard deviation, TKI = Tyrosine Kinase Inhibitor.

Table 2.
Teach-back responses and pharmacist validation of patient-reported understanding at T1–T4.

	T1	T2	T3	T4
<i>Teach-back Responses</i>	n=39	n=36	n=36	n=35
OAM name, n (%)				
Correct without tools	19 (48.7%)	28 (77.8%)	29 (80.6%)	32 (91.4%)
Correct with tools	19 (48.7%)	3 (8.3%)	5 (13.9%)	0 (0.0%)
Incorrect	1 (2.6%)	6 (16.7%)	2 (5.6%)	3 (8.6%)
When to take OAM, n (%)				
Correct without tools	34 (87.2%)	36 (100.0%)	36 (100.0%)	35 (100.0%)
Correct with tools	5 (12.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Incorrect	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Take OAM with or without food, n (%)				
Correct without tools	37 (94.9%)	36 (100.0%)	36 (100.0%)	35 (100.0%)
Correct with tools	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Incorrect	2 (5.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
OAM storage, n (%)				
Correct without tools	37 (94.9%)	36 (100.0%)	36 (100.0%)	35 (100.0%)
Correct with tools	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Incorrect	2 (5.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
<i>Pharmacist Validation</i>				n = 39
OAM taking, n (%) ^a				
Adequate	n/a	n/a	n/a	38 (100.0%)
Inadequate	n/a	n/a	n/a	0 (0.0%)
OAM handling, n (%) ^b				
Adequate	n/a	n/a	n/a	23 (59.0%)
Inadequate	n/a	n/a	n/a	16 (41.0%)

Abbreviations: OAM = oral anticancer medication

^a Adequacy of OAM taking was based on the specialty pharmacist's assessment of patients' response about OAM taking (i.e., daily, how many times per day, with food). Adequate responses were those describing behaviors that avoided compromising medication safety or efficacy.

Adequacy of OAM handling was based on the specialty pharmacist's assessment of patients' response about OAM handling (i.e., wash hands, storage, disposal). Adequate responses were those describing behaviors that avoided compromising medication safety or efficacy.

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Table 3.

Issues identified at T1–T4.^a

	T1, n=39	T2, n=37	T3, n=37	T4, n=38
Issues identified at visit, n (%)				
Intervention related only	11 (28.2%)	15 (40.5%)	6 (16.2%)	12 (31.6%)
Beyond intervention	15 (38.5%)	11 (29.7%)	20 (54.1%)	10 (26.3%)
No issues	13 (33.3%)	11 (29.7%)	11 (29.7%)	16 (42.1%)
Intermittent issues (between check-ins), n (%)				
Yes	n/a	7 (18.9%)	10 (27.0%)	12 (31.6%)
No	n/a	30 (81.1%)	27 (73.0%)	26 (68.4%)
Team member contact about intermittent issues, n (%) ^b		n=7	n=10	n=11
Pharmacist/Navigator	n/a	2 (28.6%)	4 (40.0%)	3 (27.3%)
Treatment team	n/a	5 (71.4%)	6 (60.0%)	6 (54.6%)
Both	n/a	0 (0.0%)	0 (0.0%)	2 (18.2%)

^aParticipants could identify multiple issues, but issues were summarized at the individual level.

^bRestricted to participants with intermittent issues.

Table 4.

Study evaluation at T2, T4.

	T2, n=37	T4, n=39
Helpfulness of meeting with specialty pharmacist and medication navigator, n (%)		
Very helpful	32 (86.5%)	30 (76.9%)
Somewhat helpful	4 (10.8%)	9 (23.1%)
Not at all helpful	1 (2.7%)	0 (0.0%)
Helpfulness of medication information sheet, n (%)		
Very helpful	28 (75.7%)	24 (63.2%)
Somewhat helpful	6 (16.2%)	11 (29%)
Not at all helpful	2 (5.4%)	0 (0.0%)
I have not used this feature	1 (2.7%)	3 (7.9%)
Helpfulness of medication calendar, n (%)		
Very helpful	27 (73.0%)	20 (52.6%)
Somewhat helpful	7 (18.9%)	8 (21.1%)
Not at all helpful	0 (0.0%)	0 (0.0%)
I have not used this feature	3 (8.1%)	10 (26.3%)
Helpfulness of check-in with medication navigator, n (%)		
Very helpful	34 (91.9%)	26 (68.4%)
Somewhat helpful	2 (5.4%)	11 (29.0%)
Not at all helpful	1 (2.7%)	1 (2.6%)
Frequency of use of medication information sheet, n (%)		
Daily	10 (27.0%)	5 (12.8%)
Weekly	7 (18.9%)	7 (18.0%)
Occasionally	14 (37.8%)	14 (35.9%)
Did not use	6 (16.2%)	13 (33.3%)
Parts of medication information sheet used (select all), n (%) ^a	n=31	n=26
About Your Medication	19 (61.3%)	18 (69.2%)
How to Take Your Medication	18 (58.1%)	10 (38.5%)
Storage, Handling, and Disposal	14 (45.2%)	10 (38.5%)
Important Precautions	15 (48.4%)	13 (50.0%)

	T2, n=37	T4, n=39
What Foods and Drugs May Interact	19 (61.3%)	14 (53.9%)
Side Effect Summary	25 (80.7%)	22 (84.6%)
Who to Call With Questions	12 (38.7%)	12 (46.2%)
Frequency of use of medication calendar, n (%)		
Daily	15 (40.5%)	15 (39.5%)
Weekly	6 (16.2%)	3 (7.9%)
Occasionally	5 (13.5%)	6 (15.8%)
Did not use	11 (29.7%)	14 (36.8%)
Parts of medication calendar used (select all), n (%) ^b	n=26	n=24
Check boxes within the calendar to mark when I took my medication	22 (84.6%)	20 (83.3%)
Medication listed within the calendar	7 (26.9%)	5 (20.8%)
Written dosage explanations below the calendar	8 (30.8%)	2 (8.3%)
Blank calendar for notes	10 (38.5%)	6 (25.0%)

^aRestricted to participants who used the information sheet.

^bRestricted to participants who used the medication calendar.