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A pilot to study to assess a pharmacist- and medication navigator-led intervention to enhance oral chemotherapy adherence

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Thesis

**A PILOT STUDY TO ASSESS A PHARMACIST- AND MEDICATION
NAVIGATOR-LED INTERVENTION TO ENHANCE ORAL CHEMOTHERAPY
ADHERENCE**

by

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ABSTRACT

Background: Over the past 10 years, molecular-based and targeted therapies in oral forms have emerged and continue to change the landscape of cancer care and care delivery. While cancer treatments traditionally have been administered at the hospital, oral anti-cancer medications (OAM) can be taken by patients at the comfort and convenience of their homes. However, this also creates implications for ensuring that patients take their oral chemotherapies correctly, timely, and safely, all of which can impact outcomes and tolerance. Studies have shown concerning gaps in patients' knowledge of taking and handling their OAM, including lower rates of adherence. Interventions have largely consisted of a combination of nurse- and pharmacist-led approaches along with the use of various educational and reminder tools. However, few studies have examined the potential of an intervention led by a pharmacist and a medication (patient) navigator.

Objective: This ongoing pilot study aims to assess the feasibility of the intervention, the impact on patients' understanding and adherence to their oral anti-cancer medications, and the patient perceptions of the helpfulness of the intervention.

Methods: Patients who were initiating oral chemotherapy were enrolled at Tufts Medical Center Cancer Center, which was the study site for this pilot intervention. Study participants met with the Specialty Pharmacist and Medication Navigator for their initial education session and teach-back using the Oral Agent Teaching Tool (MOATT). They were also given Information Sheets and individualized Calendars for their OAM. The Pharmacist and/or Navigator subsequently followed up with the participants for three more check-ins and educational boosters. Participants completed study measures including the self-reported Adherence Measure, MD Anderson Symptom Inventory, and study evaluation.

Results: A total of 37 patients have so far been enrolled in the study and completed their initial education session with the Pharmacist and 33 of those patients completed the Navigator-led booster check-in approximately one week later. These patients are receiving ongoing follow-up for their two remaining check-ins in the study. After the first teach-back with the Pharmacist, patients largely showed sufficient understanding of how to take and handle their medication. This level of understanding was sustained a week later at the Navigator booster. Despite high levels of self-reported adherence, patients showed insufficient understanding of refill logistics. Patients were highly satisfied with the intervention and had found both the check-ins and the educational tools provided useful.

Conclusion: This Pharmacist- and Navigator-led intervention was found to be feasible to deliver, capable in enhancing patient understanding and adherence to their medications, and helpful to the patients throughout taking their OAM.

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LIST OF ABBREVIATIONS

ALL.....	acute lymphoblastic leukemia
CML.....	chronic myeloid leukemia
GIST.....	gastrointestinal stromal tumors
MDASI.....	MD Anderson Symptom Inventory
MOATT	MASCC Oral Agent Teaching Tool
OAM.....	Oral Anti-Cancer Medications

INTRODUCTION

Advancements in Oral Anti-cancer Therapy

Over the past forty years, cancer mortality rates in the United States have decreased by nearly 30% (SEER Cancer Statistics Review, 1975-2015). Contributions made by improvements in early detection and prevention as well as advancements in treatments have led to increasing survival among individuals diagnosed with cancer. In recent years, emerging new treatments have revolutionized disease management across several cancer types, improving disease outcomes as well as the patients' quality of life.

One notable example is the treatment of chronic myeloid leukemia (CML). Historically, treatment was limited and outcomes were grim. Options for treatment were primarily restricted to interferon therapy (the non-transplant treatment of choice at the time), hematopoietic stem cell transplantation for the few with suitable donors, or supportive care measures (Chopade et al. 2018). However, the introduction of tyrosine kinase inhibitors, first with imatinib and more recently, with other oral agents, has completely transformed the care of patients diagnosed with CML. These new treatments have led to stunning leaps in disease outcomes and have offered broader access to well-tolerated oral therapy.

Oral anti-cancer medications (OAM) for other cancers have also emerged, particularly targeted oncologics, which over the past 10 years now comprise nearly 70% of all oral oncologic drugs in the U.S. (IMS Institute for Healthcare Informatics 2016). In addition to their proven efficacy, the rise in OAM shifts the way treatments are delivered. While traditional, infusion-based chemotherapies are generally administered at the

hospital and often under direct surveillance by healthcare providers, OAM can be taken at home, making it more convenient for patients.

Implications of Oral Anti-Cancer Medications (OAM)

However, while these new OAM offer greater convenience for patients, there are also implications in considering how these treatments are administered and monitored. Since these oral agents are typically taken at the patients' home, the locus of responsibility shifts from the medical provider(s) to the patients and their families. While hospital-based therapies allow the care team to monitor and promptly manage side effects and reactions on site, patients on oral therapies need to navigate these issues themselves, reaching out to their care team remotely. In addition, questions regarding the extent to which patients understand important instructions and precautions about their oral anti-cancer medications become crucial to consider.

Issues revolving around patient adherence must be properly addressed in order to optimize treatment efficacy and patient safety. Adherence has been defined as how closely or adequately patients take medications and/or follow the treatment regimen as prescribed by their medical providers (Osterberg et al. 2005). In an ideal scenario, a patient is considered fully adherent if he/she does not miss any doses and takes the correct amount as prescribed at the right time(s) (Foulon et al. 2011). Greater adherence to medication and treatment regimens has been shown to result in better outcomes (e.g., lower recurrence rates and better survival), as opposed to nonadherence. Conversely, patients with poor adherence also can sustain increased healthcare utilization, and greater

healthcare costs (Osterberg et al. 2005). Incorrect and/or insufficient intake of OAM may lead to adverse toxicities and decreased efficacy, contributing to higher hospitalization rates and increased morbidity and/or mortality (Ruddy et al. 2009). Studies done by Bhatia et al. among children with ALL (acute lymphoblastic leukemia) taking oral 6-mercaptopurine therapy, found that decreased adherence was associated with increased risk of relapse (Bhatia et al. 2012). In a separate study, an adherence rate of less than 90% correlated with almost a four-fold increased risk of ALL recurrence in a multiracial cohort (Bhatia et al. 2014). Thus, how patients fare in taking their medications correctly and as intended, as well as how they persist in taking them potentially implicate their risk for adverse outcomes and suboptimal treatment response.

Barriers to Patient Adherence

Rates of adherence to OAM have been shown by various studies to be less than ideal with considerable variability by cancer type and drug type. One study showed that patients on imatinib for CML or gastrointestinal stromal tumors (GIST) have adherence rates of less than 80% (Al-Barrak et al. 2013). Another study found that around 30% of women who initiated hormonal therapy discontinued after their first prescription, while almost 30% of those who remained on it were non-adherent (Hershmann et al. 2011). Barriers to adherence have been found to be quite multifaceted and complex. One aspect can be due to personal characteristics of the patients. Some studies have reported that patients who did not take their medications attributed it to various reasons such as forgetting to take them, actively deciding to not follow prescribed dosages, or lacking

sufficient information about the medication (Osterberg et al. 2005). In a study conducted by Stanton-Robinson et al. among patients on antidiabetic or antihypertensive medications, the patients frequently expressed concern about adverse effects from medications (Stanton-Robinson et al. 2018). Psychological factors such as mental illness or cognitive deficits; emotional factors such as feeling overwhelmed by the treatment or prognosis; and physical factors, such as inability to read instructions or labels, or difficulty ingesting pills may further impede patient adherence (McCue et al. 2014).

Barriers to adherence may also be related to inadequate physician-patient communication. One example is that physicians may not sufficiently explain the benefits and side effects of medications. Schoenthaler et al. found that patients exhibited lower adherence when there was less patient-provider communication, when interactions were not patient-centric, and when the discussions did not address sociodemographic factors (e.g. housing, family and partner relationships, financial status) or the medication regimens themselves (Schoenthaler et al. 2017).

The degree of complexity of a treatment regimen including the overall burden of a regimen may also contribute to patient adherence or nonadherence. Studies have shown that the complexity of medication regimens (e.g., medications with complex dosing schedules or multi-medication regimens) is associated with lower medication adherence (Osterberg et al. 2005). Verma et al. recently reported in a study comparing clinical outcomes and medication adherence with a single fixed-dose combination treatment versus multi-pill-combination treatment, that patients who received single-pill or fixed dose combination had better outcomes that were related to better adherence (Verma et al.

2018). This may suggest that treatment regimens that are less complicated in their administration and management may be easier for patients to follow and adhere.

Health systems and institutions may also lack adequate infrastructure and resources to sufficiently respond to the need for ensuring patient adherence. Absence of standard protocols, documentation procedures, and proper monitoring and tracking adherence may impede the ability and capacity of some cancer programs to identify issues of adherence among their patients (Greer et al. 2016). Furthermore, lack of professional training to provide adequate patient education on specific OAM, lack of developed written materials for patients, and lack of knowledge about OAM and their specific side effects have posed challenges for providers and institutions to sufficiently educate patients (Kav et al. 2008).

Current Efforts to Improving Patient Adherence

Several strategies have been tested to improve patient understanding and adherence to their oral medications. Programs have ranged from monitoring and prescribing of medications and improving institutional administration to enhancing patient education, patient-doctor communication, follow-up contact, and managing toxicities (Zerillo et al. 2018). One existing resource is a teaching guide called the Oral Agent Teaching Tool (MOATT) that has been created and standardized by the Multinational Association for Supportive Care in Cancer for clinical and research use to aid healthcare providers in enhancing patient education (Kav et al. 2009).

Tools and devices also have been developed for patients to further enhance self-management strategies. Reminder tools, such as pill boxes or electronic messaging, have been provided for patients who have reported challenges remembering to take medications. Calendars, schedules, and charts are examples of tools that have been created to help patients stay organized and to remind them to take their medications, especially for those with treatment regimens consisting of multiple drugs (McCue et al. 2014). Additional studies have indicated that overall, enhanced patient education, increased monitoring, regular patient check-ins, and multi-component interventions have resulted in improved patient adherence (Zerillo et al. 2018).

To date, many interventions designed to improved medication adherence have been led by pharmacists and/or nurses and have been implemented in multi-faceted approaches and across disease groups. Pharmacist-led initiatives have involved the pharmacists checking accuracy of prescriptions (Mancini et al. 2012). Others have featured pharmacy models integrated within oncology practices (Muluneh et al. 2018) and directed more individualized education and follow-up (Lee et al. 2006), which have shown promising results in increasing patient understanding of medications, high patient satisfaction, and improvements in adherence. Adherence initiatives led by nurses have similarly focused on improving patient education and medication management, including management of symptoms and adverse effects. One intervention among adult patients receiving new oral anti-cancer agents involved having a nurse meeting or calling patients by phone within the first week, providing standard chemotherapy education, and following up with regular phone calls found that the intervention group had higher

adherence rates than those in the control group (Schneider et al. 2014). Interestingly, a hybrid model consisting of a nurse and pharmacist team approach intervention investigated by Berry et al. for inpatient oncology patients found that there was better medication understanding (drug name, dose, route of administration and frequency) after discharge by providing patients with written instructions, giving them an educational session at time of discharge, and calling them post-discharge for knowledge reinforcement (Berry et al. 2014).

Patient Navigators as an Extension of the Care Team

The current literature suggest that interventions that involve professional guidance in educating patients about OAM and addressing side effects, as well as a systematic way of following up with patients can be quite effective in improving adherence. While healthcare professionals such as nurses and pharmacists have been deployed to educating patients and checking in with them periodically, this expansion of their roles also comes with the challenges of limited capacity.

One potential solution is to introduce lay navigators as an extension to the care team in providing ongoing support for patients and to extend the care team's capacity. Patient navigation has been utilized as a way to improve patient experience and reduce barriers of care access and the time to diagnosis, particularly among vulnerable patient populations. There is also growing literature proposing it as a potential approach to improve patient adherence. A study evaluating the impact of the Breast Oncology Navigation Program at a public hospital in New York City showed that patient navigators

at the site did improve adherence with follow-up and adjuvant therapy as well as timeliness to care among their patients who identified as ethnic minorities (Castaldi et al. 2016).

In 2014, a patient navigation program was created at Tufts Medical Center Cancer Center, located in Boston's Chinatown, to assist patients of lower socioeconomic status and/or of Chinese origin in navigating the healthcare system while receiving active cancer treatment. As the navigators provided linguistically and culturally congruent support, they also ultimately became embedded within the clinical team. Frequently, the navigators served as "medical liaisons," identifying and addressing issues directly pertinent to the patients' clinical care. In working with the patients, the oncology providers and the on-site specialty pharmacist, the navigators identified concerns regarding improper intake and/or suboptimal understanding about medications, and worked with the clinical care team to address these concerns. The successful integration of the lay patient navigators into the cancer care team suggests that they could be useful in providing an extension of the providers' roles in caring for their patients, expanding their system of support.

Specific Aims:

Studies have shown that overall there is a risk for patients to have subpar understanding and knowledge as well as substandard adherence to prescribed oral anti-cancer medications. Current interventions have evaluated the use of various tools and the implementation of nurse-led or pharmacist-led follow-ups to minimize this risk.

However, further work is needed to investigate how these interventions can be best operationalized and what the optimal method(s) are to support patients in elevating their understanding and adherence to their oral treatment regimens.

Therefore, a pilot longitudinal study was designed to improve education and support, adherence, and safety for patients starting on OAM in a hospital-based cancer program. While much of current research has involved the use of nurses, pharmacists, or a hybrid of both in interventions to improve medication adherence, this is the first to our knowledge to implement an initiative jointly-led by an oncology-specialty pharmacist and a lay navigator. To assist patients on issues related to OAM and work with the pharmacist to provide tailored, longitudinal support for these patients, the role of a “Medication Navigator” was created.

The purpose of the intervention was to enhance education and support for patients who were newly prescribed OAM(s), particularly among vulnerable populations (i.e., non-English, lower socioeconomic status, elderly). Thus, the three-fold goals of this paper are: first, to describe the feasibility of the intervention through metrics of enrollment and follow-up, team personnel availability, and mode of patient contact; second, to describe the impact of the educational teaching sessions and check-ins on patients’ understanding and adherence to their oral medications; third, to describe the feedback about the study gathered from the patient participants on their perceived usefulness of the check-in sessions and the instrumental tools provided as part of intervention design.

METHODS

Research setting and staff

Study participants were identified and enrolled in the hematologic malignancy and solid tumor clinic at the Cancer Center at Tufts Medical Center, a large urban academic hospital located in downtown Boston, Massachusetts, which served as the study site. A pharmacy was physically located at the clinic as part of an integrated system, as well as an on-site pharmacist specialized in oncology care. The Specialty Pharmacist aimed to fulfill multiple roles in the care team. First, he worked with the oncology team in providing in-depth education on prescribed medications, particularly anti-cancer drugs. Second, he worked with the pharmacy administration to check for and obtain insurance prior-authorizations, as well as look for any financial assistance programs available to help patients receive treatment. Third, he reviewed prescriptions to ensure safety and accuracy prior to dispense.

The role of a “Medication Navigator” was also recently created around the time of the study and grew from the experiences the Cancer Center’s patient navigators had in assisting patients on an increasing number of medication-related issues. The Medication Navigator received training from the Specialty Pharmacist in these issues. The role of the Medication Navigator was an extension of the professional care team, providing ongoing support for patients at planned intervals and serving as another line of communication to patients’ care teams.

The study received approval from the Tufts Medical Center Institutional Review Board (IRB) to be conducted at this site. Hematology/oncology providers at the Cancer Center were also notified by the study team to elicit their support.

Study participants – Screening and Consent

Potentially eligible patients were identified through the Specialty Pharmacist, who was notified by the oncology team of patients that were newly prescribed a new regimen including at least one OAM. Eligible patients were invited to participate in the study if they had an active diagnosis of a solid tumor or hematologic malignancy, were at least 18 years of age, were proficient in English or spoken Chinese, and were receiving their primary adult hematology/oncology care at Tufts Cancer Center. Patients who had been taking newly prescribed OAM for more than 7 days upon screening were excluded from the study.

Upon identifying a patient who was eligible for the study, the Specialty Pharmacist and the Medication Navigator planned for an initial education session on or close to the treatment start date to review specific information about the OAM(s). Together, they prepared an Information Sheet about the OAM as well as an individualized Medication Calendar. Both of these tools were created to enhance patient understanding and support.

The Specialty Pharmacist and Medication Navigator approached patients in clinic typically after their clinic visits or in the Infusion Center where they were monitored for (and in some cases administered) their first dose of oral chemotherapy. Before providing

informed consent for study participation, patients were offered the initial education session with the Specialty Pharmacist and Medication Navigator to review specific information about the medication as part of standard of care. This initial meeting was offered to all patients regardless of their decision to participate in the study. All patients were provided a Medication Calendar to help them keep track of taking their medications and an Information Sheet that included important information about the medication taking and management. During the education session, the Pharmacist discussed each part of the Information Sheet and the Calendar, using them as instructional aids and as a way to show how the patient may use these tools on their own.

Following the initial education session, informed consent was obtained from patients who were interested in participating in the study, which involved three additional check-in sessions following the initial meeting, and the completion of questionnaires assessing their understanding of and adherence to medication, symptom burden, and overall feedback about the initiative.

Given Tufts Medical Center's unique location in Boston's Chinatown, the hospital serves a large number of Chinese and/or (non-English)-speaking patients. To accommodate for Chinese participants who did not speak English fluently, all study measures including consent forms, the modified MOATT education teach-back scripts, the Medication Information Sheets, and Medication Calendar were translated into both Traditional and Simplified Chinese versions; following professional translation, the IRB approved their use. The Medication Navigator on staff was fluent in Cantonese- and

Mandarin- Chinese and was able to converse and review all study forms with any Chinese-speaking participants.

Procedure

The structure of the study as a longitudinal intervention consisted of a total of four meetings or check-ins with the enrolled patients through their first and second oral chemotherapy cycles or refills. Scheduled check-ins were conducted by the Specialty Pharmacist and/or Medication Navigator either in person or over the phone. In-person check-ins were typically coordinated with the patient's scheduled clinic visits. If scheduled clinic visits were not anticipated within the study windows or if the patients expressed preference, the study participants were contacted by phone.

Two of these check-ins served as educational sessions, led by the Specialty Pharmacist, while the other two served as interval check-ins done by the Navigator to further reinforce the level of understanding about the medication as well as to address any questions or issues the patient had.

An overview of the four sessions is illustrated in the schema below with the allowable windows around each assessment.

	Pharmacist-Led Teach-back (Time 1)	Navigator Booster (Time 2)	Pharmacist-Led Teach-back (Time 3)	Final Navigator Booster (Time 4)
Time windows	Start of new OAM	7 days (+/- 3) after Time 1	Start of Cycle 2 of medication, or date of first refill	7-28 clinic days after Time 3, or before start of Cycle 3 or second refill.
Mode of contact	In person	In person or phone	In person or phone	In person or phone
Check-in attendees	Participant, Medication Navigator, Specialty Pharmacist	Participant, Medication Navigator	Participant, Medication Navigator, Specialty Pharmacist	Participant, Medication Navigator
Modified MOATT Teach-back	X	X	X	X
Adherence Measure		X	X	X
Demographics Form	X			
Study Evaluation		X		X
MD Anderson Symptom Inventory	X	X (in person only)	X (in person only)	X (in person only)

Abbreviations: MOATT (Multinational Association for Supportive Care in Cancer's Oral Agent Teaching Tool)

Time 1: Initial Education Meeting and Teach-back

Time 1 was designated as the initial education session led by the Pharmacist followed by patient teach-back. Per study design, this was always conducted in person. This was planned on the date on which the patient started taking the newly prescribed OAM. During Time 1, the Pharmacist guided the patient through the Information Sheet

and Medication Calendar of the prescribed oral chemotherapy, teaching the patient what the medication was, when to take it, how to properly take it, and how to properly handle, store, and dispose of it. The Pharmacist then went through a modified version of the MOATT patient teach-back, a formal method of assessing how well the patient understands information about their medication(s) that was shared with them. To end the session, the Medication Navigator administered the Demographics Form and the MD Anderson Symptom Inventory to patients who provided consent to study participation. Study measures were selected to assess symptoms at baseline. The study team was notified of any clinical issues that needed to be promptly addressed.

Time 2: Cycle 1 Medication Navigator Check-In

The second check-in, “Time 2,” was scheduled to be 1 week (+/- 3 days) after the initial meeting. This check-in was an individual meeting between the participant and the Medication Navigator, and served as an opportunity to review any concerns or issues, and/or to reinforce education and knowledge about the anti-cancer medication. The Medication Navigator completed the patient teach-back and the verbal responses were recorded. If this was conducted in-person, participants also completed the Adherence to OAM measure, MD Anderson Symptom Inventory, and the initial study evaluation. If done over the phone, the Medication Navigator administered only the Adherence to OAM measure and recorded the responses, and another trained study staff administered the study evaluation to preserve the integrity of responses. The Symptom Inventory was not administered over the phone to reduce responder burden.

Time 3: Cycle 2 Start – Pharmacist Education Booster

“Time 3” was scheduled around the time when participants started on Cycle 2 of the oral chemotherapy regimen or picked up the first refill of the medication. This check-in served as a “booster” education session led by the Pharmacist as an opportunity to reinforce specific information about the oral chemotherapy. This meeting involved the participant, Pharmacist, and Medication Navigator. If done in person, the Pharmacist administered the patient teach-back and the Medication Navigator administered the Symptom Inventory and Adherence Measure. As with Time 2, if this assessment was completed by phone, the Symptom Inventory was not administered.

Time 4: Cycle 2 Medication Navigator Final Check-in

The last check-in was planned for after the first week of Cycle 2 until before the start of Cycle 3. “Time 4” consisted of a one-on-one meeting between the Medication Navigator and the participant. The same measures and patient teach-back were completed as in previous check-ins, either in person or over the phone. A final study evaluation was given to participants at the conclusion of their participation in the study.

Study Forms and Collection Measures

Study measures were administered by a study team member to participants either in-person or over the phone. All forms were translated into Simplified and Traditional Chinese and subsequently approved by the IRB.

Medication Information Sheets

Drug Information Sheets were adapted from the Michigan Oncology Quality Consortium and provided to participants upon starting on treatment. Information Sheets were translated into Traditional and Simplified Chinese for 12 of the more commonly prescribed OAM at the study site. They included instructions on medication taking and handling, most notable side effects associated with the medication, and contact information for whom to get in touch for emergency and non-emergency concerns.

Demographics Form

Upon study entry, participants completed the Demographics form, which collected information about their year of birth, gender, race/ethnicity, education, employment, and healthcare costs/insurance status.

Patient Teach-back (modified MASCC Oral Agent Teaching Tool – MOATT)

A modified version of the Oral Agent Teaching Tool was used to ask the participant questions to assess their knowledge of his/her medication(s), their ability and understanding to take and handle the medication, and understanding about drug-specific information such as dose and schedule, side effects, and interactions with foods and drugs. Question stems from the original version were tailored to the flow of the session conversation and were adapted into a script form. Evaluation options such as “Correctly

answered,” “Correctly answered with use of tools/required prompting,” and “Incorrectly answered” were added to each question.

Self-Reported Adherence to Oral Anti-Cancer Medication (OAM) Measure

This measure included 6-13 questions about the participant’s adherence to the oral chemotherapy medication, assessing self-reports on how the participant has been taking it, how well it has been taken, and how often it is refilled. Participants who were taking more than one medication completed one form for each medication, separately, as different medications have unique ways of administration and management. Three questions were modified from a 3-item validated medication adherence measure, previously used with patients with HIV (Wilson et al. 2016).

MD Anderson Symptom Inventory

The MD Anderson Symptom Inventory (MDASI) is a validated, multi-symptom patient-reported outcome measure that assesses symptoms caused by the cancer or treatment (Cleeland et al. 2000). It included 13 core items that encompassed symptoms presented with the highest frequency and/or severity in patients with various cancers on different treatments. Some of these symptoms included pain, fatigue, nausea, emotional distress, and lack of appetite. Six other items asked about how the symptoms interfere 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 and were

rated on a 0-10 scale (0 being not existent, 10 being most severe). This tool, administered at each in-person assessment, was already available and validated in written Chinese.

Study Evaluation

The study evaluation obtained the participant's thoughts on the usefulness of the check-ins and study tools (i.e., Medication Information Sheets and the Calendar). It consisted of 9-14 questions and, as with all study materials, was translated into Traditional and Simplified Chinese. Two separate evaluation forms were created: an initial evaluation given at the Cycle 1 Navigator check-in (Time 2), to obtain the participants' initial thoughts on the study and usage of the Information Sheet and Calendar; and a final evaluation given at the Cycle 2 Navigator check-in (Time 4) to gather their feedback on the check-ins during Cycle 2, their usage of the Information Sheet and Calendar during Cycle 2, as well as the study overall.

Medical Chart Review Form

The medical chart review form was completed by trained study staff and centrally reviewed by the study oncologist. Data included information on disease characteristics including cancer diagnosis, year of diagnosis, comorbidities requiring medication management, and treatment history. For the purposes of this study in terms of medication management, the definition of comorbidity was considered more broadly than what is included in the Charlson Comorbidity Index, a scale that is typically used to predict 10-year survival in patients with comorbidities (Charlson et al. 1987). Included in the study

definition were conditions such as hypertension that required long-term management with medications for certain patients, which would potentially add to overall medication burden.

RESULTS

An Overview of Study Enrollment

Study recruitment began in September 2018. Figure 1 illustrates the progress on enrollment and completion of the participants through the study as of February 2019. Fifty patients were found to be eligible for study enrollment, 11 of whom were not approached during the eligible period. Reasons for not being approached included: 1) three patients missed due to workflow (e.g. clinic visits extended past schedule, study team not being notified in time to prepare); 2) seven missed due to Pharmacist unavailability for the initial education session; and 3) one patient was unable to come to the study site for the first visit with the Pharmacist and Navigator due to logistical challenges. Of the 39 who were approached by the study team, two had refused participation (5% refusal rate).

Thirty-seven patients received the initial education and teach-back and completed all study measures at the time of enrollment (Time 1). Subsequently, the Medication Navigator was able to contact and/or meet with 33 patients for the Time 2 booster check-in approximately a week after initiating treatment, while 3 patients could not be reached and 1 patient withdrew from the study. These 33 patients would receive further follow-up by the Pharmacist and Navigator (Time 3 and Time 4) past their first medication refill and into their Cycle 2 treatment.

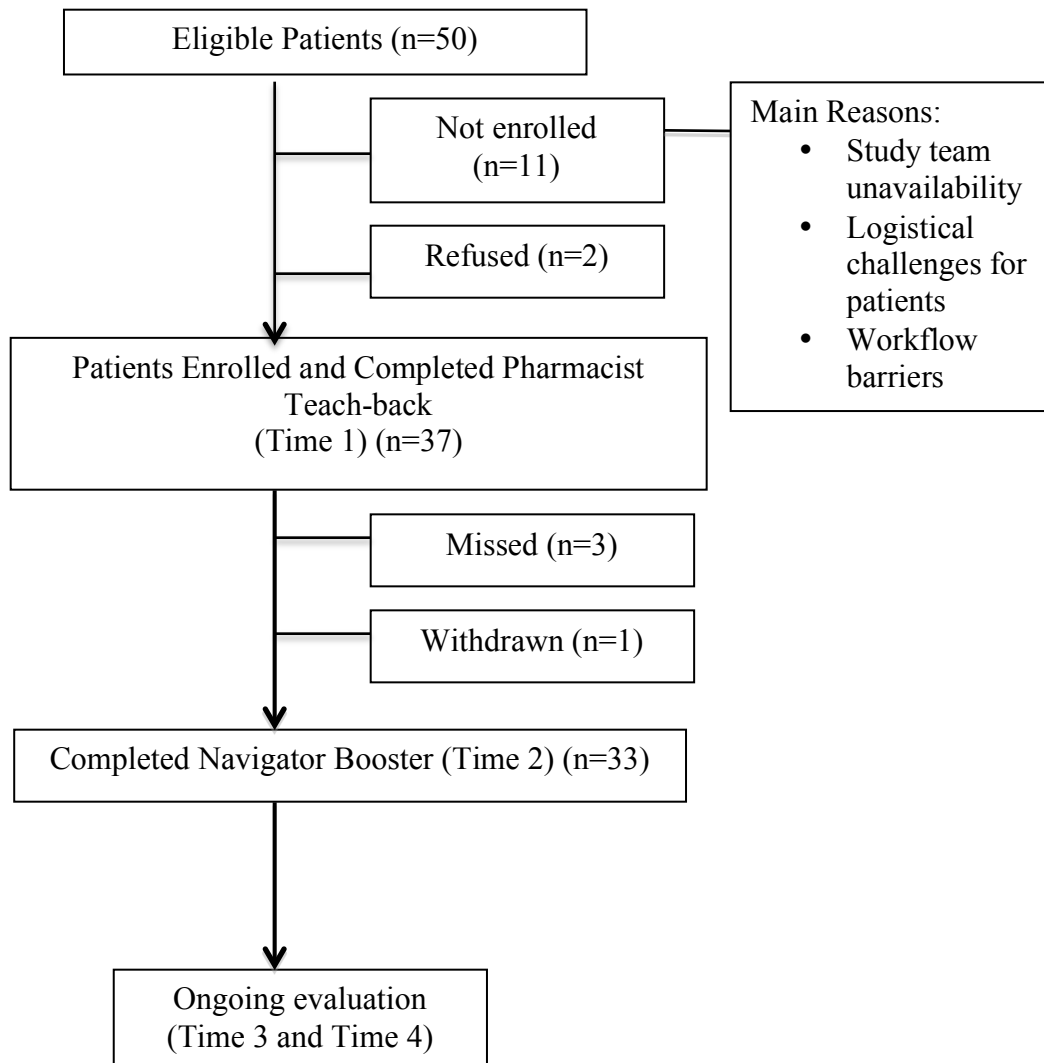


Figure 1: Study Enrollment and Completion.

Description of the Study Population

The descriptive variables of the study population are displayed in Table 2. Among the 37 patients enrolled, 51.3% were male, the median age was 65 years old and the interquartile range (quartile [Q] 3-Q1) was 17 years. While 62.2% self-identified as White, about a quarter of the patients were of Asian origin (27.0%). Of note, eight out of the 10 Asian patients spoke Chinese only, with limited to no proficiency in English. The

majority of the patients had completed some college (62.2%) and slightly over half of the patients (58.3%) had no paid employment at the time of the study. About half of the patients had some form of subsidized insurance (e.g. Medicare, Medicaid), and 86.5% of the patients reported that their insurance plans “Usually” or “Always” covered their healthcare services. When asked if whether their cancer care had caused any financial challenges for them or their families, 66.7% of the patients reported that they had not experienced any.

Disease characteristics are summarized on Table 2. Almost 60% of patients had hematologic cancers, while the remainder had solid tumors (40.5%). Among the diagnoses that could be staged using standard criteria, 63.6% were considered advanced stage (stage IV) cancers. The median number of years since their cancer diagnoses was 2.0. The purpose of the newly prescribed OAM was for second line treatment in oral (70.3%), such as in cases of cancer relapse or progression, rather than as first-line treatment (29.7%). Additionally, 64.9% had a chronic health condition requiring medication management with a median of two medications.

Table 2: Baseline Personal and Disease Characteristics.

Variable	Total Sample (n=37)
Female – no. (%)	18 (48.7)
Age – years (Q1, Q3)	
Median	65 (54, 71)
Race/ethnicity – no. (%)	
White	23 (62.2)
Asian	10 (27.0)
All other	4 (10.8)
Highest level of education – no. (%)	
Less than high school	8 (21.6)
High school graduate	6 (16.2)
Some college or higher	23 (62.2)
Employment – no. (%) *	
Paying job	15 (41.7)
No paying job	21 (58.3)
Insurance type – no. (%)	
Subsidized	18 (48.6)
Unsubsidized	19 (51.4)
Cancer type – no. (%)	
Solid tumor	15 (40.5)
Hematologic malignancy	22 (59.5)
Years since diagnosis – no.	
Median (Q1, Q3)	2.0 (0, 9)
Purpose of medication in management of current disease – no. (%)	
Frontline	11 (29.7)
Change of regimen	26 (70.3)
Any comorbidities requiring medication management – no. (%)	
Yes	24 (64.9)
No	13 (35.1)

*One patient did not respond to this question. Q, quartile. Q1,Q3 refers to the interquartile range (Q3-Q1).

Personnel Availability and Mode of Contact with Study Participants

Pharmacist and Medication Navigator attendance and how they contacted the patients were tracked at Time 1 and Time 2. During the initial education session (Time 1), ideally both the Pharmacist and Medication Navigator would be present for 100% of

the meetings. In actuality, 33 of the 37 patients (89.2%) met with both study team members present. The other 4 patients met with the Pharmacist only due to logistical or workflow reasons in the clinic. During the Navigator booster check-ins at Time 2, all patients met with the Navigator as per study design. The Navigator met with 22 patients (66.7%, n=37) in person and conducted the session over the phone with 11 patients (33.3%, n=33). All patients received study tools and where appropriate, received them in Chinese.

Assessing Patient Understanding of Medication Taking, Handling, and Refilling

At each teach-back session, the Pharmacist or Navigator asked the patients questions about how to take their OAM, how to handle/store them, and where to fill their prescriptions. Patients were encouraged to refer to their tools (Information Sheets and Medication Calendar) to answer the teach-back questions. The assessments of the patients' responses are displayed in Table 3. At Time 1, most study participants were able to name their OAM correctly either from memory (46.0%, n=37) or with the use of the Information Sheets and/or the Medication Calendar (51.3%, n=37). Similarly, at Time 2, 81.8% (n=33) of patients were able to recall the names of their medications. However, 18.2% of patients (n=33) could not remember the name or pronounce it correctly, or named it incorrectly.

At Time 1, when asked when the medication should be taken, 32 of the 37 patients (86.5%) were able to answer correctly and five patients (13.5%) answered it with the use of the tools. None of the patients answered incorrectly. At Time 2, 32 patients

(97.0%, n=33) were able to correctly describe when to take their medications. One patient was not asked this question because at the time of the check-in, the medication was on hold. Patients were also asked how they should take their OAM and specifically whether or not it should be taken with food. At Time 1, 94.6% of patients (n=37) answered correctly while 5.4% answered incorrectly. At Time 2, 97.0% of patients (n=33) answered correctly and no patients answered incorrectly. Like the previous question, the patient with the medication on hold was not asked this question per study design.

During the initial Pharmacist teach-back, 89.2% of the patients correctly described how to store the medication, 8.1% correctly answered upon referring to their tools, and 2.7% answered incorrectly (n=37). In comparison, during the Navigator booster check-in, all patients (excluding the one patient with the medication on hold) answered correctly.

Table 3: Patient Recall and Understanding of Medication Management.

Assessment Item	Pharmacist-Led Teach-back (Time 1) – no. (%) <i>N</i> =37	Navigator-Led Booster (Time 2) – no. (%) <i>N</i> =33
What is the name of the medication being taken? Correct Correct, with use of tools Incorrect	17 (46.0) 19 (51.3) 1 (2.7)	23 (69.7) 4 (12.1) 6 (18.2)
When should you take the medication? Correct Correct, with use of tools Incorrect Not applicable (medication on hold)	32 (86.5) 5 (13.5) 0 0	32 (97.0) 0 0 1 (3.0)
How should you take the medication (Does it matter if you take it with food or not?) Correct Correct, with use of tools Incorrect Not applicable (medication on hold)	35 (94.6) 0 2 (5.4) 0	32 (97.0) 0 0 1 (3.0)
How should you store the medication? (Where do you keep your medication?) Correct Correct, with use of tools Incorrect Not applicable (medication on hold)	33 (89.2) 3 (8.1) 1 (2.7) 0	32 (97) 0 0 1 (3.0)

Understanding the Extent of Patient Support

Patients were asked as part of the initial teaching session about their support system outside of the hospital in helping them manage their medications (Table 4). About 40% of patients (*n*=37) reported having someone at home to help them take their medications. Additionally, patients were asked during the teach-back about when and who to call if certain scenarios (e.g., side effects, issues with getting medications, health emergencies) came up. All patients were able to elaborate on at least one major scenario that was discussed during the teaching session, either from their memory or by referring

to their Information Sheets and/or Medication Calendars. Most patients (91.9%, n=37) were able to identify whom they should contact on their cancer care team for any problems or concerns.

To recognize the potential for questions or issues to occur in between hospital visits, patients were also asked during the Navigator booster if they had contacted anyone on their care team with concerns between Time 1 and Time 2 (Table 4). About two-thirds of the patients (n=33) reported that they did not have any issues that prompted them to reach out to their care teams. Those who did reach out to the care team had concerns such as side effects from the medication or missing doses. One patient contacted the care team about having difficulty swallowing, and the team helped arrange for him to take the medications in applesauce. Another patient actively reached out informing her oncologist that she accidentally took 2 pills of her oral chemotherapy instead of one.

Similarly, instances where the Pharmacist or the Navigator reached out to someone on the care team on behalf of the patients were also documented. During the initial Pharmacist teach-back session, the Pharmacist had reached out to another oncology provider regarding concerns shared by 12 patients (32.4%, n=37), and managed to help resolve any issues at the time of the check-in for 18 patients (48.7%, n=37). Some issues that arose from that initial session included navigating the prescription fill process, monthly copayments for the medication, concerns about medication tolerance, drug interactions with other prescribed medications (for symptom management), and difficulty with swallowing pills. In one example, at the initial meeting, the Pharmacist identified a discrepancy between the medication label instructions and the doses that were ordered.

He was able to promptly work with the patient's nurse practitioner and clarify the dosing schedule that was unique to the patient's treatment plan and that would be different from the standard instructions for that medication. He was then able to thoroughly explain this to the patient and clarify details of the treatment plan.

In comparison, during the Time 2 booster check-in, the Navigator ended up reaching out to the care team for issues brought forth by 20 patients (60.6%, n=33) and was able to address any concerns at the check-in for 6 patients (18.2%, n=33). Some examples of questions and concerns identified during the Navigator check-in were: symptoms and side effects, uncertainty over where to get refills, diet adjustments and taking nutritional supplements, logistics of upcoming clinic appointments, and overall questions about disease prognosis and the future treatment plan. The Navigator also encountered culturally sensitive issues raised by some Chinese-speaking patients. One Chinese-speaking patient was worried and hesitant to start her second treatment cycle around the Chinese Lunar New Year because it was considered "bad luck" (especially on the first day of the New Year) and also because she was experiencing some symptoms from the previous cycle. She had just told her care team of the latter concern, fearing that they would not understand the greater cultural relevance. The Navigator was able to discuss this with the Pharmacist and the care team and the patient and her team agreed upon a plan to resume treatment after the Chinese New Year.

Table 4: Medication Support and Help-seeking.

Assessment Item	Pharmacist-Led Teach-back (Time 1) – no. (%) <i>N=37</i>	Navigator-Led Booster (Time 2) – no. (%) <i>N=33</i>
Does anyone at home help you with any of your medication taking? Yes No	15 (40.5) 22 (59.5)	N/A
When should you call cancer care team (scenarios)? Recalled at least 1 major scenario Recalled at least 1 major scenario, with use of tools Unable to recall any scenarios	34 (91.9) 3 (8.1) 0	N/A
Who should you call for any problems? Able to identify Unable to identify	34 (91.9) 3 (8.1)	N/A
Has the patient contacted anyone with concerns since the first meeting with the Pharmacist and Navigator? Yes No	N/A	11 (33.3) 22 (66.7)
Did the Pharmacist/Navigator contact anyone on the care team at the time of the check-in? Yes No, issues resolved at check-in No issues raised	12 (32.4) 18 (48.7) 7 (18.9)	20 (60.6) 6 (18.2) 7 (21.2)

How Patients Perceived the Usefulness of the Study

At the end of Time 2, patients were invited to provide feedback on the two meetings with the Pharmacist and Navigator as well as the Medication Information Sheets and Medication Calendar provided to them at the beginning of the study. The results of the feedback variables are described in Table 5. Nearly all patients (90.9%, n=33) thought the initial meeting was “Very helpful” when they first received their oral chemotherapy medications. Most patients (94.0%, n=33) also found the subsequent check-in with the Navigator to be “Very helpful.”

Patients who used the tools were further asked about how frequently they used them and which parts of the tools they most often used. About 80% of patients reported that they used the Information Sheets. The section in the Information Sheets on potential side effects was most widely read. However, almost 20% of the patients did not use them at all. Some of these patients felt that they were quite complex and verbose, making it difficult to understand with the much of the medical jargon.

With regards to the Medication Calendar, about 70% of patients reported that they used it to remind them to take their medications. The remaining 30% of patients did not use the Calendar at all. Among these patients, some shared that they did not feel the Calendar was necessary due to the “simplicity” of their treatment (eg., take one pill a day in the morning) and therefore it was “easy to remember.” Other patients did not use it because they adapted the tool into their electronic calendars (eg., phone, computer). The feature of the Calendar that was most widely used was the checkboxes on each day to mark when the medication(s) were taken. Approximately a third of the patients also used the extra blank calendar that was provided to them to write down notes, questions, and any side effects they had experienced. When asked how helpful they found the Information Sheets and the Medication Calendar to be, 72.7% of patients thought the Information Sheets were “Very helpful” and 75.7% of patients found the Calendars to be “Very helpful” (n=33).

Table 5: Patient Acceptability and Feedback on Helpfulness of Intervention.

Patient-reported Feedback Variables	Evaluation (Time 2) – no. (%) N=33
Meeting with Specialty Pharmacist and Medication Navigator upon getting the medication Very helpful Somewhat helpful Not at all helpful	30 (90.9) 2 (6.1) 1 (3.0)
Check-in with Medication Navigator Very helpful Somewhat helpful Not at all helpful	31 (94.0) 1 (3.0) 1 (3.0)
How often did you use the Medication Drug Information Sheet(s)? Daily Weekly Other frequency Did not use	11 (33.3) 5 (15.2) 11 (33.3) 6 (18.2)
If you used the Information Sheet, which parts did you use? (Check all that apply) Side Effect Summary About Your Medication How to Take Your Medication What Foods and Drugs May Interact Important Precautions Who to Call with Questions Storage, Handling, and Disposal	23 (69.7) 19 (57.6) 17 (51.5) 17 (51.5) 16 (48.5) 16 (48.5) 15 (45.5)
How often did you use the Medication Calendar? Daily Weekly Other Did not use	13 (39.3) 5 (15.2) 5 (15.2) 10 (30.3)
If you used the Calendar, which parts did you use? (Check all that apply) Checkboxes to mark when medication was taken Blank calendar for notes Medication(s) listed Written dosage explanations	20 (60.6) 10 (30.3) 9 (27.3) 8 (24.2)

The Patients' Self-Reported Adherence

Table 6 presents the results of patients' self-reported adherence. Most patients reported that they did an "Excellent" job at taking their medications and "Always" took them the way they were supposed to. The majority of patients (87.9%, n=33) initiated their oral treatment on the planned day, whereas four experienced a delay due to prescription-related factors.

The Pharmacist also evaluated the free-text, written patient responses as part of the Adherence measure. Upon comparing their responses and the actual instructions for taking their respective medications, all 33 patients responded correctly. However, when patients were asked how often they were to fill their medications, 24.2% of them were unable to correctly answer. Patients were also asked where they would get their first refills for their medications. Of the 33 patients who attended the Navigator booster, nearly a quarter of them either did not know where to get their refills or answered incorrectly (e.g., provided a the name of the wrong pharmacy).

Table 6: Patient Self-reported Adherence.

Assessment Item	Navigator-Led Booster (Time 2) – no. (%) N=33
<i>Patient-Reported</i>	
Since you first started taking this medication, how good a job did you do at taking it in the way you were supposed to? Poor Fair Good Very good Excellent	0 1 (3.0) 4 (12.0) 10 (30.3) 18 (54.6)
Since you first started taking this medication, how often did you take it in the way you were supposed to? Rarely Sometimes Usually Almost always Always	0 0 2 (6.0) 3 (9.1) 28 (84.9)
<i>Pharmacist-Verified</i>	
When did you first start taking this medication? As planned/on the instructed day Experienced unintended delays	29 (87.9) 4 (12.1)
On days and weeks when you take this medication, how often are you supposed to take it? Correctly answered Incorrectly answered	33 (100) 0
How often are you supposed to fill this medication? Correctly answered Incorrectly answered	25 (75.8) 8 (24.2)
Where will you fill your prescription for Cycle 2? Correctly Incorrectly Patient unsure Not applicable (no plan in place)	22 (66.7) 1 (3.0) 7 (21.2) 3 (9.1)

DISCUSSION

Studies have highlighted the striking gaps in adherence and understanding among patients taking oral medications, including OAM. A variety of interventions have been implemented with the goal of reducing rates of non-adherence, while improving patients' knowledge of managing their medications. We sought to extend the capacities of oncology teams and improve the support for patients on OAM through a Pharmacist- and Medication Navigator-led intervention.

The Feasibility and Scalability of the Intervention

One goal of this analysis was to determine if patients who were starting on OAM could be provided with teaching sessions, regular check-ins, and patient tools (Information Sheets and Calendar), and whether or not these could be carried out by the Pharmacist and Medication Navigator in a timely fashion relative to the initiation of the OAM. A metric used to determine this was whether the Pharmacist was available to lead the initial teach-back session when the patients were starting treatment. While the Pharmacist was able to meet with the majority of the patients (78%), our results indicate the need to further address logistical barriers in terms of capacity and workflow. Effective communication between the clinical providers and the Pharmacist in identifying potential starts on OAM ahead of time could allow more time to plan for the teaching session and to prepare the Information Sheets and Medication Calendars that are personalized for each patient. Another strategy could be to more systematically introduce hand-off between the provider and the Pharmacist-Navigator and initiate the first educational

session as a planned, sequential visit after the patient's clinic visit. This could also further integrate this initiative into routine clinical care. Alternatively, to address logistical challenges for patients to physically attend the in-person visits, conducting the initial teach-back through other communication methods such as online video or by phone could be explored. This could be potentially helpful for patients who live in remote geographical areas or face other challenges for them to travel to the hospital.

The Medication Navigator was also quite successful in contacting patients for their booster check-ins approximately a week after starting treatment. In-person meetings at the hospital and phone calls appeared to both be plausible ways to reach patients for their check-ins. This suggests that there is flexibility in checking in with patients through different channels of communication without necessarily compromising the content of the check-ins.

Medication Calendars were also created for every patient enrolled in the study, each personalized to the patient's individual medications and treatment plan. The incorporation of this tool into this intervention and the ability to also provide translated versions for all Chinese-speaking patients indicates that it is possible to extend this to all other (non-English speaking) patients in the future.

The Impact of the Intervention on Patient Understanding

Patients who met with the Pharmacist and Navigator the initial education and teach-back session showed sufficient understanding of taking and handling their OAM. During the teach-back, the Pharmacist and Navigator emphasized to the patients that the

teach-back questions were not a memory assessment, but rather a way to improve how the care team can enhance patients' knowledge through direct instruction and use of prepared tools. Furthermore, having the Medication Navigator check-in at a periodic interval served as a helpful way to boost or reinforce patients' understanding.

Patients retained much of the same information about medication taking and handling about a week after they started, although some patients had difficulty remembering (or alternatively, pronouncing) the names of their medications. The high rate of retention suggests that the in-person education sessions and teach-helped the patients recall and retain the information shared with them longer term, and/or that the patients were more familiarized with the tools and more primed to use them at their disposal. Additionally, it supports current literature by illustrating that adherence to medications can be closely correlated with how well the patients know how to take and manage them, and best if augmented with routine follow-up.

These results further reflect what existing literature has shown in that interventions consisting multiple check-ins over a period of time and including a combination of different approaches were more successful in promoting patient understanding and adherence to their medications. What this study adds is that there can be substantial benefit to not only checking-in with patients to remind them to take their OAM, but also repeatedly assess and strengthen their knowledge by using educational teach-back and weaving supportive tools like the Calendar and Information Sheets into these sessions. This could further engage patients into their care and empower them in their self-management. However, while this intervention has strived to enhance patient

understanding around medication taking and handling, more efforts need to be made in clarifying confusion around the logistics of filling/refilling the medications.

Timely Identification and Resolution of Issues

We found that patients on OAM identified a variety of issues while taking them, and that the planned check-ins with the Pharmacist and/or Navigator created opportunities to address them. First, the range of issues related to OAM was striking from logistical to clinical. Second, often times these issues were identified by the Pharmacist and/or Navigator at the time of the check-ins, suggesting that these may not have been brought to the oncology teams' attention yet. Also, there were more occasions where the Navigator contacted the care team on the patients' behalf than the Pharmacist, which may suggest several reasons. First, it could have been that there were more issues raised after the patients started on treatment. Second, it could have been that some of the issues required the extra clinical expertise of the Pharmacist and other providers to be resolved. And third, perhaps having access to the Pharmacist during the check-in could have mitigated the need to go straight to the care team.

That the Pharmacist and Navigator contacted the care team from 32.4% of the initial sessions and 60.6% of the booster check-ins regarding many issues (which were often at the time of scheduled clinic visits or in between them) illustrates the potential for this intervention to be a safety net for patients and to address their issues in a timely manner. This could especially be helpful for patients with more advanced disease and/or burdened with other comorbidities, and who may require more care. Furthermore,

regularly checking in and interacting with patients fosters rapport between the patients and the Pharmacist and Navigator. This allows the patients to feel supported and perhaps more inclined to share their concerns. Effective teamwork and rapport between the Navigator and Pharmacist also increases efficiency in identifying and resolving patient issues.

Analysis on the Usefulness of the Planned Check-Ins and Educational Tools

Patients largely responded positively towards the scheduled check-ins with the Pharmacist and Navigator, indicating a significant level of buy-in. Several reasons could have explained their high degree of acceptability of the intervention. First, the check-ins may have served as times when information about their OAM could be explained in detail, and any questions and confusion the patients might have had could be addressed. This could be especially useful if patients had lingering concerns that were not addressed during their clinic visits with their oncologists, especially if time is limited. Second, the patients may have considered the Pharmacist and Navigator as additional sources of support. They may have viewed them as providers they can go to if they feel they cannot contact their primary oncology team or if they feel that their questions were more specific to their medications. And finally, patients may have simply appreciated the constant, sustained support through these check-ins. As more responsibility was placed on them in managing their treatments outside the hospital setting, they may have felt more reassured that they knew whom to contact and when to contact them if they had any issues, seeking guidance instead of trying to navigate these concerns on their own.

Patients also viewed the Information Sheets and Medication Calendars as being helpful, although these tools were not used by all patients. Among the users, patients appeared to have incorporated them into their own care management. It illustrates that rather than simply providing these informational tools for patients, actively using them as aids and as part of the educational initiative itself can help patients better understand their utility and encourage them to refer to them at home as needed.

Limitations of the Study

This study had some limitations. The teach-back in the study asked patients how they took their medications, but did not confirm that they had taken them at the right frequency (daily and weekly) and the correct dosage. This should be considered in future study design since it could be significant for patients with complex dosing schedules and to identify more specific gaps in understanding or adherence. Other intervention studies and clinical trials have also included the use of electronic monitoring devices (e.g. the MEMS caps system) for real-time tracking of pill-taking, and this can be considered in future study. Alternatively, pill counts can be taken at each check-in to see if the patients are taking the right amount of medications based on the initial dosage dispense. The intervention should also be expanded to a greater sample of patients, including a larger number of Chinese-speaking patients, to further assess the feasibility of conducting the check-ins and delivering language-congruent tools in this and other vulnerable populations. As part of this assessment, it could also be worth systematically documenting the length of each check-in or visit with the Pharmacist and/or Navigator,

and instances where the patient has interacted with either team member in between the check-ins. This could further assess workflow requirements and patient/system level burden. Adherence was assessed based on patient self-reports. While these were obtained with a validated measure, the patients' actual adherence rates might have still been misconstrued and overrated.

Conclusion and Considerations for Future Research

This ongoing Pharmacist- and Medication Navigator-led initiative to educate patients on their OAM and improve adherence has shown promising results to date. It has been feasible to operationalize, effective in enhancing patient understanding, and useful in providing continual support for patients. It also offers some insights into implications for future work.

First, how well patients retain their understanding on their OAM over a longer period of time should be investigated. Results gathered from Time 3 and Time 4, check-ins planned during the Cycle 2 of treatment, may give information on long-term recall. Additionally, different questions and challenges might arise, and it could be interesting to explore these themes as well as how the intervention might adapt to those.

Second, it may be important to acknowledge the role caregivers may play in helping patients managing their oral medications. This may especially be helpful for patients who have complex treatment regimens alongside other medications to manage chronic conditions or symptoms. Caregivers could be invited to attend these check-ins

and teach-back sessions with the patients so that they could be adequately informed as well.

While this intervention aimed to improve understanding and adherence to medications through an educational and support initiative, the mechanisms for how patients may or may not achieve this can be further explored. One aspect that can be studied is the team dynamics between the Pharmacist and Navigator and the duo with the oncology clinic team, and how they may facilitate this process. Another theoretical pathway to evaluate is to what extent patient's self-activation and emotional functioning can be factors in improving adherence and outcomes, which have been illustrated in other chronic conditions, such as diabetes (Shigaki et al. 2010) and cardiovascular conditions (Donald et al. 2011). It is possible that regular check-ins and the usage of tools, as forms of support, can enhance patients' self-efficacy in managing their medications. Approaching the issues and barriers to OAM adherence through a multifaceted and multidisciplinary framework can offer new insight on designing future interventions to improve care delivery.

REFERENCES

1. Al-Barrak, J. & Cheung, W.Y. “Adherence to imatinib therapy in gastrointestinal stromal tumors and chronic myeloid leukemia.” *Supportive Care in Cancer* (2013) 21: 2351. <https://doi-org.ezproxy.bu.edu/10.1007/s00520-013-1831-6>
2. Berry, Donna L., et al. “Improving Patient Knowledge of Discharge Medications in an Oncology Setting.” *Clinical Journal of Oncology Nursing*, vol. 18, no. 1, 2014, pp. 35–37., doi:10.1188/14.cjon.35-37.
3. Bhatia, S., et al. “6MP Adherence in a Multiracial Cohort of Children with Acute Lymphoblastic Leukemia: a Children's Oncology Group Study.” *Blood*, vol. 124, no. 15, 2014, pp. 2345–2353., doi:10.1182/blood-2014-01-552166.
4. Bhatia, S., et al. “Nonadherence to Oral Mercaptopurine and Risk of Relapse in Hispanic and Non-Hispanic White Children With Acute Lymphoblastic Leukemia: A Report From the Children's Oncology Group.” *Journal of Clinical Oncology*, vol. 30, no. 17, 2012, pp. 2094–2101., doi:10.1200/jco.2011.38.9924.
5. Castaldi M, Safadjou S, Elrafei T, Mcnelis J. A Multidisciplinary Patient Navigation Program Improves Compliance With Adjuvant Breast Cancer Therapy in a Public Hospital. *American Journal of Medical Quality*. 2016;32(4):406-413. doi:10.1177/1062860616656250.
6. Charlson, Mary E., et al. “A New Method of Classifying Prognostic Comorbidity in Longitudinal Studies: Development and Validation.” *Journal of Chronic Diseases*, vol. 40, no. 5, 1987, pp. 373–383., doi:10.1016/0021-9681(87)90171-8.
7. Chopade, Pradnya, and Luke P. Akard. “Improving Outcomes in Chronic Myeloid Leukemia Over Time in the Era of Tyrosine Kinase Inhibitors.” *Clinical Lymphoma Myeloma and Leukemia*, vol. 18, no. 11, 2018, pp. 710–723., doi:10.1016/j.clml.2018.06.029.
8. Cleeland, Charles S., et al. “Assessing Symptom Distress in Cancer Patients: the M.D. Anderson Symptom Inventory.” *Cancer*, vol. 89, no. 7, 1 Oct. 2000, pp. 1634–1646., doi:10.1002/1097-0142(20001001)89:73.0.co;2-v.
9. Donald, Maria, et al. “The Role of Patient Activation in Frequent Attendance at Primary Care: A Population-Based Study of People with Chronic Disease.” *Patient Education and Counseling*, vol. 83, no. 2, 2011, pp. 217–221., doi:10.1016/j.pec.2010.05.031.

10. Foulon, V et al. "Patient Adherence to Oral Anticancer Drugs: An Emerging Issue in Modern Oncology." *Acta Clinica Belgica*, 2011, pp. 85–96., doi:10.2143/ACB.66.2.2062525.
11. Greer JA, Amoyal N, Nisotel L, et al. A Systematic Review of Adherence to Oral Antineoplastic Therapies. *The Oncologist*. 2016;21(3):354-376. doi:10.1634/theoncologist.2015-0405.
12. Hershman, Dawn L., et al. "Early Discontinuation and Non-Adherence to Adjuvant Hormonal Therapy Are Associated with Increased Mortality in Women with Breast Cancer." *Breast Cancer Research and Treatment*, vol. 126, no. 2, 2010, pp. 529–537., doi:10.1007/s10549-010-1132-4.
13. IMS Institute for Healthcare Informatics. *Global Oncology Trend Report: A Review of 2015 and Outlook to 2020*; IMS Institute for Healthcare Informatics: Parsippany, NY, USA, 2016
14. Kav, Sultan, et al. "Role of the Nurse in Patient Education and Follow-up of People Receiving Oral Chemotherapy Treatment: an International Survey." *Supportive Care in Cancer*, vol. 16, no. 9, 2008, pp. 1075–1083., doi:10.1007/s00520-007-0377-x.
15. Kav, Sultan, and Lisa Schulmeister. "Development of the MASCC Teaching Tool for Patients Receiving Oral Agents for Cancer." *Supportive Care in Cancer*, vol. 18, no. 5, 10 June 2009, pp. 583–590., doi:https://doi.org/10.1007/s00520-009-0692-5.
16. Lee, Jeannie K., et al. "Effect of a Pharmacy Care Program on Medication Adherence and Persistence, Blood Pressure, and Low-Density Lipoprotein Cholesterol." *JAMA*, vol. 296, no. 21, 2006, p. 2563., doi:10.1001/jama.296.21.joc60162.
17. Mancini, Robert, and Dave Wilson. "A Pharmacist-Managed Oral Chemotherapy Program." *Oncology Issues*, vol. 27, no. 1, 2012, pp. 28–31., doi:10.1080/10463356.2012.11883635.
18. McCue DA, Lohr LK, Pick AM. Improving Adherence to Oral Cancer Therapy in Clinical Practice. *Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy*. 2014;34(5):481-494. doi:10.1002/phar.1399.
19. Muluneh, Benyam, et al. "Improved Adherence Rates and Clinical Outcomes of an Integrated, Closed-Loop, Pharmacist-Led Oral Chemotherapy Management Program." *Journal of Oncology Practice*, vol. 14, no. 6, 2018, doi:10.1200/jop.17.00039.

20. Osterberg L, Blaschke T. “Adherence to Medication.” *New England Journal of Medicine*. 2005;353(5):487-497. doi:10.1056/nejmra050100.
21. Ruddy K, Mayer E, Partridge A. Patient adherence and persistence with oral anticancer treatment. *CA: A Cancer Journal for Clinicians*. 2009;59(1):56-66. doi:10.3322/caac.20004.
22. Schneider, Susan M, et al. “A Tailored Nurse Coaching Intervention for Oral Chemotherapy Adherence.” *Journal of the Advanced Practitioner in Oncology*, vol. 5, no. 3, 2014, doi:10.6004/jadpro.2014.5.3.2.
23. Schoenthaler, Antoinette, et al. “Addressing the Social Needs of Hypertensive Patients.” *Circulation: Cardiovascular Quality and Outcomes*, vol. 10, no. 9, 2017, doi:10.1161/circoutcomes.117.003659.
24. Shigaki, Cheryl, et al. “Motivation and Diabetes Self-Management.” *Chronic Illness*, vol. 6, no. 3, 2010, pp. 202–214., doi:10.1177/1742395310375630.
25. Noone AM, Howlader N, Krapcho M, Miller D, Brest A, Yu M, Ruhl J, Tatalovich Z, Mariotto A, Lewis DR, Chen HS, Feuer EJ, Cronin KA (eds). SEER Cancer Statistics Review, 1975-2015, National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/csr/1975_2015/, based on November 2017 SEER data submission, posted to the SEER web site, April 2018.
26. Stanton-Robinson, Chayla, et al. “Evaluation of Community Pharmacist–Provided Telephone Interventions to Improve Adherence to Hypertension and Diabetes Medications.” *Journal of the American Pharmacists Association*, vol. 58, no. 4, 2018, doi:10.1016/j.japh.2018.04.030.
27. Wilson, Ira B., et al. “Validation of a New Three-Item Self-Report Measure for Medication Adherence.” *AIDS and Behavior*, vol. 20, no. 11, 2016, pp. 2700–2708., doi:10.1007/s10461-016-1406-x.
28. Verma, Amol A., et al. “Fixed-Dose Combination Antihypertensive Medications, Adherence, and Clinical Outcomes: A Population-Based Retrospective Cohort Study.” *PLOS Medicine*, vol. 15, no. 6, 2018, doi:10.1371/journal.pmed.1002584.
29. Zerillo JA, Goldenberg BA, Kotecha RR, Tewari AK, Jacobson JO, Krzyzanowska MK. Interventions to Improve Oral Chemotherapy Safety and Quality. *JAMA Oncology*. 2018;4(1):105. doi:10.1001/jamaoncol.2017.0625.

CURRICULUM VITAE

