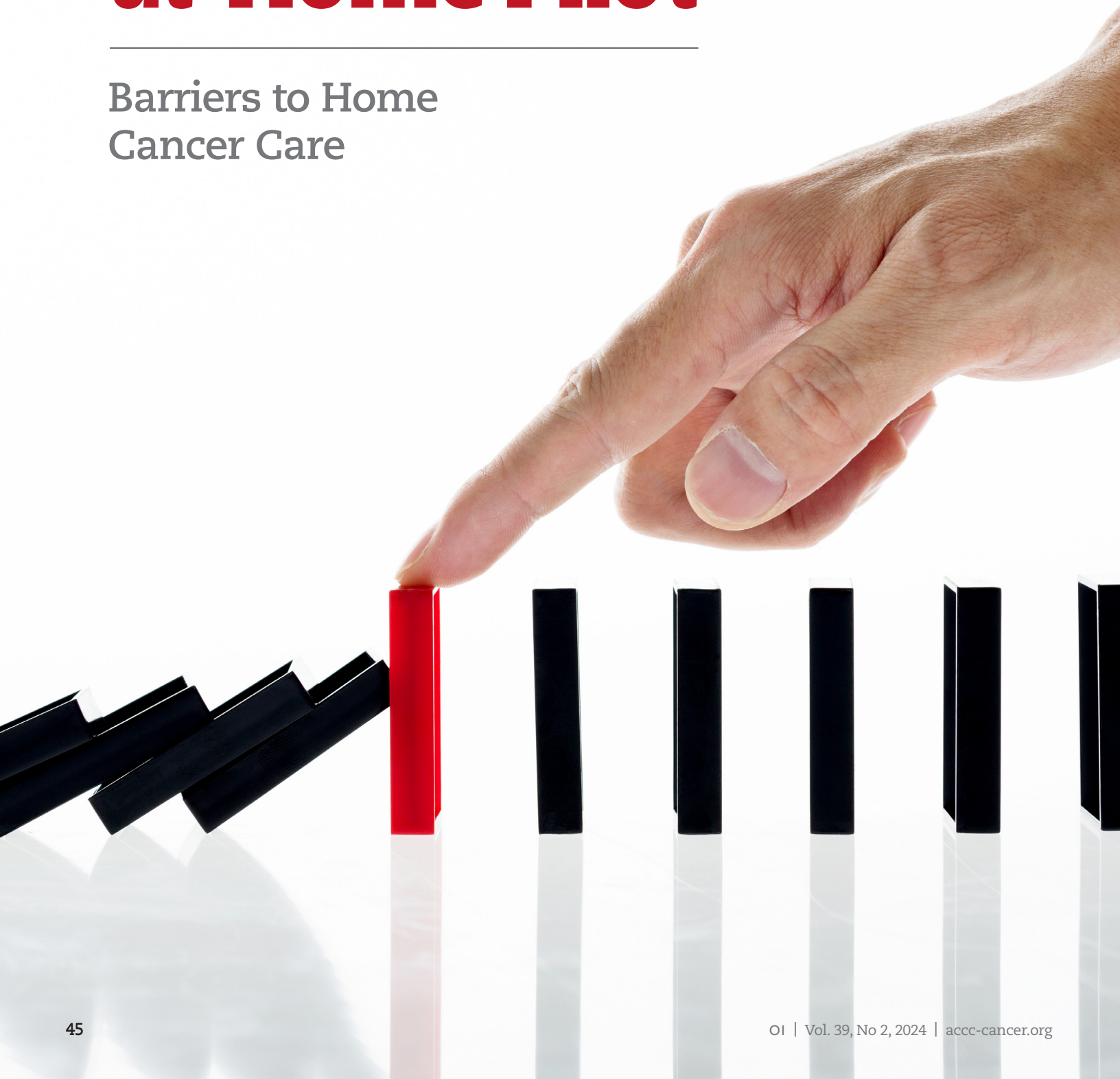


A Treatment-at-Home Pilot

Barriers to Home
Cancer Care



In Brief

During the COVID-19 public health emergency, patients with cancer faced significant challenges presenting for their in-clinic visits. In-home administration of intramuscular and subcutaneous therapies provided an opportunity to deliver antineoplastic therapy while lowering infection risk. This quality improvement study of adult patients with neuroendocrine and breast cancers at Memorial Sloan Kettering Cancer Center was conducted from February 16, 2022, to October 14, 2022, and involved nurses delivering outpatient pharmacy-dispensed in-home intramuscular or subcutaneous treatments. The study concluded that while home administration of antineoplastic therapies was safe and patient-centric, administrative barriers—primarily pharmacy benefit denial—prevented the study from achieving its primary end point. As cancer care evolves, there should be a focus on regulatory changes that minimize financial and time toxicity and allow for patient convenience.

At the start of the COVID-19 pandemic, patients with cancer were particularly vulnerable to COVID-19, as evidenced by their high rates of hospitalization and death.¹ Cancer programs and practices that administered antineoplastic therapies in the home were embraced and accelerated to lower risk and offset health care demands. The Centers for Medicare & Medicaid Services (CMS) released provisions that enabled providers to deliver care in the safest, most appropriate setting, allowing in-home pilots;² in-home delivery of antineoplastic therapy was considered safe and patient satisfaction was high.³ Many pilots occurred at large health systems that already had in-home nursing or infusion service lines.^{3,4} The feasibility, safety, and patient satisfaction for institutions implementing these programs without preexisting home services was unknown.

Patients with breast and neuroendocrine malignancies receiving subcutaneous or intramuscular therapies are an ideal population to test in-home care delivery, as therapies are administered repeatedly over extended periods, patients are generally well, and therapies have favorable safety profiles. Therefore, we hypothesized that this patient cohort could benefit from an in-home care delivery program.

Method

This feasibility study received a waiver of review and informed consent from the Memorial Sloan Kettering Cancer Center (Memorial Sloan Kettering) institutional review board because it was a quality improvement study. This study is reported following the Revised Standards

Insurance approval was the main barrier to in-home visits for 57% of visits where the patient had agreed to participate.

for Quality Improvement Reporting Excellence (SQUIRE 2.0) reporting guideline.

Program Description

The vision of the program was to test the safety and satisfaction of using Memorial Sloan Kettering expert oncology nursing care in the home to reduce travel for our vulnerable patients during the COVID-19 pandemic. A multistakeholder team comprised of nurses, physicians, pharmacists, informaticians, and administrators was convened to develop the program, including a workflow (Figure 1) and a security screening form (Figure 2). Permission was sought and received from the New York State Department of Health during the public health emergency to provide this service as a hospital under its existing license.

Pharmacy

Prescriptions were filled by Memorial Sloan Kettering retail pharmacy. External pharmacies were beyond the scope of this pilot.

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Figure 1. Treatment-at-Home Workflow

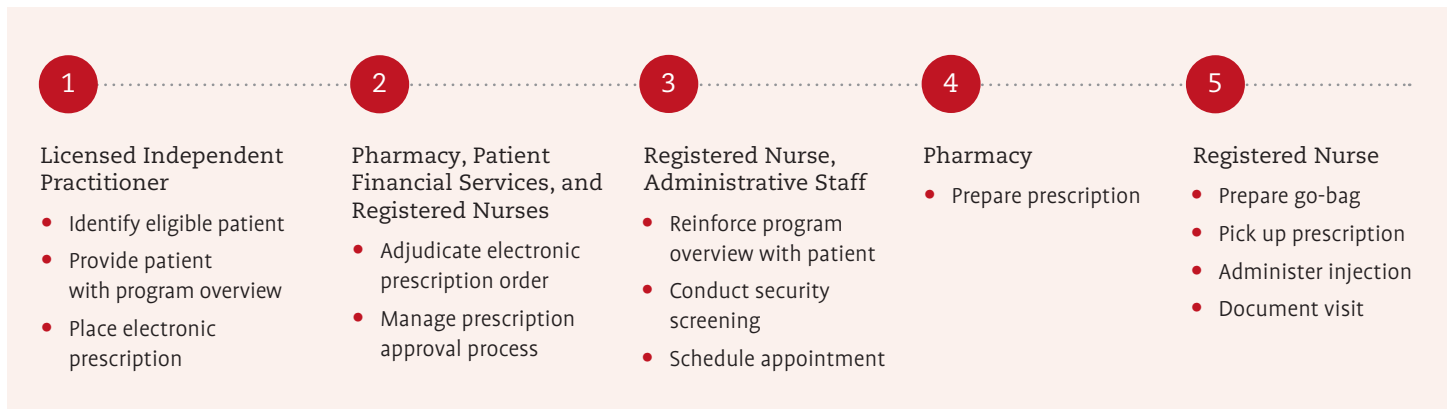


Figure 2. Security Screening Form

Patient name:					
MRN:					
Date of visit:					
Reason for visit:					
HIGH RISK	YES	NO	DON'T KNOW		
1. Is there a potential for violence or aggression in the home (ie, active order of protection, police called to the home, domestic violence, sexual abuse, violence and/or aggression with service providers, etc)?				<ul style="list-style-type: none"> • If Yes, consult with a manager to develop a safety plan (ie, buddy system, police escort, etc). • If Don't Know, carry a cell phone, consult with staff who know the family, or consult with a manager. • Reminder: complete the Sign-In/Sign-Out Sheet before conducting the visit. 	
2. Is there a history of weapon-related incidents?					
MODERATE RISK	YES	NO	DON'T KNOW		
3. Has the client or client's family been verbally abusive to service providers?				<ul style="list-style-type: none"> • If Yes to more than one of the questions in this category, consult with a manager to discuss safety precautions. • If there are false allegations from this client about service providers, consult with a manager to discuss safety precautions. • If there are dangerous animals on the property, request an office visit with the client (if possible) or request that the client restrain the animal. If the client refuses to restrain the animal, leave the home. • If Don't Know, carry a cell phone, consult with staff who know the family, or consult with a manager. • Reminder: complete the Sign-in/Sign-Out Sheet before conducting the visit. 	
4. Are there any illnesses/conditions that might affect client's behavior (eg, dementia, psychosis, brain trauma, etc)?					
5. Is there a history of drug or alcohol abuse in the home?					
6. Have there been false allegations from this client about service providers?					
7. Is the cell phone service inadequate?					
8. Is the home located in an area that one might consider dangerous?					
9. Are there dangerous animals on the property?					
LOW RISK	YES	NO	DON'T KNOW		
10. Is the home in an area that is physically isolated from other homes?					<ul style="list-style-type: none"> • If Yes, take the necessary safety precautions before conducting the visit.
11. Are there any factors affecting access to the home (eg, lighting, broken stairs, parking, etc)?				<ul style="list-style-type: none"> • Reminder: complete the Sign-In/Sign-Out Sheet before conducting the visit. 	

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Patient Cohort

Adults with breast and neuroendocrine tumors receiving octreotide, lanreotide, denosumab, fulvestrant, or leuprolide acetate living within 30 minutes of the Memorial Sloan Kettering Manhattan campus were included. We chose a 30-minute radius because Memorial Sloan Kettering registered nurses (RNs) who were deployed also had on-site responsibilities.

Care Delivery

Patients seek care at National Cancer Institute (NCI)-designated comprehensive cancer centers for the clinical expertise and experience of the multidisciplinary team. We maintained that expertise in the home by employing Memorial Sloan Kettering nurses (n=9). An evidence-based nursing standard of care was developed to support in-home nursing practice; it provided guidelines for nursing assessment, interventions, education, environmental safety, and documentation (Figure 3). We measured the amount of time the RN spent providing care, including travel, and administered an environmental and physical safety survey after each visit.

Feasibility

The study was conducted from February 16, 2022, to October 14, 2022, with a goal of converting 40 in-clinic administrations to home administrations. This threshold was determined by the multistakeholder group to represent the minimum number of visits to have an adequate understanding of home administration before making a consideration of scale.

Safety

Safety was evaluated by both patient- and provider-reported adverse events following at-home administration.

Patient Satisfaction

Patients were surveyed via telephone or electronic form after each home visit using a 5-point Likert scale to gauge patient experience. The survey was developed in collaboration with the Patient and Caregiver Engagement department, who have expertise in health literacy and question design. A net promoter score was calculated based on responses to the statement, “I would recommend receiving treatment at home to other patients like me.” The percentage of respondents who disagreed or strongly disagreed (detractors) with this statement was subtracted from those who agreed or strongly agreed (promoters). The net promoter score has been used by a variety of companies and organizations both inside and outside of health care to assess customer satisfaction.^{5,6} Based on other health care delivery studies, our goal net promoter score was 0.7. We also estimated time and cost savings to patients.

Results

Feasibility

Fifty-four eligible visits for 32 patients were identified (Table 1). For most visits, patients and providers were agreeable to home treatment (56% [30/54]). Thirty-eight percent of patients declined

to participate. Reasons patients declined are included in Table 2; the primary reason was that patients preferred to be on-site for their treatment (36% [4/11]). Representative patient quotes are below:

- “I like crossing town on the bus and visiting [the] clinic. I am 86 years old, and it gives me an excuse to get out of my house. Also, I haven’t vacuumed, and my house is dirty, so I was embarrassed.”
- “I was used to going to get the injections. I like that it’s on his calendar and [I] walk down for the day—it’s programmed. If they were to come to the house, it might be interruptive, and they are coming into ‘my personal space’ where the medical treatment wasn’t part of it.”
- “I thought about it and just thought my care and injections should be in the clinic and not in my personal space in the home.”

One hundred percent of post-home-visit respondents would recommend the program to others and agreed that it made the most of their time.

Insurance approval was the main barrier to in-home visits for 57% of visits where the patient had agreed to participate. For all orders, take-home prescriptions were initially rejected by patient’s pharmacy benefits, mainly due to plan-exclusion of the drug on their formulary; most required an appeal with a letter of medical necessity. Six patients in 11 visits had their take-home prescriptions covered after subsequent prior authorization was reviewed: 5 patients on octreotide and 1 patient on denosumab. For 2 visits, prescriptions were subsequently covered after prior authorization but did not meet our inclusion criteria due to a mandate of a specific external specialty pharmacy process.

Safety

All patients on this pilot were stratified to the low-risk category during the home safety screening. No adverse events were reported by patients or nurses for any completed visit.

Patient Satisfaction

One hundred percent of post-home-visit respondents (n = 11 responses) would recommend the program to others and agreed that it made the most of their time (Figure 4).

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Figure 3. Nursing Standard of Care Document

	ASSESSMENT	NURSING INTERVENTION	PATIENT & CAREGIVER EDUCATION	ENVIRONMENTAL SAFETY	DOCUMENTATION
	<p>Reviews patient history including allergies, contact precautions, and active orders for care in the home.</p> <p>Assesses last received dose of the medication to ensure timing is appropriate for dose administration.</p> <p>Assesses whether there have been any changes in the patient’s wellness or new problems since last being seen by a clinician.</p>	<p>Calls patient to review patient and caregiver education, home preparation, and conduct security screening.</p> <p>Conducts security screening survey. “As part of the eligibility criteria and Memorial Sloan Kettering security recommendations, we will ask a few screening questions about the safety in your home.”</p> <p>Sends completed security screening survey to security for review (24 hours before appointment).</p> <p>Charges batteries for laptop, MiFi, and cell phone.</p>	<p>Educates patient on:</p> <ul style="list-style-type: none"> • Need for a private space for medication administration. • Need for a clean surface space for medication preparation (table, counter, etc). • Securing all pets prior to arrival of RN. • Time window to expect RN arrival. • Need to report if anyone in the home becomes ill. • Medications ordered for home administration and anticipated adverse effects. 	<p>Verifies with patient that no one in the home has an active communicable disease (eg, flu, COVID-19).</p> <p>Informs patient there are 2 Memorial Sloan Kettering employees coming to the visit.</p> <p>Requests area to set up (not in kitchen) and access to faucet for hand washing.</p> <p>Requests that pet(s) be secured.</p>	<p>Telephone/electronic communication note.</p> <p>Include the security screening survey responses in the note.</p>
	<p>Assesses that no changes have been made to the patient’s active orders prior to departing for the patient’s home.</p> <p>Verifies content of Tx@ Home Go-Bag includes:</p> <ul style="list-style-type: none"> • Cell phone • Gloves • Yellow gown • Alcohol swabs • Wipes • Chucks pads (waterproof disposable underpads) • Sharps container • Resealable (eg, vial) • Primapore (wound dressing) • Gauze • Booties • Laptop • MiFi 	<p>Obtains the Tx@Home Go-Bag from the NL office on site.</p> <p>Obtains drug(s) from the retail pharmacy (M-F 9:00 to 5:45) in an insulated bag with ice pack.</p> <p>Provides handoff to coverage for ongoing clinical responsibilities during home visit.</p> <p>Documents time leaving Memorial Sloan Kettering.</p>	<p>Ask administration to print:</p> <ul style="list-style-type: none"> • Downtime form with patient’s name and address. • Home medication list. • Patient education material: <ul style="list-style-type: none"> - Preventing Falls Care Plan. - Patient Education: What you can do to avoid falling. - Patient Education: How to choose safe shoes to prevent falling. 	<p>Reviews patient history including allergies, contact precautions, and active orders for care in the home.</p> <p>Assesses last received dose of the medication to ensure timing is appropriate for dose administration.</p> <p>Assesses whether there have been any changes in the patient’s wellness or new problems since last being seen by a clinician.</p>	

(Table continued on next page)

Figure 3. Nursing Standard of Care Document (continued)

	ASSESSMENT	NURSING INTERVENTION	PATIENT & CAREGIVER EDUCATION	ENVIRONMENTAL SAFETY	DOCUMENTATION
Upon Arrival to the Home	<p>Completes patient identification following Memorial Sloan Kettering policy.</p> <p>Completes a rapid visual assessment of the environment for any safety concerns such as:</p> <ul style="list-style-type: none"> • Loose rugs • Small furniture • Clutter • Electrical cords • Poor lighting 	<p>Verifies the strength of hotspot connectivity and connects Memorial Sloan Kettering laptop.</p> <p>Removes medication from the insulated bag to come to room temperature while doing patient assessment.</p>	<p>Reinforces education that was provided in advance via phone.</p> <p>Educates patient and caregiver on the anticipated plan of care for the visit.</p>	<p>Ensures patient has secured all pets before entering the home.</p>	
Care Delivery in the Home Setting	<p>Completes a nursing assessment note.</p> <p>Assesses if there have been any changes in the patient's wellness or new problems since the patient was last seen by a clinician.</p> <p>Assesses the patient's understanding of plan of care and medication(s) to be administered.</p> <p>Conducts medication reconciliation.</p>	<p>If unable to successfully connect to Memorial Sloan Kettering hotspot, follows downtime procedures.</p> <p>Completes medication preparation and administration following standard Memorial Sloan Kettering policy.</p> <p>Escalates unexpected assessment findings to ordering licensed independent provider prior to medication administration.</p>	<p>Educates patients on medications ordered for the day and provides the patient with an opportunity to ask questions.</p> <p>Reinforces adverse effects related to the drug(s).</p> <p>Provides patient education materials on falls prevention:</p> <ul style="list-style-type: none"> • Falls • Safety 	<p>Prepares the environment for medication administration by wiping down the table and/or surface with a PDI wipe before medication preparation.</p> <p>Secures sharps after medication administration in sharps container.</p> <p>Places vial in Ziploc bag to return to Memorial Sloan Kettering.</p> <p>Disposes of all non-sharps garbage before departure.</p>	<p>Nursing Encounter, Outpatient: Medical Oncology</p> <p>Patient Education Documentation Form System: Safety Learning Needs</p>
Visit completion	<p>Assesses patient tolerability of medication administration prior to leaving the home.</p>	<p>If downtime procedures were followed in the home, documents it in the medical record upon return to Memorial Sloan Kettering.</p> <p>If full, disposes of sharps container with Memorial Sloan Kettering facilities department and obtains a new one for the Tx@Home Go-Bag.</p> <p>Restocks Tx@Home Go-Bag supplies and returns the bag.</p> <p>Emails NL/scheduler to document the time spent for the visit away from Memorial Sloan Kettering.</p>	<p>Educates patient on how and when to contact the office for any new symptoms or adverse effects.</p> <p>Informs patient that they may receive a satisfaction survey on the experience via their Memorial Sloan Kettering patient portal.</p>	<p>Laptops will be changed out by IT every 2 weeks to ensure current updates are installed.</p>	

Table 1. Eligible Patient Visits Converted to Treatment-at-Home*

	Total Visits Eligible	Licensed Independent Practitioner Agreed	Patient Agreed	Insurance Approved	Visits Completed
TOTAL	Visits: 54 Patients: 32	Visits: 51 Patients: 26	Visits: 30 Patients: 15	Visits: 13 Patients: 6	Visits: 11 Patients: 6

*2 insurance-approved visits were not completed, 1 because the patient had COVID-19 and 1 because the patient was not home when the nurse arrived.

Table 2. Reasons That Patients Declined Home Administration

REASON	PATIENTS
Didn't want anyone to go to their home	1
Has other onsite appointments	1
Preferred to be on site	4
Declined without providing a reason	5

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Patient Time and Cost Savings

The median self-reported patient commute to Memorial Sloan Kettering was 65 minutes (range: 45 to 85 minutes), and median wait time for intramuscular and subcutaneous therapies was 33 minutes from check-in to receipt of treatment. Injections in the home took a median of 15 minutes of patient time, decreasing total patient time by 83 minutes. The median transportation cost saved per patient was \$5.50.

Copays

Memorial Sloan Kettering absorbed copay costs during the pilot to reduce barriers to care during the public health emergency, with a median copay of \$30 (range: \$3.00 to \$2,277.28).

RN Time

RNs required a median of 120 minutes to provide a home administration; most of this was travel time (Table 3).

Discussion

The recent National Cancer Plan highlights challenges to ensuring high-quality cancer care delivery, including high treatment cost and socioeconomic and cultural barriers that prevent timely access to care. Additionally, the plan calls for research in cancer care

delivery innovation to overcome these barriers.⁷ One large study of cancer treatment in the home reached its feasibility end points, but studies where barriers prevented successful implementation must also be reported.³

Our feasibility study failed to meet its end point of converting 40 visits from in-clinic to at-home administration. For over half of eligible visits, the pharmacy benefit would not cover a take-home prescription or in-home administration. For in-home care programs to succeed, these administrative burdens must be lifted. Regulators should also consider how to foster continued experimentation to support the challenges identified by the National Cancer Plan.

Utilizing existing nurses for the pilot was difficult. Travel for in-home care required a median of 2 hours, which was unsustainable at scale. We are evaluating in-home self-administration of subcutaneous and intramuscular antineoplastics to potentially lower cost and ease personnel, administrative, and licensing barriers. However, not all patients can self-administer, and some drugs have safety concerns; alternative approaches to allow injections at home that can be administered by clinicians or caregivers must be considered.

Limitations

There are several study limitations, including its size and conduct at a single institution. Though we evaluated subcutaneous and

(Continued on page 53)

Figure 4. Patient Satisfaction With At-Home Treatment (n = 11 responses)*

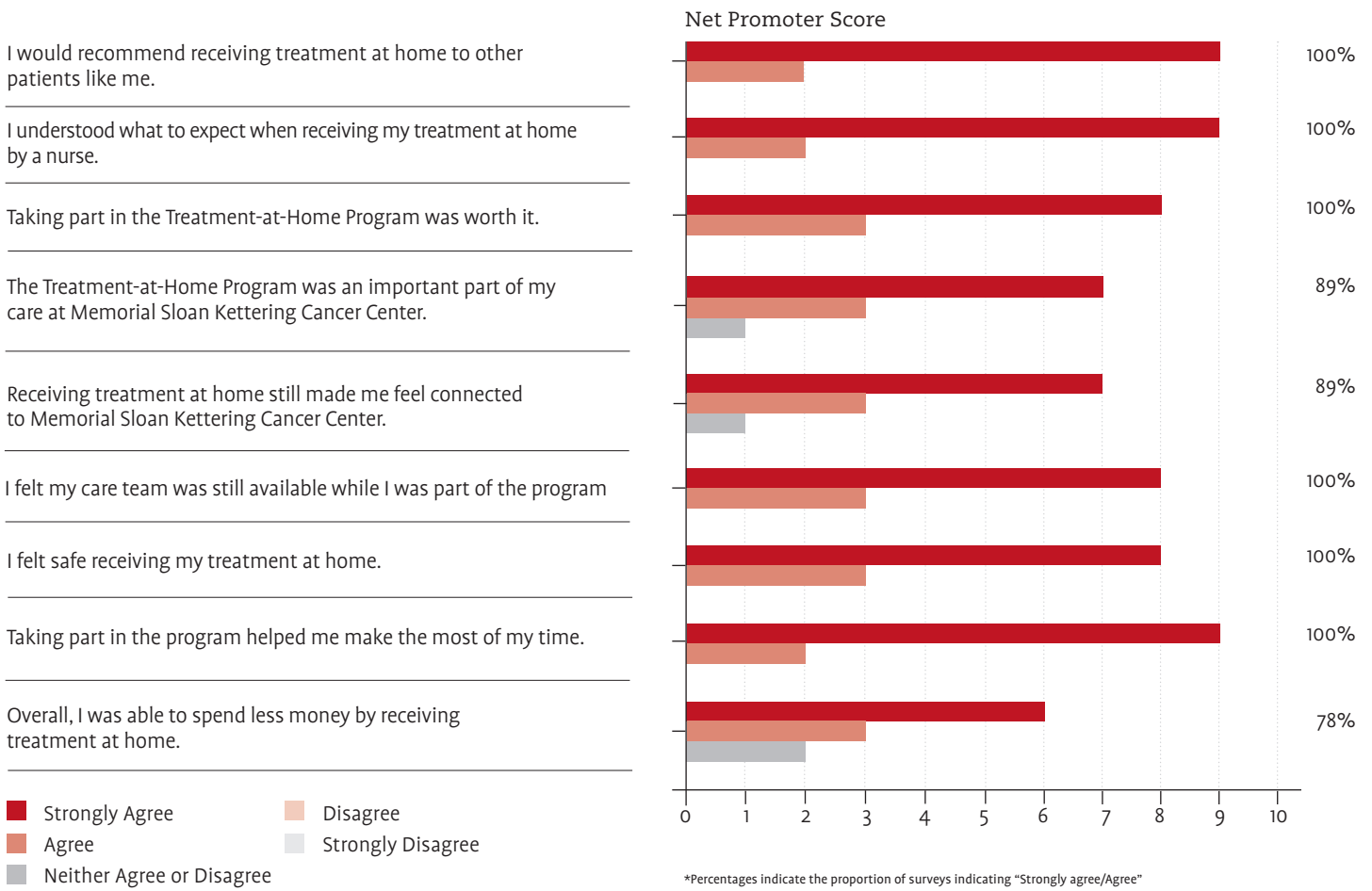



Table 3. Nursing Time Spent During Home Visit

#	Patient	Date of Visit	Time Spent Outside of Cancer Center	Time Spent in Patients' Home
1	Patient #1	04/08/2022	1:15	0:30
2	Patient #2	06/23/2022	2:00	0:15
		07/21/2022	1:45	0:15
		09/12/2022	2:00	0:15
3	Patient #3	04/29/2022	2:00	0:25
		07/11/2022	2:00	0:15
		08/10/2022	2:00	0:15
		09/07/2022	2:30	0:15
4	Patient #4	10/14/2022	2:00	0:25 (translation services)
5	Patient #5	10/14/2022	2:30	0:15
6	Patient #6	9/19/2022	2:00	0:15
		Total Hours	19:00	3:20

(Continued from page 51)

intramuscular antineoplastics, other agents might have more favorable pharmacy benefit approval processes. The patient's insurance status should be an important future consideration. Out-of-pocket costs vary greatly by primary payer, secondary insurance status and coverage, retail pharmacy coverage, and whether deductibles or out-of-pocket caps have been met. We observed wide variability in copayments. In addition, though ideal from a clinical safety profile, many eligible patients (38%) chose not to participate. Interestingly, as reflected in the patient testimonials, our urban location might have precluded some patients from participating given the small size of many New York City apartments, where personal space is prized. A larger catchment area where patients faced more time constraints and financial toxicity to a face-to-face encounter may have benefited the pilot.

Conclusion

As oncologic therapeutics evolve from intravenous to oral and subcutaneous formulations (eg, immunotherapies) the need for untethered oncology care will broaden.⁸ Patients prefer subcutaneous therapies, and these formulations reduce resource utilization and improve tolerability and health-related quality-of-life outcomes. We found high patient satisfaction with home administration, but regulatory barriers impaired our ability to realize these benefits and deliver on the goals of the National Cancer Plan. 

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