



LITERATURE AND PRACTICAL ASSESSMENT OF INNOVATIVE INFUSION PRACTICES

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INTRODUCTION AND EXECUTIVE SUMMARY

Background: The American Cancer Society (ACS) shares that approximately 609,360 deaths from cancer are expected in the U.S. in 2022 (ACS, 2022). Importantly, these estimates are based on reported cancer incidence and mortality through 2018 and 2019, and thus do not account for the unknown impact of COVID-19 on cancer diagnoses and deaths. Disruptions to health services due to the COVID-19 pandemic resulted in millions of patients either missing or postponing appointments for cancer screenings or follow-ups, as well as patients already diagnosed who experienced treatment delays and/or modifications (ACS, 2022). In response to the public health emergency, healthcare systems have begun to offer anti-cancer infusions in non-traditional settings, such as in patients' homes (Laughlin et al., 2020).

With the goal of serving Veterans through providing high quality care, the U.S. Department of Veterans Affairs (VA) represents the largest integrated healthcare system in the nation. In response to the need for innovative access points to cancer care, the National Oncology Program (NOP) formed the National TeleOncology service (NTO). This report is commissioned by NTO's Infusion Integrated Project Team (IPT), a group focused on increasing access to infusion services for Veterans. Researching clinical best practices for the implementation of novel infusion care delivery models, this literature assessment aims to provide evidence-based insights on new infusion modalities. The insights gained from this literature review inform Infusion IPT's implementation planning process.

Process: To begin the research process, literature regarding healthcare systems and organizations currently operating non-traditional infusion practices was reviewed. These "case studies" appear at the beginning of the report to provide a holistic overview of current innovations in the anti-cancer infusion space. Insights gained from this research informed the subsequent structure of the report. The topics and subtopics of this literature assessment were largely identified through the analysis of the "case study" programs. Researching and understanding best practices informed the systematic approach to this literature review.

Each topic area was researched and details findings from peer reviewed journals, as well as public and private authorities in the oncology and larger health care environment. Research was conducted via web-based query with focus on search sites such as PubMed, Springer Nature, and Advisory Board. The sections identified and researched in this report include nursing, drugs, patients, at-home care, outpatient (Community Based Outpatient Clinics - CBOCs) care, pharmacy, oncology, governance, and support services. Following a discussion of the current findings for each topic area are considerations that were not found in the literature search process. To conclude the report, there is a summary of best practices in the novel infusion space along with recommendations for the VA program.

Results: Research about novel infusion practices is not abundant in current literature, and therefore not all the information sought out was found. There remain roughly 30 key considerations where specific data or information was not published or generally available. Much of the data collected largely validates the current understanding about home and outpatient care that the Infusion IPT has. Nothing in the literature was found to strongly contradict or raise any red flags about the approach the Infusion IPT is already taking. The report provides detailed considerations and evidence for each topic area from a variety of sources. Sources that could not be summarized succinctly are linked in the [appendix](#), and further review is encouraged. Particularly proven, suggested, or recommended information was further reiterated in the best practice section. Ultimately, the report recommends 28 best practices to employ in the Infusion IPT program. One overarching consideration was the decision of whether to create a dedicated infusion program with VA staff and providers or contract these services from an outside organization. This report presents a detailed assessment of best practices in the novel infusion space to support the decision of whether to "make" or "buy" each component of this care model. The way the report is structured, with the topic areas following the case studies, leads to some information repeated throughout the document. This was intentional. The case study section was written to stand on its own, so each topic area also pulled information from the case studies to ensure comprehensive research was documented for each section. Furthermore, there is sometimes similar information in a few topic areas. That was also intentional to highlight the need to consider a wide variety of perspectives for each program component.

I. CASE STUDIES

University of Pennsylvania

Description of Program:

The Penn Center for Cancer Care Innovation launched the Joint Commission-certified Cancer Care at Home program in February 2020. The program expanded upon the existing Penn Home Infusion Therapy services, which included home infusion of fluorouracil and the subsequent supportive care (Cavallo, 2020). Within the first month of the program, nearly 40 patients were referred to receive home infusion services. At the onset of the COVID-19 pandemic, just one month after the program began, referrals scaled 700% in one month, and, by the end of the first year, roughly 1,500 patients with breast cancer, prostate cancer, lymphoma, and myeloma had received home infusion services (Penn Cancer, 2021).

The program operates an infusion pharmacy, supply warehouse, and delivery staff to manage the creation and distribution of drugs to patient homes (Penn Medicine, 2021). The pharmacy compounds 12 chemotherapeutics for home infusion including leuprolide, dose-adjusted EPOCH (etoposide, vincristine, doxorubicin, cyclophosphamide, and prednisone), zoledronic acid, denosumab, filgrastim, pegfilgrastim, rituximab, and bortezomib (Cavallo, 2020). At first, only leuprolide and dose-adjusted EPOCH were given as pilot drugs to prove the safety and efficacy of the program model (Laughlin et al., 2020). Today, the program is considering 13 new agents for use in home infusions to treat head and neck cancers and lung cancer (Cavallo 2020). All drugs are evaluated on their practicality for home use via four factors (Jardine, 2021):

- Stability and safety to deliver the drug at home
- Safety of the target population to receive the drug at home
- Insurance coverage of the drug for use at home
- Economic sustainability of production and use of the drug at home

Additional considerations include preparation complexity, ease of administration, whether the drug is NIOSH listed, and whether the drug is home mix eligible (Bekelman, 2020).

The program employs a multidisciplinary care team, all trained and educated in home infusion, comprised of clinical pharmacists, Oncology Nursing Society (ONS)-certified nurses, and palliative care providers. The specific Hematology/Oncology Clinical Care Team consists of four clinical pharmacists, four registered nurse coordinators, three patient supply representatives, and two patient service associates. All nurses must have a minimum of three years of critical care experience and be ONS-certified. The staff education checklist includes indication for use, mechanism of action, dosing, drug interactions, administration, NIOSH classification, nursing notes, and preparation. This staffing model relies on adaptability and redistribution of resources via redeployment of hospital and infusion clinic staff and the use of home health nurses to provide non-acute support at the patient home (Bekelman, 2020). When the program needed to rapidly scale due to the COVID-19 pandemic, clinic-based nurses volunteered to be trained in home infusion and join the team. The nurses train all patients and caregivers and provide customized education and manuals on the administration of their infusions at home (Penn Medicine, 2021). The program has recorded high levels of both patient and provider satisfaction.

Key Takeaways:

Best Practices:

The Cancer Care at Home program recommends the following:

- Promote communication between nurses, providers, patients, and pharmacies in both the planning and execution phases

- Plan before piloting the program – engage stakeholders, ask home-health infusion nurses for tips, train nurses, review protocols, etc.
- Follow safety guidelines and review these guidelines with every member of the home
- Ensure independent double-checks on medications prior to administration (Penn uses FaceTime to call another nurse or pharmacist to visually confirm patient and medication)
- Deploy proper and sufficient equipment; for example, the best pump is an angulatory pump and extra batteries should always be supplied with it
- Store pumps in pouches and fanny packs while actively administering drugs so the patients can be mobile
- Conduct an at-home visit and complete a screening questionnaire that asks, among other things, whether pets or kids live at the home (if the home environment is not safe or is not located close enough to an emergency center, do not proceed)
- Bring anaphylaxis kits and IVs to provide hydration or anti-nausea medication to patients (Jardine, 2021)
- Ensure patients are educated on the process and potential reactions/complications
- Deliver equipment to the patient home and collect waste separately a day or two later (Cavallo, 2020)
- Provide an emergency hotline number with an on-call nurse 24/7 for patients to contact in case of an emergency (Jardine, 2021)

In addition to the best practices outlined above, the Cancer Care at Home program identified the “best” team of stakeholders to engage. This team was comprised of executive sponsors and clinical/operational leaders across many disciplines within the healthcare system. These disciplines included (Bekelman, 2020):

- Healthcare transformation
- Cancer care transformation
- Home infusion
- Cancer care delivery
- Cancer care administration
- Outpatient infusion
- Reimbursement policy
- Financial analysis
- Inpatient and outpatient care

Challenges:

The Cancer Care at Home program has encountered a few challenges:

- In the planning stage of the program’s development, over 40 interviews were conducted with patients, caregivers, pharmacists, providers, and nurses to gauge perceptions and biases related to home infusion care. The results indicated a bias towards inpatient and outpatient care models due to a lack of experience with home care. Furthermore, patients commented on safety concerns and only trying home care if it was recommended by their physician. Physicians reported concerns about safety, an increased burden for the clinical care team, and a lack of electronic health record access at homes (Laughlin et al., 2020).

Leveraging Behavioral Economics Principles to Address Clinician and Patient Bias

Identified bias	Underlying behavioral economics principle	Design elements to address barrier
Physicians or patients prefer to stick with past experience	Status quo bias: People tend to favor the status quo and current practices rather than initiating change	Introduction of home care as the default for appropriate treatments and patients
Physicians tailor practice patterns to groups of patients, missing opportunity to identify subgroups of patients safe to be treated at home	Therapeutic norm: Physicians tend to choose treatments based on norms for broad classes of patients rather than customizing treatments to individual patients	Process changes to proactively identify patients meeting specific clinical criteria for home treatment
Physicians were deterred from ordering home treatments by complicated EHR ordering requirements and potential increased patient management burden	Friction costs: People tend to be deterred from taking action on desirable behaviors by perceived or actual speed bumps	Process changes to simplify ordering and remove other barriers

Source: The Authors

NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society

- Resistance to the program because of safety concerns, quality, and resource availability from both providers and patients (Penn Physician, 2020)
 - Mitigation:
 - The process for ordering and administrating home infusion was streamlined and all equipment delivered directly to patients' homes
 - Injections and infusions are conducted using safety and quality protocols that match what patients would experience in the hospital or clinic
 - First dose administration
 - Sit through medications
 - Infusion related reaction protocol
 - Chemotherapy double-check process (Bekelman, 2020)
 - Physicians and patients receive careful explanation to ensure that they understand the safety procedures in place and the credentialing criteria for the nurses who deliver infusion therapy (Penn Physician, 2020)
- Challenges with different electronic medical record systems
 - Mitigation: Use CPR+ and EPIC
- Challenges with patient tracking and record keeping
 - Mitigation: Hired and used a business development liaison. Developed a tracking tool. Implemented weekly status calls (Bekelman, 2020).
- American Society of Clinical Oncology and the Community Oncology Alliance have formally opposed the at-home infusion practice

Huntsman

Description of Program:

Huntsman Cancer Institute (HCI) is a specialty cancer hospital and research center located in Salt Lake City, UT, that operates as part of the University of Utah Health. Opened in 2004, the organization doubled its physical space in 2011, and continues to grow each year. They care for patients across the Mountain West with a hospital in Salt Lake City, three local community clinics, and affiliations with five hospitals

across neighboring states (Huntsman, N.D.b). HCI providers and staff daily administer 194 infusion treatments and care for 78 inpatients. Additionally, with a focus on research, HCI typically has more than 250 clinical trials open (Huntsman, 2021).

In August 2018, the HCI team began to enroll patients in the “Huntsman at Home” (HH) program, a care delivery model commonly called “Hospital at Home.” This model was implemented to address unique patient needs, specifically upon discharge from inpatient care (Journal of Clinical Pathways, 2020). The program identifies patients that may need additional clinical intervention and provides support immediately following hospital discharge. Some patients are enrolled due to risk of complications from complex surgeries, while others require intravenous (IV) antibiotics or fluids (Journal of Clinical Pathways, 2020). Huntsman at Home provides care from doctors and advanced practice registered nurses (APRNs). Patients must be referred by their oncologist to receive this care, and they must live within 20 miles of HCI’s University of Utah campus (Huntsman, N.D.a).

To assess the effectiveness of the Huntsman at Home program, HCI’s team conducted a prospective, cohort-based study of patients recently discharged from inpatient hospital care. With an aim of reducing unplanned hospitalization and cost, as well as emergency department (ED) usage, inpatient length of stay, and intensive care unit (ICU) admissions, this trial recruited 367 patients recently discharged from inpatient care at HCI (Mooney et al., 2021). About half of these patients were admitted to the HH program upon hospital discharge, with the remaining participants not enrolled in the program acting as a control group. Those participants that were not enrolled in HH either declined this form of care or lived outside of the 20-mile HCI radius.

The outcomes of the trial indicated that the odds of unplanned hospitalization for those in the HH group were decreased by 55% and participants’ health costs were 47% lower than the control group over the course of one-month post-hospital discharge (Mooney et al., 2021). Additionally, the team found that those enrolled in HH had an average of 1.1 less days of hospital care and reported to the ED 45% less often than the control group (Mooney et al., 2021).

Key Takeaways:

Huntsman’s program provides acute care in patients’ homes but does not specifically include infusion services as a part of the care model. With a focus on supporting patients recently discharged from inpatient care, best practices from this model inform how a program can care for frail patients.

One such practice is the use of a “remote monitoring patient-reported outcome system,” a daily check-in that helps patients share their symptoms for advanced detection of clinical issues (Journal of Clinical Pathways, 2020). Lead investigator of the research study mentioned above, Dr. Kathi Mooney, spoke about the need for remote monitoring:

“We found that symptomatic patients often do not report symptoms to their provider. Instead, they often wait until the symptoms are no longer tolerable and seek care in ED with many of these visits resulting in rehospitalization (Journal of Clinical Pathways, 2020).”

This practice informs programs other than purely hospital-at-home care delivery models, with remote symptom monitoring being shown to increase quality of life (Maguire et al., 2021 & Pang et al., 2020). Not only does this practice help patients, but it also ensures strong communication between patients and providers (Journal of Clinical Pathways, 2020).

CVS-CTCA

Description of Program:

In January 2021, CVS Health announced a partnership with Cancer Treatment Centers of America to increase access to chemotherapy at home for eligible, fully insured patients. Clinically eligible and fully

insured patients may receive at-home chemotherapy treatments provided by CVS's infusion care unit Coram. The program leverages Coram's home infusion capabilities, coupled with training in chemotherapy administration based on Oncology Nursing Society guidelines. The program harnesses CTCA's expertise as a top oncology care provider to give patients who may have delayed their care due to COVID-19 the flexibility to receive treatment from the safety and comfort of home (Donlan, 2021).

With the Oncology Clinic at Home program, patients who meet certain criteria receive specific chemotherapy or immunotherapy infusion or injections without leaving home. The drugs and the equipment needed to administer them and monitor their progress are delivered to their door, in a safe, comprehensive process facilitated by an in-person oncology-trained nurse from Coram and overseen by their care team (Donlan, 2021). Clinically eligible and fully insured CTCA patients with a range of cancers, including breast cancer, lung cancer, prostate cancer, colorectal cancer, head and neck cancers, and some genitourinary cancers on particular chemotherapy/immunotherapy medications, will begin their first cycles of infused chemotherapy in the hospital or outpatient care center, and, if tolerated over a number of months, may be transitioned home for continued infusions. Once home, patients receive in-home Coram nurse visits to administer the therapy, paired with regular telehealth visits and digital therapeutic check-ins with their CTCA clinician, care team, pharmacists, and other clinical staff as needed (CVS Health, 2021).

In collaboration with CTCA and their approach to quality, safe care, coupled with more than 35 years of infusion expertise, Coram can reach 97% of the U.S. population. The program is being piloted in the Atlanta market and will expand over the next few months to increase access to home-based cancer care during and beyond the pandemic (CVS Health, 2021).

Key Takeaways:

Patient Safety:

The CTCA Oncology Clinic at Home services incorporates patient safety guidelines for infusion therapy in the home. The following list highlights key protocols (Cancer, 2022):

- Chemotherapy or immunotherapy drugs are delivered to patients in safe packages with instructions for safe handling
- Home infusion therapy treatments are administered by nurses trained and certified in chemotherapy administration per ONS guidelines
- Patients are provided with state-of-the-art remote monitoring equipment to enable healthcare staff to monitor vital signs
- Before home infusion therapy begins, patients are informed about what to expect and are provided detailed information about the care processes
- Patients are given contact information to discuss any questions and concerns, or to report side effects

Qualifying Patients:

To qualify for the CTCA Oncology Clinic at Home services, patients must meet the following requirements (Cancer, 2022):

- Be in good health except for their cancer diagnosis and tolerate their treatments well in an inpatient setting
- Be treated with specific chemotherapy or immunotherapy drugs that can be safely given at home
- Live in a location where CTCA has made home infusion therapy available
- Have reliable and adequate internet service

- Adept at using a laptop computer, tablet, or smartphone
- Have full coverage insurance for home infusion therapy

Best Practices:

The CTCA Oncology Clinic at Home best practice guidelines are:

- Patients must receive the first infusion or injection at a CTCA hospital or outpatient care center
- The care team must provide detailed information to the patient on how the program works and what to expect
- Instructions must be given on the handling of chemotherapy or immunotherapy drugs and if refrigeration is needed
- Patients will be connected to their care team at key points during their home infusion to monitor vital signs and assess the development, frequency, and severity of any side effects
- The patient’s usual on-site care will continue as directed by the CTCA physician and care team for all other necessary treatments
- Video conference application is used to conduct telehealth visits and services. This allows users to communicate via chat, video, and other features. Before participating in Oncology Clinic at Home, patients will be instructed on how to use the application.

Patients are instructed on what to do if they have concerns about their treatments or if they are experiencing concerning side effects or have other conditions that may worsen with the infusion therapy (Cancer, 2022)

Australia

Description of Program:

One large multi-center program in Australia, *chemo@home*, outlines from a patient perspective, individuals who may be interested in receiving treatment at home. The program may be suited for individuals with active lifestyles and those with family and mobility challenges that make it difficult to travel to a treatment center (*chemo@home*, n.d.). Other candidates include those who have busy working lives or who wish to maintain as much independence as possible.

Based on these attributes, certain classes of drugs have been designated as part of the home-based treatment program. These include select immunotherapies, bone strengthening treatments, and colony stimulating factors (*chemo@home*, n.d.). Treatment by *chemo@home* is also offered for non-cancerous diseases such as inflammatory bowel disease, multiple sclerosis, rheumatoid arthritis, iron deficient anemia, and osteoporosis. Monitoring and engagement strategies are also offered for those receiving oral cancer therapy (*chemo@home*, n.d.).

Benefits cited by the program include a decrease in stress related to cancer care, a reduction in infection risk, and a reduction in health care costs (*chemo@home*, n.d.). When surveyed, over 90% of patients gave the program an ‘Excellent’ rating. *Chemo@home* also conducts ongoing research and received a Net Promotor Score of 89 (*chemo@home*, n.d.).

In addition to treatment, the program offers ancillary support mechanisms to help patients address challenges that arise due to their treatment. They partner with outside organizations that assist with physiotherapy, offering ‘stretchersize’ programs, as well as mental health counselling (*chemo@home*, n.d.).

Chemo@home uses a proprietary electronic health record developed by an Australian company with standardized regimens across multiple medical specialties. With the help of an advisory board, the

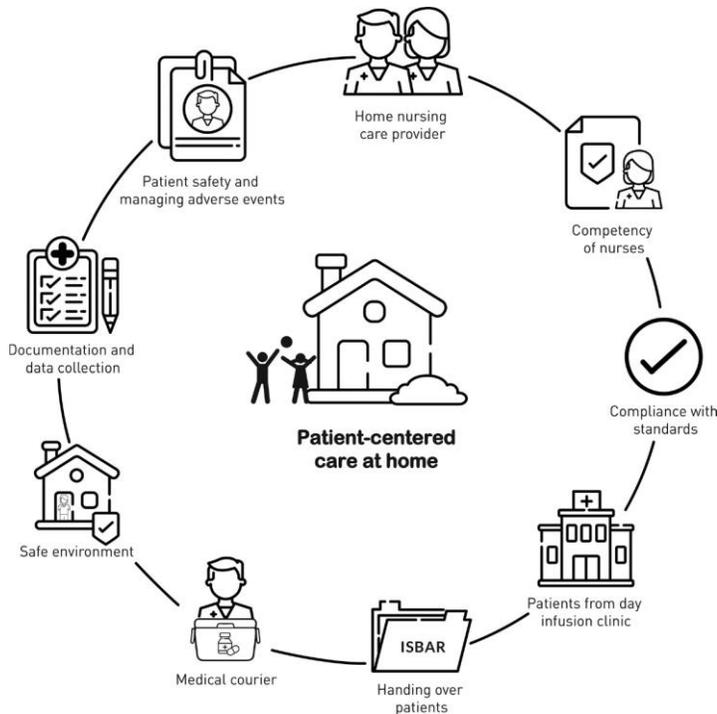
program maintains a governance structure that promotes patient safety and treatment efficacy. This group has representation from multiple specialty groups that lend accountability to the program's relevancy, provide standardized treatment regimens, and promote best-practice treatment and initiatives (chemo@home, n.d.).

Another Australian entity overseeing and establishing standards for home treatment is Cancer Australia, a resource group run by the Australian government. Spurred by the COVID-19 pandemic, they developed multi-level strategies to ensure services align with policies for efficacy and safety (Cancer Australia, n.d.). These range from system-wide to patient-level strategies. System-wide strategies include safety and sustainability, as well as implementing e-prescribing to reduce medication errors. The service and practitioner-level strategies include triage protocols, effective resourcing, and detailed escalation plans for managing adverse reactions or events. To address patient safety, awareness, and acceptability, this group implemented strategies that empower patients through support services both in-person and virtually (Cancer Australia, n.d.).

Key Takeaways:

Compelling information was provided by a 2016 study performed in South Australia. The research team focused on the treatment of multiple sclerosis with natalizumab, a targeted immunotherapy agent. This study demonstrated that infusion at home could improve the quality of life for individuals and be used to develop a model of care for home infusion overall. The model of care developed has the potential to be useful in application of future at-home infusion programs. The model has nine core elements with patient-centered care at home being at the center of all dimensions (Schultz, Thomas, Cusack, et al., 2019). The following is a summary of the key elements. In addition to the key elements listed, important considerations include equipment, nurse training, patient identification, signed consent, signed treatment orders, communication pathways, handling requirements and documentation, infection control, environmental monitoring, patient eligibility, and emergency management.

Figure 1. Model of Care for Patient-centered care at home



Analysis of Common Best Practices and Challenges

These case studies detail how organizations bring infusion services closer to patients. The programs were selected based on widespread success of large-scale home health service capabilities. The UK-based National Health Service's (NHS) home health program was researched and will be referenced; however, there was not enough pertinent information to include a formal case study. Incorporating lessons learned and best practices from these programs into Infusion IPT's implementation promotes success. Some of these measures relate directly to patient care processes, such as requirements for infusion first dose to take place in a hospital setting, or to more program-wide implications, such as guidance to create a program with wrap-around patient services providing physiotherapy and mental health counseling.

Considerations such as care coordination were a common thread amongst the cases analyzed. The need for nurses, providers, pharmacy, other support staff, and above all, patients, to be informed is of utmost importance. Using tools such as EHRs and weekly care team meetings facilitates communication across the entire Infusion Services team. While these tools are useful, systems such as EHRs can also create challenges and the implementation process must thoughtfully curate workflows. In addition to communication within the care team, having systems in place to regularly check in on patients increases value and improves clinical outcomes. Remote monitoring, whether by phone or another technology platform, helps clinicians detect changes in patient conditions and intervene as needed. These systems increase positive outcomes for both patients and providers.

Patient safety is an essential component of the programs. To maintain high standards of care and safety, it is expected that the patient home be assessed for potential dangers to the patient during infusion. In addition, training is required for patients and families to ensure they are aware of potential adverse reactions and what to do in those situations. The care team must also be properly trained and take steps to reduce errors. Performing medication double checks is particularly important in this setting, with video calls to other team members to provide a safety measure for nurses who typically enter the house alone. Ultimately, most programs recommend accessing the emergency medical system (EMS) by calling 911 if major emergencies arise outside the hospital setting.

Infusion IPT's implementation plans will be informed by these recommendations and best practices. Furthermore, the issues, barriers, and challenges encountered by the programs in these case studies provide foresight to the Infusion IPT in addressing potential problems. In addition to holistic reviews of entities offering novel infusion services, scholarly articles were reviewed for additional input on topics surrounding infusion practices. The following sections of this assessment detail those findings.

II. ANALYSIS OF KEY CONSIDERATIONS BY TOPIC AREA

The case studies provide a comprehensive foundation for the home infusion literature assessment. Following the review of existing novel infusion practices, nine key areas were identified to guide further research. The nine areas are nursing, drugs, patients, at-home care, outpatient (CBOC) care, pharmacy, oncology, governance, and support services. Each topic divided into additional subtopics to inform specific research areas. For the nursing section, each subtopic covered one of the varied approaches that implementation of this program could follow. Research was guided by input from team members and stakeholders providing essential considerations and questions regarding feasibility, concerns, and lack of topic knowledge. Between five and ten final considerations were listed for each subtopic and researched accordingly.

Nursing

In-home administration of infusion therapy for cancer care is a developing area of oncology nursing care, which includes many challenging and complex nursing facets. In addition to staff training, establishing a home-based infusion program requires coordination of multiple aspects of care, including pharmacy, lab, documentation, safety monitoring, and managing adverse events. Programs in place today provide valuable insight into key components of the overall efficacy and resulting patient satisfaction with administering oncology-related infusions at home. Qualifications of nursing staff to perform in-home infusion of chemotherapy and immunotherapy agents are outlined in several sources discussed below.

ONS has published a position statement on the training of nurses who will perform in-home infusions, which states that nurses must be approved as chemotherapy and immunotherapy competent with whatever supporting institution or agency is employing them. This competency is defined as the successful completion of didactic learning followed by a clinical practicum (ONS, 2020). In addition, nurses should hold basic life support certification (BLS), have access to a licensed independent practitioner and complete annual competency assessments (ONS, 2020).

Patient safety and medication verification prior to infusion is essential, with ONS (2020) noting that nurses should have access to a second chemotherapy competent professional to verify patient identification. Infusion information such as drug name, dose, rate, route of administration, infusion volume, and expiration dates/times are infusion verification points. Additional guidance from ONS (2020) on infusion reactions recommends that nurses have access to a licensed independent practitioner competent in emergency medication and support care measures. Clear instruction on how to manage delays in accessing emergency services based on patient location should also be outlined. Managing patient safety also involves review and interpretation of laboratory results. However, there is little information available on specific procedures for how, when and where patients have labs drawn prior to chemotherapy. This requires further guidance.

Communication among the care team is essential to promote patient safety and quality care. According to the Infusion Therapy Standards of Practice, nurse, pharmacist, oncology provider, and patient communication is essential through the continuum of care. Details, such as changing order, laboratory results, and patient assessment, occur through telephone and secure electronic communication, which the Penn Center program implemented (Jardine, 2020; Gorski et al., 2016). Adverse events should be reported promptly to the healthcare team, as should changes to the patient care plan, which must also be reviewed with the patient (Gorski et al., 2016). It is important to note that each program is unique and needs to address channels of communication in a standard operating procedure (SOP) specific to their program. Additionally, nurse travel for each program needs to be site-specific. One example of travel standards comes from the Huntsman at Home program where service is limited to those who live within 20 miles of the University of Utah campus or in one of three identified rural counties (University of Utah Health, 2022).

In the current Cincinnati VA Hospital in Home (HIH) program, nurses facilitate the delivery of a communication or hand-off packet to patients enrolled in the program. This packet contains vital information such as current medications and provider information. These packets can be used for

reference if a patient sees a provider either inside or outside of the VA system. If a patient wishes to enact a Do Not Resuscitate (DNR) order, the nurse adds the record to this packet. Otherwise, living wills or advance directive documents should be included. This information is important in communicating information to caregivers and clinicians outside the patient's immediate healthcare system.

The following sections will detail five options for staffing nurses in home care programs. These options were determined via examples in the case studies listed above, as well as other research.

Home Care Option 1: Existing Chemo Nurses Provide Home Care

The Penn Center for Cancer Care at the University of Pennsylvania is an example of a program developed as an expansion of the already-existing Penn Home Infusion Therapy services. To staff the program, infusion clinic nurses volunteered and were paired with nurses who were already in a home infusion role, but also had prior oncology-based infusion or inpatient experience (Jardine, 2021). Penn Center programming requires that nurses have a minimum of three years of critical care experience and be chemotherapy-certified by ONS standards. The Penn Center has implemented a training checklist that includes drug knowledge, including the following: indication for use, mechanism of action, dosing, drug interactions, administration, National Institute for Occupational Safety and Health (NIOSH) classification, nursing notes, and preparation (Bekelman, Major & McGettigan, 2020).

The Brigham and Women's Hospital at Home Program staffing model 0 paired physicians with nurses and paramedics in a matrix that covered a range of six to 16 patients. In the case of six patients, for example, they had one physician and three nurses or paramedics. In the case of 16 patients, the ratio expanded to three physicians and five nurse/paramedic staff. This program is designed to provide various levels of hospital-like care in a patient home and does not directly parallel the idea of providing infusion therapy alone, but still provides insight into potential models to be applied or modified for home infusion therapy. They also found that staggering shift times allowed for flexibility to meet the needs of patient flow that occurred from admittance into the program during late afternoon and evening hours, with 10-hour shifts being optimal. A comparison was drawn between staff who had more acute care vs. home care experience. The comparison noted that there was greater comfort with uncertainty from those who had expertise in home care, and a reliance on having access to a greater pool of resources from those with more acute care experience (Levine & Boxer, 2022).

They highlight key attributes to staffing the program. These include having a patient- and family-centered approach to care, as well as having a more generalist view of their work, as there may at times be fewer resources available, or they may be encountering unusual situations that need to be solved. Comfort with a certain level of risk, inherent with an environment outside the controlled hospital or clinic, was also acknowledged. One of the most important characteristics they valued when selecting staff was a commitment to the mission of the program. Challenges related to growth were closely related to scale and resources. They recommend maintaining close and open communication with the program sponsor, so alignment of resources is in line with the program trajectory (Levine, 2022).

A study of home infusion multiple sclerosis patients applied a nine-point model of care to ensure well-rounded and patient-centered care. Directly relating to the nursing aspect of this model was the focus on competency of nurses, compliance with standards, and structured communication processes from both a day-to-day detail capture standpoint and a hand-off tool. The competency factor outlined that nurses should be well educated in safety aspects of home care, vascular access device management, and patient education. Communication factors included such aspects as fostering and maintaining therapeutic relationships that had been established between nurses and patients from prior time of treatment at a clinic. Approval of treatment outside the clinic was also an important aspect that facilitated a positive transition from clinic to home treatment. Hand-off between caregivers was noted to be an essential item in managing essential safety aspects, but also showed to ease transition and foster positive interaction between nurse and patient by including things such as patient preference for venous access and sharing contact and scheduling details from the very beginning (Schultz, 2019).

Home Care Option 2: Home-based Primary Care Nurses Provide Care

As noted above, when home chemotherapy is administered, best practices strongly emphasize chemotherapy certification, either by the individual organization's credentialing, or by demonstrating an ONS-sponsored certification such as Oncology Nursing Certification (ONC). A program that includes administration by home-based primary care nurses will refer to the same guidelines for any administration of chemotherapy. Additionally, home-based primary care nursing could be utilized through partnership with either VA-based or outsourced oncology infusion resources to coordinate associated functions such as labs and infusion take-down procedures. There are examples of a combination of existing home infusion services expanding or combining with more specialized chemotherapy infusion models.

The home-based primary care (HBPC) program that originated with VA is an example which provides framework for reference. With HBPCs establishing management, coordination, and support services, the model accommodates collaboration with other services and has a multidisciplinary team incorporated into the delivery model. Research done on HBPC programs has not determined absolute best practices due to the lack of standardization of the programs (AHRQ, 2014).

The interventions outlined in the AHRQ review are identified by type of visit and staff performing the visits and provides limitations or exclusions of the review. Being focused on outcomes, rather than staff qualifications, the review highlighted that HBPC covered patients primarily in the following groupings: adults (>18 years old) at home (not in any form of institutionalized setting) who had a chronic illness or disability and who received care directed at management of those illnesses or disabilities. The goal aims to minimize negative outcomes and avoid institutionalized care. Visits made in the HBPC and the extent to which outcomes are influenced is not clearly outlined or evaluated in these programs. The organizational framework includes nurses (qualifications unspecified) but can also include providers such as physicians, nurse practitioners and physician assistants, as well as social workers and community health workers.

Home Care Option 3: Outsource Home-health Nurses to Provide Care

Healthcare providers have found external partners to provide home-based infusion of cancer treatments. United Healthcare in Florida partnered with Optum Infusion Pharmacy to provide this service both as a convenience and to minimize exposure to COVID-19. In this program, patient cases are reviewed and assessed for eligibility based on submission of their treatment plan and an assessment that care can be given without compromising safety or the highest expected efficacy and results of treatment (United Healthcare, 2020). Nurses are trained in "caring for oncology patients, administering chemotherapy medications and managing potential side effects due to cancer treatments" (United Healthcare, 2020). This care is provided throughout the state of Florida and also includes ambulatory infusion suites at select facilities.

Outsourcing versus insourcing is addressed by Levine of the Hospital at Home program. While there are cost savings with internal sourcing, outsourcing may provide an infrastructure already in place which offers time savings. Some disadvantages noted with outsourcing include less control, potentially less commitment, and workflow variability due to the vendor serving more than one organization (Levine & Boxer, 2022).

Fairview Health Services, based in Minnesota, provides home infusion services in 12 states. A number of infusion medications are offered, including chemotherapy and biologics administered by employed nurses, as well as equipment delivery, laboratory specimen draws, and consults. They also offer referrals to several support services, including social work, home health aides and palliative care (Fairview, 2019).

Coram Home Health, partnered with CVS & Cancer Treatment Centers of America (CTCA), utilizes licensed nurses trained in chemotherapy administration based on ONS guidelines (Coram Healthcare, 2020). In the program, patients must complete the first cycle of treatment in a hospital or outpatient care setting, then can be transitioned to home if the treatment is tolerated. The drugs and equipment needed to administer treatment and monitor progress are delivered directly to the home in a safe, comprehensive process facilitated by an in-person oncology-trained nurse from Coram and overseen by the care team.

While direct infusion activities are done by the nursing staff, other aspects of care, such as check-ins with their clinician and education with a pharmacist, are carried out via telehealth visits (CVS Health, 2021). This originated as a pilot program, spurred by the COVID-19 pandemic, in response to the need to maintain cancer treatments on schedule and prevent delayed care and treatment.

The cost of outsourcing care and the reimbursement mechanisms are important factors. The Federal Code of Regulations provides standards for Medicare eligibility and states the following for plan of care and those providing home infusion therapy:

- (a) All patients must be under the care of an applicable provider
- (b) All patients must have a plan of care established by a physician that prescribes the type, amount, and duration of the home infusion therapy services that are to be furnished
- (c) The plan of care for each patient must be periodically reviewed by the physician

Further specifications with those regulations indicate that care is provided by professional nursing services and patient education is done if durable medical equipment is involved and the provision of remote monitoring for the infusion service and drugs is provided (eCFR, 2022).

Cost implications of providing cancer care in the home setting have been evaluated in a few studies. Consideration of direct medical cost of drug and staff allocations, in addition to transportation and coordination activities, were part of a group of five articles examined. All pointed to a direct cost-reduction when providing at-home care in the range of nine to 53%, with a 16% cost benefit in favor of home treatment (Cool, et al., 2018).

Home Care Option 4: Patients Self-Administer Care

For this assessment and review, consideration of self-administered chemotherapy is limited to oral chemotherapy agents, as there is little information available on any programs who oversee patients self-administering chemotherapy infusions, or even non-chemotherapy infusions, aside from the well-established ambulatory infusion pumps. Safety for patients, caregivers and others who are present in the home setting is a primary concern. Patients and those coming in contact with them during their treatment should be adequately educated on safety protocols.

The *Clinical Journal of Oncology Nursing* published a guide for patients receiving chemotherapy treatment at home which outlines best practices for safety measures (Polovich, Olsen and LeFebvre, 2014). The guidelines instruct nurses to ensure that patients are educated on both self-administration of oral chemotherapy agents as well as overall safety in the home while receiving nurse-delivered infusion chemotherapy. Nurses must instruct patients to wash linens separately, discard disposable diapers in plastic bags, dispose of gloves in a chemotherapy waste container if used when handling drugs, and know how to use a spill kit. Nurses also typically visit the patient periodically to support with infusion site/port site access and provide dressing changes. When nurses can't visit in-person, remote monitoring and virtual engagement strategies should be offered and employed (Schultz, 2019).

The Oncology Nursing Society also developed a guide to educate patients and caregivers on safety aspects of oral home chemotherapy. It includes the nurse's responsibility of identifying the risk that some patients don't view oral chemotherapy as comparably dangerous to a liquid or infused chemotherapy, thus stressing the importance of adherence and the use of personal protective equipment. It also outlines safe-

handling checklists and education strategies to mitigate potential risks of non-compliance and possible exposure to patients and others living in the same household (Becze, 2020).

Outpatient Nursing Care

Based on the Cincinnati Hospital in Home program SOPs and discussion with Andrea Stone who manages the Minneapolis-based program, there are several important factors to consider regarding nursing care at a CBOC or outpatient infusion center. The Cincinnati VAMC Hospital in Home program outlines basic infection control practices, including procedural standards for transport of laboratory specimens in a cooler, recommending the use of gowns and single-use patient supplies when appropriate, and discarding in the home of use. For care at CBOC or other outpatient areas, staff accesses EMS by calling 911 when emergencies arise that cannot be effectively handled by CBOC staff.

The Victoria home-based cancer care program recommends that policies around drug transportation include the requirement of a hard-walled secure container that is also secured in the vehicle while in transit. Further requirements about temperature tracking and light-sensitive accommodations are also included when necessary. The guidelines also specify that no more than a single patient medication should be brought in each home and at the conclusion of treatment, waste is disposed of in a designated cytotoxic waste container, which is then secured in the vehicle for transport (State of Victoria, 2020).

Nursing staff administering chemotherapy agents should be trained specifically in chemotherapy administration. This chemotherapy training should be, at a minimum, the ONS-recommended curriculum. If there are staff who do not meet a chemotherapy-trained criteria, workflow should be altered to accommodate assigned patients who do not require chemotherapy or immunotherapy administration. ONS outlines recommendations in its position statement regarding Ambulatory Treatment Centers. Staffing models are based on patient acuity ratings but also include the nursing experience and skillset available on any given day or week. Scheduling is done on a four to 12-week time frame and shifts in day-to-day staffing are done according to care requirements for upcoming volumes and services. Institution-based considerations of patient mix, treatments administered, and accreditation requirements are all pieces of assembling an outpatient infusion treatment center (ONS, 2019).

Drugs

Drug Administration in a Home or Outpatient Setting

When patients require long-term infusion therapy, the administration of complex drugs and biologicals at home or at an outpatient clinic can be utilized as alternative care models to the traditional inpatient setting. Furthermore, these care models can result in cost savings when compared to inpatient care, and they allow patients to return to their daily routines and work activities quicker.

There are various modalities to administer IV infusion drugs and biologicals. Some drugs are given via IV push, while most are infused over time from minutes to hours. Infusion pumps may be portable or stationary and may feature electrical or battery operations. Pumps can be attached to a pole with wheels to allow for patient mobility. Even so, pumps and poles can be cumbersome and limit activities of daily living since electronic pumps still need to be plugged in and battery packs must be charged prior to each use. Elastomeric infusion pumps are ball-shaped devices that use elastic pressure, rather than electricity or batteries, to create medication flow and are a much less cumbersome option. These pump devices are for single use only and are pre-filled with medication by a pharmacy. Infusion therapy providers may deliver a supply of these ready-to-infuse devices to the patient (Wolf Medical Supply, n.d.).

Patients and caregivers must keep certain drugs refrigerated and only remove them for an infusion. Medications and supplies that do not require refrigeration should be stored at room temperature in a clean container and away from children and pets. The medications and supplies should not be exposed to heat or moisture, and medical sharps should be disposed of in an appropriate sharps container (National Home Infusion Association, n.d.).

Because medications delivered via elastomeric pumps offer ease of use and most patients can self-administer, certain insurance plans may consider the professional nurse services for continuous drug delivery monitoring not medically necessary. When possible, individual consideration should be made to accommodate care needs since this may decrease costs in the long term and enhance patient quality of life.

Drug Transportation

Complex drugs and biologicals for infusions must be stored and transported at the proper temperature, be protected from light sources, and be used within an allowable time to maintain stability and efficacy. Infusion pharmacies or companies have vast experience with infusion drug implications and all aspects of dispensing and transporting them. While their services may help facilitate the home infusion transportation and packaging processes, the medication costs may be higher than procurement within hospital systems. Depending on the drug and the geographical area, contracting arrangements with an infusion pharmacy may have advantages; this could be considered on a case-by-case basis for select drugs and biologicals (National Home Infusion Association, n.d.).

Drug Approvals

Research on infusion therapy show that public and commercial health plans offer benefits through infusion pharmacies and centers, visiting nurses, home health, durable medical equipment, and others (Aetna, n.d.; CMS, n.d.). Findings for approved drug lists were limited to Medicare medical policy. Other health plans only describe coverage based on drug classification and medical necessity. Many health plans require prior authorization for infusion drugs and biologicals, and coverage and reimbursement are based on the formularies. For example, TRICARE offers home infusion benefits, but as is standard practice, approval for this service requires prior authorization (Health Net Federal Services, n.d.).

CMS publishes comprehensive home infusion therapy policy and information for Medicare beneficiaries. The Medicare Home Infusion Therapy (HIT) Monitoring Report describes HIT services, approved drugs, and utilization (Centers for Medicare and Medicaid Services, 2022b). This benefit allows for the administration of IV or subcutaneous drugs at home. Medicare coverage criteria covers three categories of

drugs stratified based on risk level. Category one is anti-infectives, chelation, pain management, and cardiovascular drugs. Category two drugs are immunoglobulins, and category three includes chemotherapy drugs. The category three chemotherapy drugs are doxorubicin; blinatumomab; bleomycin sulfate; cladribine; cytarabine; fluorouracil; vinblastine sulfate; and vincristine sulfate. It is important to note that this report does not detail their methodology for choosing these specific drugs (Centers for Medicare and Medicaid Services, 2022b).

The development of an approved drug list presents a challenge that may vary by facility and unique patient needs. Once such consideration is the number of doses to be administered in a hospital setting prior to transitioning the care to the patient home, for a given drug must be considered for tolerance and safety. While infusion therapy in the home has many benefits for the patient and the healthcare industry, physician and other staff 'buy-in' for home infusions may have resistance for implementation (Hummel, 2017; Shaw, 2020).

Patients

The patient perspective in cancer care is an important viewpoint and must be integrated into the decision-making process throughout the treatment course. This concept is further validated by the healthcare industry moving toward a more patient-centered cancer care approach. (Anjali, 2021). Many physicians believe cancer patients must be included in their care decisions and feel empowered to share what quality care means to them (Bailo, 2019). Furthermore, having a patient-centered home care approach is beneficial to the well-being of the patient. Patients feel more in control of their cancer care when they are a part of the team, which has also been correlated with patient reported quality of life improvements (Hess, 2013). The shift to a patient-centered cancer care approach is especially important with the impact of the COVID-19 pandemic.

Patient Selection for At-home setting

At-home cancer treatment has grown in acceptance over the last decade and is now generally approved by most healthcare agencies. One study compared at-home treatment to outpatient treatment of colorectal cancer, looking at patient safety, compliance, use of health services, quality of life, and satisfaction with treatment. The results demonstrated that at-home chemotherapy treatment was “an acceptable and safe alternative to hospital treatment for patients with colorectal cancer that may improve compliance and satisfaction with treatment” (Sirilerttrakul, 2021).

At-home cancer treatment for oral or intravenous chemotherapies is practical and can be delivered safely if individuals and their caregivers are carefully selected and trained. It is important that cancer patient eligibility criteria include learning capability, home environment, and geographic accessibility (Tralongo, 2011). Tralongo (2011) demonstrates that providing cancer care at home has shown many advantages for both patients and health providers. Reported health provider advantages include a reduction of calls to the office, a reduction of malpractice claims, and more accurate monitoring of patient at home. Reported patient advantages include improved medication management and adherence, optimized treatment outcomes through minimized or avoided treatment delays, improved quality of physical and spiritual aspects of life, enhanced psychosocial and caregiver support, reduced unnecessary emergency visits and hospitalizations, reduced length of hospital stays, and a reduction in wait times.

Australia’s leading provider of home-based infusion treatments, chemo@home, provides an example of factors influencing patient choice for home cancer therapy. The program provides cancer treatment in the home setting and notes that patient advantages for home care include greater convenience; a more relaxed environment; a sense of familiarity; less hassle with time, transportation, and scheduling; fewer costs associated with travel and parking; a decreased need to rely on caregivers or childcare; and a decreased risk of infection and anxiety around being exposed to infection (Viewhealth, 2021). Chemo@home outlines from a patient perspective which types of individuals might be interested in receiving treatment at home. Those aspects include having an active lifestyle and family and mobility challenges that make it difficult to travel to a treatment center. Other attributes also include those who have busy working lives or those who just wish to maintain as much independence as possible (Viewhealth, 2021).

According to the Oncology Nursing Society, when considering at-home infusion of cancer treatment, the safety of patients, families, and healthcare workers is of prime importance. Healthcare facilities must take a programmatic approach to evaluate their ability to offer home infusion of antineoplastics, and not all facilities will have the capacity, staff, and resources to do so. Determining the feasibility of home infusion of cancer treatment requires careful patient selection, provider and patient education, and extensive planning (Gorski, 2020).

The exclusion criteria for cancer patients getting at-home cancer care varies among home care services and included prior history of cancer, psychiatric diagnoses, and concurrent clinical trial participation. Many patients have vastly different care requirements, diagnoses, and comorbidities, which makes standardizing eligibility/exclusion criteria difficult (Penn Cancer, 2021). Some disqualifications for patient admission include lack of insurance coverage for the medication to be given at home, homelessness, large and/or

mobile animals in the home, patient rural location, cognitive status, lack of caregiver, inability to adhere to safety procedures, and lack of motivation to be involved in medical care. Limited studies have been done to study these disqualifiers.

The type of cancer treatment that a patient receives is an important factor as to whether the medication may be given in a hospital setting, at home, or at an outpatient clinic. The complexity and risk of infusion-related complications should be evaluated to determine if the regimen is suitable for home infusion (Penn Cancer, 2021). Penn Cancer looks for suitable patients for at-home cancer treatment, and screening of cancer patients for at-home cancer treatment is common practice. The CC@H coordinating team screens patients for a few of the following: cancer type and stage, cancer medication prescribed, insurance coverage, patient cognitive status and ability to follow directions, patient age and excessive mortality risk, patient home location, and availability of caregiver (Penn Cancer, 2021).

Penn Cancer does not home infuse taxanes or other drugs with high risk of severe adverse reactions. They also recommend administering at least one round of therapy in a clinic before approving a patient for home infusion (Rinde, 2021). The Community Oncology Alliance (COA) vice president, Miriam J. Atkins, MD, FACP, has concerns about at-home chemotherapy infusion. Dr. Atkins states, "It may look good in theory, on paper, but in my office, we've had patients have severe reactions. We've had patients die within a minute of an infusion. Some places are thinking, well, we did the first infusion in the doctor's office, and we'll do the rest at home. No, because we've seen patients do fine with the first three, and then with the fourth or fifth they have a serious reaction" (Rinde, 2021).

Patient Selection for an Outpatient Setting

Moving chemotherapy administration from the inpatient to the outpatient setting has been a common practice in the oncology world for many decades. Chemotherapy administration in the outpatient setting has been shown to be safe and effective, and some providers find it to be a much easier setting in which to treat patients. Treating cancer patients in outpatient settings has many advantages: comfort with a clinic setting, familiarity with drug administration and staff operations in the clinic setting, avoiding hospitalization and related costs, convenient care, and presence of an oncologist and/or multiple competent staff.

The University of Arizona Cancer Center developed specific criteria for selecting patients for outpatient chemotherapy. Barriers to outpatient chemotherapy include excessive travel time or unreliable transportation. Eligible patients include those with a good support system who are often accompanied by caregiver(s) during treatment. To provide the quality care that patients with cancer need, they offer after-hours care since patients no longer receive the 24-hour care provided in the inpatient setting (McBride, 2020).

Cancer patients in the outpatient setting often express dissatisfaction with wait times and excessive appointment delays. Interviews conducted with cancer patients at MD Anderson clinics confirmed these frustrations. Additionally, staff were also frustrated with patient wait times (Kallen, 2012). Another obstacle for cancer patients in the outpatient setting is getting to and from cancer treatment, especially for low-income cancer patients. (Sparling, 2016). The American Cancer Society has developed the Road to Recovery Program to help address transportation issues by providing rides for cancer patients to their cancer treatment (American Cancer Society, n.d).

Patient Safety and Legality

Patient safety in cancer treatment was identified by the Institute of Medicine (IOM) as a major healthcare quality issue. Standards and guidelines for cancer therapy in the outpatient setting were identified and set by a joint effort with the American Society of Clinical Oncology (ASCO) and Oncology Nursing Society (ONC) in 2009 (Neuss, 2016). Over the past eight years, the ASCO and ONC have continued to monitor patient safety to provide standards for quality cancer treatment in various settings (Neuss, 2016).

According to a *JAMA Oncology* special communication dated October 2015, experts share that medication errors in the outpatient chemotherapy setting are approximately three to 19%, noting that most were not

serious incidents (Chera, 2015). However, patient safety in cancer care continues to be an issue needing improvement. A few high-profile cancer patient medication errors that resulted in death were identified and underscore the need to improve patient safety in outpatient settings (Chera, 2015). Understandably, some patients have resisted novel home or outpatient infusion services due to safety concerns (Penn Physician, 2020).

Another element of patient safety is ensuring informed consent before administering chemotherapy, which is the standard model of care. For outpatient and home care services, the informed consent document should be tailored towards the newly assumed risks the patient and providers will be accountable for. The consent document should include information about medical uncertainty and comfort care and must inform patients about treatment side effects, as well as cost. Meeting these informed consent requirements protects patient independence and minimizes physician liability (Michels, 2005). Many physicians use the informed consent as a checklist to educate the patient and family on expectations and side effects of treatment. Education can be provided by the nurse or cancer care team. The physician is ultimately legally responsible for obtaining patient consent (Michels, 2005).

Understanding the financial barriers and impact on patient cancer treatment is an important factor that influences care. The financial burden of cancer treatment is increasing, which causes more stress on cancer patients and families. Robin Yabroff, PhD, MBA, founding member of Interagency Consortium to Promote Health Economics Research on Cancer (HEROic), shares that her research “identifies factors at the patient, provider, health system, and policy levels that can be modified to improve access to and receipt of affordable cancer prevention, screening, treatment, survivorship, and end-of-life care” (ACS, 2021).

One article discusses how a cancer diagnosis has a triple toxicity impact for patients: the physical effects of the disease and the treatment are both a physical toxic effect of cancer; treatments are expensive and may inhibit the patient’s ability to work, leading to financial toxicity; and this results in the third toxicity of cancer, the psychosocial or mental toxicity. The triple toxicity can take a stressful toll on a person’s wellbeing. The NCCN clinical guidelines for evaluating Distress During Cancer Care are important to use in patient-centric cancer care to ensure quality care and to improve the patient experience (2020). In the healthcare industry, this is a well-known screening instrument and studies show it works well. Most patients will feel sad or fearful at times during their cancer diagnosis and treatment. It is critical to assess their mental status and emotional well-being to help alleviate feelings of despair and to promote comfort, coping mechanisms, care compliance, and ultimately the best possible health outcomes (NCCN, 2020).

At-home Care

In recent years, the healthcare industry has experienced increased demand from patients and family caregivers for the delivery of healthcare services in their homes. Formal home healthcare policy for such services already exists in both public and commercial healthcare plans, with innovative home care expansion in progress. A key driver of demand is increasing patient desire to receive care in the comfort of the home (Jacobs & Eggbeer, 2021). This enhances quality of life, enables work and daily routines, facilitates healing, and even improves patient safety with respect to minimizing falls, complications, and infection control concerns (Hummel, 2017).

Keeping vulnerable patients safe during the COVID-19 public health emergency demands industry shifts to innovative home care solutions for healthcare delivery. Additionally, studies show that home care decreases the need for hospital readmissions during the first 30 days post-acute care discharge, with patients healing faster and better in familiar surroundings (TRACIE, 2021). Emerging technologies such as smart infusion pumps and digital monitoring provide more choice and offer patients options for home care services and self-care treatments.

Outside the United States, publications specific to home infusion therapy in the United Kingdom (UK), administered by National Health Services (NHS), describe hospital-based home infusion services surrounding noncomplex pharmaceuticals. Their home infusion considerations largely mirror those found in U.S. literature; they include discussions on patient appropriateness, coordination of care, self-care abilities and training, caregiver training, safety, infusion administration protocols, treatment goals, medications, side effect management, nursing support, ongoing monitoring, and frequent evaluations (Royal Brompton and Harefield Hospitals, n.d.).

One example of chemotherapy services offered outside of the clinical setting in the UK is a mobile clinic, or “ChemoBus.” This bus parks in neighborhoods central to patient locations and delivers care inside of the mobile unit. A UK web blog post by Cottier et al. (2021) highlights the mobile bus clinics and discusses patient demand for cancer treatment in the home. It also references guidelines from the Penn Medicine case study on home infusion therapy. The mobile unit “is a roaming cancer care, dispensary, support, and infusion service that is staffed by two nurses and can see up to four patients at a time at a preferred care location.” The program “partners with local hospitals who provide staff, coordinate and operate care services, conduct risk assessments, and define eligibility and exclusion criteria for their patients.”

Within the United States, the Centers for Medicare & Medicaid Services (CMS) on November 25, 2020, announced several flexibilities aimed at allowing healthcare services to be provided outside of a hospital setting in response to the surging COVID-19 pandemic. And as such, the American Hospital Association (AHA) urged CMS to expand the Hospitals Without Walls program by introducing the Acute Hospital Care at Home program. This program allows for providers and hospitals to bring acute care to the patient’s home, with program expansion allowing for more flexibility in regulations (American Hospital Association, 2020). Per the CMS QualityNet web page as of February 3, 2022, the current counts of approved health systems for Acute Hospital Care at Home are: 91 systems, 201 hospitals in 34 states (Centers for Medicare and Medicaid Services, 2022a).

The increasing numbers of healthcare systems participating in Acute Hospital Care at Home services are a significant development for growth in home infusion services, as both services converge in coordination of care and discharge planning. Patients that meet clinical criteria for home infusion may be inpatients nearing discharge, emergency department patients with a need for long-term intravenous (IV) antibiotics or other injectable therapeutics, or patients from outpatient clinics where their treatment plans are progressing towards outpatient infusion therapy. The cost of infusion therapy administered in the home is significantly less than inpatient settings.

Infusion therapy patients are considered outpatients and, as such, have lower care acuity than inpatient care patients; despite this, complex drug infusions may require continuous nurse presence to manage infusions and potential side effects. Most patients need pre-infusion laboratory tests and pre-infusion

medications, and this requires a multidisciplinary team approach, physician examinations, and orders (CMS, 2020).

It is notable that “effective on January 1, 2021, Section 5012(d) of the 21st Century Cures Act (Pub. L 114-255) amended sections 1861(s)(2) and 1861(iii) of the Social Security Act, requiring the Secretary to establish a new Medicare Home Infusion Therapy (HIT) services benefit under Medicare Part B. The Medicare HIT services benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education, remote monitoring, and monitoring services for the provision of home infusion drugs furnished by a qualified HIT supplier” (Centers for Medicare and Medicaid Services, 2020). In the U.S. healthcare industry, medical policy developed and published by CMS for Medicare beneficiaries is often adopted at least in part by private, commercial healthcare insurance, and other federal and state agencies such as Medicaid and TRICARE.

At-home Setting

A March 2021 research article supports infusion therapy in the home for cancer care. The article reasons that the concept “allowed for the continuation of anti-cancer injections without postponement during the pandemic” (Mittaine-Marzac et al.). The concept also reduced unnecessary travel to hospitals and therefore risk of contracting COVID-19 for patients. (Mittaine-Marzac et al., 2021). As more infusion therapy is delivered in the home, it is essential to have a nurse case manager to coordinate the infusion therapy with the multidisciplinary healthcare team. A comprehensive patient assessment and home assessment should be performed before initiating infusion therapy at home to ensure that the patient is an appropriate candidate for home care. The home environment should be safe, free of fire hazards, have working utilities, adequate internet if there are remote monitoring needs, a refrigerator for medication storage, and adequate caregiver support (Mittaine-Marzac et al., 2021).

Remote monitoring of patients by the healthcare team may be indicated before, during, and after infusion, so that problems are identified early. Patient comorbidities may be impacted or exacerbated by complex infusion drugs and therefore must be monitored along with infusion drug side effects. Telehealth monitoring equipment, such as digital blood pressure cuffs, stethoscopes, glucose monitors, and pulse oximeters, can record and transmit data to clinicians (Health Recovery Solutions, n.d.; Thomson, R. & Titchener, K., 2021; Jacobs & Eggbeer, 2021).

Addressing common home infusion therapy challenges is essential to the creation of a home infusion program. Programs such as these are intended in part to serve patients living in rural areas, yet the increased distance may pose issues when supporting both outpatient care needs and at-home services. Working in rural areas may also pose issues ensuring that patients have access to reliable internet or wireless services for telehealth visits. An additional concern is patient home viability for delivering care with the need for refrigeration, space for infusion, and staff safety posing potential issues. Additionally, scheduling around patients’ work and daily routines may be difficult if there is increased demand for off-hours infusions. Last, reliance upon caregivers, and the obstacles that may arise when patients lack a caregiver, can be barriers for home infusion care.

Providing At-home Care

Infusion therapy at home creates additional flexibility that allows for certain healthcare services to be provided outside of a traditional hospital setting and within a patient’s home or outpatient settings such as infusion centers and outpatient clinics. Because patients may have other comorbidities and difficulties with performing activities of daily living (ADLs), a multidisciplinary team approach is essential for patient safety and wellbeing (Mittaine-Marzac et al., 2021).

The delivery of infusion therapy and associated care provision should include many of the same services available for inpatient and outpatient infusion. Upon the multidisciplinary team approval for individual patients to receive home infusion services, a nurse or case manager should obtain and review physician orders and pre-infusion labs, schedule infusion appointments, and complete any other activities to initiate home infusion therapy (Infusion Nurse, n.d.).

Regularly, patients will need diagnostic testing and physician visits either performed in person at a healthcare facility or via home visit and telehealth, respectively. Data from these visits should be recorded in the patient chart, which can then be used to create a nursing care plan. Before the home infusion visit, patients and caregivers should be educated and notified of the potential delivery of medications and durable medical equipment, if applicable. During and following the home infusion, the nurse monitors patient vitals, oxygen levels, and blood glucose. They also perform line maintenance, assessing line site and patency regularly, keeping infection control and prevention a priority. In the event of an emergency during infusion, the program must have a policy instructing staff on when to access EMS (Infusion Nurse, n.d.).

Complications may impact patients in any clinical setting; however, the provision of care in the patient home requires the multidisciplinary healthcare team to have a keen awareness or patient safety could be compromised. Some challenges that may arise include weather-related events that keep nurses from traveling to the patient home, burnout or illness of caregiver, fevers or infections, changes in cognitive status, severe side effects, and patient complications or worsening comorbidities (Hummel, 2017; Shaw, 2020).

At-home Care Approval

In studies, the approval process is accomplished on a case-by-case basis, with flexibility to accommodate changes in the patient condition such as inability to tolerate complex infusion drugs without severe side effects, increasing frailty, and other issues. Discharge planning for the infusion therapy transition from hospital to home is essential to avoid interruption in infusion therapy (Mittaine-Marzac et al., 2021, 2022).

Before choosing to receive care in the home, the patient and caregiver should understand the processes and requirements, including the role of the caregiver and expected duration of treatment. To reduce stress for the patient and caregiver, ample time is necessary to prepare and receive training. Studies describe increased stress when patients and caregivers only had a couple hours or an overnight to prepare (Mittaine-Marzac et al., 2021, 2022).

Outpatient Care

Patients are increasingly accessing chemotherapy treatments at outpatient sites of care (Hopson et al., 2018). When patients are diagnosed with cancer, they may be offered one or multiple forms of treatment. These treatments include but are not limited to chemotherapy, bone marrow or stem cell transplantation, hormone therapy, immunotherapy, radiation therapy, or surgery. Treatments can be administered either intravenously or orally in either a hospital, outpatient clinic, or at the patient home (ASCO Answers, n.d.b.; ASCO Answers, n.d.a.). These settings differ from traditional inpatient care, as they allow patients to receive anti-cancer infusions without traveling to major hospitals or being admitted for an overnight stay. Additionally, with the rise of telehealth, care offered in outpatient settings can use teleoncology consulting, which allows providers to manage patients in various geographical locations (Bertucci et al., 2019). This care model uses outpatient clinics with similar attributes to VA's Community Based Outpatient Clinics (CBOCs). For the purposes of exploring care delivery in this setting, literature and standards generally concerning outpatient infusion were used to gain insight on this practice.

Outpatient Setting

To provide high quality care, the outpatient setting must be held to high standards for safety. As defined by the National Infusion Center Association (NICA), outpatient infusion clinics must adhere to specified standards (NICA, 2019). These include the need for the facility or organization to have policies concerning the preparation and administration of drugs; thorough documentation practices; education and competency of staff; protocols for medication labeling, handling, storage, and disposal; patient education; observation of patients; clinician-to-patient ratios; adverse reaction kit maintenance and use; adverse event reporting and documentation; injection protocol; infection control; and responding to needle-stick injuries (NICA, 2019).

The standards set by NICA stipulate that drug orders must be specific for each patient and include clinically relevant details for administration (2019). This includes the medication name, dosage, administration route and rate, dosage frequency and duration, staff monitoring requirements, pre-medications, and instructions for potential adverse reactions. A Licensed Independent Practitioner must provide these details before administration (NICA, 2019). Additionally, according to the American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society's (ONS) joint standards, verbal orders for chemotherapy are not permissible; providers must issue electronic or written orders and sign the orders either manually or electronically (2016). Before administration commences, the patient must give consent for treatment, and staff must document this (Neuss et al., 2016). This process must ensure that the patient receives information in an appropriate manner and maintains the ability to choose other treatment alternatives if they desire (NICA, 2019).

The need for policy is underscored by ASCO and ONS joint standards (Neuss et al., 2016). These standards additionally call for infusion staff to collect medication allergy history, psychosocial state, and pain levels. Furthermore, the organization must have a pathway to provide 24/7 access to emergency triage for patients, whether that be a provider on call or direction for the patient to seek care in an emergency department/call 911 (Neuss et al., 2016).

In the event of an adverse reaction, the infusing facility must keep certain supplies on hand, as well as ensure that staff administering and preparing medications maintain Basic Life Support (BLS) certification (NICA, 2019). The supplies necessary to treat adverse reaction include medications such as epinephrine, corticosteroids, and IV fluids. The facility should also maintain equipment for resuscitation and breathing support (NICA, 2019). To maintain a culture of safety, standards set by ASCO/ONS require that facilities maintain a policy for both reporting adverse events and near misses and for reviewing these events (2016).

In addition to detailed guidelines for administration, NICA standards require specific precautions for the preparation, handling, and storage of medication. These include, but are not limited to, the requirement for staff to store drugs according to manufacturer instructions, to properly dispose of expired medications, and to ensure that drugs meet consistent and safe standards (NICA, 2019). The standards set out by NICA are

supplemented by the requirement to adhere to applicable OSHA and CDC standards (2019). Additional standards for storage of chemotherapy medications and removal of hazardous waste promulgated by the United States Pharmacopeia (USP) 800 should be followed as well.

Providing Outpatient Care

According to NICA standards, the facility must ensure that a physician or nurse practitioner is available for consult in person or by phone (2019). This standard differs from those provided by ASCO/ONS, as their guidance specifically requires that a provider be on site to consult staff administering chemotherapy (ASCO/ONS, 2016). ONS notes that no current standard staffing models exist for ambulatory chemotherapy centers; however, they note nursing should have appropriate education, and the number of staff should be determined on a clinic-by-clinic basis, dependent on clinic patient classification and acuity (2019).

Before infusion services are rendered, the patient must be assessed by nursing staff (NICA, 2019). This assessment should verify patient identity; inform the patient of what to expect during treatment; ensure patient vitals, height, and weight are acceptable; review medical and medication history; confirm a lack of contraindications; assess need for further information regarding treatment; and provide written information on the patient's treatment (NICA, 2019). Following assessment of the patient, the patient identity and correct dosage must be verified and documented by two staff members (ASCO/ONS, 2016).

While the patient undergoes infusion treatment, staff should monitor the vitals and assess for any reaction. Additionally, before and following treatment, staff must collect the following vitals: body temperature, blood pressure (BP), heart rate, oxygen saturation, and respiratory rate (NICA, 2019). Any changes to infusion rate must be directed by a licensed provider; however, staff administering the medication may decrease infusion rate, if necessary, by using clinical judgement (NICA, 2019).

Infusion facilities must maintain a policy that requires staff to assess patient symptoms following treatment. Once treatment is completed, staff must document chemotherapy toxicity, if applicable (ASCO/ONS, 2016). In the event of toxicity, dose modification must occur before the patient continues their treatment regimen. Documentation of doses is imperative for tracking those drugs that may lead to cumulative toxicity (ASCO/ONS, 2016).

Pharmacy

Pharmacy Setting and Compounding

Pharmacists play a vital role in the treatment of cancer patients and are integral to a variety of aspects of their care, including pre-admission assessment, education, clinical monitoring, and care plan development (Option Care, 2017). Determining pharmacy staffing needs should be informed by the complexity of patient clinical management as well as the incorporation of prescription and order development timing. The pharmacy should also provide enough staff to manage a pharmacy during business hours and allow for a pharmacist on call 24 hours a day and seven days a week. (ASHP, 2019).

Pharmacists compound a variety of non-sterile (i.e., topical, pills) or sterile (i.e., injectables) medications. (APhA, 2021). Antineoplastic drugs may require compounding and are considered hazardous drugs under the NIOSH listing (NISOH, 2016). Compounding of these drugs requires adherence to state board of pharmacy regulations and, with the passing of the Drug Quality and Safety Act (H.R 3204) section 503A, of the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration (FDA) has oversight on pharmacy compounding (NHIA, 2021; FDA, 2018). Pharmacies should comply with guidelines set by DHHS and the DEA for compounding and maintain active accreditation for compounding from organizations including The Joint Commission, Community Health Accreditation Program (CHAP), Pharmacy Compounding Accreditation Board (PCAB), Healthcare Quality Association on Accreditation (HQAA), Accreditation Commission for Healthcare (ACHC), and Medicare (APhA, 2021).

Pharmacies should also adhere to principles outlined in the U.S. Pharmacopeia (USP) Chapters 797 for sterile compounding and 800 for handling of hazardous materials. USP 800 notes that all hazardous drug compounding should occur in a negative-pressure room; however, if unavailable, containment segregated compounding area (C-SCA) must be utilized. Additionally, compounding areas should have a primary engineering control (C-PEC), which is a ventilated device to prevent exposure and contamination (USP, 2008). Separate storage space must be used, and safety measures must be put in place, such as spill kits available where the drug is located (USP, 2016). Establishing a pharmacy that has sterile compounding capabilities requires investment in facilities, equipment, personal protective equipment, record maintenance, and, most importantly, education and training of staff that will be completing compounding methods.

For pharmacists, there is no mandatory education or certification requirements for compounding; however, certification is available through the Joint Commission Medication Compounding Certification and the Pharmacy Compounding Accreditation Board (PCAB) (Holle et al., 2021; ASHP, 2013). Pharmacist that compound antineoplastic drugs should have experience and be specially trained. The Penn Center for Cancer Care Innovation program operates its own infusion pharmacy with clinical pharmacists trained in home infusion (Penn Medicine, 2021).

For transportation, packaging should ensure integrity, sterility, and stability of the medication during transport (USP, 2016). Spill kits should be provided, and SOPs should address accidental spills or exposure. Policies and procedures should be available to ensure product integrity and temperature control during home delivery. The pharmacist should also ensure that the medications are delivered in a timely manner (ASHP, 2013). The entity must have written SOPs to describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, and mode of transport. Other sources of information may include the chemical or formula and the safety data sheet (USP, 2016). For delivery, utilization of in-house drivers provides the benefit of added oversight but is more financially costly. Courier services may be more financially feasible but could encounter issues with availability for deliveries (ASHP, 2021).

Pharmacy Approval

Integration of new medications into the VHA formulary should follow the VHA Formulary Management Process (VHA, n.d.). Formularies cannot be modified at a local level and require use of the VA National Formulary. Requests for additional modifications must be submitted to the PBM by appropriate personnel

for consideration (VA, n.d.). VHA directive 1108.07 outlines pharmacy general requirements and includes information on requirements for provision of medications in a home health setting (VA, 2021). Transportation of drugs should adhere to EPA standards and safety standards as outlined by USP 800 (USP, 2016).

Utilization of drugs in clinical trials for home infusion has additional complexities and may be out of scope for this project. Treatment in clinical trials may vary from standard administrations with dosing, drugs, and scheduling differences that pharmacists may be unfamiliar with (Clinical Oncological Society of Australia, 2008). Investigational drugs require strict monitoring by study sponsor and may be limited in ability to dispense in home setting. Institutional Review Board (IRB) review and approval would also be required for clinical trial drug administration and protocols will need to outline if medications will be delivered offsite, with oversight management plans to ensure appropriate clinical management of patients.

Oncology

Oncology Departments

Oncology departments serve as the leader for implementing novel infusion therapy. Thus, creating buy-in and support from providers is of utmost importance. Innovative infusion practices, such as home care and outpatient care, require specific workflows, policies, and procedures to be in place for implementation. The creation of new workflows should also follow recommendations made by authorities in the field of oncology. For example, the Oncology Nursing Society developed a position statement titled, *Infusion of Antineoplastic Therapies in the Home*, which was approved by the ONS Board of Directors in August 2020. These guidelines provide insight to the feasibility of home infusions for cancer treatment as well as the safety of patients, families, and healthcare workers, and should be strongly considered by oncology department staff (*Infusion of Antineoplastic Therapies in the Home*, 2020).

Adhering to safety standards ensures that policies and procedures remain in place to minimize risk for error and patient harm. Safety standards can and should be amended to apply specifically to settings such as the patient home. In addition to adherence to administration safety standards, healthcare facilities must consider the elements of antineoplastics that make their administration a specialty, requiring focused training and competency validation of staff involved (*Infusion of Antineoplastic Therapies in the Home*, 2020).

In addition to ensuring safety measures, oncology department staff should anticipate changes to their day-to-day activities. Patients who receive infusion therapy in alternate settings must be screened for treatment to process. Accordingly, staff must be trained to assess patients and make clinical decisions on their ability to tolerate infusion outside of the hospital. In a 2016 study published in *The American Journal of Emergency Medicine*, 31 of 32, or 97%, of patients enrolled in home infusion therapy for cellulitis avoided a hospital admission. Staff screened for “patient ability and willingness to administer IV antibiotics at home and insurers’ approval of home infusion services” (Rentala et al., 2016).

This study also highlights that hospital staffing changes may occur because of program implementation and consequent shifts in care setting needs. While home infusion care involves nurse services closer to eight hours a day, inpatient hospital care requires staffing 24 hours a day (Rentala et al., 2016). While staffing concerns impact adding a home infusion therapy service to the VHA, overall, the nurse home care staffing may require less staff than needed to support both inpatient and outpatient settings.

Studies conducted during the COVID-19 pandemic found that providing antineoplastic injectable drugs at home freed up hospital staff to care for sicker patients. To support increased staffing levels for home infusions, part-time nurses changed to full-time, and some nurses returned from retirement to assist new home infusion programs. Other hospital ancillary staff, including pharmacy, may have neutral staffing changes depending on patient census (Mittaine-Marzac et al., 2021).

For oncologists, there will be increased time demands for patient discussions, paperwork, care coordination, and taking calls from nurses and patients during and after home infusions. Increased demands on the oncologist may be relieved in part with staffing of advanced practice nurses, physician assistants, and case managers. Ideally, this support staff would work together with the oncologist on care coordination activities. This may include being a first-line resource for home infusion nurses, with additional staffing depending on the oncology department patient load. Additionally, infusion nurses will educate patients on the oncologist’s healthcare plans, allowing for physicians to focus on other clinical tasks.

The oncology department may also benefit from support provided by the organization’s data analytics team, if available. Hospital data can be used to screen the patient population of potential candidates for home infusion therapy. Furthermore, data analysis could be used to help providers select patients meeting specific criteria and metrics for home infusions based on approved home infusion drugs (CareCentrix, n.d.).

An important goal of outpatient chemotherapy including the provision of it in the home and other nontraditional settings is to minimize ED visits and hospital admissions. This requires effective communication strategies between the oncologist, the multi-disciplinary healthcare team, and the patient. To reduce complications such as ED visits and hospital admissions after a patient has received chemotherapy in an outpatient setting, CMS through its PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program developed an outcome-based quality measure for eligible hospitals referred to as PPS-Exempt Cancer Hospitals (PCHs) (CMS, 2021a). The measure description from the CMS Measures Inventory Tool evaluates inpatient or emergency department visit rates for adult cancer patients within 30 days of outpatient chemotherapy treatment at a short-stay, acute care hospital. The tool evaluates for several diagnoses, including anemia, dehydration, fever, neutropenia, pneumonia, or sepsis (CMS, 2021b).

As technology advances, the delivery of medical care has vastly changed. In addition to using clinical decision support to assess patients' fit for outpatient and home infusion therapy, virtual visits allow providers to provide oncology care for patients without travel for those appointments. VHA's National Oncology Program Office's innovations in cancer care are striving to provide care where Veterans are located through TeleOncology services. This allows for oncology care and oncology sub-specialty care to be available to Veterans across the United States through virtual visits. A 2021 research study in the American Society of Clinical Oncology notes that, "Veterans are broadly satisfied with teleoncology," yet the technology needed to provide these services can pose obstacles for those patients living in rural areas (Jiang et al., 2021).

An example of an organization leading the way in novel infusion practices is the Cancer Treatment Centers of America (CTCA). They strive to make chemotherapy infusions and injections as comfortable and convenient as possible by offering qualified patients the option to receive treatment at home through their Oncology Clinic at Home program in partnership with CVS Health (CTCA, n.d.). Like VHA TeleOncology services, CTCA's Oncology Clinic at Home program includes telehealth services provided by CTCA Anywhere, "a virtual visit technology that allows eligible patients to meet remotely with their oncologists and other members of their care team" (CTCA, n.d.).

Oncology Providers

Oncology providers serve as an integral player in the provision of novel infusion practices. Their clinical knowledge and expertise play a critical role in not only providing services to patients, but also to the creation of the program. Their input will be necessary for the creation of workflows and other programmatic clinical guidelines. One example of this process was when 250 infusion providers and advocates wrote a letter about the implementation of Medicare's Home Infusion Therapy (HIT) benefit. The infusion provider industry collaborated to offer suggestions to CMS in developing the HIT medical policy (Verma, 2020).

The group strongly supports HIT services and demonstrated that current home and outpatient-based infusion programs have reported high levels of provider satisfaction. The care model recommended by industry leaders allows providers to meet face-to-face with patients to outline care options, including home infusion and outpatient infusion. They also suggest that before a provider recommends home infusion services, the provider must conduct an evaluation on medical appropriateness of that specific patient (NHIA Stakeholder Letter to CMS, 2020).

Other groups, such as CVS Health's Transform Oncology Care, closely follow National Cancer Care Network (NCCN) guidelines to aid providers with the adoption of home infusion and reduce potential documentation burdens that this change may incur. These guidelines provide evidence-based clinical recommendations for over 97% of cancers. Based on the latest clinical trial results, these guidelines enhance safety by enabling evidence-based personalized patient care, reducing medication errors, and anticipating and managing adverse events. At CVS Health, the organization has leveraged NCCN guidelines in their oncology platform to provide clinical decision-making help (Pennic, 2019). This product

reduces physician workload by automatically approving “therapeutic regimens that align with NCCN guidelines” (Pennic, 2019).

Additionally, CVS Health created Transform Oncology Care, “a precision medicine program that uses genomic testing results at the point-of-prescribing to help patients start on the best treatment” (CVS Health, n.d.b.). This testing helps oncologists prescribe the most appropriate treatment regimen based on their patients’ genetic background. Aetna has adopted the new program for fully insured commercial populations and is rolling it out with participating Aetna provider networks in 11 states (Minemyer, 2019). Shortly after this implementation in June 2020, it was reported that this new endeavor improved care coordination, increased clinical support for physicians, resulted in faster treatment starts, and reduced emergency visits and hospitalizations (Pabst, n.d.).

While there are many positive examples of provider engagement with novel infusion therapy, an ASCO Position statement from June 2020 discusses concerns some oncologists have about infusion therapy safety in the home and outpatient clinic operations during the COVID-19 pandemic (ASCO, 2020). Not all oncologists promote the industry shift to home care. This statement details concerns specifically about home IV infusions of anticancer therapy. In addition to concerns about patient safety, they detail the potential ramifications for oncology providers during the shift to home care. This includes liability issues and potential staffing strain caused by oncology nurses previously able to care for multiple patients at once in an infusion center now infusing only one patient at a time (ASCO, 2020).

While these concerns are important considerations for the process of implementation of novel infusion therapy, there are many benefits showing the efficacy and viability of this practice. With reduced patient travel, this care model provides great benefit to patients. Furthermore, technological advances make connecting patients and providers even easier. To ensure that providers adopt this care model, it is important to include their input on creating workflows and clinical guidance that will best serve their patients.

Governance

A key component to healthcare delivery operations is to implement governance processes to ensure program quality and safety. Oversight responsibility often falls on an advisory or governing board that includes members representing different stakeholder groups. The primary functions of this body are to establish and maintain program policies, to define program scope, and to provide advisory support. In current literature for alternative infusion program governance, very little specific information was found, though more broad healthcare findings are available.

The practices of Australia's chemo@home program are like those in current literature. With representation from specialty groups that serve the program, their advisory board maintains program accountability (chemo@home, n.d.). Additionally, this group ensures that relevant and new services are available for patients while promoting the use of best practices and evidence-based care (chemo@home, n.d.). More specific stakeholder groups are defined in the University of Pennsylvania's Cancer Care at Home program with individuals from the following groups being included: Healthcare transformation, home infusion, cancer care delivery, cancer care administration, outpatient infusion, finance, and inpatient/outpatient care (Bekelman, 2020). In both instances, a multi-disciplinary group offers guidance and structure for innovative care delivery models.

For resources that are oncology-specific, the American Cancer Society's (ACS) governance committee charter serves as a model. The board is comprised of five to seven members with one being the ex-officio chairperson (American Cancer Society, n.d.). Serving on the board, members are responsible for reviewing policy, organizational risks, and compliance, as well as various responsibilities associated with maintaining the governance structure. The committee is assessed every two years for its ability to perform against defined metrics (American Cancer Society, n.d.). This model provides translational structural attributes that can be applied to programs and organizations different to the ACS.

The Association of Community Cancer Care Centers gives a more focused description of the activities performed by boards overseeing clinical oncology practices. In their guidelines, they suggest the establishment of a cancer committee to provide program leadership (Association of Community Cancer Centers [ACCC], 2012). ACCC guidance focuses in depth on the needs of patients navigating cancer treatment, with recommended committee members ranging from physicians and nurses to quality improvement and rehabilitation staff. This structure encourages programs to focus on patient outcomes, both granularly, in the form of patient chart audits, and with a broader population health approach (ACCC, 2012). In addition to patient care, attention is paid to measuring the performance of the program overall against defined metrics and goals. Structurally, this committee allows for a multidisciplinary approach to governance. While this approach can achieve high quality care, there are strengths and weaknesses to governance models with increased membership.

In Romiti et al., a team in Italy studied governance in two clinical oncology networks. Their findings demonstrate certain characteristics to be considered when building a governance model. A key finding contrasts the power of efficiency vs. inclusiveness. This phenomenon in governance describes the difficulties associated with ensuring processes are thorough and consider the perspectives of all stakeholders, while also maintaining an agile decision-making process (Romiti et al., 2020).

To gain trust and buy-in from stakeholders, inclusion in the governance process is necessary. Maintaining this engagement must be balanced with the ability to quickly make decisions and adjustments to program policies as needed without the added burden of getting approval from every stakeholder (Romiti et al., 2020). Governance structures may find an equilibrium that balances these considerations by employing informal communication channels to gauge perspectives. To satisfy this need, key stakeholders, or champions reporting to the governance board, will ensure wider perspectives are considered, while also maintaining deft decision-making capabilities (Romiti et al., 2020).

Governance plays a key role in the success of cancer programs. As discussed above, optimization between inclusion and efficiency should inform the structure of the organizational model. Including various

stakeholders in governance is key to creating trust; however, decision-making processes must be agile enough to react to programmatic issues (Romiti et al., 2020).

Support Services

Remote Monitoring

Patients receiving care outside of the traditional hospital setting can benefit from alternative methods of connection to the care team. Available methods for monitoring oncology patients rely heavily on patient-reported outcomes, with the collection of symptoms informing clinician intervention. Currently, there is a lack of literature suggesting the use of implantable devices for oncology patients; thus, the use of patient reporting is the suggested standard of care (McGregor et al., 2020). An initial study conducted by Wright et al. found that a wearable device collecting activity data was acceptable and recognized as effective by patients (2018). Despite these findings, literature regarding remote monitoring largely surrounds studies reliant upon patient-reported symptoms.

Practices described in literature largely reflect those used alongside Huntsman and CVS-CTCA's innovative home care delivery models. Using monitoring methods such as daily, online symptom reporting surveys and telehealth visits, these programs can ensure consistent communication between providers and patients. CVS-CTCA employs digital telehealth check-ins with various members of their care team, such as their oncologist and pharmacist, allowing patients to report concerns and get information about their treatment (Donlan, 2021). Other forms of connection are utilized in Huntsman's program, which employs a daily online self-check-in that allows patients to report symptoms and providers to track progress (*Journal of Clinical Pathways*, 2020).

Both methodologies are underscored by findings in literature that symptom survey assessments blended with human contact yield the most favorable results (Breen et al., 2015). In a multi-site randomized clinical trial conducted in Europe, researchers found that implementation of their Advanced Symptom Management System (ASyMS) reporting tool within a patient's first three cycles of chemotherapy yielded the most benefit for patients (Maguire et al., 2021). Using the Functional Assessment of Cancer Treatment – General scale (FACT-G), the team measured physical, social/family, emotional, and functional well-being during treatment (Maguire et al., 2021). These findings suggest that monitoring should be implemented at the beginning of a patient's chemotherapy regimen.

Effective symptom monitoring can confer higher quality of life for patients and can reduce ED visits and unplanned hospitalizations. In a study conducted by researchers at Memorial Sloan Kettering Cancer Center in New York City, patients receiving chemotherapy in outpatient centers were asked to complete weekly survey assessments at home in between chemotherapy treatments (Basch et al., 2016). Notifications of worsening symptoms allowed nursing staff to provide recommendations for medication regimen alterations, as well as referrals to seek ED or hospital care. Not only did this practice help to increase quality of life, but it also coincided with patients' ability to withstand chemotherapy treatment for a longer period (Basch et al., 2016).

Further benefits of remote monitoring in cancer patients include a reduction in anxiety and depression scores (Pang et al., 2020). Additionally, significant advantages for quality of life have been demonstrated for caregivers enrolled in a remote monitoring program (McGregor et al., 2020). Benefits of monitoring were even found to be greater for older and less computer-experienced patients, with investigators theorizing that structured symptom questioning may be beneficial for those patients with less perceived health literacy (Basch et al., 2016).

In surveying available literature regarding remote monitoring of patients receiving anti-cancer drugs, scant evidence of poor outcomes associated with the practice were found. Pang et al. found that lung cancer patients were more likely to benefit from telephone-based interventions as opposed to web-based surveys and surmised a correlation between the average lung cancer patient age and this preference (2020). Despite this, as shown by Basch et al., even patients with less computer skills benefitted from this practice, indicating the ability for this practice to provide significant positive results regardless of the population's skills (2016).

Below are several studies employing various methods for remote monitoring. These interventions range from patient self-reporting to wearable devices, with the use of devices being less frequently employed. Studies collecting patient symptoms often asked about 10 to 13 common symptoms associated with the side effects of antineoplastic drugs.

Table 1. Remote Monitoring Techniques

Engagement Method	Description	Frequency	Study
Smartphone-based app	Self-assessment of 10 symptoms (nausea, vomiting, diarrhea, constipation, mucositis, paraesthesia, sore hands/feet, flu-like symptoms/infection, tiredness, pain)	Daily (optionally PRN)	Maguire et al., 2021
Web-based (Sentinel PRO system (Hyperion))	Self-assessment of 13 symptoms	Weekly	Denis et al., 2019
Email prompting survey response	Self-assessment of 12 symptoms (appetite loss, constipation, cough, diarrhea, dyspnea, dysuria, fatigue, hot flashes, nausea, pain, neuropathy, and vomiting)	Weekly	Basch et al., 2016
Wearable device and smartphone-based app	Fitbit Zip (worn around the waist) and Fitbit Charge 2 (worn on the nondominant wrist) to measure performance status. Self-assessment of 10 symptoms (abdominal pain, nausea, vomiting, constipation, diarrhea, dizziness, peripheral neuropathy, fatigue, anxiety, and depression) using branching logic.	Continuous/daily	Wright et al., 2018

Integrated Care Team

Integrated care teams are standard practice for providing cancer care. This model translates to alternate care setting programs as well. For example, the Cincinnati VA Hospital in Home program includes a multidisciplinary team of caregivers involved with the patient's care while in the program. The team includes a nurse manager, a medical director, a physician(s), a nurse, a nurse practitioner, a social worker, a dietician, a clinical pharmacist, and administrative support personnel (Hubbell, 2022). In addition to this standard group of providers, other members of a cancer care team can also include physical, occupational, and speech therapists, as well as psychologists and psychiatrists (National Cancer Institute, n.d.).

Continuing with the example of the Cincinnati VA HIH program, the interdisciplinary care team meets daily, Monday through Friday, to discuss, plan, and make decisions regarding specific patient care issues. The medical director evaluates patients and coordinates physician coverage, as well as facilitates any necessary communication among other physicians, care providers, or community clinicians. The nurse manager oversees administrative and compliance aspects, while nurses provide direct care, assessment, monitoring, and education to patients in the program. Nurse practitioners, quality and administrative personnel, a social worker, and a dietician also collaborate with the team. The team pharmacist oversees drug administration and therapy, monitors drug levels and potential interactions, as well as provides patient education when appropriate or necessary (Hubbell, 2022).

Current literature mentions the referral to, and availability of, multiple areas of supportive care that should be available to a patient receiving chemotherapy at home. UPenn's Cancer Care @ Home program employs a multidisciplinary care team, all trained and educated in home infusion, comprised of clinical pharmacists, ONS-certified nurses, and palliative care providers. The specific Hematology/Oncology Clinical Care Team consists of four clinical pharmacists, four registered nurse coordinators, three patient supply representatives, and two patient service associates (Bekelman et al., 2020). Other programs, such as Huntsman at Home, partner with community-based nursing services that can provide connections to physical therapists and social workers (Healthcare.utah.edu, 2022). CVS Coram infusion business, partnering with Cancer Treatment Centers of America (CTCA), provides home-based therapy for cancer patients as well. Eligible CTCA patients receive in-home infusion from Coram nurses along with virtual telehealth and therapeutic check-ins. Through technology like Microsoft Teams, care is coordinated to monitor vital signs and side effects (CVS Health, 2021).

Nurse navigators are identified by ONS as being beneficial to patients experiencing cancer diagnoses, beginning with prevention, and screening activities all the way through end-of-life care. The oncology nurse navigator is particularly skilled in reducing barriers throughout the continuum of cancer care, including education, resourcing, and coordination aimed to "facilitate informed decision making and timely access to quality health and psychosocial care..." (ONS, 2021).

CMS additionally notes that the home infusion team requires coordination of care across medical services, including health plans, home health agencies, and home infusion pharmacies, along with patients and physicians (CMS, 2022). Home infusion treatment requires a vast coordination of care across nursing, professional services, physician, laboratory, and other departments.

The State of Victoria (2020) has recommendations for handover and communication between clinicians that follow an 'ISoBAR' format as shown below. This is used in care coordination handoffs; however, the specific timeframes are not listed.

ISoBAR HBCC minimum dataset – clinical handover

I	Identification	Introduce or identify patient, self, and team
S	Situation	Provide current working diagnosis, specific clinical problems, concerns, and critical laboratory results
O	Observation	Check, update and discuss recent vital signs
B	Background history	Update and discuss relevant medical and support information
A	Agree to plan (Actions)	Outline plan for assessment, treatment, and discharge
R	Responsibility and risk management	Confirm shared understanding, clarify tasks (read back critical information to check understanding), timing and responsibility transferred

Involvement with and referrals to a variety of support services are part of the home infusion care model with many programs. The Victoria program utilizes a screening form for referrals to supportive care services that assess a variety of problems that a patient might be facing, such as childcare, depression, bathing/dressing, pain, or spiritual concerns. This tool incorporates the NCCN distress thermometer as well as a malnutrition screening tool (State of Victoria, 2020). In addition to the actual treatment, chemo@home in Australia offers referrals to help patients address some of the other challenges that may be present with their treatment. They partner with outside organizations that assist with physiotherapy and 'stretchersize' programs and provide counselling for mental well-being (chemo@home, 2022).

III. GAPS BY TOPIC AREA

This literature assessment sought facts and evidence to provide answers to the questions and considerations gathered by the team in the initial research process. While a great deal of information was found in this process, there remain some considerations unanswered by current literature. Below is a listing, by section, of specific topics that were searched for but not found in peer-reviewed literature.

Nursing

All Nursing Options' Gaps:

- Lack of literature pertaining to nursing unions, the impact they can have, and tips for managing their role on home and/or outpatient infusion programs
- Lack of literature on communication protocols and pathways between nurses who travel for home or outpatient infusion programs and the program leads or team – this includes day-of communication when nurses are traveling and general team communication updates
- Lack of literature regarding lab schedules, timeline for labs prior to chemotherapy, and guidelines around labs in the home setting

Drugs

Drug Administration, Transportation, and Approval Gaps:

- Lack of literature on specific infection control guidelines for nurses traveling with medications for multiple patients
- Lack of literature on the specific methodologies that Medicare and other organizations used to choose and classify the drugs that were recommended
- Lack of guidance on transporting antineoplastic drugs and biologicals from a pharmacy that does not have experience and equipment for transporting these drugs

Patients

Patient Selection, Safety, and Legality Gaps:

- Lack of literature about how far patients can live from the hospital due to nurse travel and emergency protocols
- Lack of peer-reviewed literature on specific patient disqualifiers to be considered for a home or outpatient infusion service program

At-home Care

At-home Setting, Care Provision, and Approval Gaps:

- Lack of literature outlining the preferred or required distance a patient home must be from the nearest emergency center for being accepted into a home infusion program
- Lack of literature pertaining to the continued evaluation of home and outpatient infusion programs by various compliance, accreditation, or governing boards/agencies

Outpatient Care

Outpatient Setting, Care Provision, and Approval Gaps:

- Lack of literature pertaining both to specific staffing ratios and a standard staffing model for outpatient infusion clinics
- Lack of literature on the minimum requirements for the physical space of an outpatient clinic or the specific rooms where the infusion takes place
- Lack of literature on the maximum or minimum distance requirements that an outpatient infusion clinic needs to be in proximity to an emergency department
- Lack of literature clearly stating the ONS certification requirements for outpatient infusion clinic staff

Pharmacy

Pharmacy Setting, Compounding, and Approval Gaps:

- There is no specific case study example for pharmacy best practices with respect to compounding and transporting drugs outside of the hospital setting
- Lack of literature on the approvals necessary, and/or laws in place, for nurses and pharmacists to be able to transport drugs outside the hospital setting
- Lack of literature about VA-specific formulary updates and processes for changing pharmacy workflows

Oncology

Oncology Department and Provider Gaps:

- Lack of best practices or tips for securing physician and provider buy-in for implementation of new and novel infusion practices
- Lack of best practices or tips about how oncology departments can manage workflow changes
- Lack of literature detailing specific criteria for oncologists to use to determine if a patient is fit for home infusion care and/or outpatient infusion care

Governance

Program Governance Gaps:

- Lack of literature on building equity into governance models specific to Oncology programs
- Lack of literature explaining specific check-and-balance responsibilities between and amongst governance board members
- Lack of literature explaining how issues are identified and the policies in place to ensure each issue is resolved

Support Services

Remote Monitoring Gaps:

- Lack of literature on purely telephone-based remote monitoring

- Lack of recommendations for ensuring equity between patients that do not have internet access and those that do
- Lack of literature supporting a single best remote monitoring technique

Integrated Care Team Gaps:

- Lack of literature describing the utilization of mental health providers or nurse navigators within the cancer care plan for patients in home infusion programs
- Lack of literature providing specific team communication guidance, such as meeting cadence, meeting structure, communication modalities for team updates, process for immediate and non-immediate updates, timeframes, or time requirements for communication processes
- Lack of literature explaining management protocols of this project team, especially if team members maintain some responsibilities supporting inpatient infusions too

IV. BEST PRACTICE RECOMMENDATIONS BY TOPIC AREA

This section builds off the information in Section II to provide specific, best-practice recommendations for the Infusion IPT program to employ with respect to each topic area. These recommendations are based in the evidence and research findings that are presented in Section II. However, that evidence is not always repeated in these brief recommendations. For more context and information regarding each recommendation, please refer to the respective topic area of Section II. Additionally, the recommendations presented below are categorized into either “make” or “buy,” except for the patient recommendations. A large goal of this literature review was to assess the feasibility of building each program component from scratch within VA or hiring contract help. These recommendations are founded in literature, but also include some inherent bias around the author’s knowledge of what is best for this program.

Nursing

All Nursing Options’ Recommendations:

- Recommend that nurses who perform in-home infusions be ONS-certified, approved as chemotherapy and immunotherapy competent with whatever supporting institution or agency is employing them, hold basic life support certification, have access to a licensed independent practitioner, and complete an annual competency assessment
- Recommend following ONS guidelines for patient safety and verification and ensuring that nurses have access to a second chemotherapy-competent professional to verify patient identification in the home setting
- Recommend reviewing nurse candidates for the program on the following qualifications (not an exhaustive list): having a patient and family-centered approach to care; having a flexible attitude with their work responsibilities as there may at times be fewer resources available or they may be encountering unusual situations that need to be solved for; being comfortable with a certain level of risk with an environment outside the controlled hospital; a commitment to the mission of the program
- Recommend maintaining close and open communication between nurses and program leaders, so nurses remain satisfied, heard, and focused on program goals
- Recommend that nurses and programs administer the first dose of the medication to patients in a hospital setting to monitor reactions and potential adverse effects before approving patients to receive care in outpatient or home settings
- Recommend that the patient self-administration option only be utilized for oral chemotherapies
- **Make:** Recommend insourcing nursing services if program is trying to control costs and can afford time for nurse training and education about novel infusion services, as well as building a program from the ground up; additional pros to insourcing include more oversight of program staff, likely more commitment and dedication from staff, and more control over workflows
- **Buy:** Recommend outsourcing nursing services if cost is not a barrier and the program needs to scale quickly and use staffing infrastructure that is already in place

Drugs

Drug Administration, Transportation, and Approval Recommendations:

- Recommend use of a temperature-controlled cooler to store and transport antineoplastic drugs between pharmacies, outpatient clinics, and home settings

- Recommend including multiple stakeholders in the development of an approved drug therapy list for the program to ensure all perspectives are considered
- Recommend reviewing the Medicare-approved drug list for determining program-specific drugs to be included
- **Make:** Recommend creating a program-specific list of approved drugs and therapies that aligns to the program's capabilities and patient populations. Furthermore, when Veterans receive drugs at VA, it costs significantly less than when Veterans receive the same drugs outside of VA.

Patients

Patient Selection, Safety, and Legality Recommendations:

- Recommend obtaining each patient's informed consent specific to receiving care in a non-inpatient setting prior to inclusion in a novel home or outpatient infusion program
- Recommend creating a model to evaluate patients based on their disease risk and acuity
- Recommend patients who have a caregiver, prior consistency with travel for treatments (for outpatient), good learning ability, safe home environment (for home), and no physical or mental impairments that would impact treatment and caretaking

At-home Care

At-home Setting, Care Provision, and Approval Recommendations:

- Recommend conducting a comprehensive patient assessment and home assessment before approving a patient for participating in a home infusion therapy program. The home assessment should include whether the home environment is safe, free of fire hazards, has working utilities, has adequate internet if there are remote monitoring needs, has a refrigerator for medication storage, and has adequate caregiver support.
- Recommend a patient has a reliable caretaker or family member who is willing to support the patient throughout their home infusion therapy journey and assist with daily living activities
- Recommend the use of telemonitoring equipment such as digital blood pressure cuffs, stethoscopes, glucose monitors, and pulse oximeters to be provided to patients to record and transmit data to clinicians
- Recommend detailing an emergency procedure that instructs patients, nurses, and caregivers to call 911 in the event of an emergency; for other non-life-threatening emergencies, home infusion programs should have a nurse on call 24/7 to address patient concerns and needs
- **Make:** Recommend insourcing the creation of a home infusion service program if funding is available, if it is cheaper to build than buy, if there is ample time to understand the regulations and best practices, as well as hire and train program staff, and if direct oversight of all staff and program operations is desired or required
- **Buy:** Recommend outsourcing home infusion services if cost is not a barrier, if the program wants to operationalize quickly, if the program does not want, nor require, direct oversight over staff, and if the outsourced infrastructure has a geographical reach that makes sense for the program

Outpatient Care

Outpatient Setting, Care Provision, and Approval Recommendations:

- Recommend creating a detailed emergency plan for adverse events that includes 24/7 emergency triage for patients whether that be a provider on call, or directing a patient to seek care in an emergency department, or calling 911 on behalf of the patient if necessary
- Recommend the development of SOPs that cover the following: the preparation and administration of drugs; thorough documentation practices; education and competency of staff; protocols for medication labeling, handling, storage, and disposal; patient education; observation of patients; clinician-to-patient ratios; adverse reaction kit maintenance and use; adverse event reporting and documentation; injection protocol; infection control; and responding to needle-stick injuries
- **Make:** Recommend utilizing only VA outpatient clinics for the provision of outpatient infusion services to avoid sending Veterans to seek care from non-VA clinics and the costs associated with such services. This recommendation aligns with this program's goals.

Pharmacy

Pharmacy Setting, Compounding, and Approval Recommendations:

- Recommend closely following the USP 797 and 800 guidelines during implementation planning, and then adhering to those rules throughout program implementation
- Recommend closely reviewing the American Society of Health System Pharmacists guidelines on home infusion services, as well as the question-and-answer portion
- **Make:** Recommend insourcing pharmacy workload and operations as it was hailed as a best practice by the UPenn "Cancer Care @ Home" program and would offer greater opportunity for oversight and streamlined communications with the team. Furthermore, VA pharmacy compounding is much cheaper than outsourcing this service. If a site does not have pharmacy compounding abilities, recommend purchasing a mobile pharmacy compounding unit from VA.

Oncology

Oncology Department and Provider Recommendations:

- Recommend providers undergo specific training to understand the criteria and decision-making process for assessing patient fit for either home infusion care or outpatient infusion care
- Recommend using telehealth capabilities and services to connect with patients in both the outpatient and home settings via video visits
- Recommend engaging oncology providers at the beginning of the implementation planning process to garner department buy-in, mitigate provider concerns, adequately plan for workflow changes, establish a communication pathway, and ensure there will be no unaccounted-for new burden on providers
- **Make:** Recommend building this team in-house by employing VA oncologists. Veterans have many unique healthcare needs, and existing VA oncologists will have the best qualifications and experience to provide care to Veterans. Furthermore, some of the patients may already have relationships with these VA oncologists. Lastly, if Veterans choose to seek their care at VA instead of elsewhere, is it imperative that their care providers understand the nuances of Veteran healthcare

Governance

Program Governance Recommendations:

- Recommend building a governance board or team that balances the need for input from multiple stakeholders while maintaining an agile decision-making process. Therefore, this team should be comprised of no more than six to eight members and include representatives from only the most consequential stakeholders for program evaluation and growth.
- **Make:** Recommend building a VA team that includes one nursing representative, one pharmacy representative, one NTO representative, one oncology representative, one leadership representative, one scheduling/administrative representative, a member without direct program responsibilities, and a board chair (could also be one of the positions already listed)

Support Services

Remote Monitoring Recommendations:

- Recommend evaluating the effectiveness of remote monitoring for patients after four to five uses. If remote monitoring is not found to be effective for a patient, consider trialing alternate options for patient monitoring (phone calls, in-person visits, caregiver reports, etc.).
- Recommend employing a blended remote monitoring approach that uses both telehealth visits and human contact visits intermittently, so that the benefits of both can be reaped by the patients and providers
- **Make:** Recommend making a VA-specific model and protocol for remote monitoring of infusion patients
- **Buy:** Recommend buying any apps, web-based tracking systems, or already established remote monitoring techniques/services for use at VA

Integrated Care Team Recommendations:

- Recommend employing an interdisciplinary team specifically for this project, consisting of a nurse manager, a medical director, an RN, a nurse practitioner, a social worker, a dietician, a clinical pharmacist, and administrative support personnel
- Recommend employing a specific patient-focused nurse navigator, case manager, or patient experience officer to provide support to patients throughout the duration of their treatment process within the program
- **Make:** Recommend building this team in-house by employing VA staff. Veterans have many unique healthcare needs, and existing VA support staff will have the best qualifications and experience to provide care to Veterans.

V. APPENDIX

Table 2. Additional Resources for Review

Resource Name (hyperlink embedded)
Oncology Nursing Society Position Statement: Infusion of Antineoplastic Therapies in the Home
OncoLink Patient Treatment Binder
MD Anderson Cancer Center: Chemotherapy at home, 9 things to know
CVS Health: Transform Oncology Care
NCCN: Development and Update of Guidelines
Clinical Oncology: At-Home Cancer Care, Infusions Widespread Amid Pandemic
State of Victoria, Department of Health and Human Services: Home-based Cancer Care

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