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Care delivery options for infusion therapy services

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Abstract: Patients have various options to consider when determining the optimal location for receiving outpatient infusion therapy and specialty treatments. Understanding the benefits and challenges of each site of care will enable nurses to help patients make informed decisions.

Keywords: chemotherapy, infusion therapy, antiviral therapy, hospital outpatient department, stand-alone infusion center, specialty office infusion, home infusion therapy, autoimmune disorders

Infusion therapy, including I.V. or subcutaneous administration of drugs and biological agents, is frequently administered outside of the hospital—a trend that is projected to continue.[1,2] In addition to the hospital outpatient department (HOPD), infusion therapy may also be administered in a stand-alone infusion center, a dedicated infusion area within a specialty medical clinic or office building, or a patient home when coordinated through a qualified pharmacy and professional staff. Prior to the COVID-19 pandemic, healthcare systems and physician practices had begun to evaluate alternative infusion therapy strategies and determined that many treatments could be safely administered in an outpatient setting at less cost to the patient. The pandemic, in addition to the rising prevalence of chronic diseases and projected increase in cancer diagnoses, has accelerated the use of outpatient treatment settings.[3,4] The COVID-19 public health emergency (PHE) declaration and expanded home infusion coverage through the US 21st Century Cures Act has supported access to infusion services previously unavailable for many; however, reimbursement and out-of-pocket expenses can vary and limit where services

HOPD: Advantages and disadvantages

Advantages

- Capable of caring for more complex patients with comorbidities.
- Resources and staff are in place to help patients navigate their treatment and plan of care.
- Pharmacists are on staff to provide consultations and prepare medications that require mixing, compounding, and packaging under special ventilation hoods to prevent exposure of staff, patients, and environment to hazardous drugs.
- Lab, radiology, and other ancillary services are readily available if needed.
- Access to a hospital response team for an emergency or adverse reaction.
- Established compliance with regulatory agencies—CMS, TJC, and pharmacy regulators such as the FDA and the individual state boards of pharmacy.
- Infusion-qualified staff are often available during weekends and holidays if needed.
- Patients may already have an established electronic health record within the health system making it easier to review health history and treatment plans, manage care, and update patient records.

Disadvantages

- Overhead expenses make this option less attractive for commercial payers.
- The cost of administration of medications per member per month is generally higher in the HOPD setting versus the physician's office for all payers (Commercial, Medicare, and Medicaid).[8]
- Patients may be required to have preauthorization for a specific drug, confirmed eligibility for an HOPD infusion, or make a copayment prior to any treatment.
- Maintaining the separation of immunocompromised patients from other patients and assuring a clean environment between patients and the general hospital staff, patients, and visitors may be problematic.
- Travel distance to the facility, adequate parking, and other factors may negatively impact patient satisfaction.

or treatments are provided.[5] As of this writing, it is also unknown how the end of the public health emergency will affect service access and reimbursement in the future.[6]

This article provides a guideline for nurses to articulate the primary outpatient sites for treatment as well as the benefits and challenges of each service delivery platform and associated cost considerations. With this knowledge, nurses can help patients and caregivers understand the range of therapies available at each location and make informed decisions regarding their treatment options and the possible financial implications of each.

Sites of care

HOPD

HOPD infusion therapy reduces the length of stay for inpatients receiving infusion therapy and avoids unnecessary readmissions. Given the scrutiny the healthcare system is receiving to lower costs and provide treatments on an outpatient basis, the HOPD is a viable choice for transitioning a patient from inpatient to outpatient status.[7] The departments are often accessible through the hospital building with access to intensivists, hospitalists, or on-call specialists if needed. Patients are usually adults 18 years and older, with various comorbidities and diagnoses. The pediatric and adolescent population may receive therapy in a children's HOPD dedicated to those under 18 years of age.

Infusions at HOPDs include chemotherapy; biologics and biosimilars (common medications for autoimmune diseases); antivirals; I.V. antibiotics, blood and blood products; subcutaneous or I.M. injections; fluids for rehydration; and adjunct treatment, such as drugs or extracorporeal photopheresis to reduce graft versus host disease complications in patients with stem cell transplants or antiemetic and pain medications to alleviate the adverse reactions of treatments. Infusions may last 30 minutes to several hours (see *HOPD: Advantages and disadvantages*).

Stand-alone infusion center

As in the HOPDs, most patients receiving care in a stand-alone center are adults age 18 or older. These locations may not be limited to one specialty medicine or surgical service; however, there may be limitations in the ability to treat some adults or children. Stand-alone infusion centers (also referred to as free-standing sites) are often part of a healthcare system but may be independently owned. As with other independent outpatient treatment facilities, such as dialysis centers, a stand-alone infusion center must meet state and federal regulations along with healthcare building and life safety codes to ensure a safe environment of care for patients and staff.

Regulatory agencies overseeing stand-alone infusion centers include the FDA, National Institute for Occupational Safety and Health, and National Fire Protection Association. With the exception of the FDA, the other regulatory agencies noted require the purchase of current editions. The Joint Commission (TJC) has also published standards to ensure the quality of care and safety guidance for ambulatory care.[9] State regulations and building codes may be viewed on a state-bystate basis.

Infusions at stand-alone infusion centers include I.V. antibiotics, biologics and biosimilars, antivirals, fluids for rehydration, and chemotherapy depending on the drug toxicity and associated risk factors. Drugs administered in a stand-alone center require vital sign monitoring and depending on the medication, cardiac rhythm monitoring as well. Blood and blood product administration is not common in stand-alone facilities due to stringent lab testing

for patient compatibility with blood components, oversight of storage and temperature regulation, and the potential for a serious adverse reaction during the transfusion.[10,11]

Stand-alone centers associated with a healthcare system typically use clear or gold bagging, which refers to the packaging of a drug to be administered and the delivery method to the infusion site. Clear bagging is the use of a healthcare or hospital system pharmacy to compound or mix medications and then transport the solution to the infusion center for administration. Gold bagging has replaced the term clear bagging as hospital and specialty pharmacies become more patient-centric and accessible to infusion teams. The term indicates the most stringent, high-quality process of prescription procurement, mixing and drug packaging, labeling, and delivery of the right medication to the right patient.[12] Two other methods for obtaining infusion medications—white and brown bagging—have been problematic and, in some cases, no longer legal due to quality control concerns and the multiple steps needed to obtain a drug from a manufacturer and timely administer it to a patient.[12] Brown bagging requires a patient to personally procure their medication and take it to the infusion site for the staff to mix and administer. With white bagging, the drug is usually ordered from an off-site pharmacy and then shipped to the infusion location for administration. If the medication ordered or the dosage has been changed prior to receipt of the drug, patients or infusion services may still be responsible for the cost. (see *Stand-alone infusion center: Advantages and disadvantages*).

Specialty physician office

Patients receiving infusions in a medical office vary depending on the specialty practice and whether the patient population includes adults, children, or adolescents. Medical specialty services provide infusions, injections, and other medications which are administered either by the physician or qualified nursing staff employed by the clinic. The Hematology/Oncology care team may infuse some low-risk chemotherapy and adjunct medications to chemotherapy, such as antiemetics, in a dedicated infusion area within their office or the medical office building.

Stand-alone infusion center: Advantages and disadvantages

Advantages

- Less institutional setting, familiar staff, and consistent care.
- Majority of nurses are infusion-certified and capable of treating adverse reactions.
- Staff work closely with physicians and advanced practice clinicians, pharmacists, and service payers.
- Required to meet certification and compliance with federal and state regulations providing oversight of the facility, services, and medication administration system.
- CDC guidelines are followed to ensure a clean, safe environment.
- Usually less travel distance for patients and available parking close to the center.
- May have extended hours and limited weekend hours.

Disadvantages

- Patients who require after-hour, weekend, or holiday treatments, or who need blood or blood products, would need to go an HOPD, ED, or a nursing unit to receive therapy when the center is closed.
- Insurance approval and any copayment for medication/treatment at an infusion center must be confirmed prior to receiving therapy.
- Safety and supply chain of specialty pharmacy for delivery and/or compounding of costly injectable and infusible medications.[12]
- Medications are the property of the patient, creating a disposal dilemma if no longer needed.
- Patient health records may or may not be accessible or compatible with the provider or hospital system.

Specialty physician office: Advantages and disadvantages

Advantages

- Employ RNs knowledgeable of a specific patient population(s) and infusion therapy.
- May combine infusions or treatments for their patients in the office in conjunction with a scheduled exam or office visit.
- Familiar staff often have group support available for their patients.
- Other benefits are similar to those found in the stand-alone infusion center.

Disadvantages

- Patient treatments are only provided during office hours.
- Must maintain an adequate patient population for service to be viable.
- May require additional staff to verify eligibility as well as manage preauthorization and billing associated with the service.
- Staff is responsible for managing inventory control, storage, labeling, and record-keeping.
- Safety and supply chain of specialty pharmacy for delivery and/or compounding of costly injectable and infusible medications.[12]
- Patient health records may or may not be accessible to hospitals in case of an admission.
- Depending on the location and prescribing physician's association with a healthcare system, a "facility fee" could be charged in addition to other out-of-pocket expenses.

Home infusion services: Advantages and disadvantages

Advantages

- Numerous private insurers support home care over the other options due to the lower cost and patient preference.[17-19]
- Accredited programs with qualified staff are covered by Medicare Part B if requirements are met.[20]
- Many of the medications may be safely administered by the patient or caregiver following instruction, training, and competency validated by an RN or other qualified healthcare professional.[21]
- Provided in the comfort of the patient's home with family present, no travel involved, and reduced risk of infections from exposure to other patients and staff as in the infusion settings noted previously.

Disadvantages

- Requires coordination among multiple entities, including patients, physicians, hospital discharge planners, health plans, home infusion pharmacies, and, if applicable, home health agencies.
- Not an option for all patients due to health conditions, medications with stringent transport, storage, and disposal requirements, and lack of ability to create and maintain a safe home environment for other members of the household.
- Understanding and maintaining safety precautions when handling or infusing toxic medications.[22]
- Medications, supplies, and infusion devices are the responsibility of the patient. There is a risk of infection from contaminated supplies or improperly stored medications.
- A single nurse may visit multiple homes during a day and must be conscientious about sanitizing equipment and safeguarding supplies brought in and out of a patient's home to avoid spreading infections between patients or compromising the integrity of the medication/infusion solutions.

Vital sign and cardiac monitoring capability is required.

Infusions at a specialty physician's office include I.V. antibiotics, biologics and biosimilars, antivirals, injections, and fluids for rehydration. Administering chemotherapy in an office setting is dependent on the toxicity of the drug, the patient's clinical status, secure drug storage, and an adequate disposal system. An office setting requires the ability to address potentially serious adverse reactions such as difficulty swallowing or respiratory distress from biologics and biosimilars or other medications. For example, onabotulinumtoxinA (botulinum toxin) injections for migraine headaches are commonly injected in a medical specialty office and are associated with serious adverse reactions, such as difficulty swallowing and respiratory distress.[13] (see *Specialty physician office: Advantages and disadvantages*).

Home infusion services

From 2008 to 2019, there was a 300% increase in the number of patients receiving infusion therapies in the home or an alternate setting.[14] Patients receiving home infusion services are usually adults, but some home infusion services are dedicated to children and adolescents. Eligible patients may have disorders including cancer or cancer-related pain, dehydration, gastrointestinal diseases or disorders, heart failure, Crohn disease, hemophilia, immune deficiencies, multiple sclerosis, or rheumatoid arthritis.

Infusions at a patient's home include I.V. antibiotics, biologic and biosimilars, injections, subcutaneous immunoglobulin G infusions, antivirals, and fluids for rehydration. Depending on the drug and associated risk factors, chemotherapy may also be administered.

The COVID-19 pandemic necessitated more medical treatments and therapies be administered outside of the traditional hospital or specialty care setting. Home infusion therapy is a safe and cost-effective alternative that is beneficial to patients.[14,15] Insurers began to see its validated safety and potential cost savings, resulting in more insurers accepting home infusion under their coverage.[15,16]

For Medicare Part B to cover home infusion services, the Centers for Medicare and Medicaid Services (CMS) requires infusion therapy providers to be accredited and enrolled in Medicare. This applies to durable medical equipment (DME) and professional services, including nurses and home health agencies (see *Home infusion services: Advantages and disadvantages*).[20]

Other nursing considerations

Nurses must consider how a patient prefers to receive information and their level of understanding. Patients should be directed to reliable resources and be provided with printed material related to the diagnosis and treatment plan. Including family members or caregivers in the conversation would benefit patients when determining the best site of care.

Meetings or support groups led by experienced infusion nurses are also helpful to patients. Nurses, case managers, discharge planners, and infusion therapy managers play a vital role during hospital discharge planning or managing patient care plans. From receiving an order for a prescribed treatment to coordinating scheduling and administration of the medication in an infusion setting, nurses are the guides who support patients as they navigate the often complex process of infusion and outpatient therapy.

Conclusion

By providing relevant and comprehensive information about sites of care, nurses can help patients and their caregivers gain a better understanding of the treatment options and

associated requirements and costs, thereby helping them make decisions that best support their needs. ■

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