

COVID Antibody Infusion Clinic Learnings

The following Key Learnings are based on Lilly's experience working with health networks and hospital systems to establish pilot infusion centers across Indiana.

These Key Learnings are not medical, regulatory or legal advice. It is important that anyone operating an infusion clinic know and understand the specific laws, regulations, institutional policies, accrediting standards, or other requirements that may apply to their circumstances and that they follow all applicable regulatory letters of authorization and/or labeling for the infusion of COVID antibody treatments. Lilly desires to share this information to assist health networks and hospital systems in establishing infusion clinics.

KEY LEARNING: Leverage nursing staff to assist with IV admixture preparation

In many hospital settings, pharmacists routinely perform all IV admixture preparation. In order to accommodate pandemic-related resourcing constraints, we utilized an alternative approach by having qualified nursing staff prepare the IV admixture immediately prior to administration. Nursing staff adhered to standard aseptic technique in a designated workspace.

KEY LEARNING: Flexible staffing arrangements may help alleviate resource constraints

The pandemic has placed significant stress on health networks and impacted ability to meet resourcing demands. We utilized flexible staffing arrangements to support infusion services. This included use of nursing staffing vendors (e.g., traveling nurses) on a contract basis. Additionally, qualified nurses were utilized to prepare IV admixture, eliminating the need for on-site pharmacy staff. Licensed practical nurses (LPNs) could also be used for designated tasks in order to free up critical Registered Nurse (RN) resources for other tasks.

KEY LEARNING: Facility/space designation may have different requirements

Space designation may impact licensing and practice requirements. Infusion clinics may be deemed hospital or outpatient treatment areas. Health networks should carefully consider their operations and determine the most appropriate approach to avoid unnecessary delays in implementation.

KEY LEARNING: Alternative approaches may be used when available space is not equipped with directional air flow design

It is often standard practice to equip infectious disease treatment areas with directional or negative air flow capabilities. Converting existing space to meet these specifications can be timely and costly. In some settings, we were able to use an alternative approach of increasing the level of air exchanges/hour (e.g., 6 air exchanges/hour) in the treatment areas in combination with appropriate personal protective equipment and clearly designated clean/less clean areas.

KEY LEARNING: Scheduling flexibility is a key to successful operation

Given time sensitivity to administering monoclonal antibodies within the required window from symptom onset, we built a flexible scheduling system to allow for same-day scheduling. Late cancellations due to improving or worsening patient condition should also be anticipated.

KEY LEARNING: Paper-based systems provide more flexibility versus electronic medical records

Hospitals and health networks often have complex medical record systems. Updating these systems to accommodate new operations and procedures can be a difficult and lengthy process. We utilized an alternate paper-based system to allow infusion units to stand up in a matter of days. This approach also offered flexibility to accept same-day patient appointments. In order to meet hospital EMR needs, paper documentation was subsequently scanned into the EMR to ensure accurate patient records were appropriately maintained.

KEY LEARNING: Ordering process must be easy and efficient

Ordering and prescribing products designated with emergency use authorization is not typical medical practice as there is no flexibility provided to the prescriber outside the Emergency Use Authorization (EUA) criteria. As such, we implemented a standard ordering process to facilitate adherence to EUA requirements and assist prescribers. Two approaches we utilized included: (1) a standardized order form that included the EUA criteria and consent on the order so the prescriber is aware of EUA requirements and can ensure the patient meets all criteria; and (2) having all orders reviewed by a virtual “triage” physician(s) to ensure requirements have been met prior to patient scheduling.

KEY LEARNING: Leverage rapid testing to expedite ordering and scheduling

Treatment eligibility criteria require patients to receive a positive COVID test. To date, the type of test required (PCR vs rapid) has not been specified in EUAs. While PCR is often believed to provide more reliable results, rapid testing allows the physician to receive test results and complete the infusion order (and scheduling) during the patient visit, ensuring patients are scheduled to receive the infusion within the required treatment window.

KEY LEARNING: Anticipate needs to accommodate patients

Patients may present to the infusion clinic with unique needs. Many patients have impaired mobility and require wheel-chair assistance upon entering facility. COVID-19 symptoms vary dramatically, and site should be prepared to manage (e.g., GI symptoms require easy access to restroom during the infusion).

KEY LEARNING: Plan for management of oxygen needs

Current EUAs restrict product usage in patients requiring supplemental oxygen related to COVID-19 diagnosis. However, many high-risk patients are on baseline supplemental oxygen prior to COVID-19 diagnosis and thus may present for treatment at the infusion clinic. Hospitals and physicians providing medical oversight must provide clear guidance to ensure oxygen usage is consistent with EUA criteria.

Non-hospital settings may not be routinely equipped with sufficient oxygen supply to accommodate these patient and prior planning is necessary to ensure adequate supply.

KEY LEARNING: Management of infusion reactions

As with any infusion, some patients may develop a hypersensitivity reaction. Staff must be equipped and prepared to manage these situations. Our pilot infusion clinics developed hypersensitivity reaction protocols to manage these events. Additionally, emergency protocols were developed to instruct staff when and how to initiate emergency medical services.

KEY LEARNING: Patient education prior to arrival is critical

Many patients have never received an infusion. Prior to arrival, it is important that patients understand the following:

- (1) this is not a simple injection and rather it is an infusion of up to 1 hour followed by an observation period.
- (2) this is a monoclonal antibody infusion and not a vaccine; there is a lot of patient confusion given the media emphasis on vaccines.
- (3) For those patients requiring oxygen for an underlying disease, they should be encouraged to bring their oxygen supply with them especially for those non-hospital-based settings.

KEY LEARNING: Efficient use of Infusion Chairs

Infusion chairs can be expensive, scarce or hard to order. In order to maximize use of infusion chairs, we established a separate observation area to accommodate patients during the observation period. This allowed us to use a fewer number of infusion chairs. If infusion chairs are not available, infusion clinics may also consider utilization of comfortable chairs that are not standard infusion chairs. In all cases, equipment should have a wipeable surface that is easy to clean between patients.