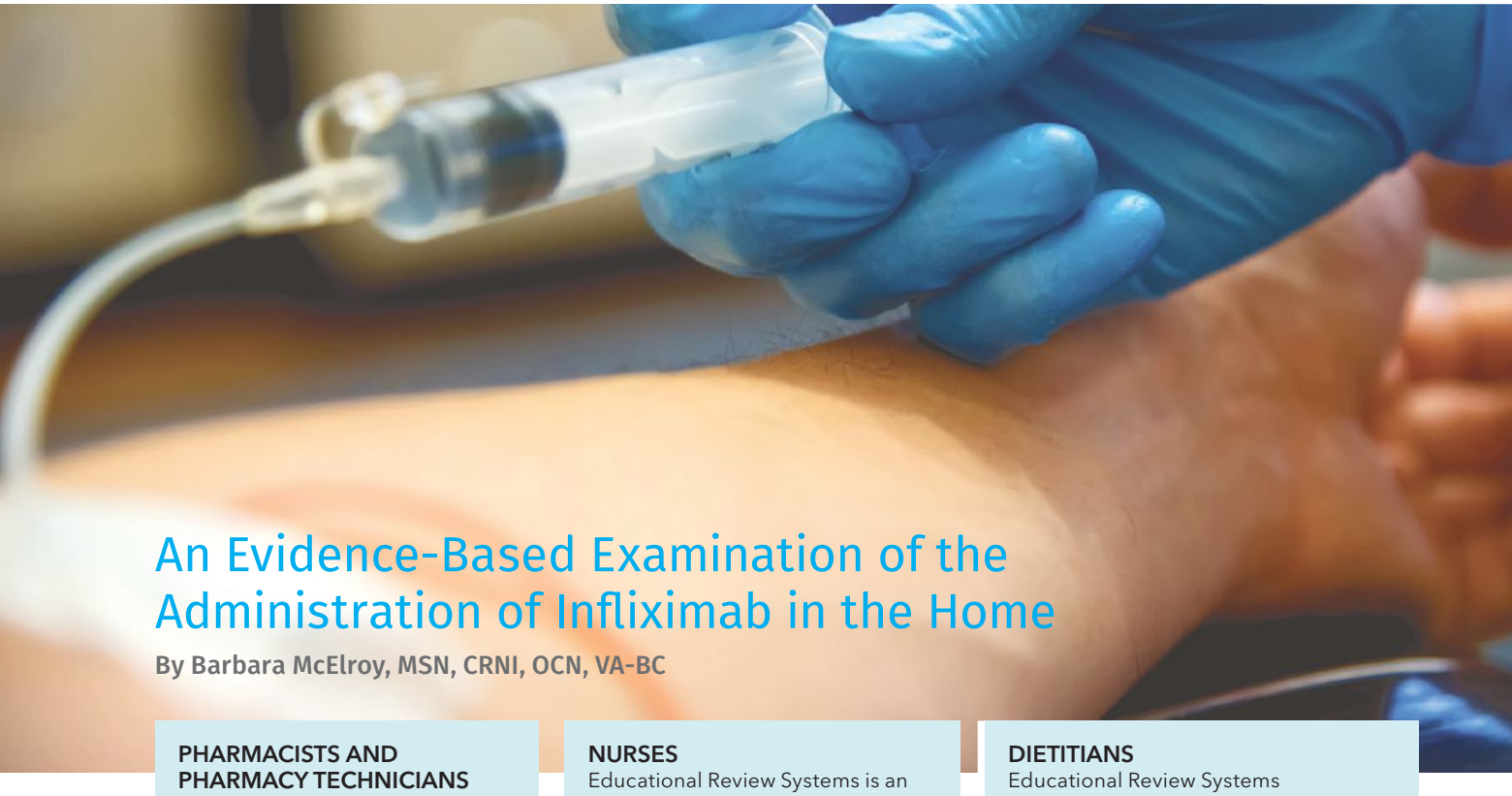
Home Infusion
RN Essentials



An Evidence-Based Examination of the Administration of Infliximab in the Home

By Barbara McElroy, MSN, CRNI, OCN, VA-BC

PHARMACISTS AND PHARMACY TECHNICIANS

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Learning Objectives:

- Understand history of Infliximab in the home environment
- List the various interventions for acute infusion reactions
- Review the data supporting rapid infusion of Infliximab

AUTHOR BIO:

Barbara McElroy, MSN, CRNI, OCN, VA-BC has over twenty-five years of experience in infusion therapy with the last decade focused on clinical education. McElroy is a clinical resource nurse at New England Life Care; has provided nursing instruction in BSN programs at Plymouth State and Rivier Universities; and provided clinical expertise in legal cases related to infusion therapy. In addition to certifications in vascular access, infusion and oncology nursing, she holds an MSN from American Sentinel University. McElroy has developed multiple CE courses in the area of infusion and is a frequent contributor to INFUSION magazine and presentator at the NHIA Annual Conference. She is a member of the Association for Vascular Access, Infusion Nurses Society, Oncology Nursing Society, and the American Nurses Association.

AUTHOR DISCLOSURE STATEMENT

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Introduction

Remicade (Infliximab [IFX]), the first tumor necrosis factor-alpha (TNF-α) antagonist approved by the U.S. Food and Drug Administration (FDA), has become one of the most prescribed biologic agents in the country and a mainstay of the home infusion industry.[1] Initially approved for the treatment of acute, moderate to severe Crohn's disease, the FDA has since expanded its approval for use in several autoimmune disorders where TNF-α leads the attack on healthy tissue.[2] Through inhibition of TNF-α, home administration of infliximab achieves clinical endpoints such as, reducing symptoms and inducing remission, while improving quality of life.[3]

Use and Mechanism of Action of Infliximab Therapy

TNF-α, a proinflammatory cytokine produced by activated immune cells, plays a pathogenic role in several inflammatory conditions. First described in 1975, TNF-α can be found in elevated concentrations in inflammatory bowel disease (IBS), rheumatoid arthritis (RA), ankylosing spondylitis (AS), psoriatic arthritis (PsA), and plaque psoriasis (PsO). Infliximab, a chimeric monoclonal antibody, neutralizes the biological activity of TNF-α, protects intestinal epithelial cells, stimulates apoptosis of activated lymphocytes in the gut mucosa, and aids mucosal healing, often resulting in rapid abatement of symptoms.[3, 4, 5, 2] Although FDA approval is limited to the above conditions in adult populations (and IBS patients ≥ 6 years of age), researchers have identified several other diagnoses that benefit from IFX therapy.[6]

Potential Occurrence of Adverse Events

With any treatment approach, benefit must be weighed against potential risk to determine the right modality for each unique patient. IFX is highly effective in inducing response and remission in patients with elevated TNF-α disorders, with some researchers suggesting initiation of therapy sooner may provide a greater benefit.[7] Serious adverse events to IFX are infrequent and may be avoided through appropriate pre-screening. See Exhibit 1 on recommended screening prior to initiation of home infusion of Remicade. Treatment is contraindicated for those who have previously had a hypersensitive reaction to IFX or any of the inactive compounds, or to any murine proteins. IFX should not be administered to individuals with moderate to severe heart failure, demyelinating disease, latent tuberculosis (TB) or other active infections. As IFX suppresses immune response, patients should be screened for TB and Hepatitis B prior to inception of therapy.[5] In addition to opportunistic infections, other adverse events include infusion reactions, antibody development, and increased risk of malignancy or development of an additional autoimmune disorder.[3]

Immediate infusion reactions (IR), are those that occur within two hours of the infusion, include mild (transient flushing or rash); moderate (urticaria, myalgia or fever); or severe (bronchospasm, angioedema, hypotension) reactions. Severe reactions are rare, with most occurring in the first dose. As prior exposure

EXHIBIT 1

Recommended screening prior to initiation of home infusion of Remicade:

- Confirm negative TB and Hepatitis B testing
- History of demyelinating disease (MS, GBS, optic neuritis)
- History of heart failure
  - Limit dose to ≤ 5 mg/kg in patients with heart failure
- Allergies to medication
  - Prior hypersensitivity reaction to Remicade or any inactive components
  - Prior reaction to any murine products
- Active infection, fever, or illness or recent exposure to others with infection or illness
  - Assess for travel to TB or mycoses-endemic areas
  - Live vaccines are not recommended during treatment
  - Assess current medications
    - Concomitant use of other immunosuppressant agents may increase risk of opportunistic infection
    - Antimicrobial agents may indicate a current infection[5, 8, 2]

EXHIBIT 2:

Sample Acute Infusion Reaction Treatment Algorithm

Acute Infusion Reaction Begins With . . .

MILD S/S

- Flushing
- Dizziness
- Headache
- Sweating
- Palpitations
- Nausea

MODERATE S/S

- Chest tightness
- Shortness of breath
- Hypo/hypertension (> 20 mmHg change in systolic BP)
- ↑temperature
- Palpitations
- Urticaria, flushing

SEVERE S/S

- Hypo/hypertension (> 40 mmHg change in systolic BP)
- ↑temperature with rigors
- Chest tightness
- Shortness of breath with wheezing
- Stridor

Is there an acute infusion reaction protocol for the infused drug?

NO* → **STOP INFUSION**

- Monitor vital signs
- Notify prescriber
- Administer epinephrine if symptoms progress to moderate or severe after drug is stopped

**If drug is not associated with acute infusion reaction, suspect an IgE-mediated allergic reaction and treat accordingly*

YES → **IMPLEMENT DRUG-SPECIFIC ACUTE INFUSION REACTION PROTOCOL**

- Stop infusion (or slow to predetermined rate)
- Assess vital signs at regular intervals, every 5-10 minutes
- Administer prescribed treatment (e.g., acetaminophen, diphenhydramine, using caution if already given as pre-meds)
- If symptoms subside, resume ramp-up of infusion rate in accordance with prescription/ protocol
- If symptoms persist, notify prescriber before resuming infusion
- If symptoms worsen, follow "Severe S/S" steps

Is there an acute infusion reaction protocol for the infused drug?

YES → **IMPLEMENT DRUG-SPECIFIC ACUTE INFUSION REACTION PROTOCOL**

NO → **STOP INFUSION / CALL 911**

1. Assess the patient's circulation, airway, breathing, mental status, and skin
2. Inject epinephrine IM into the mid-anterolateral aspect of the thigh; repeat in 5-15 minutes if needed

   ADULTS: .01 mg/kg of 1:1,000 (1 mg/mL) solution, up to .5 mg

   CHILDREN: .01 mg/kg of 1:1,000 (1 mg/mL) solution, up to .3 mg
3. Place patient on the back or position of comfort if respiratory distress or vomiting occur; fatality can occur within seconds if patient sits or stands suddenly
4. Administer oxygen if available
5. Initiate IV access and administer normal saline, if prescribed
6. At any time, administer CPR if needed
7. At frequent, regular intervals monitor vital signs and respiratory status until EMS arrives

Sources: Simons FE, Ardusso LR, Bilo MB, El-Gamal YM, Ledford DK, Ring J et al. World Allergy Organization guidelines for the assessment and manage-ment of anaphylaxis. *J Allergy Clin Immunol* 2011;127:587–593 and Vogel, W. (2010). Infusion reactions: Diagnosis, assessment and management. *Clinical Journal of Oncology Nursing*. 2010;14(2):E10-E21

is necessary for anaphylaxis, researchers suggest first-dose reactions are related to other etiologies such as cytokine release syndrome.[8] See Exhibit 2 on management of acute infusion reactions.

Strategies to reduce the risk of immediate infusion reactions in IFX administration initially included a graduated infusion rate, although this has not been validated through controlled studies; concomitant use of other immunomodulators (although these may add to the risk of infection or malignancy); and premedication with antihistamines, antipyretics, and/or corticosteroids (although findings to support this intervention have been inconsistent and may be associated with higher rates of IR).[8] Most infusion reactions are mild, with pruritis as the most reported symptom. Slowing or stopping the infusion resolves the majority of reactions and dosing was successfully resumed in most cases.[9] For moderate reactions, stopping the infusion and administering an oral second-generation antihistamine and acetaminophen with a graduated IFX dose resumption are recommended.[8]

Although corticosteroids, antihistamines and/or antipyretics are commonly prescribed prior to IFX dosing, there is a lack of evidence to support this practice. Prescribers identify history of infusion reactions, interruptions in therapy, and presence of antibodies, as rationales for pre-medication. Researchers suggest that standardized order forms, pre-populated with pre-infusion medications may also contribute to this prescribing practice.[10] Although acetaminophen, when used alone, appears to have some protective benefit, pre-medicating with antihistamines have been associated with an increased incidence of infusion reactions.[9, 10] Further research is warranted on this controversial practice.

Late or delayed infusion reactions typically present as serum sickness and may be more likely to occur with therapy interruptions and the development of anti-drug antibodies. Symptoms include fever, rash, headache, and arthralgias which are well-managed with acetaminophen or, for those more acutely ill, a short course of oral steroids.[8, 2]
The development of antibodies to infliximab increases the risk of more acute reactions, particularly with antibody levels of 8 mcg/mL or greater. Antibody development is also correlated with lower IFX troughs and associated loss of drug efficacy. Although most patients respond to IFX initially, antibodies develop in about half of treated patients. Testing for antibodies and serum IFX levels are typically done only when a suspected antibody-mediated reaction or an increase in disease symptoms occurs. Antibody testing is critical in determining the appropriate dose for patients with low IFX titers as dose increases in the presence of antibodies is associated with an increased risk of adverse events. Researchers posit that proactive monitoring may optimize dosing and therapeutic benefit while decreasing the risk of immunogenic response.[11, 8, 12]

Safety of Infliximab in the Home Setting

In addition to the high efficacy and associated disease remission with IFX, multiple studies demonstrate a twenty-year history of safe IFX infusions in the home with very few serious adverse events.[9, 13, 14] One retrospective, two-year study of home and alternate site IFX infusions found no serious adverse events. Mild (3.48%) and moderate (0.7%) reactions were all successfully managed at the site of service.[15] In 2017, the National Home Infusion Association (NHIA) published a position statement on home infusion of biologics noting the well-established safety of these infusions secondary to the risk reduction strategies employed by home infusion organizations. These strategies include pre-infusion screening, standardized protocols, clinical monitoring, and collaboration with prescribers. Additionally, cost savings, reduced exposure to pathogens, improved adherence, and better patient quality of life were all identified as benefits to utilizing the home as the site of care.[16] Interestingly, patients who received treatment at home were less likely than those treated in a facility to seek urgent medical care within two days of infusion.[1]

Taking Into Account Infusion Rates for Administration

The initial IFX manufacturer recommended initiating the infusion with a test dose, gradually escalating the dose to the full infusion rate.[8] Currently, the manufacturer's prescribing information states IFX should be infused over a period not less than two hours.[2] However, researchers note that infusion rates have not been shown to increase the occurrence of adverse events.[8] Multiple studies demonstrate

that patients who tolerate two-hour infusions, can be safely accelerated to one hour without any increase in adverse events. Patients also reported higher satisfaction with one-hour infusions citing less disruption to life and work and improved quality of life.[17, 18, 8, 19, 20, 21, 22] Additionally, accelerated infusion may decrease side effects and improve disease control.[23, 8]

Conservation of Resources and Patient Consideration

Specialty medications for inflammatory conditions account for more than 20 percent of drug spending in the U.S.[24] and managing costs is essential to ensure adequate resources for those who suffer from these chronic, debilitating disorders. Currently 5-20 percent of infliximab infusions are provided at home with substantial cost savings.[1] Due to the need for ongoing treatment with IFX to maintain remission, accelerating the infusion will benefit patients and provide additional cost savings in the drug administration process.[20] Accelerated dosing is safe, effective, conserves resources, improves efficiency, enhances patient quality of life,[21, 22, 23, 25] and may improve therapy adherence.[21]

Summary

IFX is effective in the management of immune-mediated inflammatory diseases, reducing hospitalizations, and delaying or preventing a need for surgery.[26, 22] One-hour dosing has demonstrated safety, efficacy, and improvement in patients' lives.[8, 17, 18, 19, 20, 21, 22, 23] Additional research indicates that thirty minute IFX infusions appear equally safe and effective in disease management.[27, 8] Collaborative relationships with prescribers, pre-infusion screening, and IR protocols are essential to successful home infusion of IFX.[28, 6] Although serious reactions remain rare, skilled clinicians with the knowledge to assess and intervene, are fundamental in the continued safe administration of this life-altering medication.

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ASPEN Guidelines Support Need for Clinical Research and Industry Data

As part of their effort to improve patient care through safe and effective nutrition, the American Society for Parenteral and Enteral Nutrition (ASPEN) underwent an exhaustive search for studies and recommendations on the selection and care of central venous access devices for adult home parenteral nutrition (HPN) patients. A task force of ASPEN experts conducted a comprehensive literary search in order to answer six key questions related to HPN and the impact of device choice and maintenance practices in reducing complications. *The Guidelines for the Selection and Care of Central Venous Access Devices in Home Parenteral Nutrition Administration,* released this fall, included a recommendation to use the fewest lumens possible, the use of ethanol or antimicrobial locks to combat reoccurring catheter infections, and the use of tunneled catheters for patients in need of long-term HPN. The task force was unable to make recommendations related to heparin vs. saline flushes or the impact of catheter material on a central line-associated bloodstream infection (CLABSI). The recommendations are summarized in Exhibit 1. Providers are encouraged to read the ASPEN guidelines to determine how they may impact their current practice.

The demand for accurate, reliable data has never been more important, and underscores the significance of NHIA's data initiative and the National Home Infusion Foundation's Patient Satisfaction Benchmarking in developing best practices to improve patient care. In addition, participating in NHIA's annual poster session is an excellent way to support the advancement of the industry through original research and the sharing

Exhibit 1: ASPEN Research Questions on Selection and Care of CVAD in HPN

Question	Recommendation	Quality of Evidence	Grade Recommendation
Does the type of CVAD (Tunneled, implanted or PICC) influence CLABSI rates?	Tunneled CVAD should be selected for adult patient expected to need long term daily PN infusions. For patients with unknown or short duration, PICC can be used	Low	Weak
Does the number of CVAD lumens influence CLABSI rates?	Use the fewest number of lumens necessary for the patients' therapy	Very Low	Weak
Does the CVAD material influence CLABSI rates?	Unable to make recommendation	Very Low	Further research needed
What is the best CVAD for minimizing mechanical complications?	Mechanical complications not influenced by catheter type	Low	Low
Should antimicrobial or ethanol locks be used vs. standard care for treating or preventing CVAD Infections?	Ethanol and Antimicrobial locks should be considered when used to prevent reoccurring infections	Low	Weak
Should saline or heparin locks be used for CVAD maintenance?	Unable to make recommendation	Very Low	Expert Opinion

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