Home Infusions:
Monitoring for Safety

By Bob Geng, MD

OVER THE PAST two decades, immune globulin (IG) therapy has undergone dramatic transformations. One of the most significant is the shift from center-based infusion therapy to home infusions. This shift away from the hospital/clinic setting to patients' homes is a positive trend leading to greater convenience, lower cost, less exposure to high infection-risk settings and less disruption of patients' lives. However, this change also has led to decreased direct contact between patients and their healthcare providers, which could potentially compromise adequate communication and monitoring of patients' ongoing medical conditions. As such, there is a need to find a way to better regularly monitor patients' status in the home setting. A system of remote collection and monitoring of patients' clinical data would enable patients to have all the advantages of home infusions, as well as improved communication and quality of care.

The Importance of Clinical Monitoring

There are many reasons why it is important to monitor the clinical status of patients. First, while there are dosing guidelines, each patient is different, and the right dose needs to be tailored to both laboratory values and patients' clinical status. Second, IG infusions can be associated with a constellation of adverse events, which need to be monitored and addressed in a timely manner. Most importantly, because many of the conditions that are treated with IG therapy can progress over time and predispose individuals to develop new complications, it's crucial to be vigilant about the development of new symptoms.

For primary immunodeficiency disease (PI) patients, the main goal of IG therapy is to decrease frequency of infections. While it is conventional to start patients on an IG dose of 300 to 600 mg/kg per month, the exact dose will depend on whether it is reducing the frequency of infections in a clinically meaningful manner. Therefore, to arrive at the optimal dose for a patient, all the infectious complications need to be documented to provide adequate information for proper titration of dose or adjustment of administration frequency.

IG therapy has greatly decreased the infectious mortality and morbidity of one of the more common PI diagnoses: common variable immunodeficiency (CVID). However, CVID has to be understood as not simply a deficiency of the immune system, but as a syndrome of immune dysregulation, which is what predisposes individuals to develop autoimmune, gastrointestinal and malignant complications — none of which IG replacement treats. Early signs of many of the autoimmune and malignant complications can be subtle and nonspecific such as fatigue, malaise, unintentional weight loss, easy bruising, decreased exercise tolerance, etc. And, because it's not easy to diagnose autoimmune disorders or the early stages of malignancies, frequent and accurate collection of clinical data is extremely important to enable physicians to determine whether action needs to be taken.

As an example, one CVID patient in our clinic who suffered no infectious complications while on home infusion IG therapy developed massive enlargement of her spleen and liver due to formation of granulomas in the liver (autoimmune disease) over a period of six months. Unfortunately, she only came to clinic every four months. So, while we were able to proceed immediately to a thorough evaluation once we saw her, she could have been evaluated sooner if there was a better way to monitor her clinical status at home on a monthly or even weekly basis.
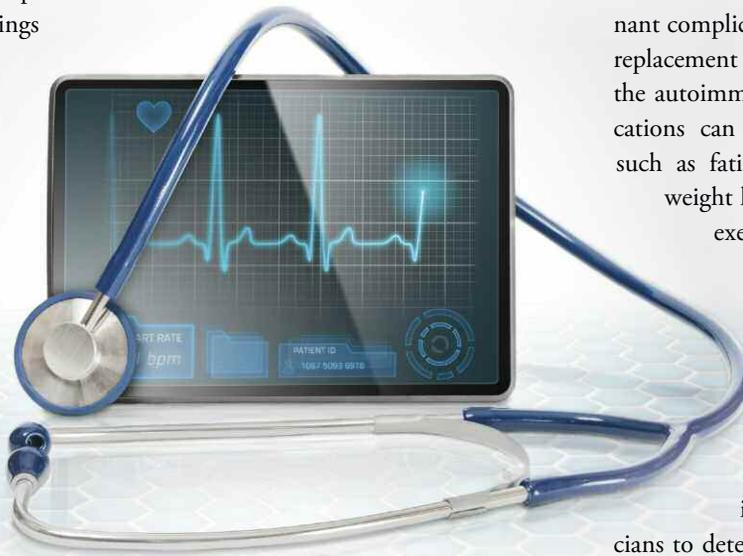
Collecting the Clinical Data

Clinical data monitoring for home infusions can be performed in several ways depending on who is entering the information and how it is transmitted and presented to providers.

Since patients administer their own subcutaneous infusions, they would need to enter their clinical data and subsequently deliver it to either their physician or infusion agency. The advantage to patients tracking their own data is that they know their bodies best, and it is the most direct way of collecting information. However, the disadvantage is that patients are not trained in clinical care, and they may focus on certain benign symptoms while overlooking more ominous ones. Furthermore, without the vigilance of a healthcare provider, patients may forget to document clinical information leading to incomplete collection of crucial data.

There are greater advantages to infusion nurses collecting clinical information. Because they are at patients' homes for several hours during each infusion, they have ample opportunity to ask patients questions about their clinical status and perform necessary diagnostic procedures. Furthermore, infusion nurses are already charting nursing notes, and the additional clinical information can be collected using the same or similar platform. However, while nurses are trained to assess clinical status, they come to patients' homes only once every three to four weeks. During the interim, symptoms may have developed that patients may forget to mention. Therefore, collection of clinical information by infusion nurses may improve efficiency, but it would not be collected as frequently or in real time as it would with patients collecting the data.

Whether nurses or patients enter the data, comprehensive clinical data monitoring software is needed. The ideal software program should allow for both breadth and depth of clinical information collection. It

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has to be broad enough to cover all the possible organ systems that the disease may affect and the myriad of symptoms that commonly present in those conditions. It also has to be flexible enough that it can be adaptable across disease states and groups of disorders. However, within each symptom or assessment of organ dysfunction, there needs to be considerable depth of data collection to account for nuances of symptom presentation and severity of disease.

For instance, data could be collected in the following fields: efficacy, adverse effects, disease-related symptoms, dose/medication, healthcare usage and general well-being. Efficacy of treatment is examined by evaluating disease-specific outcome measures that should improve with IG replacement. For example, for PI, the IG-related outcomes are number/frequency of infections, severity of infections, frequency of fevers and lung function as measured by spirometry. Disease-related symptoms for PI can include symptoms related to gastrointestinal complications (i.e., diarrhea, abdominal pain, nausea/vomiting, etc.), hematologic complications (i.e., easy bruising, bleeding, anemia manifested by chronic fatigue, etc.), musculoskeletal complications (i.e., muscle aches, joint pains, immobilizations, etc.) and dermatologic complications (i.e., rash, hives, etc.). Adverse event monitoring includes IG administration-specific issues such as fever, diffuse body aches, blood clots, headache, etc. Dose medication tracking specifically monitors the patient's administered dose and any changes in the dose, frequency, administration sites, brand of

IG or route of administration. Healthcare usage would note the amount of additional doctor office visits, urgent/emergency care visits, hospitalizations and antibiotics used. Lastly, general well-being would track the patient's overall activity level, energy level, mood, weight gain/loss and satisfaction with treatment.

While the program needs to be comprehensive, it also should be user-friendly and not overwhelming or time-consuming. Finally, this information needs to be transmitted to providers in a timely manner to help them make clinical decisions. This can be done by patients uploading it and making it electronically accessible by the physician as data is entered, or by the specialty pharmacy (possibly with pharmacist involvement) that sends a summary report on a quarterly or monthly basis.

Better Data Equals Better Care

Development of clinical data monitoring systems for home infusion patients is crucial to achieving better care and more optimal outcomes. In addition, these systems have enormous potential for developing a better understanding of and guidelines for IG therapy. While there are some programs in use today by specialty pharmacies, the best method of collecting and transmitting data will be determined as more of them are developed. ◢

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