Chapter 3

# HOME DRUG INFUSION THERAPY EQUIPMENT AND SERVICES

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# **Overview**

# Introduction

The home infusion therapy industry today is the product of technological and medical advancements achieved primarily during the past two decades, and it is still evolving in response to continuing changes in both these areas. Twenty years ago, home drug infusion therapy (HDIT) without round-the-clock nursing services would have been unthinkable. Today, programmable infusion devices with built-in safety mechanisms and safer, more comfortable vascular access devices that can remain in place for longer periods of time have enabled even bedridden patients on complex therapeutic regimens to go home.

Skills as well as equipment have advanced, and many nurses and pharmacists now specialize in the particular professional skills needed in HDIT (e.g., placement of a peripherally inserted central catheter, drug regimen review). But not all HDIT techniques demand such a high level of skill. Some (e.g., simple wound care, drug administration) can be performed by trained family caregivers'or by patients themselves. This chapter describes the variety of equipment and supplies used, the broad range of techniques and services involved, and the skilled and nonskilled caregivers who provide HDIT in the 1990s.

# Summary of Conclusions

• The services and supplies needed for HDIT vary significantly depending on the route of administration, type of vascular access device, type of therapy, and rate of administration. For example, patients with peripheral venous access require more ongoing skilled nursing visits than patients with central venous access. Patients with central access, however, may need more intense training, more early supervisory visits, and more phone support until they become comfortable caring for their catheter and administering their medication. Patients who self-administer antibiotics three times a day may require 20 times as many intravenous (IV) administration supplies as patients on continuous-infusion antineoplastic therapy or pain management.

- Although infusion devices have become increasingly sophisticated during the last decade, less expensive gravity drip systems are still safe and appropriate for many therapies. Most antibiotic therapy and hydration therapy can be delivered via gravity drip or special disposable infusion devices, provided patients (or their caregivers) are capable of operating these devices. In-home gravity drip systems often include special devices that enhance safety and ease of operation by patients. Factors that may necessitate the use of programmable infusion pumps include: cognitive or functional limitations of patients/ caregivers; extremely high or low dose volume; therapies of long or otherwise inconvenient duration; therapies requiring frequent administration; intraarterial infusions; and need for carefully controlled rate of administration.
- While some of the specific techniques used in HDIT require the skills of specially trained registered nurses (RNs), many tasks can be performed by the patient or by a family member who has been taught the proper techniques by a qualified health professional. However, because Medicare beneficiaries are likely to be sicker than other patients and they and their spouses are more likely to have functional limitations than younger patients, they are more likely to need paid assistive services in order to receive infusion therapy at home. If the frequency and intensity of professional services required by a home infusion patient are great (e.g., a functionally disabled patient on a 4-dose per day antibiotic regimen who has no informal caregiver available), a skilled nursing facility (SNF) or other nonhospital institutional setting that offers 24-hour supervision might be a more reasonable alternative to hospitalization than traditional home care.
- Within the nursing and pharmacy professions, home infusion specialization is based primarily

<sup>&</sup>lt;sup>1</sup>In this report, the term "family caregiver" refers to a friend or family member who assists an HDIT patient in self-care talcs on a nonpaid basis.

on experience and has not yet achieved separate recognition by professional organizations. Increasing availability of formal training in infusion therapy techniques, however, is expanding the pool of qualified personnel. Although HDIT providers may occasionally have difficulty recruiting qualified staff, available evidence does not suggest a critical shortage of qualified personnel.

• The continual emergence of new HDIT technologies constantly broadens the types of patients who can be treated at home and changes the parameters of service delivery. Each new device involves the use of new techniques that must be learned by nurses, pharmacists, and patients and caregivers. Some recently developed technologies have reduced the amount of skilled nursing intervention required for patients at home and made it easier for patients to self-administer complex drug regimens.

# Equipment

The two fundamental items of equipment used in HDIT are the vascular access device<sup>2</sup> (the path through which a drug enters the bloodstream) and the infusion device (the means of controlling the rate of an infusion). Advances in vascular access and infusion technology during the past two decades are what have made HDIT possible, and the range of patients who can receive therapy at home continues to expand as new technologies emerge.

# Vascular Access Devices

Twenty years ago, the most common mode of parenteral administration was a steel needle inserted into a vein in the hand or arm (peripheral vein). Today, an increasingly broad array of vascular access devices is available, ranging from peripheral catheters (thin tubes inserted into a hand or forearm vein) to totally implantable catheters that access the centralmost vein of the body. The type of vascular access device used in HDIT has implications for both the amount of skilled nursing intervention required and the nature and extent of certain therapy-related risks for infusion patients.

The choice of a vascular access device depends on the drug(s) to be infused, the route of administration, the duration of therapy, and the physical condition of the patient. Data from a recent survey of specialty HDIT providers show that peripheral catheters are used most frequently for antibiotic therapy, while central catheters are more common for antineoplastic therapy, pain management, and patients on multiple therapies (256). Most vascular access devices can be used for more than one route of administration. For example, tunneled catheters and subcutaneous ports (see below) can be used for intravenous, intraarterial, epidural, intrathecal, or intraperitoneal administration; and peripheral catheters can be used for intravenous or intraarterial therapy.

# **Peripheral Catheters**

Many drugs (e.g., most antibiotics) can be infused into a vein in the arm by way of a small catheter inserted into the blood vessel. Peripheral catheters are particularly appropriate in patients who require relatively short-term therapy (e.g., 1 to 3 weeks) and whose veins are healthy and can withstand repeated punctures (145). Maintenance of peripheral routes of administration requires frequent skilled nursing intervention. Although able-bodied patients can often manage the dressing changes (periodic replacement of bandages covering the catheter exit site) with the assistance of family caregivers,<sup>3</sup> catheter insertion requires professional skills.

Peripheral catheters must be changed frequently to prevent swelling and irritation at the entry site that can lead to infection. When this is done, the old catheter is discarded and a new one inserted, usually at a different site in the vein. Catheter change must be performed by a nurse or physician skilled in peripheral catheter insertion technique (174). Although the Intravenous Nurses Society (INS) standards of practice recommend that peripheral venous sites be changed every 48 hours (174), recent studies suggest that, barring other complications, peripheral venous catheters can often remain in place for up to 72 hours (206). The 72-hour rotation schedule has been widely adopted by HDIT providers (364). For peripheral arterial catheters, the INS recommends

<sup>2</sup> Many observers would categorize vascular access devices as "supplies," since they are generally intended for one-time use, but they are considered equipment hem to distinguish them from the routine disposable HDIT supplies discussed later.

<sup>&</sup>lt;sup>3</sup>Assistance maybe required for dressing changes on peripheral catheters because the exit site is typically on the lower arm, precluding the use of one of the patient's hands.

less frequent site rotation (every 96 hours) due to the more limited number of arterial access sites (174).

Certain factors may necessitate more frequent site rotation for peripheral catheters. For example, a patient receiving a particularly irritating drug may experience painful swelling at the catheter site after only a small number of doses (390). Some elderly patients with poor venous access may experience more rapid site deterioration than younger, healthier patients (364).

Most peripheral catheters today are made of rigid Teflon<sup>TM</sup> rather than steel. The rigidity of the material sometimes contributes to mechanical phlebitis, an inflammation caused by irritation of the surrounding tissues (154). Some newer peripheral catheters are made of a polymer that expands to the required diameter after it is in the vein, making insertion less painful (141). The reported increased comfort and lower risk of complications associated with these catheters may reduce the frequency with which they must be replaced (84,154,330).

This new technology highlights the difficulty of adjusting protocols quickly to reflect new products and techniques. Some home infusion companies are hesitant to use the new catheters; others use them but replace them at the recommended intervals for Teflon<sup>TM</sup> catheters; and at least one large home infusion company reportedly has protocols that allow the new catheters to be left in place for up to 14 days if there are no complications (84,141).4

For HDIT patients, it is generally the nurse who is responsible for deciding when peripheral catheters should be changed. The decision to leave a catheter in place for a longer or shorter period than the recommended standard is based on an assessment that includes consideration of the condition of the current catheter site, availability of new sites, condition of the patient's skin, type of drug, and expected duration of therapy (141).

## **Central Catheters**

**Drugs** that are potentially toxic or irritating to a vein must be introduced into a large volume of blood, to dilute the drug and reduce the likelihood of blood vessel damage. These drugs are delivered by

way of a catheter whose tip rests in a large central vein such as the subclavian vein or the superior vena cava (which feeds directly into the heart). Central catheters require especially meticulous care by the patient or caregiver to prevent infection at the open site where the catheter enters the body, but they usually require less frequent skilled nursing intervention than peripheral catheters. Routine site changes are not necessary with central catheters, and patients can use both hands for catheter care procedures. Another advantage of central over peripheral catheters is that patients are spared the discomfort of repeated venipuncture, because central catheters can remain in place much longer (145). The implantation of a traditional central catheter is a minor hospital surgical procedure that must be performed by a physician (161). Placement of the tip of the catheter must be confirmed by x-ray.

Central catheters may be appropriate not only for drugs requiring greater dilution, but for long-term infusions of other drugs, for patients needing infusions of multiple drugs, for patients likely to need repeated episodes of infusion, and for patients with peripheral veins unsuitable for repeated puncture (140,145).

The two traditional types of central catheters are:

- *Nontunneledcatheters (e.g.,* Hohn, subclavian), which are inserted through an opening in the neck or shoulder directly into the vasculature (blood system). The tip of the catheter rests in a large vein near the heart-either the subclavian vein or the superior vena cava.
- *Tunneled catheters (e.g.,* Corcath, Hickman, Broviac), which are inserted into the chest wall and are tunneled through the skin several inches before entering the vasculature.

Tunneled catheters are used commonly in home patients because they are associated with a lower risk of infection and are easier to care for (260).

A relatively recent addition to the menu of catheter choices is the peripherally inserted central catheter (PICC line), which is being used increasingly in the home setting (50). The PICC line is an alternative to both surgically placed central catheters and traditional peripheral venous access. In this

<sup>&#</sup>x27;The use of these new catheters has not yet been reflected in recognized standards of practice, which still state that peripheral lines should be changed every 48 hours (174).

<sup>&</sup>lt;sup>5</sup>Central catheters come in single- or multiple-lumen styles. Each lumen is a separate path through which a drug can be administered. Multiple-lumen catheters facilitate multiple infusions and, in some cases, allow for continuous venous pressure monitoring during and between therapy (264).

case, a long catheter is inserted into a small vein, usually in the forearm, and threaded up the vein toward the heart (50). The catheter is anchored with a suture or special tape at the exit site in the arm; like the exit site of a surgically placed central catheter, this site requires meticulous care to prevent infection (140,145). Unlike other modes of central venous access, placement of the PICC line does not necessarily have to be performed by a physician; in most States, specially trained nurses can insert it. Because the specific point of placement of a PICC line is crucial, proper placement should be confirmed by x-ray (50,174).

PICC lines are sometimes favored over traditional peripheral catheters because they allow for greater dilution of the drug and do not have to be changed as often. Complications of PICC line insertion can include tendon or nerve damage, bleeding, cardiac arrhythmias, chest pain, respiratory distress, catheter embolism, and malposition of the catheter (50). However, many consider these complications to be fewer and less severe than those associated with traditional central catheter implantation and use (50). Furthermore, the risk of an air embolism (see ch. 2) is decreased because the line is maintained below the heart.

The quality and safety of PICC line use in the home setting depends on the skill of the health professional who inserts and maintains the device PICC. Safety also depends on the ability of the health professional, patient, and/or caregiver to properly care for the PICC line and recognize related complications.

For some medications, the peripherally inserted catheter need only be threaded up to the large vein in the upper arm to achieve adequate dilution. When this method of placement is used, the catheter is referred to as "midline' and radioscopic confirmation of placement is not usually necessary (50). As with the PICC line, midline insertion can be performed either by a physician or (in most States) a nurse specialist at the patient's bedside (174). Although midline catheters allow for greater dilution of the drug than traditional peripheral catheters and are frequently left in place for considerably longer periods of time (141), they are still considered peripheral lines by the INS for purposes of maintenance and replacement (i.e., INS recommends replacement every 48 to 72 hours) (174).

PICC lines and midline catheters are made of one of three materials: polyurethane, which is rigid but softens once in the vein; silicone elastomer, which is very soft and must be inserted through a needle or another Teflon<sup>TM</sup> catheter; and elastomeric hydrogel, which is rigid but both softens and expands once in the vein (140).

## **Totally Implantable Catheters**

Because they exit through an opening in the skin, all of the above types of central catheters are accompanied by the risk of infusion-related phlebitis and infection. To reduce these risks, totally implantable catheters were developed for patients on long-term infusion therapy (396).

Totally implantable catheters, also known as subcutaneous ports, consist of a small reservoir that is surgically implanted under the skin and tunneled to a catheter. The catheter itself may lead to a central vein, a large artery, or into the intrathecal or epidural space (174). The side of the port facing the skin consists of a self-sealing septum. The port is accessed by a special needle designed for this purpose which is inserted through the patient's skin into the septum. If desired, the needle can remain in place up to 7 days at a time, at which point it is changed by the patient or a nurse to minimize the risk of contamination (174). The drug is infused through the needle into the port and thence into the catheter (80,145).

Like other central catheters, subcutaneous ports are appropriate for patients on long-term therapies and those for whom peripheral infusion is unsuitable (145). One disadvantage is that the patient's skin must be punctured at least once a week. Also, although the need for surgical replacement due to catheter site infection is reduced, the port itself must be replaced approximately every 2,000 punctures (about once every 5 years if punctured once a day) (145).

## Access Devices for Other Modes of Drug Delivery

For patients with relatively short-term needs for infusion, or who for some reason are unsuitable for alternative modes of access, some drugs may be infused by way of a needle that is simply inserted under the skin. Subcutaneous infusion is limited to drugs that require administration of a relatively low volume of fluid over any given period of time (see ch. 2). Narcotics to manage pain in patients with advanced cancer, for example, can be administered by continuous subcutaneous infusion. When infusion is continuous, needles should be changed every 48 hours (174).

Narcotics to manage pain may also be delivered directly into the epidural or intrathecal spaces surrounding the spinal cord. In either case, a catheter is inserted between the vertebrae and threaded several inches up along the spinal cord in a minor surgical procedure (326). The procedure is performed by a physician and may be done in the hospital or in an ambulatory surgical setting. As with central venous catheters, epidural and intrathecal catheters may be connected to a subcutaneous port or tunneled under the skin to an exit on the side of the body. Patients with intrathecal catheters intended for long-term use may have the catheter connected to a implanted infusion pump, requiring no external apparatus at home at all and greatly reducing the risk of infection (326).

For a given HDIT provider, the proportion of patients with a particular type of vascular access device is a function of both patient needs and characteristics and the provider's preference for and expertise in the use of certain devices. For example, providers who serve pimarily terminal cancer and parenteral nutrition patients may use surgically implanted central catheters almost exclusively, while providers of shorter-term antibiotic therapies may use peripheral catheters more frequently (364). PICC lines have become the device of choice for some providers, while others do not use them because their staff are not trained in PICC line insertion and maintenance (364).

# Infusion Devices

Any drug infusion requires some kind of device that controls the rate at which the drug enters the body. Infusion devices used in home therapy today range from simple gravity drip systems to highly sophisticated programmable electronic pumps. The choice of an infusion device depends on both therapy and patient characteristics. Some IV therapies can be delivered safely and effectively through gravity drip systems, while others require the increased control, positive pressure, and greater flow rate range offered by electronic pumps.

# **Gravity Drip Systems**

The simplest infusion device is the "gravity drip": the bag or bottle is hung on a hook or pole above the level of the patient, and fluid flows by gravity down the line and into the catheter. The rate of flow in a simple gravity drip system is controlled primarily by a special clamp or valve on the line that can be manually adjusted to permit the prescribed amount of fluid to flow through (usually described in drops per minute). These devices range in complexity and ease of operation from roller and slide clamps to more sophisticated rotating valves. Compared with slide and roller clamps, rotating valves are less awkward to manipulate and provide a more consistent flow rate (264). Even the most sophisticated manual drip valve, however, cannot offer precise flow control, because the viscosity of the solution being infused (the *infusate*) affects the volume of each drop and hence the rate of flow (264). The size of the needle at the end of the line. through which the fluid flows into the catheter, offers a second flow control; the smaller the needle, the slower the maximum rate of flow into the body.

*Controllers can* provide an added measure of security against uneven or "runaway' flow of infusate in a gravity drip system (264). These electronic devices use a drop sensor to monitor flow rate and can detect infiltrations and malpositioning of the catheter or IV tubing by measuring backflow. An alarm sounds when flow rate is altered or when backflow is detected (264).

The gravity drip is conceptually simple, cheap, and requires less equipment than most other infusion systems. In the home setting, however, it has some limitations. First, it is difficult to maintain a constant infusion rate in a gravity drip system due to factors such as the decreasing volume of fluid in the bag (i.e., the infusion rate will decrease as the bag empties) and changes in the shape of the tubing around the clamp (264). Consequently, a gravity system may provide insufficient flow control for drugs that require a very slow, very precise, or very long infusion time, such as antineoplastic (103). Second, errors in using the gravity drip that remain unnoticed can result in serious complications. For example, if the clamp malfunctions or the flow rate is improperly set, a drug may flow virtually unrestricted into the body, giving rise to severe adverse drug reactions and other complications.

*In* addition, a gravity drip system may be an inappropriate choice for certain patients due to functional limitations of the patients or their caregivers. Because the IV bag is suspended well above the catheter site in this system, patients with decreased mobility may have difficulty changing the bag. Ambulatory patients on continuous infusion may also find gravity drip frustrating because the system is not easily portable.

Despite the drawbacks of this traditional method of IV administration, it does maintain some important fuctional advantages over more the expensive electronic infusion devices discussed below. Because the drugs are forced into the vein under the pressure of gravity alone, there maybe less irritation at the catheter site, especially peripheral catheter sites (390). Gravity drip systems may also be preferred for patients who are confused by and resistant to learning how to use more complex, computerized drug delivery systems.

# **Infusion Pumps**

The availability of an electronically controlled device that could deliver constant and precise amounts of fluid over time was a major technological advance in infusion therapy. Although many therapies can be delivered safely and effectively via gravity drip systems, others require the highly precise and constant flow rate offered by electronic infusion devices (103). For example, intraarterial infusions usually require positive pressure pumps because the back pressure is higher in arteries than in veins (397).

Most infusion pumps work by peristaltic action i.e., by alternately squeezing and releasing the tube containing the fluid to force the fluid through at a predetermined rate. A second type of pump uses a syringe-type pushing action to force the drug down the tubing. Most infusion pumps used in HDIT are modern, sophisticated versions of one of these two types of pumps (103).

With the advent of home infusion therapies in the 1980s has come the development of small, portable pumps with specialized uses for particular types of therapies and adaptations for use by nonprofessionals. Because computerized pumps can deliver medication at a wide range of dose frequencies and intensities, they broaden the scope of therapies that can be safely and effectively administered at home. Pumps specifically for the infusion of narcotics to

treat cancer-related pain, for example, may have adaptations that provide a low level of ongoing infusion but also permit patients to dose themselves with bursts of medication when pain becomes intense, up to a preprogrammed number of such extra doses per day (215). Other pumps, designed for the volume of fluid typical of most antibiotic therapy, can be preprogrammed to deliver infusions at standard intervals (e.g., 4 times per day), thus enabling patients to sleep undisturbed while receiving therapy (215). Pumps used for long-term IV nutrition administration, on the other hand, may be designed to administer the large volume of fluid required for the overnight infusions typical of patients receiving this therapy (103,283). One syringetype pump permits the simultaneous administration of several different therapies at different intervals, with dosages and administration regimens preprogrammed on a microchip which fits in the back of the pump (86).

Pumps currently available for home use range in complexity and sophistication from very simple, single-medication stationary infusion pumps to fully programmable, ambulatory pumps that can deliver multiple medications and are equipped with a variety of alarms, bells, and other 'failsafe' mechanisms (103). While stationary pumps may be appropriate for patients who are bedridden or whose medications are delivered over shorter periods of time, ambulatory pumps provide greater independence for patients on continuous, frequent, or longterm therapy regimens. For example, ambulatory pumps enable patients to receive antineoplastic therapy continuously while engaging in normal daily tasks. Many pumps also have automatic "piggyback" mechanisms that control secondary infusions at an independent rate, decreasing the nursing time required for multiple infusions (103).

Infusion pumps do have certain disadvantages. If patients, caregivers, or even health professionals find the level of sophistication of these pumps confusing, the patients' safety could be jeopardized through misuse of equipment (103). Many patients, and the nurses who instruct and care for them, might prefer simpler models that are easier to operate. Even many hospital nurses are unfamiliar with or unaware of sophisticated features of pumps they use on a regular basis (103). Highly sophisticated pumps cost more and often require considerably more training for both the health professional and the patient than simpler models (283). New types of electronic infusion pumps are constantly evolving, widening the menu from which providers must choose and which patients and health professionals must learn to operate. For example, one recently developed pump uses a built-in scanner to self-program, based on a bar code on the bag of infusate, thereby eliminating the extra step of manually programming the pump (40). Another device currently under development is a watch-sized delivery system for low-volume therapies such as pain management and antineoplastics (228).<sup>6</sup>

## **Elastomeric Infusers**

Elastomeric infusers are recently developed devices that can be used as substitutes for infusion pumps. These infusers consist of disposable containers with inner elastic bladders that can be filled with the medication. The devices are sold empty and are filled by the pharmacist through a port at the top of the bladder (28,29,40). The drug flows through an opening at the base of the bladder membrane and into the tube leading to the patient. The force of the flow, and thus the rate of infusion, is determined by the elasticity of the bladder (which pushes inward, delivering the drug under positive pressure) and the concentration of the drug in the infusate, regardless of whether the bladder is above, below, or on level with the IV site (28,29,40). Different drugs and dosages require devices of differing size and bladder membrane composition.

Most devices currently on the market are designed for either antibiotic or antineoplalstic therapy administration. They can be used for IV, intraarterial, and subcutaneous administration of drugs (28). A patient on a twice-a-day regimen of home IV antibiotics would use two infusers per day, while a patient on continuous antineoplastic therapy might use a single device for several days at a time (28). Some devices allow patient-controlled administration of bolus doses above and beyond the continuous infusion rate. A disadvantage to the use of these devices for patient-controlled analgesia is the lack of a memory function that can record the frequency of patient-requested bolus doses, like that found in some electronic infusion pumps (see above). Bladder devices are also not appropriate for multiple drug regimens.

According to one home infusion provider, the availability of disposable elastomeric infusion devices has increased the feasibility of home-based care for disabled elderly patients (249). Like sophisticated electronic infusion pumps, these devices can deliver a precise dose over a specific period of time. However, because they are self-contained and much simpler to operate, they may be less confusing for patients who are uncomfortable with high-tech equipment. The patient or caregiver need only hook the device to the catheter at dosing time and disconnect and dispose of it when the dose has been completed.

## **Implantable Pumps**

Some therapies that require very small drug dosages can be administered by way of totally implantable pumps. Examples include insulin delivery, continuous epidural morphine administration for chronic pain management, and continuous venous antineoplastic therapy infusion for liver cancer patients (the catheter is threaded into the portal vein leading to the liver). Due to the limited range of conditions for which they are currently used and the much lower intensity of services required, however, they are not discussed further in this report. The only service directly related to infusion therapy for these devices is refilling of the pump's reservoir, which may be done weekly or even less frequently in a medical outpatient or home setting (260).

# **Techniques and Supplies**

The supplies and skills needed for HDIT depend on the type of therapy being administered, the vascular access device, and the infusion device. This section describes procedures associated with the use of different types of home infusion equipment and the supplies required for those procedures.

Some supplies are needed by nearly all patients on HDIT, although specific amounts vary depending on the patient (table 3-1). Examples of general HDIT supplies include such items as special soaps, swabs, catheter clamps, and sterile gloves.

Other supplies relate to specific HDIT procedures (table 3-1).<sup>7</sup> A patient receiving antineoplastic therapy, for example, needs special containers to

<sup>&</sup>lt;sup>6</sup> The system includes a miniature programmable pump that operates electrolytically rather than by peristaltic or syringe-pump action. A weak electric current causes gas in a tiny reservoir to expand, thereby expelling the drug from a neighboring chamber into the catheter (228).

<sup>&</sup>lt;sup>7</sup>The specific supplies listed in the table reflect the practice of this particular infusion company. Other providers may use different supplies.

	Type of therapy				
	Cent	ral catheter	Periphera	al catheter	
Supplies*	Pain management⁵ (1 dose/5 days)	Continuous infusion antineopiastic therapy⁵ (1 dose/5 days)	Antibiotic therapy (2 doses/day)	Hydration therapy <sup>b</sup> (1 dose/day)	
Drug administration					
Intravenous (IV) pump (monthly rental)	1	1			
Pump cassette (100 ml) (5-day)	7	7			
Battery, 9V°	4	4			
Disposable elastomeric pump		—	56		
Gravity drip flow regulator (disposable)		—		28	
IV pole				1	
V administration set, 96 inch		7		28	
V administration set, 66 inch	Cision .	7			
V in-line filter set, 1.2 micron		<u> </u>			
Extension set, 6 inch		_			
Extension set, 30 inch	7	_			
Extension set, 36 inch	7	_		_	
Catheter clamp		2			
Peripheral catheter kit <sup>4</sup>		<u> </u>	1		
V catheter, 22 gauge <sup>*</sup>		_	-	4	
Click lock needles.	8	8		-	
Needles, 21 gauge X 1	0	<u>o</u>	56	00	
			20	28	
Catheter/site care					
Alcohol preps (box)	1	1	1	1	
odine preps (box) (central line only)	1	1			
Antiseptic hand cleanser, 8 oz. bottle	1	1	1	1	
Sterile gloves	8	8	56	28	
Antiseptic table wipes (for work area)	7	7	56	28	
Disposable sterile work surface	7	7	56	28	
Dressing change kit (central line only)	12	12			
Fegaderm dressing medication	12	12	9 to 12	9 to 12	
Tape, plastic 1 inch wide (roll)	1	1	1	1	
SASH kits (for catheter flushing)'		7	56	28	
Injection caps, click lock		12	9 to 12	9to12	
Other					
other 10 cc syringe with needle (for drawing blood) .		4		4	
	4	4	4	4	
Sharps container/disposal		1	2	1	
Anaphylaxis kit		1	1		
Chemo spill emergency kit <sup>®</sup>		1		_	
Chemo waste bag	—	2			
Chemo protection kit <sup>h</sup>		1			

<sup>a</sup>Supplies may vary depending on individual patient characteristics and needs. Does not include drugs ortherapeutics.

bSupplies listed are for a 1-month regimen of the following therapies: pain management—morphine sulfate approximately 100 mg dose daily; antibiotic-Cefobid 1 g twice daily; hydration-dextrose 0.45 percent in 1 liter saline once daily; chemotherapy-fluorouracil 2500 mg/50 ml every 5 days continuous infusion.

CThe antineoplastic therapy and pain management pumps need 9-volt batteries for backup power. dIncludes all supplies required to do three IV restarts (catheter, SASH kit, needles, etc.). These are usually performed every 3 days, although antibiotic patients

may require more frequent restarts due to irritation. eFor hydration therapy, the full peripheral catheter kit is notrequired. ISASH = saline-administration-saline-heparin. These are prepackaged kits used for periodic flushing of catheters. Some infusion therapy providers choose to use heparin alone rather than a SASH kit (see box 3-B).

9Includes special towels, goggles, warning signs, etc. in the event of a spill. hUsed bynurse, patient, or other caregiver who administers antineoplastic therapy.

SOURCE: S. Wyremski, Abel Health Management Services, Inc., Great Neck, NY, personal communications, Jan. 18 and 22, 1991.

ensure that the wastes associated with the therapy are suitably disposed of. A patient with a small, ambulatory pump may not require an IV pole to hang the pump, but he or she may need the special drug-containing pump cassettes. A patient on a 2-dose-per-day course of antibiotics needs 14 times as many dose administration supplies as a patient with a 7-day cassette for continuous antineoplastic therapy. A patient with a subcutaneous port requires specially designed needles that do not puncture the base of the port.

Most supplies fall into two categories: those used to prevent infection, and those needed to actually

## Box 3-A—Aseptic Technique

To minimize the risk of infectious contamination in home infusion therapy, aseptic technique must be used each time the catheter site is exposed or the catheter or tubing is accessed. Examples include dressing changes, IV administration set changes, drug administration, and catheter care procedures (e.g., catheter flushing). The aseptic technique requires:

. A clean, disinfected work area (disposable sterile work surfaces can be used for extra protection).

- Meticulous handwashing with a disinfect soap before performing *any* home infusion therapy procedure. *Care in handling syringes* so the hands do not come in contact with the sterile needle or the lower part of the syringe plunger.
- . Care in use of needles. When needles are used to access catheters or administration sets via external or subcutaneous injection ports, or are inserted directly into the skin for subcutaneous infusions, they must be fully engaged up to the hub and taped securely to the patient to prevent in-and-out motion of the needle from introducing bacteria into the vascular system.
- \* Disinfection and cleanin, of injection ports (if they are used) prior to access with a needle.
- . Use of sterile gloves for catheter site care and dressing change.
- . Metculous care of the catheter site, which should be cleaned three times in an outward circular motion with an alcohol swab, using a new swab each time, and then with three providone-iodine swabs in the same pattern. Sterile gauze can be used to gently pat the site dry. After applying the new dressing, catheter tubing should be resecured with tape to prevent motion.
- SOURCES: A.L. Plumer, "Bacterial, Fungal, and Particulate Contamination," in *Principles and Practice of Intravenous Therapy, 4th Ed.*, A.L. Plumer and F. Cosentino (eds.) (New York, NY: Little, Brown and Co., 198'7); National Medical Care, Inc., Homecare Division, *Central Line Catheter Care: Patient Information Guide* (Waltham, MA: National Medical Care, Inc., 1989).

administer the drug. These are discussed in more detail below. $^{\rm s}$ 

### **Infection Control**

The three main sources of microbial (bacterial and fungal) contamination that can cause infusionrelated infection are the skin, the air, and the blood (264). Although risk of infusion-related infection can be reduced by minimizing exposure of the catheter site, the administration set, and the container of infusate to these sources, exposure cannot be eliminated. To further reduce the risk of contamination, additional steps must be taken.

The most important method of controlling the risk of infection, whether at home or in the hospital, is the aseptic technique (see box 3-A). This technique must be applied to all procedures that involve exposure of any part of the infusion administration assembly (catheter site, catheter lock, tubing, etc.) or of any infused substances to the environment (264). These procedures include drug compounding and mixing, drug administration, peripheral site changes, catheter flushing, dressing changes, and administration set changes (see below). Strict adherence to the aseptic technique requires ample backup supplies, because if a piece of sterile equipment (e.g., administration set tubing, catheter cap, injection port, syringe plunger) is accidentally contaminated it must be discarded and replaced with a new one.

Another factor that can increase the risk of infusion-related infection is the use of multiple-dose vials of drugs for home administration. Because multiple-dose vials must be accessed repeatedly, they increase the risk of contamination from environmental sources. They may also be more susceptible to tampering by patients or other individuals who handle them (207). To minimize the risk of infection and tampering, some hospitals and home infusion companies use single-dose vials of drugs that are discarded after each administration (207,364). Inline bacterial and particulate filters and simplified catheter flushing procedures are additional infection control measures (see below).

#### Drug Administration

The supplies used in drug administration depend on the delivery system being used.<sup>9</sup> Most patients have separate tubing-the *administration set—that* 

<sup>&</sup>lt;sup>\*</sup>Although peripheral and midline catheters are treated in this chapter as equipment, they are usually considered supplies because they are not reusable.

<sup>9</sup> Patients who use elastomeric bladder devices may not need additional administration tubing because the bladder pump comes with tubing.

connects the infusion device to the catheter. Administration sets, which come in varying lengths and configurations, must be changed on a regular basis to prevent infection, clogging, and harmful drug decomposition or interaction (174). Some administration sets have special extensions for 'piggyback' infusions, where a second drug is administered through a Y-gap at the patient's end of the administration set, thereby avoiding mixture of the two drugs in the tubing. Many electronic infusion devices require administration sets that are designed specifically for that pump (103). Extension tubing is also available to increase the patient's mobility during drug administration.

The INS recommends that administration sets be changed at least every 48 hours (174). However, some types of drugs and drug regimens require that tubing be changed with every new drug administration (15).<sup>10</sup>

*Injection ports are* rubber caps that are attached to the administration set or directly to the catheter and are used for the periodic injection of drugs or other solutions into the vascular system (174). Ports that are integral to the administration set are changed whenever the administration set is replaced. Ports attached to peripheral catheters should be replaced whenever the catheter is changed, and ports on central catheters should be changed at least every 7 days (174).

*In-line filters* may be attached to administration sets to prevent air, particulate matter, or bacteria from entering the vascular system and causing infection or other complications. The costeffectiveness of using in-line filters has been the subject of some debate (5,107,117,147,277), and practices vary among HDIT providers (3,15). INS standards, however, advocate their use inmost cases (174).

The type of filter needed varies depending on the therapy. A small (0.2 micron) filter is recommended for routine use in most IV therapy because it prevents bacteria as well as air and particulate matter from entering the vein (174). Transfusion of blood and blood products requires special falters, with a separate filter used for each unit of blood product

transfused so that signs of contamination can be traced **to a** specific unit. Special **surfactant-free** filters are required for intraspinal infusion of any medication (174).

Some in-line falters are add-ens that must be attached to the IV administration set; others are integral to the infusion device or the IV administration set itself. The INS recommends that *in-line* falters be changed each time the administation set is changed (every 48 hours) (174). A recent study, however, found that some disposable in-line antimicrobial filters lose their ability to retain bacteria after 24 hours (27), indicating that more frequent change might be appropriate.

## Catheter and Site Care

Patients with either central or peripheral vascular access must care for their catheters and the site where their catheter exits the body in order to minimize risk of catheter malfunction (e.g., clogging or breakage), site irritation, and secondary infection. The following are typical methods used to accomplish this care.

- *Catheter protection—To* protect a catheter from contamination between doses, special cannula caps are used. The INS recommends that these caps be replaced whenever they are removed to minimize risk of infection (174).
- *Catheter site care—The INS* recommends that the bandages (dressings) that cover the exit site of a catheter be changed at least every 48 hours or whenever they are soiled, wet, or loose (174). Dressing changes can be conveniently performed by the patient or caregiver at the same time as administration set changes. When dressing change coincides with rotation of a peripheral IV site, it may be performed by the skilled nurse. For subcutaneous ports, dressings need only remain in place when the port is accessed by a needle.
- *Catheter flushing-All* catheters are susceptible to clogging either by the patient's own blood or by other deposits (174,396). For this reason, most catheters are flushed periodically, most commonly with saline (salt solution) or with heparin, an anticoagulant." Catheters are

<sup>&</sup>lt;sup>10</sup> For example, when two incompatible drugs are infused through the same catheter, the administration Set mUSt be changed between drugs (174). Also, some drugs with limited periods of stability may form precipitates after a certain number of hours (15). When these drugs are being infused, IV administration tubing must be changed with every new drug administration (15).

<sup>11</sup> Heparin is used because it is the only soluble anticoagulant.

# Box 3-B-Controversy Over Catheter Flushing Methods

The issue of saline v. heparin v. SASH (saline-administration-saline-heparin) flushing is one of considerable debate, and literature exists to support the relative efficacy and cost-effectiveness of each method (18,72,104,124,144, 166,245,337). There is as yet no consensus on which method is most appropriate, and practices vary among providers (36). Current published standards suggest that the SASH method should be the exception rather than the rule (174). However, some home infusion providers use the SASH method with every type of therapy because they believe it results in decreased complications (36,402).

One argument against the use of the SASH procedure (as opposed to heparin or saline alone) as a default for catheter flushing is that it increases the risk of infection because it necessitates multiple accesses to the catheter lock (36). Risk of conlamination may also be increased when catheter flushing substances are provided to the patient in multiple-use vials. Although some home infusion therapy providers supply patients with a larger vial of heparin solution from which they fill their own syringe for each flushing procedure (181), most providers use prefilled syringes to avoid increased risk of contamination and to simplify the procedure for the patient (181,402). One medical equipment company has recently introduced a closed, 3-chamber SASH flushing system that reduces to one the number of catheter accesses required (40). Some catheters are pre-heparinized or have special valves at each end that minimize the backflow of blood into the catheter, decreasing the need for flushing (138,260).<sup>1</sup>

<sup>1</sup>Pre-heparinized catheters can only be used inpatients who are not sensitive to heparin and with heparin-compatible drugs. These catheters may be routinely flushed with saline alone (260).

generally flushed after each administration of medication and after the drawing of a blood sample. When two incompatible drugs are administered through the same catheter, or when the drug being administered is incompatible with heparin, a special flushing procedure called the SASH (saline-administration-salineheparin) method is often used. In this procedure, the catheter is flushed with saline before and after administration of the drug to avoid any contact with the heparin solution (174). Catheter flushing supplies are often delivered to the patient in prepackaged kits. There is considerable variation among providers in the flushing methods they recommend to patients (see box 3-B).

. *Catheter clearance—The* risk and expense of surgically replacing a clogged central catheter can sometimes be avoided by using urokinase, an enzyme that helps degrade clots and restore catheter patency (2). The urokinase is injected into the catheter using a syringe and allowed to sit for several minutes before the catheter is aspirated to remove the clot (2). This procedure must be performed by a skilled nurse or a physician (260).

Table 3-2 describes variation in the frequency of procedures required by HDIT patients with different types of vascular access devices and therapeutic regimens.

Certain therapies require special techniques and supplies. For example, home transfusion patients may need special warmers to bring blood products to normal body temperature prior to infusion (174). Patients on antineoplastic therapies need special supplies to protect them from exposure to these toxic drugs when performing routine catheter maintenance or drug administration (174). Patients on intraspinal therapy need special diluent solutions and in-line filters because many preservatives, stabilizing agents, antioxidants, and surfactants<sup>12</sup> typically found in dilutents and filters can cause nerve damage if they enter the intraspinal area (100,202).

# Services and Staffing

HDIT involves a broad range of services, including patient screening and assessment; patient training; and ongoing medical, pharmacy, nursing, laboratory, delivery, and coordination services. These services, in turn, are performed by a variety of health professionals, including registered nurses (RNs), RN specialists (e.g., IV, oncology, and critical care

12 A surfactant is a substance added to a solution to reduce surface tension of the fluid. The use of surfactant-containing antimicrobial or particulate filters on intraspinal administration sets is strictly contraindicated because surfactants often contain alcohol (202).

– Vascular access device	Procedure				
	Catheter Change <sup>⊾</sup>	Needle Change <sup>°</sup>	Catheter flushing <sup>d</sup>	Dressing change <sup>®</sup>	Administration set Change
Peripheral catheter	_				_
Venous	48 hours	NA	Variable	48 hours	48 hours
Arterial	96 hours	NA	Variable	48 hours	48 hours
Midline catheter	• 48 hours	NA	Variable	48 hours	48 hours
Central venous catheter					
Tunneled catheter	NA	NA	Variable	48 hours	48 hours
Nontunneled catheter Peripherally inserted central	NA	NA	Variable	48 hours	48 hours
venous catheter	NA	NA	Variable	48 hours	48 hours
Totally implanted catheter	NA	7 days	Variable	NA	NA
Subcutaneous Infusion	NA	• 48 hours	NA	48 hours	48 hours

#### Table 3-2—Recommended Routine Frequency of Selected Catheter Maintenance Procedures Performed for Home Infusion Therapy Patients, by Type of Vascular Access Device<sup>®</sup>

NOTE: NA = not applicable. Asterisks (\*) indicate that this procedure can only be performed by a qualified health professional-usualiy a registered nurse. Some procedures may be performed by a nonskilled person (e.g., patient or caregiver). In many cases, the functional ability of the patient determines who will perform thetask. In some cases, the patient's medical condition may be such that skilled personnel are required to perform what would normally be nonskilled functions (e.g., a dressing change if the catheter site shows signs of infection). Nonskilled procedures may also be performed by skilled staff in conjunction with skilled procedures (e.g., a dressing change when a peripheral catheter site is rotated).

staff in conjunction with skilled procedures (e.g., a dressing change when a peripheral catheter site is rotated). aFrequencies reflect recommendations of the Intravenous Nurses Society in its revised standards of practice for intravenous nursing (both in inpatient and outpatient settings). Actual frequency of procedures may vary among providers.

<sup>b</sup>Catheters other than peripheral or midline are not routinely changed, but change maybe necessary if an infection or malfunction occurs.

<sup>C</sup>The needles on implanted catheters can remain in place for up to 7 days, and all infusions and heparin flushing can be achieved through that needle. <sup>C</sup>Catheters are generally flushed after each administration of medication and afterabloodsample isdrawn; hence, flushing could occur as infrequently as one

a week for patients on continuous infusion or as often as fourtimes a day for patients on four times a day antibiotics. Frequency and type of flushing depends on type of catheter and drug being used. When not in use, catheters require less frequent flushing. PDressings must also be changed whenever they become solied, Wet, or loose.

<sup>1</sup>For patients on continuous infusion of chemotherapy via an Infusion pump with amultiple day drug reservoir, set canbeleft in place until reservoir is changed. SOURCES: Intravenous Nurses Society, Intravenous Nursing Standards of Practice (revised 1990), *Journal of Intravenous Nursing* Supplement 1990, April 1990; OTA site visits to providers, 1990-91.

nurses), licensed practical nurses, nurses' aides, pharmacists, pharma cy technicians, and other on-thejob trained personnel. Because HDIT is a relatively new mode of practice, providers generally look for employees with extensive hospital infusion therapy or pharmacy experience and rely heavily on in-house training to prepare their staff for the specific demands of HDIT patients (364). For some nurses and pharmacists, HDIT practice is an attractive career choice because it allows them to gain independence and further their career in ways that practice in other settings does not (364).

The distribution and coordination of responsibilities among HDIT staff depend on the organizational structure of the home infusion provider, the capabilities of individual staff, limitations of State licensure and practice acts, and size of the geographic service area. For example, pharmacy-based providers often utilize clinical pharmacists for patient assessment, education, and clinical monitoring tasks (see box 3-C), while nursing-based providers place these responsibilities in the hands of nurses.<sup>13</sup> Small providers with limited staff and a small service area may have one pharmacist and one nurse as the sole providers of services. Other providers may contract with home health agencies or visiting nurses associations to provider nursing services to patients in more remote areas (see ch. 4). Large, full-service providers in concentrated metropolitan areas may organize their many nursing personnel into teams responsible for the care of a defined group of patients and rely heavily on central coordination staff to ensure that services are delivered properly and in a timely fashion (box 3-C).

The next section describes in more detail the specific services involved in HDIT and the qualifications, abilities, and availability of the staff who provide those services.

## Box 3-C-Staffing and Organization of Home Drug Infusion Therapy Services: Two Contrasting Models

Anne Arundel General Hospital Outpatient IV Therapy Services Program, Annapolis, MD

*Outpatient specialists are* pharmacy technicians with a minimum of 3 years' hospital experience. Under the supervision of pharmacist staff, they are responsible for patient training, care coordination, and preparation of all IV medication in the outpatient center pharmacy facility.

*The RN specialist,* a registered nurse (RN) with extensive experience in hospital IV therapy, is responsible for the initial patient assessment, some patient training, and all peripheral catheter insertions and changes. The RN specialist also plays an active role in training outpatient specialists and any other health professionals who may become involved in home IV therapy services (e.g., home health nurses who see homebound patients).

*Clinical pharmacists are* Pharm.D.s with hospital pharmacy experience and a minimum of 2 years' experience in a clinical setting. They are responsible for designing and monitoring therapy and examining patients in the outpatient center three times per week, Although the pharmacists do not diagnose and treat patients, they do examine patients and report any concerns immediately to the physician for further investigation. Pharmacists are also directly involved in developing and prescribing therapy regimens, under the supervision of staff physicians.

The microbiologist performs and/or coordinates IV therapy-related laboratory work which is generally done at the referring hospital.

*Physicians see* patients at least once a week in their offices or in the outpatient center and consult with the pharmacist and other staff about patient progress, therapeutic changes and response, etc. A medical director is on staff at the center.

ABEL Health Management Services, Inc., Great Neck, NY

*Field nurses are* primarily RNs with strong clinical skills and experience, although some are licensed practical nurses (LPNs). Field nurses are organized in teams depending on their qualifications and availability. Each patient is assigned a team of field nurses who share call duty. Each field nurse is equipped with a 4-wheel-drive vehicle, car phone, fax machine, and 24-hour beeper. Field nurses average 6 to 8 patients per day overall, but the number for any one nurse depends on geography and patient needs.

*Patient education specialists are* baccalaureate-prepared RNs who do initial patient assessments and initiate the patient training process (field nurses finish it). They also train other staff in home infusion techniques.

*Nursing care coordinators (NCCs) are* baccalaureate-prepared RNs who serve as the point persons for all communication from nursing, pharmacy, lab, and patients. They generally do not perform clinical functions.

*Nurse managers are* baccalaureate-prepared RNs who are responsible for overseeing the activities of NCCs and managing and monitoring any problems that may arise.

*Clinical pharmacists are* registered pharmacists (R.Ph.s). They are responsible for coordination of all clinical functions of pharmacy service, including receiving physicians' telephone prescriptions, maintaining patient medication profiles and checking for possible drug interactions, providing drug information to other nursing and pharmacy staff, and reviewing patient lab work. They are recruited from both retail and hospital settings and undergo 8 to 10 weeks of initial training in infusion therapy techniques before assuming full staff responsibility.

Staff pharmacists are R.Ph.s who are primarily responsible for drug preparation and compounding.

*Pharmacy liaisons are* on-the-job trained personnel who act as support staff for staff and clinical pharmacists, aiding in the preparation of drugs and facilitating communication between nurses, physicians, pharmacists, and patients.

*Other staff* include customer service representatives (responsible for distribution of drugs, supplies, and equipment), armed escorts for staff who serve patients in dangerous neighborhoods, and others.

SOURCES: Anne Arundel General Hospital Outpatient IV Therapy Services Program, Annapolis, MD, informational visit with OTA staff, Oct. 25, 1990; ABEL Health Management Services, Inc., Great Neck, NY, informational visit with OTA staff, Nov. 9, 1990.

# Patient Screening and Assessment

Patient screening is perhaps the most critical element in the decision of whether or not to administer HDIT (see ch. 2), and it is the first service an HDIT provider renders to a prospective patient. In determining candidacy for HDIT, the provider must consider the patient's medical condition, the patient's and caregiver's willingness and ability to perform self-care, and the environmental characteristics of the home setting. These considerations must be balanced against both the demands and associated risks of the prescribed HDIT regimen and the level of services the provider itself is capable of delivering. At a minimum, patient assessment includes a visit to the patient in the hospital prior to discharge, in which the patient's medical stability is evaluated and where the patient is questioned about other relevant aspects of the home and family environment. In addition, it may include a visit to the patient's home to confirm that the home environment is suitable (24). Patients who are referred from outpatient care may receive their assessment visits in a physician's or provider's office.

Although the actual assessment is usually performed by a nurse (364), other professionals (e.g., physician, social worker, clinical pharmacist, dietitian) may also participate (24,270,335). Box 3-D provides an example of criteria that one home IV antibiotic therapy program uses to screen patients.

## **Patient Characteristics**

The overall condition—medical, physical, mental -of a patient will affect the level and nature of care required. Specific conditions that typically affect administration of IV therapy in the elderly include cardiovascular disease, poor venous access, thinning of the skin and underlying tissues, diabetes, joint disease, paralysis, effects of long-term use of certain drugs, and poor response to acute disease processes (62). Therapeutic decisions and patient safety may also be complicated when a patient is taking other drugs in addition to the prescribed therapy. HDIT can only be safe and effective if the nurse and pharmacist are aware of the patient's individual needs and (in conjunction with daily caregivers) can anticipate and handle related complications.

Some elderly patients are fully capable of performing self-care and need only periodic skilled nursing services to receive HDIT. Other patients who normally require no assistance may have

# Box 3-D—Patient Screening Criteria for One Home Intravenous IV) Antibiotic Therapy Program

Disease Criteria

- . Infection responded clinically/clinically stable
- . Has not had a fever for at least 5 days prior to discharge
- •Only in hospital for IV therapy

**Treatment Criteria** 

- . Good venous access
- Received and tolerated IV antibiotics in hospital

Patient Criteria

- Alert
- Cooperative
- . Average intelligence
- Good motivation
- . Reliable
- . Emotionally stable
- •Acceptable lifestyle/home environment
- . Likelihood of compliance
- No history of mental problems or substance abuse
- . Understands therapy and gives consent
- . Patient and one family member taught
- . patient's family agrees to therapy
- Adequate support system at home
- Completed IV training session
- Proficiency in IV techniques
- Can care for venous catheter and reliably self-administer antibiotics
- Telephone and refrigerator at home
- . Access to health area
- •Transportation available

SOURCE: K. Lee and J.I). Andrews, "Assessment of the Need for a Home Intravenous Antibiotic Program," Canadian Journal of Hospital Pharmacy 41(6):295-301, 307, December 1988.

specific fictional or cognitive problems that limit their ability to perform the specific self-care procedures associated with HDIT. These patients require more supportive services to make HDIT feasible and safe.

Still other patients require assistance with normal activities of daily living even *without* infusion therapy due to certain conditions that are especially prevalent among this population. For example:

• Eighty-six percent of elderly persons have one or more chronic conditions, compared with 50 percent of the general population (361).

- Dementia, which can limit both cognitive and functional capacity, affects an estimated 15 percent of persons of 65 years of age or over, compared with approximately 1 percent of younger persons (336,339).<sup>14</sup>
- Depression, which can also cause cognitive and functional impairment, affects 2 to 10 percent of the elderly (39,139).
- Visual and auditory impairment, which can limit a patient's ability to learn and perform self-care functions, are common among the elderly. Nine percent of persons 65 years of age or older are visually impaired, and 32 percent of elderly persons are hearing impaired (4).
- Orthopedic impairments or deformities, which can limit a patient's ability to perform self-care, are present in 13 percent of the elderly compared with 8 percent of the general population (361).
- Within the population with chronic conditions, the rate of functional limitations is much higher for the elderly: 18 percent of elderly people with chronic conditions reported limitation in a major normal activity of daily living,<sup>15</sup> compared with 4 percent of the general population with such conditions (361).
- Two-fifths of community-dwelling elderly 65 years of age and over report limitation in a major normal activity of daily living, compared with 14 percent of the total noninstitutionalized population (361).

The patient's role in HDIT will vary depending on the type of therapy, venous access device, and drug delivery device. Some drug delivery systems and access devices require considerable manual dexterity and physical mobility to operate. For example, a patient on a gravity drip system must be able to reach the bag, remove it from the IV pole or hanger, change the bag, and assemble anew set of tubing. A bedridden patient with debilitating arthritis would be incapable of performing these tasks. In the absence of a capable caregiver, the patient could be put on an automatic drug delivery system (e.g., a fully programmable infusion pump) that would greatly reduce the amount of effort required on the part of the patient. Some patients, however, would be too debilitated to operate even the simplest infusion pump and would require assistance in drug administration either by an informal caregiver or a nurse.

A patient who is willing and physically able to administer HDIT may still be unable to do so due to cognitive barriers. For example, an impaired patient who is instructed in central catheter care and administration of his or her specific drug regimen may be able to repeat the required procedures perfectly right after training but may be unable to repeat them on the following day.

If a patient is incapable of performing the required self-care, a capable and reliable home caregiver must be available for HDIT to be feasible. Even when the patient is capable of self-care, an additional trained caregiver can be an important backup mechanism should the patient become temporarily or permanently unable to perform certain tasks (24,209,335). For patients who require 24-hour attention (e.g., some terminal cancer patients), more than one home caregiver maybe required for the safe administration of therapy (246). Dysfunctional patients with no available caregiver may be able to receive HDIT if the risks of that therapy are not life-threatening, but these patients will require considerably more paid nursing visits (table 3-3).

Regardless of their clinical stability and objective ability to perform the required tasks, some patients may simply be unwilling to undergo treatment in the home setting due to fear or discomfort with the therapy, equipment, or associated risks. Unwillingness is an absolute contraindication to HDIT; providers and the published literature unanimously agree that safe and effective home therapy cannot be provided to patients (or by caregivers) who do not want to be on it. The right of the patient (or the caregiver) to decline treatment in the home setting in spite of the urging of other interested parties is an issue of quality assurance as well as of patient rights.

# **Home Environment**

In order to safely and effectively carry out HDIT, a home must have certain basic features. These include running water, electricity, refrigerator space for drug and supplies storage, a clean area where aseptic catheter and simple wound care can be performed, and, perhaps most importantly, access to a telephone for emergency and routine communica-

<sup>14</sup> Includes moderate and severe dementia. 15 For example, housekeeping.

Table 3-3-Average Number of Nursing Visits Per Week for Home Infusion Therapy Patients, by Selected Types of Vascular Access Device, Type of Therapy, and Functional Status of Patient<sup>a</sup>

		Number of other nursing or assistive service visits per week if patient/caregiver.°		
NType of vascular access device and therapy	lumber of skilled nursing visits per week <sup>ь</sup>	can perform all drug administration and self-care tasks	cannot perform any drug administration or self-care tasks	
Peripheral or midline venous catheter				
Hydration therapy once a day	2 to 3	0	7	
Antibiotics three times a day	2 to 3	0	21	
Tunneled or nontunneled central catheter or peripherally Inserted central catheter				
Hydration therapy once a day	. 1	0	7	
Antibiotics three times a day Continuous chemotherapy or pain	- 1	0	21	
management with infusion pump	. 1 to 2⁴	0	2 to 3	
Fotally Implanted catheter				
Hydration therapy once a day	. 1	0	7	
Antibiotics three times a day		0	21	
Continuous chemotherapy or pain		-		
management with infusion pump	. 1 to 2⁴	ο	2 to 3	
Totally implanted pump		0	0	
Continuous subcutaneous morphine				
Infusion with Infusion pump	. 3 to 4	0	0	

<sup>a</sup>Represents the average minimum number of recommended nursing visits per week for drug administration, catheter care, and dressing change based on recognized standards of infusion therapy practice and actual practice of current home infusion therapy providers. Nursing visits maybe more frequent toward beginning of therapy as patient is still becoming familiar with self-care techniques. Number of visits will vary depending on medical condition of patient and occurrence of infusion therapy-related complications.

occurrence of infusion therapy-related complications. bDoes not include initial assessment and training visits. Does not include additional skilled nursing visits (up to three per week) required for drawing blood samples for laboratory monitoring. The minimum of one skilled nursing visit for ail types of patients and therapies is for ongoing skilled assessment and monitoring of patient's condition.

CDoes not include separate supplies delivery visits. Does not reflect reduction i, nonskilled visits due to performance of nonskilled tasks during skilled nursing visits.

dDepends on capacity of pump's drug reservoir.

SOURCE: Office of Technology Assessment, 1992. Based on information from: Intravenous Nurses Society, Intravenous Nursing Standards of Practice (revised 1990), Journal of Intravenous Nursing Supplement 1990, April 1990; A.L. Plumer and F. Cosentino (eds.), Principles and Practice of Intravenous Therapy 4th Edition (New York, NY: Little, Brown and Company, 1987); Perivascular Nurse Consultants, Rockledge, PA, information on frequency and cost of infusion therapy nursing visits, provided to OTA Jan. 18, 1991; L.C. Hadaway, "An Overview of Vascular Access Devices Inserted via the Antecubital Area," Journal of Intravenous Nursing 13(5):297-306, September/October 1990; information provided to OTA by home drug infusion therapy providers, manufacturers, and others, 1990-91.

tion between the patient and home infusion therapy staff (24,364). In certain instances, some of these features may not be necessary (e.g., some drugs need no refrigeration). Generally, however, the HDIT provider must ascertain during initial patient assessment whether the patient's home is adequately equipped for the patient's particular therapy needs (24).

Other characteristics of the home environment can also pose problems for HDIT For example, large pets or small children may tamper with the drug delivery system (tubing, buttons on a computerized infusion device), potentially interrupting a dose or causing more serious harm to the patient.

#### Proximity to Service Provider

Accessibility of needed services, drugs, equipment, and supplies is another important consideration in the patient screening process. In an urban area, patients may be close enough to an HDIT provider to obtain emergency drugs, supplies, equipment, or services within a short time. Patients in areas more remote from the provider, however, may have to wait longer to obtain the supplies or services they need.

This problem can be addressed in part by the decentralized provider model. For example, an infusion company in an urban location may contract with a local home health agency to provide skilled nursing care to a patient in an outlying area. Because there is no guarantee that the local home health agency nurses possess the knowledge and skills required for HDIT maintenance, the infusion company may have to provide special training to these nurses before releasing a patient to their care. For patients who are either very ill and require intensive services or who are in an area where skilled home

# Box 3-E—Screening Critetia for Home Transfusion Therapy Patients

*In* order to be accepted for home transfusion therapy, the American Association of Blood Banks (AABB) recommends that patients meet all of the following criteria:

. They are not ambulatory (mobile patients are more appropriately treated in hospital or outpatient facilities); They have a stable cardiorespiratory status (i.e., no recent history of acute angina or congestive heartfailure); The patient's transfusion history has been carefully screened, paying special attention to reactions (if present) and appropriate chronic diagnoses;

They did not experience a reaction during the administration of their last transfusion;

- They are cooperative and able to respond to verbal commands;
- They we able to detect and respond appropriately to body symptoms;
- . A responsible adult is present during the duration of the transfusion (this does not include the nurse), presumably to assist in getting emergency services to the patient in the event of a situation that requires the nurse to give the patient undivided attention;
- A working telephone is available during the transfusion; and
- The patient's medical condition is suitable for home transfusion. (Diagnoses the AABB considers potentially appropriate for home transfusion therapy include chronic gastrointestinal bleeding, anemia in the presence of chronic renal disease, anemia with bone marrow failure, anemia associated with malignancies, sickle cell anemia, and thalassemia).

SOURCE: American Association of Blood Banks, Improving Transfusion Practice: The Role of Quality Assurance, S. Kurtz, S. Summers, and M. Kruskall (eds.) (Arlington, VA: American Association of Blood Banks, 1989).

nursing services are simply not available, HDIT may not be a reasonable alternative.

### **Disease- and Therapy-Specific Considerations**

Some patients-either due to complications stemming from their medical condition or other factors (environmental and social) that can interfere with the safe and successful administration of infusion therapy-will require special consideration and attention by HDIT providers. Acquired immunodeficiency syndrome (AIDS) patients, for example, are highly susceptible to infections, which may affect decisions regarding their treatment (e.g., which kind of catheter to use) (238).<sup>16</sup> AIDS patients on HDIT who have a history of IV drug abuse will require close monitoring to assure that they are not using their venous access devices for selfadministration of illicit drugs. Also, patients with AIDS-related dementia may be unable to understand or perform self-care functions adequately (238). Although the patient may be able to perform self-care initially, he or she is likely to lose that ability as the dementia progresses. Ongoing nursing assessment is key in determiningg the specific home infusion therapy needs of AIDS patients.

Home blood transfusion patients also require special consideration. The American Association of Blood Banks (AABB) has published specific criteria that patients should meet before they can receive in-home transfusion (see box 3-E).

# **Ongoing HDIT Services**

All HDIT involves at some level medical, pharmacy, nursing, laboratory, and coordination services. Although the exact responsibilities of each of the types of service personnel (e.g., nurses or pharmacists) varies among infusion providers (see box 3-C), all of the basic services must be available for HDIT to take place. The setting in which specific services are delivered varies depending on both the provider and the patient (see ch. 4). Some patients receive all services in their home; others receive some services in an outpatient center but administer the drugs themselves at home; still others receive their infusions in a physician's office or outpatient center and have no home care or self-care responsibilities at all. The following describes existing variation in how certain HDIT services are provided and by whom. It does *not* attempt to define optimum arrangements.

<sup>16</sup> Studies suggest that tunneled central catheters present a lower risk of site infection than surgically implanted ports or percutaneously inserted catheters (238).

## **Medical Services**

All professional services provided to HDIT patients must be overseen by the patient's physician, who prescribes the therapy and orders the home care. The physician has primary responsibility for informing the patient about the anticipated results and potential complications of therapy, and the physician is consulted in the case of emergency or lesser complications of therapy. The physician also receives the results of laboratory tests and orders any necessary changes in the therapy, based on the results of those tests and on the patient's visits to the physician during the course of the therapy.

The extent of physician involvement during the course of HDIT can range from an arm's-length role (e.g., endorsing prescription changes suggested by the home infusion pharmacist) to a highly interactive one (e.g., seeing patients several times a week and initiating any therapy changes). Physician involvement is affected by both clinical and nonclinical considerations. Some medical conditions routinely demand frequent physician contact (either over the telephone or an actual patient encounter), while others can be followed by a skilled nurse who reports patient progress and complications back to the referring physician. Patients in poor physical health may need to see a physician more frequently than otherwise healthy patients on HDIT. Some programs recommend weekly physician visits for patients on antibiotic therapy, to confirm patient response to therapy and monitor progress in the resolution of infection, but this practice is apparently not universal (96,364).

organizational characteristics of an HDIT provider can also influence the frequency of physicianpatient or physician-staff contacts. A center-based provider, for example, has patients come to an outpatient center for their supplies, catheter site changes, physician visits, and other professional services (15). Other HDIT providers play a less active role in ensuring patient-physician contact; many leave the scheduling and frequency of followup visits entirely to the discretion of the referring physician (203,364).

## **Patient Training**

Patient education is required before a particular patient begins home therapy. At a minimum, this service includes a visit to the patient in the hospital prior to discharge, where the patient's ability to perform the needed infusion-related functions are affirmed (24). In addition, patient education maybe continued once the patient has returned home. Patients are instructed in infusion techniques, site care, the nature and risks of their therapy, drug storage and stability, equipment maintenance and use, recognition of signs and symptoms of possible complications, and recordkeeping (134,209). This instruction may be performed by one or more of a number of professionals, including nurses, pharmacists, and medical equipment personnel proficient in the use of a particular infusion pump. Written instructional materials should be provided for reference and reinforcement of skills (209,364).

The time required for instruction varies depending on the level of complication involved in that care and patient factors (209,364). Sometimes the initial training visit must be followed up with one or more additional visits to ensure that the patient is indeed capable of and comfortable performing the necessary procedures (240,364). All instruction should be documented in the patient record (209). Many providers have patients sign forms stating that they have been instructed in and are capable of performing the requisite self-care (209,364).

## **Pharmacy Services**

At the least, HDIT pharmacy services involve compounding the drugs to be infused, educating nurses and patients regarding potential drug interactions and side effects, monitoring the patient's drug regimen, and being available to respond to concerns regarding the therapy. Pharmacist responsibilities may also extend to participating in patient education regarding self-care technique; monitoring patients via conversations with nurses or patients themselves; monitoring laboratory results; collaborating with physicians in establishing drug regimens and making prescription changes; and, in some cases, educating physicians about which therapies are safest and most effective in the home setting (14,24). Home infusion pharmacists also monitor patients during therapy and consult with the referring physician on patient progress (24,364). The degree to which a pharmacist talks on the telephone or visits the patient in his or her home varies depending on the provider.

An infusion pharmacy differs dramatically from most retail pharmacies. While retail pharmacies generally dispense only oral medication, infusion pharmacies must have the equipment necessary to safely prepare and store parenteral solutions. These usually include laminar flow hoods to reduce risk of contamination,<sup>17</sup> modified storage areas for certain drugs, and additional supplies and equipment needed for mixing solutions (364).

How a parenteral drug is prepared depends on: 1) the specific drug prescribed, 2) the dosage, and 3) the type of drug delivery system (149). Preparation can include mixing or titrating to the proper concentration. Some therapies, such as hydration therapy, require little preparation because the solutions come in premixed bags with varying dilutions of dextrose. Other therapies require more extensive preparation either in-pharmacy (e.g., an antineoplastic drug must be prepared in a special vertical flow cabinet) or in the patient's home.

Some infusion delivery systems require specialized in-pharmacy computer hardware. One type of infusion pump sometimes used for multiple drugs, for example, has a removable microchip that must be programmed in the pharmacy. Another newly developed pump requires a barcode labeler in the pharmacy (40).

Some pharmacy-based providers delegate drug compounding tasks to pharmacy technicians who are supervised by managerial pharmacists (149). Others use only registered pharmacists for drug compounding (see below) (3).

Pharmacist Training and Recruitment— Although some formal training in infusion pharmacy is available, it is not a nationally recognized specialty .18 The pharmacy profession includes baccalaureate-prepared registered pharmacists (R. Ph.s), who undergo a 5-year training program, and doctorallevel pharmacists (Pharm.D.s), who complete 6 years of training (385).<sup>19</sup> Either one of these degrees is required for Iicensure in all States (385). Residency training in hospital pharmacy, clinical pharmacy, and a variety of other specialties is also available (385). A 1989 survey of the 74 schools of pharmacy in the United States<sup>20</sup> found that 42 offered some form of instruction specific to home infusion therapy (224). Of those 42, only 13 had a course primarily devoted to home infusion therapy, and only 2 schools required all their students to take that course.

Home infusion pharmacists are quite different from retail ("community drug store" pharmacists, who usually have comparatively little experience in infusate compounding techniques or the pharmacokinetic<sup>21</sup> aspects of infusion therapy (14). Existing standards for home infusion therapy providers make explicit a wide range of proficiencies that a community pharmacist must have in order to be an accredited infusion therapy provider (see ch. 5) (179,237). Although most States do not have a separate license category for infusion pharmacists, an increasing number of States license and regulate pharmacies that prepare drugs for infusion (210). These laws act as a "back door" regulatory mechanism for the practice of home infusion pharmacy by mandating certain physical plant characteristics and staff proficiencies.

Thus, although some pharmacists may receive formal training in home infusion therapy techniques, the majority of training takes place on the job. Many HDIT providers rely on hospitals as both recruitment and training grounds for their pharmacists, requiring anywhere from 1 to 3 years previous hospital pharmacy experience (364). Additional training, both initial and ongoing, is provided to these pharmacists on the job (364).

Physician acceptance of the pharmacist in an expanded clinical role varies. Some physicians value pharmacists' contributions greatly and rely upon them extensively for advice in drug therapy decisions, while others consider pharmacists' involvement an encroachment on physician's clinical decisionmaking (177,329). Physicians coming out of training today are more likely than their predecessors to have had interdisciplinary training experiences and hence may be more aware of and

<sup>17</sup> Some infusion pharmacies have specially constructed, positive pressure "clean rooms" for the preparation of parenteral solutions. While these do provide an additional level of protection against contamination, they are costly to build and are not required in existing infusion pharmacy standards (178331,237).

<sup>18</sup> There are currently three nationally recognized pharmacy special ties: nuclear pharmacy, pharmacotherapy, and nutritional p harmacy. The American Society of Hospital Pharmacists is proposing two new specialties, psychopharmacy and oncology pharmacy (14).

<sup>19</sup> Both programs include baccalaureate education.

<sup>20</sup> All 74 schools responded to the survey.

<sup>21</sup> Of or pertaining to characteristic interactions of a drug and the body in terms of its absorption, distribution, metabolism, and excretion (393).

accepting of the capabilities of the clinical pharmacist (177).

Pharmacy Technician Training and Recruitment—Larger infusion providers often employ pharmacy technicians to assist pharmacists in compounding drugs. Pharmacy technicians are trained either on the job or in 2-year certificate programs (14,385). The American Society of Hospital Pharmacists (ASHP) accredits technician training programs in hospitals and community and vocational colleges (14). In 1988 there were 68 formal training programs in 19 States, of which 11 were accredited by ASHP (385).

The degree to which HDIT providers use pharmacy technicians to compound drugs depends on State practice acts and licensure mechanisms. Four States (Illinois, Massachusetts, Michigan, and New Hampshire) offer certification exams for pharmacy technicians, and three States (Illinois, Nevada, and Washington) require licensing (385). In some States (e.g., California and Arizona), pharmacy technicians in retail pharmacies cannot compound or otherwise prepare drugs (186). This may explain the fact that, although pharmacy technicians can be found in hospitals in all States, 9 States have no pharmacy technicians in retail pharmacies (385).

## **Nursing Services**

HDIT services that must be provided by a skilled nurse (usually an RN) include:

- patient education regarding administration of the infusion and care of the infusion site,<sup>22</sup>
- periodic monitoring of the catheter exit site for signs of infection or other complications,
- peripheral catheter site changes,
- peripherally inserted central catheter placement,
- drawing blood samples for laboratory tests, and
- general monitoring of the patient's health status.

Many other tasks (e.g., dressing changes, drug administration, general catheter maintenance) can be performed by less highly skilled personnel under the direct or indirect supervision of IV nurse specialists. These personnel (including licensed practical nurses, nurse aides, and home health aides) can play an especially important role for patients with limited self-care ability. They may also be involved in ongoing service coordination activities, acting as liaisons between patients and staff.

The amount and skill level of nursing services required by an **HDIT** patient varies dramatically depending on the route of administration, type of drug delivery system, type of therapy, and functional status of the patient (see table 3-3). For example, a patient with a peripheral catheter who receives antibiotics 4 times a day will need a skilled nursing visit every 2 to 3 days for catheter site changes. At the other extreme, a patient with a totally implanted catheter may need only weekly visits. Skilled nursing visits for these latter patients generally consist of catheter site inspection and other monitoring activities. Patients unable to perform self-care procedures may need additional paid assistive services on a daily basis if no family caregiver is available.

Additional skilled visits may be needed for patients who require frequent laboratory tests (see ch. 2). Drawing blood, either directly from a vein or through a catheter, is a skilled procedure that must be performed by or under the direction of a skilled nurse or phlebotomist.

Placement of peripheral catheters (including midline catheters) must be performed by an RN with training and experience in this procedure (174,291). The procedure usually takes from 10 to 20 minutes to perform, although it may take longer if the patient has poor venous access or other complicating conditions (291). Peripheral lines and midlines are usually inserted in the patient's home (291,364).

Insertion of a PICC line is a more involved and highly skilled procedure that takes from 1 to 2 hours to perform (see box 3-F) (291). In order to place a PICC line, an RN must have special training and experience (174,291). INS standards require radiographic confirmation of PICC line placement (174), which is most convenient to perform in a hospital or outpatient setting where x-ray facilities are available. However, some nurses reportedly perform PICC line insertions in the patient's home either with or without portable x-ray equipment (291). The ability of RNs to perform PICC line insertion is limited by availability of training and by State nurse practice acts (see box 3-F). Although this particular area of specialty practice has yet to be officially recognized and is even prohibited in some States,

<sup>&</sup>lt;sup>22</sup> Pharmacists may also participate in patient education activities.

# Box 3-.F—The Peripherally Inserted Central Catheter (PICC Line): New Technology and Nursing Practice

*The* PICC line is an example of how recent technological advances innfusion therapy are shaping new areas of nursing specialty practice. Insertion of a PICC line is a highly skilled procedure that can be performed only by a physician or by registered nurse with special training (174,291). The procedure involves:

- \* measuring the patient to determine the length of catheter required;
- \* aseptic/ antiseptic preparation of the catheter entry site;
- . insertion and threading of the catheter
- . radiographic confirmation of catheter placement; and
- . suturing and dressing of the exit site (50,291).

Although training in PICC line insertion technique is widely available, the quality of training programs varies tremendously (291). Some courses are 8 hours long and involve no practice on live subjects. other courses are longer and require numerous supervised and documented successes on live subjects. Some programs present "certificates" to participants on completing the course, but them is no officially recognized "certification" in PICC line insertion or any other specific nursing skill (e.g., peripheral catheter insertion, catheter repair). To date, no nationally recognized accrediting bodies accredit PICC line insertion training programs (291).

State nurse practice acts sometimes limit the ability of nurses to perform PICC line insertions, From 60 to 70 percent of States' nurse practice acts can be interpreted as allowing PICC line insertion by an RN (291). In some States, however, the wording of the acts suggests that such a skill would not be approved, and in a few States, language has been adopted that specifically prohibits nurses from performing PICC line insertions (291). As the use of PICC lines in both home and hospital settings grows, the role of the registered nurse in PICC. line insertion will likely be increasingly recognized at both the State and national level through standardization of training and further modification of nurse practice acts.

<sup>1</sup>Although practice on live subjects is preferable from a quality of training standpoint, it poses legal risks and has been the subject of some controversy among trainers and practitioners (291).

many home infusion providers employ nurses with this skill (364).

Nurse Training and Recruitment—HDIT providers generally look for nurses with extensive experience in infusion therapy nursing (364). Nurses with national certification in certain areas of advanced practice (e.g., IV nurses, critical care nurses, oncology nurses) are more likely to have the skills and experience needed for home infusion practice, although certification is not a guarantee of proficiency in particular skills (291,364). The burden is therefore upon the employer to determine, through testing, practice, and knowledge of educational and training background, whether an individual is proficient in those skills. Providers often recruit hospital nurses who have done infusion therapy in cardiac care units, critical care units, or emergency rooms. Although demand for skilled nurses in hospital settings is high (291), home infusion providers have been successfull in drawing some nurses out of these settings because they offer greater autonomy of practice and, in some cases, more opportunities for career advancement (364).<sup>23</sup> Nurses who specialize in or are skilled in transfusion therapy are also increasingly being sought by home infusion providers as the demand for home blood transfusion expands (box 3-G).

Home infusion companies that provide nursing services through contractual arrangements often must take additional steps to ensure that the nurses are qualified to perform the required services. Contract nurses in visiting nurses associations and home health agencies, or nursing personnel in skilled nursing facilities or other nonhospital institutional settings, may not be familiar with particular HDIT equipment and techniques. To address this

<sup>23</sup> Fo, example, one home infusion provider has a five-step "career ladder" for its field nurses based on qualification, expertise, and specialty certification (3). Nurses can move up the career ladder by seeking outside continuing professional education or certification, or by participating in in-house continuing education and certification programs. Five factors considered in the career ladder are: 1) antineoplastic therapy skills/certification, 2) blood transfusion skills, 3) PICC line insertion skills, 4) catheter repair skills, and 5) degree of difficulty of venous across the nurse is capable of handling (3).

## Box 3-G-Home Blood Transfusion Services: Special Considerations

Home blood transfusion is a relatively new service in the home infusion therapy market, and it involves intensive, specialized nursing services and careful coordination with suppliers of blood products (e.g., local blood banks). The great risks associated with blood transfusion therapy demand that home providers develop distinct and stringent protocols that address the unique aspects of this therapy.

According to the American Association of Blood Banks (AABB), in-home transfusions should be performed by a registered nurse (RN) with formal training and extensive knowledge and skills relating to IV therapy generally. During the nurse's initial visit 24 to 48 hours before the actual transfusion, a blood sample for type and crossmatch is drawn, carefully labeled, and delivered to the blood bank for compatibility testing. The blood bank must keep an accurate record of the physician's orders, informed consent form, laboratory results, nurse's notes, and a transfusion flow chart for each patient transfused.

On the day of the transfusion, the crossmatched and inspected units of the relevant blood component are picked up by the nurse, who reinspects them for gas formation, streaking, and color. The blood is transported in a quality-controlled insulated cooled container. At the patient's home, the nurse doublechecks the patient's identification and checks each unit to be given for compatibility.

The nurse then reviews the physician's orders, evaluates the patient's condition, administers any prescribed premedications (e.g., antihistamines to avoid mild allergic reactions), and starts the infusion therapy. During the infusion, the nurse monitors vital signs and other signs of the patient's reaction every 30 minutes. once the components have been infused, the nurse discontinues the transfusion, the IV line is kept open, and the nurse remains with the patient in order to watch for adverse reactions and take the 30-minute posttransfusion vital signs. Before leaving, the nurse gives the patient and any caregiver present posttransfusion instructions and collects equipment and contaminated supplies. The nurse returns the day after the transfusion for a followup visit that includes tests such as hemotocrit, platelet count, and coagulation test. In the event of a medical emergency during the transfusion procedure, the patient's residence must be easily accessible. AABB guidelines for procedures in event of a reaction are as follows:

- *Mild reaction* (*e.g.*, rash or itching): The transfusion is stopped and the physician is notified. Usually antihistamines are given and, if the reaction ceases, the nurse will continue with the transfusion while monitoring the patient closely.
- Severe reaction (symptoms including rash, increased heart rate, fever, chills): The transfusion is stopped, the physician is notified, and the nurse administers appropriate medications as ordered by the physician. The blood units, administration set, a fresh urine specimen (to inspect for free red blood cells), and a blood sample (to regroup and crosshatch to donor blood, and to perform a Coombs test for hemolytic antibodies) are sent to the blood bank. The nurse stays with the patient until the patient is stabilized, or makes arrangements for transportation of the patient to the hospital.
- Life-threatening reaction (symptoms include red urine, unexplained bleeding, fever, chills): The transfusion is stopped and another person present contacts the emergency number while the nurse attempts to stabilize the patient (performing resuscitation if necessary). The patient is immediately transported to the nearest hospital.

Under all of the above circumstances, there remaining blood components and administration set are returned to the blood bank for crossmatching. A transfusion reaction report, completed by the nurse, is also required.

Safe disposal of equipment, such as empty blood bags, IV tubing, blood-soaked gauze, needles, and other contaminated objects is a major concern. The nurse must collect all such materials in special biohazard containers and return then-i to the blood bank for proper disposal.

If blood warming in the home is desired either for patient comfort or clinical considerations, only approved electric blood warmers should be used because overheated blood can lead to hemolysis (rupture of red blood cells) and protein precipitation.

SOURCES: American Association of Blood Banks, Home Transfusion Therapy, E.L. Snyder and J.E. Menitove (eds.) (Arlington, VA: American Association of Blood Banks, 1986); American Association of Blood Banks, Improving Transfusion Practice: The Role of Quality Assurance, S. Kurtz, S. S ummers, and M. Kruskall (eds.) (Arlington, VA: American Association of Blood Banks, 1989); M. Monks, "Home Transfusion Therapy," Journal of Intravenous Nurses 11(6):389-396, November-December 1988; P.C. Miller, 'Wine Blood Component Therapy: An Alternative," NITA 9:213-217, May-June 1986. problem, some HDIT companies have highly specialized nurses on staff who train personnel in contracting agencies before they are allowed to serve patients (364).

# **Delivery Services**

In HDIT, all drugs, equipment, and supplies must reach the patient at home in a timely manner. In some cases, a pharmacist or nurse may deliver the supplies directly in the course of a patient visit. Larger providers may deliver supplies to patients' homes in a truck or van. Occasionally, patients may be responsible for collecting their own home supplies (e.g., at each visit to an outpatient clinic).

Most supplies are delivered to patients on a monthly basis in quantities great enough to allow a comfortable margin for the accidental contamination of sterile products by the patient (see box 3-A) and for accidental loss or damage. Additional supplies are brought by visiting nurses as needed.

The drugs themselves must sometimes be delivered more frequently, with frequency depending on the drug prescribed (209). Some require weekly, and some monthly delivery (149). Some parenteral solutions can be stored safely at room temperature or in a refrigerator for days, while others lose their potency after several hours (364) (ch. 2).

For some highly unstable drugs, delivery to the home setting may be unsafe or impractical. For others, increased frequency of delivery from the pharmacy or patient involvement in drug preparation can make home infusion feasible. New technological developments can also affect drug storage life in the home environment. For example, 5-fluorouracil has been found to remain stable for 16 weeks when stored at low temperatures in either polyvinyl chloride drug reservoirs used in electronic infusion pumps or in elastomeric bladder devices (276).

## Laboratory Services

Most HDIT requires some degree of laboratory monitoring, either to keep track of the level of infused drugs in a patient's bloodstream or to monitor the patient's bodily reactions to the therapy. Laboratory results are used by the physician and pharmacist to monitor the effects of the chosen therapy and to alter the dosage level or change the therapy when necessary.

Specimens (e.g., blood samples) are usually taken by a nurse during a home or outpatient visit and sent to a laboratory, which reports the results back to the pharmacist and the physician. The pharmacist and the physician, and often the attending nurse, then discuss any changes in therapy that maybe indicated based on those results. It is generally the nurse who implements the prescribed therapeutic changes by reprogramming the rate of the infusion pump or instructing the patient in a different dosing schedule. Although a few HDIT providers operate their own laboratories, most rely on an outside, independent laboratory for analyses (364).

# **Coordination Services**

Centralized coordination services are critical to HDIT, but the extent and type of coordination and the staff who perform these services vary tremendously among providers. Coordination exists on two levels. First, the various HDIT-related services themselves must be coordinated: the appropriate supplies must reach the patient in a timely manner, the appropriate nurse must visit the home on the appropriate day and time, and emergencies, complications, and patient questions must be dealt with. Second, the infusion services must be coordinated with other services the patient may be receiving, such as basic home nursing, physical therapy, or respiratory therapy. If the patient is receiving separate care for medical conditions not related to the infusion therapy, the HDIT provider must maintain communication with other care providers to ensure that their efforts are not duplicative or in any way harmful to the patient.

Coordination services are often performed by a nurse who acts as case manager (see box 3-C), but some organizations employ nonnurse personnel to perform some of the coordination functions (364). In very small organizations, such as an independent pharmacy provider, the pharmacist may perform some coordination functions as well as pharmacy service (391).