AMERICAN HEALTH CONSULTANTS®

HOME INFUSION THERAPY MANAGEMENT™

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MARCH 1999

VOL. 7, NO. 3 (pages 25-36)

American Health Consultants® is A Medical Economics Company

Industry looks for end of Abbokinase shortage during FDA review

Abbott, FDA tying up loose ends

It's been well over a month since Abbott Laboratories released any of its Abbokinase product, a thrombolytic agent with Food and Drug Administration (FDA)-approved indications for pulmonary embolism, coronary artery thrombosis, and IV catheter clearance. At press time, the FDA has yet to allow Abbott to begin shipping Abbokinase.

The problem results from an FDA inspection from Oct. 25, 1998, through Nov. 25, 1998. According to FDA spokeswoman **Lenore Gelb**, the main concern was Abbott "did not validate their viral inactivation. You have to be able to validate that the viral inactivation worked. That was one of the more major concerns we see."

Gelb tells *Home Infusion Therapy Management* the findings, which report 27 various deviations from Good Manufacturing Practices, do not mean Abbott failed to conduct such viral inactivation. The problem could lay in the lack of documentation, which the FDA wants to resolve.

"We have to have the paperwork to know that everything was done properly," says Gelb. "We're working with the company, reviewing our inspectional finding, and want to make sure everything is safe."

Abbott spokeswoman **Melissa Broats** tells *HITM* the company is in contact with the FDA.

"We provided them with a response in late November, and have had an ongoing dialogue with them throughout December. . . . We are awaiting their response," she says. "At this time, they have not communicated any additional questions."

When asked whether the problems were due to a failure to conduct viral inactivation or required paperwork, Broats tells *HITM*, "I'm not going to be able to go into that much detail with you. I can say the process to make Abbokinase is the same process that we have used for the 20 years that we have been making it. It has provided a safe and effective product . . . and there are no reported cases of viral transmission. . . . We believe the lots being held are safe and effective as the previous [ones]

Neither the FDA nor Abbott could speculate when Abbott will be

able to resume shipment. According to an FDA press release, none will be released until the FDA reviews the inspectional findings, as well as information later submitted by Abbott.

Until Abbokinase is readily available, the FDA holds there are alternative products available for certain situations. The FDA issued this list of thrombolytic products available in the United States, as well as their indications:

• Streptase (Hoechst Marion Roussel) — distributed by Astra USA
— Acute evolving transmural myocardial infarction
— Pulmonary embolism
— Deep vein thrombosis
— Arterial thrombosis or embolism
— Occlusion of arteriovenous cannulae

• Kabikinase (Pharmacia & Upjohn AB)
— Acute evolving transmural myocardial infarction
— Pulmonary embolism
— Deep vein thrombosis
— Arterial thrombosis or embolism

• Activase (Genentech)
— Acute myocardial infarction
— Acute ischemic stroke
— Pulmonary embolism

• Eminase (Wulfing Pharma GmbH) — distributed by Roberts Pharmaceutical
— Acute myocardial infarction

• Retavase (Centocor)
— Acute myocardial infarction. ■

Are you ready for ORYX?

Tips on preparing for data submission

When the Oakbrook Terrace, IL-based Joint Commission on Accreditation of Healthcare Organizations (JCAHO) introduced its integration of performance measures to the accreditation process last year, the implementation date for ORYX was nothing but a distant spot on the horizon for home care organizations. That's not the case anymore, though, as the third quarter of 1999 will see the first stream of official ORYX data being collected for JCAHO.

It's easy to procrastinate for something that won't be required for some time, but ORYX is something you shouldn't push off until the last minute. Here's how to get yourself on track and make the best use of the initiative.

When it comes to where you should be now, there's no single correct answer, according to **Caryn Bing**, RPh, MS, FASHP, and president of CB Healthcare Consulting, a home care and long term care consulting firm in Burr Ridge, IL.

"Every provider's situation is going to be different," says Bing. "By now, organizations should have taken a very careful approach to selecting a system."

JCAHO's Dec. 31, 1998 deadline required providers to:

• Select one or more JCAHO-approved performance measurement systems, and notify the Joint Commission of the selections.

• Select between two and five approved clinical or perception of care measures that monitor at least 20% of patients.

• Report these selections to JCAHO on the form sent to each accredited home care organization.

Assuming you met the deadline, Bing notes much of what you can do depends on the capabilities and requirements of the vendor you selected.

"Once you have selected the performance measurement vendor and the measures you anticipate collecting, you may be able to start testing data collection, but it all depends on your vendor's capabilities," she says. "If your vendor is just getting started with the actual data collection process, be sure to work closely with your vendor. If your vendor is saying they will not be able to accept your test data until March or April, but want you to start collecting in February, you better do it."

The first step in making ORYX as painless as possible is finding your vendor and when you can begin testing data collection. With one phone call, your vendor should tell you exactly what you can be doing to make the third quarter data collection process as painless as possible.

Bing adds the vendor should provide a template or a process to follow for data collection and submission. Whether collecting data using a computerized system or Scantron sheets, a template will allow you and your staff to see how easy it

can be to collect the necessary information.

If you can collect data and test your system now, Bing advises do so.

"Data collection just to comply with Joint Commission's ORYX requirement doesn't have to take place until the third quarter of 1999," says Bing. "But if you have the ability to pull that data from your information management sources, I would suggest that you do a trial run. It would be a good idea to know it is working and you can implement the data collection process into the daily work flow well before the first of July."

Virginia Tritschler, RN, MHA, director of quality improvement and outcomes measures for the Visiting Nurse Association (VNA) of Boston, already knows how difficult it can be to implement a data collection system, thanks to her organization's participation in the Health Care Financing Administration's Prospective Payment System demonstration project using the OASIS data collection tool. She agrees with Bing that data collection can present problems.

"You have to consider what the process is going to be for your flow of information," explains Tritschler. "How are you going to get the information into whatever system you select?"

She notes selecting the performance measures was easier due to VNA of Boston's involvement in OASIS, but warns that collecting the necessary data will be difficult for field staff.

"Education of staff is a major issue because there is a learning curve; you have to count on a reduction in productivity," says Tritschler. "You really have to put the time in up front for education."

That would mean the time is now, not later, to start training staff on the data collection and input.

She adds that the reduced productivity likely won't be a one-time occurrence.

"We're worried there is going to be a reduction in productivity even after the learning curve, because you're talking about adding a lot of documentation," she says.

Depending on the size of your organization, you may need to require your staff to input the data directly into the system rather than passing it to a data input staff.

Look beyond ORYX

A key to the ORYX data collection process is to look beyond the accreditation process and data collection. Bing notes any home infusion provider implementing ORYX should look at the required data collection and reporting more as an improvement initiative than strictly as a Joint Commission requirement.

"Providers should not select all of their measures for areas in which they know they are doing things very well already," says Bing. "Don't collect data for something that is just fine. Select something that is going to be a meaningful comparison to other organizations so you can identify opportunities for improvement."

Make data meaningful

Keep in mind that one of the purposes of collecting data is to allow for comparisons to other providers and benchmark results. To do this, you must make sure you're comparing apples to apples.

"Don't focus exclusively on how you collect data and get it to the vendor, but also consider the content and validity of that data," says Bing. "Is it really the same measure that other providers using the same measurement are reporting? Otherwise the data won't be meaningful outside that organization."

Along the lines of performance improvement, Bing adds that the last thing JCAHO surveyors want to see when looking at performance measures are numbers that say everything is fine.

"Surveyors know everything isn't perfect, and perfect numbers are an indication that the organization is not looking for areas they need to improve upon and make better," she says. "I would anticipate that, over time, as the ORYX data becomes more readily integrated into the accreditation process, it will highlight areas that surveyors can address. By sometime in the year 2000, when surveyors go into organizations, they will know a little bit more about where to focus or where to not have to bother focusing."

Looking for more?

Julie Roberts, a JCAHO spokeswoman, notes the Joint Commission addressed dozens of commonly asked questions concerning ORYX. They can be accessed at the Joint Commission Web site by going to www.jcaho.org, or calling the ORYX information line, (630) 792-5085.

Roberts points out the Joint Commission recently changed the data collection start date for accredited home care and hospice organizations from July 1, 1999, to Jan. 1, 2000. Also, the initial receipt of performance data from the performance measurement system to the Joint

Commission has been postponed from March 31, 2000, to July 31, 2000.

Also, deadlines for home care and hospice organizations with an annual volume of less than 120 patients have also been delayed. Such organizations will be required to select four measures from a template (available from JCAHO sometime this year) and report their selections to the Joint Commission by Oct. 1, 1999, rather than June 30, 1999. Surveyors will not begin on-site review of the results of data collection and analysis from those measures until after July 31, 2000. ■

The ins and outs of inotrope infusion therapy

Special considerations for critical patients

With the advancement of home health care in general and home infusion in particular, patients are returning home earlier than ever during their disease states. Along those lines, it's not unusual for home infusion providers to receive referrals for cardiac patients receiving inotrope therapy.

Providing inotrope therapy in and of itself is not dangerous, but **Kellie Hayes**, RN, director of clinical services for Baylor HomeCare in Dallas notes there are numerous problems somewhat unique to inotrope therapy that home infusion providers should be aware of.

"We get calls from different providers in the community who have received a referral, and they are not well-versed in what the drugs are and how to deal with those patients," she says.

Hayes adds there are also discrepancies within the medical community.

"Within the cardiology community, there is no one way to provide inotrope therapy," she says. "We see both intermittent and continuous, so we see it used in a lot of different ways. There have been multiple studies that attempt to show which way is the best way, and no one agrees."

It's not a rarity

Although Hayes points out that inotrope therapy is infrequent, it's not a rare occurrence, either. In the Baylor HomeCare cardiovascular program, at any given time, up to 5% of patients are receiving inotrope therapy.

"It's essentially a last-resort drug," says Hayes. "It's an end-stage treatment that is sometimes used as a bridge to transplantation for patients. Generally speaking from a nursing perspective, the physician should have maxed out all regimens before going to an IV inotrope."

Know the risks

There are several risks involved in providing the therapy. With those in mind, Hayes says any provider accepting an inotrope therapy patient should be aware of these hazards and pitfalls:

1. **Fibrin sheath formation**

"You have a low cardiac output syndrome with these patients and an increased potential for fibrin sheath formation at the end of the catheter," says Hayes.

Baylor HomeCare has documented three instances of fibrin sheath formation. To identify the problem, the nurse must tell the doctor she suspects a fibrin sheath has formed, and before the line is pulled, a radiogram is performed to confirm the problem.

Because of this danger, Baylor HomeCare's protocols for flushing these lines are different than for the maintenance of normal central venous catheters. The first difference, according to Hayes, is that the procedure is a daily vigorous flush of 10cc-20cc of saline.

"If there is a chance of some formation around the catheter, that may be lessened by a vigorous flushing," she says. "Rather than 3cc-4cc going through the catheter every hour, we push 2cc, stop, and push 2cc more."

This creates turbulence at the end of the catheter to prevent a fibrin sheath formation. However, there are dangers in the procedure as well.

"You're also trying to balance that with the fact that there may be something in there you don't want to embolize," says Hayes.

2. **Staff training**

Hayes suggests, before you accept an inotrope therapy patient, your nurses be familiar with the drug, its administration and how to assess the patient.

At Baylor HomeCare, all nurses hired to treat cardiac patients have previous experience. Nurses dealing with inotropes also receive IV training.

Ann Frantz, RN, a Pontiac, MI-based independent health care consultant specializing in alternate-site cardiovascular care, agrees cardiac

How safe is inotrope therapy in the home?

Study points to safety and cost efficacy

A study published in the *American Heart Journal* found that continuous home intravenous inotropic drug therapy is safe and cost-efficient.[1] The study followed 20 patients awaiting heart transplantation who were unable to be weaned from intravenous inotropic therapy on two or more occasions, but were stable while receiving inotrope infusion therapy in the home.

Thirteen patients received dopamine, four received dobutamine, and three received both. The mean duration of the therapy was five months, 70% of which was spent as an outpatient. When the study was completed, 11 patients received transplants, two were still on the waiting list, and seven died after having been removed from the list because of general deterioration or renal dysfunction. Survival was 71% at three months, which is expected for an inotrope-dependent population.

All patients with idiopathic dilated cardiomyopathy survived to transplantation, while all three patients with right heart failure caused by pulmonary vascular disease and four of seven patients with cardiomyopathy died. Inpatient days for the 20 patients were reduced by 70%.

Reference

1. Sindone A, Keogh M, Macdonald P, et. al. Continuous home ambulatory intravenous inotropic drug therapy in severe heart failure: safety and cost efficacy. *Am Heart J* 1997; 134:889-900. ■

experience is critical in providing appropriate care to patients receiving inotrope therapy. To assist providers in establishing policies and procedures, Frantz and Hayes were on an independent consensus panel established to create cardiac homecare practice guidelines.

Final guidelines

"This particular version of the guidelines does not deal specifically with patients receiving inotropic therapy. It does state that to take care of a heart failure patient in the home, the nurse should have at least three to five years of experience in a cardiovascular care setting, then have competency within the agency as well," says Frantz.

Guidelines can be ordered from the Home Healthcare Nurses Association by calling (800) 558-HHNA.

3. **Arrhythmia**

Patients receiving inotrope therapy often suffer from arrhythmia, particularly those on continuous infusion in the home. In such instances, a pump malfunction could be disastrous for the patient. To combat the problem, Baylor HomeCare places an extra pump in every such patient's home.

4. **Patient/caregiver education**

Because of the critical nature of inotrope therapy patients, patient/caregiver education is of utmost importance. Education includes changing cassettes and hooking up a new pump.

"In the home, we're looking at a population that if it's end-stage disease they are generally 65 and older. But in managed care, we are looking at a bridge to transplantation and it's generally a younger population," says Hayes.

"We're teaching skills that don't come naturally to them and they need to understand that if something goes wrong with this drug, they need to act appropriately and quickly or bad things could happen."

5. **Payer driven**

Many times a payer source will determine who gets the referral. That means a provider without cardiac experience may find itself suddenly caring for a cardiac patient.

"A physician may know that he has to find someone to care for the patient, but it may be more driven by who is going to pay for it than by who can appropriately care for the case," says Hayes.

Rather than allowing managed care dictate what is needed, it should be up to professionals to dictate what is, advises Frantz.

6. **Infection**

Because you have a central venous catheter in the body, you have to deal with infection. The more critical the patient, the more dangerous any infection can be. ■

IV guide prompts coordination, cooperation

Assists in coordinating care between care settings

What started as the development of a practical vascular access guide for nurses in the Sharp HealthCare system of San Diego has, in the course of two years, developed into a board of multispecialty professionals that keep the entire Sharp system updated and on track with the latest business, clinical, and legal issues in the vascular access field.

Two years ago, the Sharp Grossmont Hospital home infusion company realized home care nurses needed assistance to provide successful home infusion. As vascular access became more scientific and home infusion felt increasing pressures from managed care, it became apparent nurses and their home infusion patients would benefit from the leadership of an infusion clinical nurse specialist.

"We were asking the nurses to do the right thing the right way the first time, and they deserved educational and clinical support," says **Pamela Johnson**, MSN, MBA, CNS, and an infusion nurse for Sharp HealthCare/Sharp Grossmont Hospital Homecare, who was given the task of providing that support.

"The first thing that was apparent to me was that our patients were coming from different settings," she says. "Some came from our inpatient setting; sometimes they were seen in ambulatory care, [or] were seen in home care or their doctors' offices. The patients were told different things regarding their infusion in each setting. Not only were the patients confused, they didn't think the professionals ever talked to one another."

Seeking structure

To alleviate the problem, Johnson decided to compile a vascular access guide that clarified the various policies and procedures of each care setting within Sharp HealthCare, then disseminate this information to the system's professionals. **(See charts, p. 31.)**

"The first thing I did was talk to the inpatient and ambulatory IV nurses [to] try to set up something that provided structure by matching all the Sharp procedures and policies," she says. "That's why some of the sections have ranges. Inpatient nurses tended to change dressings more frequently, and we didn't want to ask them not to do that."

Johnson adds that is why the resource is called a guide.

"The frequency of dressing changes or the amount of saline flush to use in one setting may not be strictly the same in another setting," she says. "That is why some of the guidelines have a range instead of a specific answer."

Not a strict guide

The guide's purpose is not to tell nurses exactly what to do, but to stimulate the nurses' thinking and give a general guideline for the nurse to make decisions about care.

Also, when nurses know other parts of the health care continuum may approach a patient procedure in a slightly different way, they can better educate patients on the basics of vascular access care, rather than have patients memorize a list of steps that makes little sense to them.

"I didn't want to say, 'This is the bottom line,' because the guide just gives you an idea of what everyone is doing," adds Johnson, noting she also reviewed existing standards of recognized organizations while compiling the guide.

"We tried to work with the standards we had and make them meet with Oncology Nurses Society, Intravenous Nurses Society, and Centers for Disease Control standards, which can be a bit vague sometimes because there is not much research available, especially for site care and dressing changes to recommend anything hard and fast," adds Johnson.

She also points out the guide is a living document and is updated every six months or so to remain current with the most recent studies and research on vascular access and patient care.

Upon completion, copies of the document were posted at all the home care companies. At each orientation, every home care nurse receives a copy of the orientation packet. Sharp has also used the guide to market its services to physicians by showing what vascular access devices are available, when to select each device, and how Sharp treats patients with them.

"Familiarity with the management of the many vascular access devices is knowledge many physicians lack, while infusion nurses are comfortable and skilled in this area," says Johnson. "We see this as a unique opportunity to gain credibility

(Continued on page 32)

SHARP HEALTHCARE

Grossmont Home Infusion Therapy

Resource Guide for Adult Vascular Access Devices (VADs)

VASCULAR ACCESS (Adults)	SUB-CUTANEOUS INFUSION	PERIPHERAL IV < 2"	PERIPHERAL IV 3"-8" (MIDLINE)	PICC PERIPHERALLY INSERTED CENTRAL CATHETER (single or double lumen)	CENTRAL VENOUS CATHETER: NONTUNNELED 1-2-3 lumens	CENTRAL VENOUS CATHETER: TUNNELED (single or double lumen)	CENTRAL VENOUS CATHETER: Pheresis/Dialysis (Large Bore 10F+) Tunneled	VALVED CATHETERS (groshong® PICC, groshong® midline, groshong® CVC, groshong® port)	IMPLANTED PORTS (Chest/Arm)
PATIENT SELECTION CRITERIA	• Slow administration • Ex: Pain Management or pre-term labor patients	• Short term therapy • Available veins in arms/hands	• 2-12 wk simple therapy • Available antecubital vein • Cooperative patient • Reliable access needed	• 2-24 wk therapy • Available basilic, cephalic veins • Patient consent • Cooperative patient • Tip resides in SVC	• Short term therapy • Patient consent • Subclavian, jugular, femoral	• Long term therapy • Patient consent	• Dialysis & pheresis • BMT patients	• Patients c̄ sensitivity to heparin	• Patient preference • Cosmetically desirable • Must use non-coring needle to access • Most costly
EQUIPMENT	• Short butterfly needle or sub-cutaneous cannula or needle • Ex: Sof Set	• IV catheter 18-26g • Start kit • Ex: Intima, Jelco, Protective Plus	• Midline catheter • Insertion tray • Sterile gloves • Patient ID Card • Ex: V-cath, groshong, Per-Q-Cath	• Various brands • PICC insertion tray • Sterile gown • Pt. ed. materials • Patient ID card • Ex: Groshong, BD	• Various brand CVCs • Insertion tray • Xray confirm in SVC • Sutured in place • Ex: Cook, Arrow	• Various brand CVCs • Insertion tray • Chest Xray • Ex: Groshong and Hickman	• Various brand of CVC's • 1000-5000 u/ml heparin per MD • Ex: Perma-Cath	• Midlines, ports, CVC's & PICCs • No heparin flush needed • Use saline flush	• Any brand port • Single or dual septum
NURSE QUALIFICATIONS All approved RNs have demonstrated competency	• Approved RN	• Approved RN	• Approved RN	• Approved RN	• MD	• MD	• MD		• MD
SITE SELECTION	• Any available sub-cutaneous tissue where stable; not over bony prominence • Ex: Flank, abd., thigh, upper arm	• Upper extremities, lower to higher, avoid joints	• Antecubital veins only • Basilic preferred	• Must have chest film to check placement. • Antecubital area 1. Basilic - first 2. Median cubital - next 3. Cephalic - last	• Jugular or subclavian veins to SVC • Femoral vein	• Subclavian to SVC	• Subclavian to SVC • R or L chest wall		• Chest wall over bony area for stability (subclavian to SVC) • Upper or lower arm (basilic vein preferred)
TUBING CHANGES	With set Δ	Q24° intermittent Q48°/72° continuous CADD = Δ c̄ cassette Δ	Intermittent therapy Q24°, Continuous therapy Q48°/72°, CADD tubing Δ c̄ cassette						
SITE CHANGES/ SITE CARE • Always Δ drsg if soiled or loose	• Q3-7 days • cleanse c̄ alcohol and povidone iodine (PVI) • Dress c̄ transparent drsg (TM)	• Q3 days • Cleanse c̄ alcohol and PVI • Stabilize well c̄ tape • Cover c̄ TM	• Q3-7 days • Catheter may remain in place until s/s complications	• Δ drsg p̄ 24° then q3-7 days. • PICC may remain in place for as long as 6 mos or more until s/s complications • Note length/external portion of catheter at drsg Δ	• Q 3-5 days. • Sterile drsg Δ Q 3-5 days c̄ alcohol, PVI & TM	• May remain in place until s/s complications • Sterile drsg Δ Q3-7 days c̄ alcohol, PVI & TM drsg.	• Remain until s/s infection or other complications. • Sterile drsg Δ Q 3-7 days using alcohol & PVI & TM drsg.		• Remain until s/s infection or other complications. • Δ needle & reaccess Q6-7 days • No special site care if unaccessed
FLUSHING • Positive pressure technique • Push pause method • 5-10cc Syringe ONLY for CVCs		• Q8-12° c̄ 2-3 cc NS • In Home follow c̄ 1-3cc heparin flush 100 u/cc • May use 10 u/ml heparin if indicated	• Q8-24° c̄ 2-3 cc NS • In Home followed c̄ 1-2cc heparin flush 100 u/cc • May use 10 u/ml heparin if indicated	• Q8-12°-24° c̄ 3-5cc NS followed by 3cc heparin flush if not valved. • Flush Q day/Q week if not in use	• Q8-12°-24° c̄ 3-5cc NS in each lumen followed by 3 cc heparin flush. • If CVC NOT IN USE, may flush with heparin flush only Q day	• Q24° c̄ 3-5cc NS followed by heparin flush 3cc in each lumen if non-valved • Flush Q 3–7 Days if not in use	1. [illegible] each lumen 2. [illegible] (usually 2.5cc) 3. Flush 10cc NS 4. [illegible] 5. Using 1000-5000 u/cc hep [illegible] (usually 2.5cc) [illegible] lumen	• No need to use heparin flush D/T special 3-way value (groshong®) • Use saline flush	• 3-5 cc 100u/cc heparin flush • Flush Q month if not in use

SHC-PH-667-NS (3-98)

	SUB Q	PERIPH	MIDLINE	PICC	CVC	CVC-T	CVC-Lg	VALVED	PORTS (Chest/Arm)
INJ CAP CHANGES		• c̄ every site Δ	• Q 7 days & p̄ blood draws, if soiled	• Q 7 days & p̄ blood draws, if soiled	• Q 3-7 days & p̄ blood draws, if soiled	• Q 7 days & p̄ blood draws, if soiled	• Q 3-7 days & p̄ blood draws, if soiled		• Δ c̄ non-coring needle change, p̄ blood draws & if soiled
BLOOD DRAWS			• Only if no alternative. • Preflush 5 cc NS • Discard 3-5cc. • Post flush 10cc NS	• Preflush 5cc NS • Discard 3-5cc • Postflush 10cc NS • Not for drug levels or coagulation studies	• Preflush c̄ 5cc NS • Discard 3-5cc • Postflush c̄ 10cc NS • Lock c̄ heparin flush	• Preflush c̄ 5cc NS • Discard 3-5cc • Postflush c̄ 10cc NS • Lock c̄ heparin flush	• OK Using special flush protocol per MD order	• May use for draws - flush well p̄ draw c̄ NS using push pause method	• Use 2cc extra saline for flush before & after draw to be sure port chamber is cleansed. • Instill heparin flush p̄ draw if non-valved
TROUBLE SHOOTING	✓ absorption ✓ effectiveness ✓ redness, pain, warmth	✓ S/S phlebitis infiltration ✓ drsg & connections	✓ S/S phlebitis infiltration ✓ drsg & connections ✓ flush ✓ Drug osmolarity, pH	✓ flushing ✓ tip placement c̄ xray ✓ S/S phlebitis infection or thrombosis	✓ flush ✓ placement ✓ S/S infection ✓ temp ✓ tip location c̄ xray	✓ flush ✓ placement ✓ S/S infection ✓ temp ✓ palpate tunnel ✓ tip location c̄ xray	✓ temp, pain ✓ S/S infection ✓ placement ✓ flushing ✓ report s/s thrombosis ✓ tip location c̄ xray	• All other precautions plus call if blood visible in line	• All CVC precautions • Be sure needle is WELL SEATED into port chamber • Where is tip?
FLOW RATES TO MAINTAIN PATENCY	• .1 - 3CCs per hour	• .2 - 400+ CCs per hour	• .2 - 400+ CCs per hour	• .2 - 400+ CCs per hour	• 1 - 500cc + per hour	• 1 - 500cc + per hour	• 1 - 1000cc + per hour	• 1 - 500cc + per hour	• 1 - 500cc + per hour
LINE REMOVAL	• RN, LVN • Patient @ home c̄ instruction	• RN, LVN • Patient @ home c̄ instruction	• Approved RN, LVN	• Approved RN	• Approved RN • Clip Sutures • Hold pressure	• MD	• MD	• RN or MD	• MD • Surgical procedure
PATIENT TEACHING	• When to call RN • Keep site dry	• Call RN if pain swelling, & redness or stops infusing • Keep site dry	• When to call RN, MD, 911 • Keep site dry	• When to call RN, MD, 911 • To protect & care for line	• S/S bacteremia • appearance of site, • who to call if problems • emergency procedure	• S/S bacteremia • appearance of site, • who to call if problems or emergency	• S/S infection • When to call for problems or emergency • S/S thrombosis	• Same as non-valved	• S/S bacteremia & infection • appearance of site • normal • function • who & when to call for help
DOCUMENTATION	• Site appears • Flow rates • Patient response	• Appearance, function • Patient response	• Appearance function • Patient response • Length of external portion • Upper arm circumference 3" above site	• Insertion procedure • Patient response • Xray - tip location • Lot # of PICC & Manufacturer • Length of external portion • Upper arm circumference 3" above site	• Clinician placing catheter • Brand, Lot # if available • Patient response • Xray - tip location	• Clinician placing catheter Brand, Lot # if available • Patient response • Xray - tip location	• Flush protocol • Site appearance • Patient tolerance • Function	• Flush • Site appearance	• Non-coring needle only • Obtain blood return prior to use • Where is tip?
COMMENTS	• Can use c̄ PCA pump	• Can use c̄ pumps & competent patient • Use 18g or 20g for blood transfusion	• May use gauze drsg if TM problems • Change drsg if loose or soiled. • More flush needed if extension used	• Repair kit available/size? • May use for transfusion if 18 or 20g • Must have chest Xray to confirm tip in SVC • Dwell time months to year	• May pull out & danger of bleeding • Highest infection rate of all CVCs	• Repair kit available (obtain correct size) • Dwell time is years	• These are very large catheters to withstand the high pressure of dialysis & pheresis • Thrombosis & infection possible complications	• Heparin flush will not damage catheter • Flush infrequently when not in use: 1x/week to 1x/month	• Very low infection rate • Remains patent 4-6 wks when flushed c̄ 5cc-10cc 100u/ml heparin • May remain in place for years

For Add'l Info Call Grossmont Home Infusion 644-4969 or 541-3400 Sharp Memorial IV Team. Meets Sharp Healthcare Policy & Procedures

REFERENCES: **Access Device Guidelines**, 1996. Oncology Nursing Press, Inc., Phillips, L.D. (1993) **Manual of IV Therapeutics**, F.A. Davis, Co. Reviewed 2/98

Source: Sharp HealthCare, San Diego, 1998.

and respect from our physician colleagues."

While compiling the guide, Johnson realized the various resources strewn throughout Sharp's system could be changed from negatives to positives. That very idea eventually led to the development of Sharp's Vascular Access Council last March.

"We worked under the vice president of ambulatory care for the system and formed the council," says Johnson. "It reports to two systemwide medical staff committees: infection control and quality assurance."

Laurie Ecoff, RN, MS, director of ambulatory services for Grossmont Hospital, Sharp HealthCare, says the council adds the council was a result of the evolution of vascular access within the system.

"There was a need to address vascular access issues from a systemwide approach," she says, "and this meant bringing the experts together that are involved in vascular access across the continuum of care."

Ecoff says the council is in its formative stages.

"We spent a number of the meetings developing our charter and quality plan that establishes what we want to do," she says. "We see this as a quality improvement activity to link all the different sites and infusion centers together to ensure the best practice throughout the entire system."

Ecoff points out the Vascular Access Council will focus on standardizing clinical practice through looking at quality improvement as well as the latest clinical research. The process thus far has been time consuming, but not necessarily challenging.

"It's a matter of trying to meet with people across the system throughout San Diego County and get everyone together once a month," says Ecoff. "It has helped to send information [via] e-mail so members can review minutes and charter plans between meetings."

The Vascular Access Council has an advisory function; any questions relating to vascular access can be presented for review and recommendations. Seated on the council are members from interventional radiology, infection control, inpatient, and ambulatory settings, as well as the cancer center — basically anyone having anything to do with vascular access.

The council meets monthly and addresses the need to inform the system that it exists and what it can do. Plans are to use the entity-based Quality Councils to help disseminate information, as well as consider different groups within the system the Vascular Access Council can present information to.

Each member of the council also has an obligation to disseminate information. "Members of the council need to make sure they bring the information back to their leadership and staff at each entity," says Ecoff. ■

Insulin infusion pumps to lead market

Latest report forecasts continued growth

In its report on the U.S. Infusion Pump Market for the period 1994-2004, Frost & Sullivan, an international marketing, research, and training company based in Mountain View, CA, reports insulin pumps and enteral feeding pumps will experience the greatest growth.

In 1997, the total market for infusion pumps in the United States was estimated at more than $586.4 million, with a revenue growth rate of 5%. Trends that affected the market and will likely continue to play a major role are the consolidation of market participants, cost-containment pressure, and a change in care settings to follow the patient from one care setting to another.

A period of growth

The report forecasts the insulin infusion pump market to experience the greatest growth from 1997 to 2004, with an anticipated growth of 17%. The total insulin infusion pump market generated revenues of $44.6 million in 1997, with a growth rate of 19%.

The market consists of two segments: external insulin infusion pumps and implantable insulin infusion pumps. However, because implantable pumps are not yet approved by the Food and Drug Administration, the U.S. market is represented only by the external insulin infusion pumps.

The report notes the market drivers for this particular segment are tighter control over blood glucose level, uncaptured patient population, product features and an increased number of prescriptions by primary care physicians. Restraints include price comparison, reimbursement, customer fears, and the rapid growth of oral drugs.

Also looking at rapid growth is the implantable

infusion pump market. The report forecasts a growth of 14.3% from 1997-2004, following a growth rate of 8% on revenues of $80.6 million in 1997.

Market drivers figure to be a large potential patient population, Class III classification, ease of use, reliability and efficiency of the product, and a pushed-based marketing strategy. Restraints are likely to include replacement rate, uncertainty about life expectancy of product, cost, and catheters.

Two syringe markets

The syringe infusion device market also enjoyed a growth rate of 8% in 1997 on generated revenues of $46.3 million. The compound annual growth rate from 1997 to 2004 is forecast at 9%. The market is broken into two segments: syringe infusers and syringe infusion pumps.

The enteral feeding pumps market grew 13% from 1994-97, with generated revenues of $51.7 million in 1997. However, the anticipated growth rate from 1997-2004 is just 6.5%, largely due to market restraints of reimbursement issues, contamination risks, the training required, and the transition from parenteral to enteral nutrition.

When it comes to the ambulatory infusion pump market, the 6.2% forecasted growth rate comes as welcome news after 1% growth for the $65.7 million revenue market. Composed of two segments, non-electronic and electronic infusion pumps, the decline in reimbursement for home infusion could be a leading restraining factor for non-electronic pumps. While non-electronic pumps are easier to use and cheaper than electronic pumps, the electronic pumps are better suited for long-term therapies and offer a wide range of infusion configuration.

The large-volume infusion pumps market generated revenues of $297.5 million in 1997, but experienced just 1% growth and is forecast to grow at just 1.6% from 1997-2004. Leading restraints on growth will be hospital consolidation, training issues, bundling practices, and increasing importance of GPOs (group purchasing organizations). Market drivers will be product features, a decrease in disposable prices, increasing computer interface, and multichannel / single channel option.

A total of 36 U.S. companies were involved in 1997. Leading factors in the changing market dynamics include the concentration of manufacturers and an emergence of a number of smaller competitors. The report notes large competitors failed to rapidly react enough to infusion pump market changes, resulting in small competitors being able to capture market share in areas not covered at the time by the large, well-established manufacturers. Frost & Sullivan expects a new wave of concentration will take place that will reduce the number of total competitors.

With competition in the market based on product features, service, and price, the report notes most of the products are complex; thus, requiring significant investment into research and development. This restraint results in an infrequent launch of products. ■

Latest JCAHO manual published

The Oakbrook Terrace, IL-based Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recently published its *1999-2000 Comprehensive Accreditation Manual for Home Care.* Some 25 standards were deleted through the incorporation with other standards, intent statements, or other examples. The manual costs $195, and may be ordered by calling (630) 792-5800 and using order code CAHC-99EM. ▼

Flagship purchases IV Concepts

Miami Lakes, FL-based Flagship Healthcare recently acquired IV Concepts, the largest infusion therapy provider in south Florida, increasing Flagship's annual net revenues to $80 million. Flagship raised $42 million to finance the acquisition and provide capital for future growth. The purchase assists the company's goal of building a network of post-acute healthcare services in various markets along the East Coast. ▼

Taxotere provides favorable results

According to a recent study presented at the 21st annual San Antonio Breast Cancer Symposium, the addition of Taxotere (docetaxel), an active single chemotherapy agent, to the combination of Adriamycin (doxorobicin) and Cytoxan (cyclophosphamide, is an effective and safe first-line therapy for women with metastatic (spreading) breast cancer. The combination did not cause an increase in cardiotoxicity, a side effect frequently resulting in the cumulative doses of doxorubicin.

The Phase II multicenter study included 55 patients diagnosed with previously untreated metastatic breast cancer. The patients were administered Adriamycin, 50 mg/m^2, as an intravenous bolus, followed by Cytoxan, 500 mg/m^2, as an IV bolus, and Taxotere, 75 mg/m^2, one hour later as a one-hour infusion. This regimen was repeated every three weeks. The overall response rate was 77% of the 47 patients evaluable for response.

For more information on the study, visit their Web site, www.pninternational.com, or contact the Alberta Cancer Board at (403) 437-0859. ▼

Apria leaving infusion markets

In an effort to return to profitability, Apria Healthcare Group, of Costa Mesa, CA, recently sold its California infusion operations to Cerritos, CA-based Crescent Healthcare. Apria retained enteral therapy services. It is also shopping its home infusion businesses in Texas, Louisiana, various parts of Pennsylvania, and West Virginia. ▼

CA continues move to health care worker safety

California recently approved Assembly Bill No. 1208, requiring Cal/OSHA and the Department of Health Services to compile a list of "Needleless systems which shall be available to assist employers of health care workers to comply with the requirements of the new standard." The new regulations are to become effective no later than Aug. 1. ▼

CINA conference is coming

The Canadian Intravenous Nurses Association annual conference will be Oct. 20-22, 1999, in Toronto. The association is seeking abstracts on subjects that include home IV therapy, ethics, pediatric IV therapy, IV insertion techniques, basic IV skills, and IV therapy for the elderly. For more information, call the association at (416) 292-0687. ▼

Trial shows long-term results of Rituxan

Results of a long-term follow-up single agent pivotal trial of Rituxan recently presented at the American Society of Hematology conference showed that 48% (80 of 166) of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma responded to treatment.

Six percent were complete responses and 42% were partial, with the median duration of response 11.6 months. However, the remission of 22 of the 80 respondents is from one-and-a-half to three years.

COMING IN FUTURE MONTHS

- Who s the judge? Establishing competency standards for home infusion nurses
- Get consent: The real reason you should be getting PICC consent forms
- Looking at liability: A four-step process to assess your legal liability
- Teacher, teacher: Developing top-notch patient education materials
- Gauze or transparent: What industry leaders recommend for catheter dressings

The only approved monoclonal antibody therapy for non-Hodgkin's lymphoma and the first new agent in 11 years, Genentech and Idec Pharmaceuticals recently sent a letter to doctors regarding their Rituxan drug, following several severe infusion-related adverse events.

Eight deaths, with severe symptoms (severe bronchospasm, dyspnea, hypotension, and/or angioedema) occurring in seven of the eight instances during the first infusion. The cause of death was not reported or remains unknown for two of the eight cases. ▼

Health care-focused Y2K resource available

Rx2000 Solutions Institute, a Minneapolis-based non-profit organization, has established a Rapid Response Communications Center to alert health care providers of year 2000 (Y2K) problems identified with computers and medical devices. Providers can call (888) 835-4478 or (612) 835-4478 and leave a message regarding any Y2K problem they encounter. Information will be collected and disseminated to member providers.

For more information, contact Rx2000 by visiting its Web site at www.rx2000.org. ▼

ACHC releases pharmacy and infusion manual

The Accreditation Commission for Home Care, of Raleigh, NC, recently released its Pharmacy/Infusion Accreditation Resource Manual. ACHC has accredited companies in 14 states from coast to coast. For more information, contact ACHC at (919) 872-8609; E-mail: achc@mindspring.com, or visit the organization's Web site at www.achc.org. ▼

Amedysis takes final step in restructuring

Baton Rouge, LA-based Amedysis recently acquired 67% of Tanglewood Surgery Center, a multispecialty outpatient surgery center in Odessa, TX. Amedysis also sold its DME division and is now entirely focused on home health care, infusion therapy, and ambulatory surgery centers. Amedysis secured a $25 million asset-based line of credit and a $3 million three-year term loan from National Century Financial Enterprises. ▼

Unsolicited tender made for Amedysis stock

The Bradford Group, a newly formed Louisiana limited liability company, recently

Home Infusion Therapy Management (ISSN 1082-8648) is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodical postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Home Infusion Therapy Management**, P.O. Box 740059, Atlanta, GA 30374.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291. Hours of operation: 8:30 a.m.-6:00 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday EST. E-mail: customerservice@ahcpub.com. World Wide Web: www.ahcpub.com.

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commenced an unsolicited tender offer for $5 per share for all the outstanding shares of Amedisys common stock. ■

• **Healthcare Information and Management Systems Society (HIMSS) Annual Conference and Exhibition** — Feb. 21-25, Georgia World Congress Center, Atlanta. For more information, call (312) 664-4467, ext. 152, or visit the HIMSS Web site at www.himss.org.

• **LITE 99** — Feb. 25-27, Marriott City Center, Pittsburgh. For more information, contact the League of Intravenous Therapy Education at (412) 678-5025.

• **American Society for Parenteral and Enteral Nutrition teleconference on Nutrition Support in Critical Care** — March 18. For more information, call (301) 587-6315, E-mail aspen@nutr.org, or go to ASPEN's Web site at www.clinnutr.org.

• **Health Industry Distributor's Association Home Care Washington Conference** — April 20-21, Washington Court Hotel, Washington, DC. For more information, contact HIDA at (703) 549-4432.

• **INS Annual Meeting and Industrial Exhibition** — May 1-6, Charlotte, NC. For more information, call INS at (800) 694-0298.

• **Center for Healthcare Environmental Management certification seminar** — May 17-21, Plymouth Meeting, PA. For more information, call (610) 825-6000, ext. 145.

• **National Home Infusion Association Eighth Annual Conference** — May 19-22, 1999, Fort Lauderdale, FL. For more information, call (703) 549-3740.

• **HIDA/99 Trade Show** — Oct. 9-11, Navy Pier Convention Center, Chicago. For more information, call (703) 549-4432.

• **Medtrade 1999** — Nov. 3-6, Ernest N. Morial Convention Center, New Orleans. For more information, call (770) 641-8181.

• **Medtrade 2000** — Oct. 3-6, 2000, Orange County Convention Center, Orlando, FL. For more information, call (770) 641-8181. ■

CE objectives

After reading the March issue of *Home Infusion Therapy Management*, CE participants will be able to:

1. Identify the most essential criteria to consider when treating an inotropic therapy patient.
2. Identify the primary use of collecting outcomes data.
3. Identify a patient education problem that results from the moving of patients from one care setting to another.
4. Define the biggest benefit of creating an infusion resource guide for nurses. ■