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INSIDE

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Bayer Corp. changes Prolastin sales from infusion providers to contractors

Exclusive deal with Express Scripts questioned by NHIA

Bayer Direct, a product distribution channel created by Bayer Corp., has signed an exclusive distribution contract with pharmacy benefit manager Express Scripts to distribute Bayer Corp.'s widely used infusion drug Prolastin. Bayer is the sole manufacturer of Prolastin, which is used for patients with alpha1-antitrypsin deficiency, a lung dysfunction for which there is no cure. Prolastin distribution through infusion therapy providers stopped Nov. 1, 1999.

Lorrie Kline Kaplan, executive director of the Alexandria, VA-based National Home Infusion Association (NHIA), says the Bayer Direct program raises serious concerns for the infusion community because infusion services must now contract with Express Scripts in order to continue providing infusion services.

Conflicts highlighted

Kaplan says NHIA contacted Bayer Direct and expressed concern about this manufacturer-controlled program and its implications for patient care. "There was conflicting information and misinformation about the program," she says. "For example, the alpha1 support group Web site [sponsored by Bayer] stated that 'nursing and infusion services will be arranged through Express Scripts as part of the Bayer Direct program.' However, it also suggested that patients 'talk with Bayer Direct or your current nurse to see what possibilities exist for keeping your current nursing services.'"

However, Bayer Direct representative attorney **Doug Bell** says infusion providers' concerns may derive more from the fact they can no longer purchase Prolastin for resale to their infusion clients. "I think the issue is that they were purchasing and providing the product, as well as providing the infusion services," he says. "Now they are looking at just

providing the infusion services."

Bell says the Bayer Direct/Express Scripts distribution system was designed to ensure equal distribution of Prolastin to all alpha1 patients. "Essentially, the (Prolastin) patients came to Bayer, the media, and folks on Capitol Hill complaining about product hoarding [by infusion service providers who purchased Prolastin for resale to patients] and exorbitant prices being charged where the product was in short supply."

According to Bell, the current supply of Prolastin does not meet demand for the drug. "Our manufacturing facilities are running 24/7, 365 days a year because of the increasing number of patients being diagnosed with alpha1," he says. "What we've got here is a system that tries to level the playing field by giving identification numbers to all patients. . . . Each patient receives a 28-day supply of Prolastin, delivered to the location of choice. This distribution sequence continues until every patient who is enrolled in the Bayer Direct program has received the product. Shipment continues until all available product is shipped. If there is a temporary interruption of delivery due to lack of supply, the next patient in the sequential line receives his product shipment when the supply is replenished."

Follow the patient

Bell sees another benefit for infusion patients with the Bayer Direct system because in the past, due to Prolastin's short supply, a patient who moved to another state without first creating a relationship with a distributor could have difficulty obtaining the product. "With the Bayer Direct program, wherever the patient goes, there also goes the Prolastin," he says. "Bayer Direct has contracted with AlphaNet, a for-profit organization that provides consultation services to alpha1 patients on how to obtain the product and receive insurance reimbursement."

AlphaNet began as a not-for-profit group and is still described that way on the Bayer Direct Web site.

Kaplan says Bayer Direct patient representatives told her they are "making every effort to allow patients to retain their current nursing service." She adds NHIA understands that this would mean becoming a contracted provider through the Express Scripts network. NHIA representatives were unable to speak directly to the Express Scripts contracting department to gain additional information about the contracting process, Kaplan says.

According to Kaplan, Bayer says it has positioned the Bayer Direct program as designed to meet the needs of patients, specifically to deal with product shortages of the past year and pricing variations. However, Kaplan says Bayer inaccurately implies that infusion providers are the source of those problems, and that moving the product out of the infusion provider community is the only solution to them.

"Providers have worked diligently to serve their alpha1 patients under extremely difficult product shortage conditions," says Kaplan. "There is no evidence that Bayer attempted to discuss these problems with the provider community to develop a solution that could truly be a win-win for all concerned."

Kaplan says NHIA believes that Bayer Direct may be good for Bayer, but that it's not good for patients. She adds that while the Bayer-sponsored Alpha Foundation Web site raves about the new program, actual discussions among alpha1 patients produce a different story. She says some patients fear they will be unable to receive their next scheduled dose, suffer anxiety over the loss of choice of provider, and are concerned over the possible implications of Bayer Direct's control of the distribution process. Though Bell says Bayer Direct has no ability to increase the cost of Prolastin, Bell acknowledges that Bayer Direct is a channel for Bayer Corp., which could increase the drug's cost.

Kaplan says NHIA "supports freedom of choice and opposes this cynical attempt by a manufacturer to shortcut the nation's drug distribution system and infusion provider community for its own profit. All consumers should have the right to obtain quality pharmaceutical services from a provider of their choice. This right is guaranteed by law for Medicare and Medicaid patients and in more than 30 states under pharmacy freedom-of-choice legislation. The Bayer Direct program clearly violates these principles."

Alpha1 Association in middle of the road

Sandy Brandley, executive director of the Alpha1 Association, a nonprofit 501C3, membership-based organization incorporated in 1991, says her group's position lies between Bayer Direct and NHIA.

"For better than two years, the association has been actively investigating and pursuing a direct patient allocation system," says Brandley. "By that we mean to link the product with the end-user and somehow have a way that the end-user enjoys a

greater level of portability because the product is being provided to them personally rather than first being sold to an intermediary."

Brandley says that a shortage of Prolastin began in January 1998. "There's a sole manufacturer for this product for this patient community. Two other biological manufacturers have the potential of making a product like this for the alpha1 community. But at this point in time, neither one of them have a product to market."

Brandley says that the reason is that the alpha1 community has only a population of about 5,000 people identified with the disease — a market too small for other pharmaceuticals manufacturers to find sufficient financial incentive to compete with Bayer. "The potential for the number of people we feel have the severe form of the deficiency is somewhere between 80,000 to 100,000 people. We know that because of the frequency of the gene in the (general) population," Brandley says. There is a simple blood test available for alpha1, but it's not done in many cases because of a "profound under-appreciation and under-recognition of the disease in the medical community."

According to Brandley, only about 3,000 of people diagnosed with alpha1 are considered appropriate for therapy with Prolastin. "Alpha1 is a disease in which the liver fails to produce a protein that protects the lungs," she says, in either an adequate amount or in a form the lungs can use. The disease also manifests itself as liver disease in infants and children. It may be that most of the people with the genetic marker live their entire lives with no symptoms of alpha1 and still have a severe deficiency of this particular protein. They either have very few symptoms, which leads their physicians to believe they have allergies, asthma or slight chronic bronchitis, or they have no symptoms whatsoever. Symptoms include shortness of breath after exercising, a cough that won't go away, infections that fail to resolve in a timely manner, or year-round allergies.

Brandley says radiological evidence for alpha1 is emphysema in the lower portions of the lungs, and the people most easily diagnosed are those with profound symptoms in their 30's or 40's. "If they go into their 50's," she says, "we believe they are often misdiagnosed with chronic obstructive pulmonary disease or asthma."

She says that living with the current Prolastin shortage has meant that new patients have been identified with no product available for them to take. "We've also watched the portability issue," she says. "We've had patients whose spouse's insurance has changed, the home care company they were with is not the same company the new insurance company uses, and the previous company has been either unwilling or unable to notify Bayer they are losing that particular patient and request assignment of that product allocation to another company."

She also says there's been a difference of as much as 50 cents per milligram in the prices that non-Medicare, non-VA patients are being charged for Prolastin. Prolastin dosage is 60 milligrams per kilogram of body weight per week, creating a treatment expense of about $1,000 per week for the average patient in the 18-to-20-cent-per-milligram price range. "This is a very, very expensive product," Brandley says, "so even small variations in the cost of the product can create a huge burden on the end-user."

Finding a rate

Jean Marc Quach, vice president and general manager of the Special Distribution Division for Express Scripts, says that if home infusion therapy companies want to continue to provide infusion services to their existing clients, they must become subcontractors to Express Scripts.

"In the Bayer Direct program," he says, "Bayer sells Prolastin directly to the patients. Express Scripts acts as a distribution arm for the product." Express Scripts does not charge infusion companies an application fee, but the companies and Express Scripts must agree upon a fee rate for nursing services that is acceptable to both.

"Let's say the market rate for infusion is $80," Quach continues, "and a home infusion company that wants to continue providing nursing services wants to charge $150. That's obviously over the market and we would work out a rate that is acceptable to both of us."

Express Scripts arranges for infusion services, but does not provide them to patients. "In the best interests of the patient, we get the rates that are competitive, as well as usual and customary. A home infusion therapy provider that wants to try and make up for the loss of revenue on the drug by charging more for its nursing services is probably not being fair to the patient. Express Scripts is a pharmacy benefits manager. We provide pharmacy benefits management to HMOs, employers, and insurance companies.

"If the HMO wants to use its own nursing contracts, that's fine; we'll work with the HMO and distribute the products directly from Bayer to the

patients," he continues. "If the HMO does not want to use its own nursing contracts, Bayer Direct will arrange for nursing services to be provided to the patient. We like to do this at a rate that is competitive. We think it is in the best interests of the patient that Bayer went to this system, and we are working with Bayer to distribute the product."

Bayer's concerns

Quach says that an infusion company that wants to continue serving its alpha1 clients needs to contact Express Scripts can call (800) 305-7881 and ask to become a subcontractor. "Assuming we can work out rates," he says, "it's not a long process at all."

Part of the list of questions submitted to Bayer Direct on Nov. 8, 1999, in which NHIA asked, "How Bayer Direct will:

☐ **address infection control issues** such as: monitoring patients for infections potentially due to admixture outside the confines of a laminar air flow hood, disposal of empty vials of Prolastin (biological waste), disposal of used sharps?

☐ **ensure that nurses visiting patients are competent** to administer medications in a non-controlled setting? How will Bayer Direct ensure that nurses are competent in accessing implanted ports, maintaining long-term indwelling catheters, and starting peripheral IVs?

☐ **monitor for and report adverse reactions** experienced by patients? Monitor a patient's total medication profile for medication interactions or duplication of therapy, or monitor for and report outcomes of therapy?

☐ **anticipate ancillary supply needs and preferences** for individual patients?

☐ **supply infusion pumps and poles** to patients for a controlled rate of infusion? Will Bayer Direct have 24 hour-a-day, seven-day-a-week access to a pharmacist and a nurse for emergencies?

☐ **ensure access for nursing visits** that may increase from four hours to six hours with the addition of the time necessary to reconstitute product in the home?

☐ **ensure that a patient's environment is acceptable** for home care (i.e., cleanliness of home, access to electricity for refrigerated storage of a 28-day supply of medication, and access to running water)?

☐ **ensure that a patient is capable of learning** to administer their medication or ensure continuity of care when a patient is travelling?

☐ **monitor for compliance** to therapy?

☐ **communicate current patient clinical information** to a hospital if a patient is admitted either acutely or planned (infection or transplant), or screen patients for nutritional risk, or help in accessing other needed therapies, such as oxygen therapies or intravenous antibiotics?"

In response to the Bayer Direct / Express Scripts exclusive distribution agreement, NHIA urges all infusion therapy providers to:

☐ **Read the details of the Bayer Direct program on the Web** at www.bayerdirect.com / pro.htm — or at www.alpha1.org / bayer.htm. NHIA will fax this information to providers who lack Internet access.

☐ **Contact your Bayer service representative** and voice your opinions about this program.

☐ **Continue providing services to your Prolastin patients** for as long as you have sufficient drug supplies available. Under your managed care contracts, you are still the contracted service provider — not Bayer or Express Scripts, the NHIA says.

☐ **Notify your patients** that due to a new program at Bayer, you will no longer be able to provide services. Urge them to call (800) 305-7881.

☐ **Urge your patients to express their sentiments** to Bayer if they are displeased with the new program.

☐ **Notify your payers and referring physicians** that you are no longer able to provide products and services to alpha1 patients as described under current contracts.

☐ **Remember that JCAHO standards require accredited providers** to "have a policy to refer, transfer, and discharge patients appropriately." In

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addition, "appropriate information [should be] exchanged when the patient is referred, transferred, or discharged."

□ **Providers should make every effort to continue to meet** those standards despite the lack of information from Bayer on how to ensure a safe transition for the patient, and the apparent lack of interest from Bayer Direct in obtaining clinical history data from current providers, the NHIA says. ■

OSHA directive mandates move to safety needles

Update reflects new technology

In what may be the death knell of the market for basic needle technology, the Occupational Safety and Health Administration (OSHA) on Nov. 5, 1999, issued a promised compliance directive that mandates use of improved and safer needles. The directive will help minimize serious health risks faced by workers exposed to blood and other potentially infectious materials. Among the risks are human immunodeficiency virus, hepatitis B and C.

Goal: Reduce exposure

The new Bloodborne Pathogens Compliance Directive updates the agency's 1992 directive and reflects the availability of improved devices, better treatment following exposure, and OSHA policy interpretations. Secretary of Labor Alexis M. Herman said the new directive "doesn't place new requirements on employers, but it does recognize and emphasize the advances made in medical technology. And it reminds employers that they must use readily-available technology in their safety and health programs."

The directive guides OSHA's compliance officers in enforcing the standard that covers occupational exposure to bloodborne pathogens and ensures consistent inspection procedures are followed.

The 1992 directive required only a review of the feasibility for using improved technology and better safety controls to avoid needlestick accidents and the potential for infection. The revision requires that improved needles and sharps must be used in order to "reduce employee exposure either by removing, eliminating, or isolating the hazard." Tougher wording in the latest the directive refers to "the growing market of safer medical devices that minimize, control, or prevent exposure incidents."

The directive does not mandate use of particular needle devices or specific needle technologies. Basically, it requires that health care facilities use the safer needles on the market. It includes detailed instructions to compliance officers on inspections of multi-employer work sites including home health services, employment agencies, personnel services, physicians and health care professionals in independent practices, and independent contractors.

To enforce compliance, health facilities must do annual reviews of their safety and compliance plans to evaluate whether they are making use of safer needle systems. Besides recording and reporting all incidents of accidental needlesticks, every employer must now establish an Exposure Control Plan that documents the evaluation and implementation of appropriate, commercially available, and effective engineering controls designed to eliminate or minimize exposure to bloodborne pathogens. Compliance will have the power to cite facilities that are not using upgraded safety devices or they may consult with regional bloodborne pathogens coordinators to determine whether or not a citation ought to be issued. The directive includes decontamination requirements, guidelines on hepatitis vaccinations and post-exposure treatments, and employee training.

OSHA inspectors are obligated to inspect for potential violations involving the hazard of occupational exposure to blood or other potentially infectious materials when: 1) The Exposure Control plan or employee interviews indicate deficiencies in complying with OSHA requirements; 2) Relevant formal employee complaints are received that are specifically related to such occupational exposure; and 3) an actual occupational exposure occurs.

The Exposure Control Plan must also identify and document all job classifications in which all employees have occupational exposure, and/or those job classifications in which some employees have occupational exposure.

OSHA requires the Exposure Control Plan to be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures that affect occupational exposure and new or revised employee positions with occupational exposure.

The job classifications and employees who could be identified as having potential occupational exposure to bloodborne pathogens is extensive. OSHA identifies the potential group to include: physicians and physician's assistants; nurses and nurse practitioners; dentists, dental hygienists, dental assistants, and dental laboratory technicians; home health care workers; emergency medical technicians, paramedics, and other emergency medical service providers; health care and diagnostic employees; fire fighters, law enforcement personnel and correctional officers; housekeeping, maintenance, custodial workers, laundry staff, and regulated waste collectors; medical equipment service and repair personnel; production facility workers; and support employees in health care and other facilities, such as physicians and dentists' offices, various clinics, laboratories, blood banks and plasma centers, hemodialysis centers, nursing homes and long-term care facilities, educational, correctional facilities and public safety institutions, emergency first-aid facilities, and funeral homes and mortuaries. This covers virtually all of the health care employers and employees in the United States and suggests a dramatic increase in the demand for safety-engineered needles.

What are they saying?

Companies manufacturing sharps devices with improved safety features hailed the new directive in immediately issued press releases. Med-Design (Ventura, CA) issued a statement saying that the new directive would result in the "total conversion of the medical sharps market from conventional to safety-engineered devices in a short period of time."

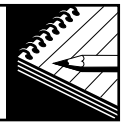
James Donegan, chairman and CEO of the company, estimates the OSHA directive will save the lives of thousands of health care workers annually.

The company produces 21 safety needle products and predicts heavy demand for those and other products yet to be developed. Biomedical Disposal (Atlanta), issued a statement saying that, in the wake of the OSHA directive, it was launching a nationwide sales effort to promote its Sharpx sharps disposal system, and company president **Michael Smith** predicts "explosive growth" of company sales in the coming months.

The company also operates a Web-based "behavioral incident control system," and says it is readying the launch of a new safety needle technology. Specialized Health Products International (Bountiful, UT) produces 13 different systems for improving needle safety and says the directive would expand its current and future contracts. "The new OSHA mandate gives emphasis to our sense of urgency in bringing safety products to market," says company president and CEO **David Robinson**.

The revised guidelines are the result of OSHA's request last year for ideas and recommendations on ways to better protect workers from contaminated needles or other sharp objects. OSHA administrator **Charles Jeffress** reports that the agency received nearly 400 comments in response to that request. According to Jeffress, the responses "told us that safe medical devices already available are effective in controlling hazards and that wider use of such device would reduce thousands of injuries each year." Copies of the new directive can be obtained by calling OSHA's Publications Office at (202) 693-1888. ■

GUEST COLUMN



Dealing with a nemesis: Handling cath occlusions

By **Lynn Hadaway**, MEd, RNC, CRNI
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Occlusions of central venous catheters remain a serious challenge to clinical practice, especially when the catheter must be used for multiple therapies over extended periods of time. Occlusions can be categorized into three major groups — **mechanical, precipitate,** and **thrombus.**

Mechanical occlusions include pinch-off syndrome, catheter tips positioned against the vein wall, and numerous external problems, such as tight sutures. **Precipitate** is caused by contact between drugs or minerals that are incompatible, usually leading to changes in the pH and creating a precipitate inside the lumen. **Thrombotic** causes include the development of thrombus and fibrin accumulation inside the catheter lumen and around the catheter inside the vein.

The frequency of catheter-related thrombosis ranges from 3% to 70%.[1] This wide variation is caused by the lack of standard definitions for assessing and diagnosing the problem. The problem includes occlusion of the blood flow in the vein around the catheter and occlusion of the catheter lumen.

Immediately following the catheter insertion, proteins accumulate on the catheter wall and develop into fibrin. The catheter can become completely encased in a fibrin sheath or have a fibrin tail or flap that acts like a valve closing the lumen on aspiration. Thrombus can form on the vein wall, on the catheter wall, or both. Venous blood flow is slowed, causing edema and discomfort distal to the site of the thrombus. Many studies link vein thrombi with catheter-related infection.[2]

Proper catheter flushing

Thrombus forms inside the catheter because of blood reflux into the lumen. Reflux occurs from changes in intrathoracic pressure — changes that happen during coughing, sneezing, heavy lifting, or in the presence of congestive heart failure. Reflux also occurs when catheter flushing is performed without the use of positive pressure techniques. Needleless systems leave a small, dead space inside the injection cap. When the system is disconnected from the cap, the fluid flushed into the catheter refluxes to fill this space, causing blood to reflux into the catheter's internal tip. This reflux does not allow the blood to mix with the heparinized saline solution. Over time, we notice greater resistance when the catheter is flushed.

Many patients with central venous catheters also have hypercoaguable states. Hypercoaguability comes from disease processes such as cancer and diabetes. Pregnancy, use of oral contraceptives, and cigarette smoking also cause hypercoaguability. Your patient may have congenital clotting problems — such as deficiencies of antithrombin III, proteins C and S — plasma proteins that prevent abnormal clotting from occurring. However, the connection between those congenital problems and the incidence of catheter-related thrombus has not been confirmed.

One strategy for managing those problems is removing and replacing the catheter; however, this can be expensive and painful for the patient. Attempts to salvage the catheter or restore its patency are frequently successful. When the problem is caused by thrombus or fibrin, urokinase (Abbokinase, Abbott Laboratories), a drug made from human kidney cells, has become the drug of choice. Over the past year, there has been concern about the potential contamination of urokinase and manufacturing deficiencies. Until those problems are resolved, Abbott can no longer distribute the drug.

New choices

The shortage of urokinase drove the need to look at other drugs to restore catheter and vein patency. Because of clinical experience and published studies, our focus has shifted to streptokinase and alteplase. Although the streptokinase drug literature includes "occlusion of arteriovenous cannulae" as an indication, many question the drug for this use. Streptokinase is made from a protein in the streptococcus bacteria and is known to be an antigen in humans, producing allergic and anaphylactic reactions. Therefore, treatment should not be repeated more than every six months, and there is serious concern about using it in the home care setting.

Alteplase is a recombinant-tissue plasminogen activator that binds to the fibrin in a blood clot to break it down. In 1994, Haire et al published a study demonstrating the effectiveness of this drug for catheter clearance. Fifty patients with radiographic confirmed occlusions were randomized and treated with urokinase 10,000 units (n = 22) or alteplase 2 mg (n = 28). In the alteplase-treated group, patency was restored in 89% (22/28), while the urokinase group had 59% (13/22) restored.[3]

Currently, the FDA has approved the use of alteplase (Activase; Genentech) for acute myocardial infarction, acute ischemic stroke, and acute massive pulmonary embolism. Although clearing occluded central venous catheters is not an FDA-approved indication at this time, use of alteplase for this purpose is growing. Dosage for the labeled indications ranges from 50 mg to 100 mg while the dosage being used for catheter clearance is 2 mg. The most common protocol is alteplase 2 mg in 2 ml allowed to remain in the lumen undisturbed for two hours, then aspirated using familiar declotting procedures. The drug half-life is between four to six minutes. Small doses, properly instilled into the catheter lumen and aspirated suggest that bleeding problems are unlikely.[4]

In addition to the challenge from the lack of FDA-approved labeling, there are also limitations from the current packaging of Alteplase. It is a

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sterile, preservative-free, lyophilized powder in 50 mg or 100 mg vials. Drug wasting, contamination, and costs are major concerns when a small dose is needed. Many pharmacies are now dividing the 50 mg vial into syringes filled with 2 mg in 2 ml and freezing until needed. A recently published study demonstrated bioactivity in polypropylene containers such as syringes at –20° C for up to six months; glass vials at –70° C for up to two weeks; and glass vials at –20° C for up to one month.[5]

Prevent the problem

Many questions are yet to be answered in clearing catheter occlusions caused by thrombus or fibrin. The return of urokinase to the market is unknown at the present time, so clinical trials are necessary to determine the optimal dose and dwell time of alteplase. We also need to confirm the most appropriate dose and infusion criteria of alteplase to treat venous thrombosis surrounding the catheter. Future studies will lead to the necessary FDA-approved language for using alteplase for catheter clearance and the packaging of alteplase in unit doses.

Rather than finding the best solution to resolve catheter-related thrombi, we must direct our attention to prevention of these problems. Prevention methods fall into four categories:

1. Use of prophylactic warfarin. Studies have shown a decrease in catheter-related thrombus formation when Coumadin 1 mg per day was given.[6]

2. Proper positioning of central venous catheters. Catheter tips should be positioned in the lower third of the superior vena cava (SVC) to ensure that the catheter will lie parallel to the vein wall and avoid impinging on the wall. Catheter tips placed distal to the SVC, also known as midclavicular catheters, have been associated with a four-fold greater risk of venous thrombosis.[7,8]

3. Use of appropriate flushing techniques. Positive-pressure flushing techniques prevent blood reflux into the catheter lumen. Perform this procedure by withdrawing the blunt cannula as the last .5 ml of solution is flushed into the injection cap or by closing a clamp on the catheter extension set before disconnecting the flush syringe. Using a push-pause flushing technique creates turbulence in the lumen to aid in removal of blood products. Following blood administration or sampling, flush with 20 ml to 30 ml of preservative-free saline.

4. Use technological advances to overcome blood reflux problems. Valved catheters are designed to prevent the backflow of blood into the catheter lumen. (Groshong, Bard Inc.; PASV Catheters by Catheter Innovations Inc.)

Continuous flushing solutions (One-Step KVO, I-Flow Corp.) eliminate the need for immediate flushing when the drug has infused.

New designs of needleless injection systems overcome the problem of blood reflux by returning a small fluid volume to the catheter tip. (CLC2000 by ICU Medical Inc; Posi-Flow by Becton-Dickinson Inc.; UltraSite by B. Braun Inc.)

Many facilities have chosen to use alteplase for declotting catheter lumens, while others prefer to wait for the appropriate FDA-labeling and more convenient unit-of-use packaging. Appropriate flushing techniques combined with improved technology can decrease the incidence of catheter-related thrombus, although thrombolytic agents will still be needed.

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Checking your own performance

Benchmarking program enters new phase

There is still time to get in on the Intercompany Benchmarking Project for Infusion Therapy. Developed by the National Home Infusion Association (NHIA) and funded by a grant from B. Braun McGaw (Bethlehem, PA), the IOB project recently changed its time format from semi-annually to quarterly.

Designed by providers for providers, the program measured cost of goods sold, inventory value, net revenue, net receivables, and core pharmacy payroll at 84 sites during its first phase. Demographics such as therapy mix, payer mix, territory radius, and treatment setting are also analyzed. Participating providers receive confidential reports that benchmark their performance against that of other participants. While some providers engage in benchmarking within their own companies, and others participate in proprietary systems, most of the infusion therapy provider community is not involved in intercompany benchmarking.

NHIA key benchmarks

The key benchmarks for the infusion therapy industry according to NHIA are:

☐ **improving operational processes;**
☐ **enhancing profitability;**
☐ **developing best-demonstrated practices for infusion therapy;**
☐ **creating a data foundation for advancement of infusion therapy practice;**
☐ **developing appropriate performance measures for staff and management.**

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Inclusion in the IOB project is voluntary and free of charge. Target enrollment is 200 sites of service. "Through the IOB project, home infusion providers across the nation will be able to review their operational performances in relation to those of other providers," says NHIA vice president **Tony Powers**, PharmD.

The project's aggregated data is available to NHIA and the broader infusion community, but all data submitted will be kept in strictest confidence. A respondent identifier code is used to "blind" the process so that respondents can identify their own responses and compare them with those of others without being able to identify who the others are. The University of Texas College of Pharmacy is handling the blinded data and administering the program.

Home infusion therapy providers interested in participating in the project should contact NHIA at (703) 549-3740 for an application form. ■

NAVAN sets new goals, creates vision for future

"We are very definitely now an international, multidisciplinary organization," says **Kelli Rosenthal**, MS, RNC, CRNI, CANP, current president of the National Association of Venous Access Networks (NAVAN). "I've just started a membership campaign called '1,000 in 2000.' NAVAN currently has about 700 members, and we're trying to get more people with a vascular access focus involved in the organization. Though our membership now is predominantly nurse-based, we just started a committee for outreach to consumers of vascular access services."

Rosenthal describes NAVAN as a very education-focused organization. The group has started a capital campaign to provide scholarships and support research in vascular access, and has a program for evaluating peripherally inserted central catheter (PICC) training courses.

"Anyone who offers a PICC course can submit it to NAVAN for review," she says. "We assess it using very strict quality management standards. Many of our members are educators who teach PICC courses, and many of our manufacturer members offer PICC programs. It's valuable to have a consistent set of criteria that people can apply to their programs."

Rosenthal says that consumers of those

programs can be sure that if the courses they are considering have received the NAVAN approval it contains what they need to know. "Our review is a very exhaustive process, covering everything from the course content to ascertaining if the instructors who teach the courses have backgrounds in both PICC and adult education. There really isn't another program out there that can help consumers evaluate how good a course is before they lay out their $150 to $200 to take the class. Since there is no PICC certification, any sort of portable credential is valuable for clinicians who place these devices to benchmark their practice against others."

Lynn Hadaway, MEd, RNC, CRNI, president-elect of NAVAN, concurs that the organization is proactive. "We've had a year of dynamite growth, and had a very successful conference in Orlando Sept. 25-29 with over 250 registered people and 47 exhibits."

Meeting of the minds

Hadaway believes one of the biggest highlights of the past year was a meeting between the boards of directors of NAVAN, the Intravenous Nurses Society, and the League for Intravenous Therapy Education. The resulting collaboration is currently in the process of creating position papers on safety issues around IV catheters and needlestick injuries, and the absence of Abbokinase and the catheter clearance issue.

"The major point is that we are working together on a lot of these things," she says. "We're in the process now of gathering information about the state of all the states, the legislation that's going on in the individual states, as well as the legislation at the federal level."

NAVAN's conference committee and a group of manufacturers who usually display their wares at nursing and clinical conferences spent the last two years completely redesigning the group's annual conference, reworking virtually everything.

"There's going to be a lot more interaction beyond the exhibit hall," Rosenthal says. "We'll have manufacturers' roundtables and showcases in manufacturers' theatres, where new ideas, new and potential products can be presented to groups of clinicians and maybe also groups of patients so the manufacturers can get feedback. This means the new devices on the market will already have the needs of the people using them addressed before the devices are ever released for use."

Rosenthal points out that this benefits the manufacturers because they know that if they include those recommendations people are going to use them. "It's also useful for patients and clinicians because manufacturers are listening and are going to give them devices that meet their needs, so everybody's happy," she says. "We want to open the doors to the conference and get the people who've been stuck in the exhibit hall in to listen to the lectures and benefit from their interactions with the patients and physicians."

"In the past year, we've dramatically improved the *Journal of Vascular Access Devices [JAVAD]*, our official publication," Hadaway adds. "We now have a managing editor, Tom Lawson, who is working to bring in new authors and get their research and data published. We have several new departments in the publication, including the chapter connection section and a legal opinion column. We've invested heavily into getting a peer review process started. We've added a newsletter, *Practical Access*, that comes with *JAVAD."*

Hadaway describes NAVAN's current goals, mission and visions as:

☐ **To continue expansion to build and strengthen local networks.**

☐ **To promote, communicate, and facilitate the art and science of vascular access.**

☐ **To ensure NAVAN's vision for the future that all vascular education is scientifically sound and learner-driven; that we accomplish communication by a variety of delivery methods in which we use all the different types of learning technology.**

☐ **To base vascular access education in scientifically sound and learner-driven criteria.**

☐ **To ensure communication is accomplished by delivery methods encompassing all types of learning technologies.**

COMING IN FUTURE MONTHS

- PPA effect: Elimination of venipuncture benefit fallout
- Sound off: The use of ultrasound in infusion therapy
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- Unapproved drugs: A lawyer looks at declotting lines

Need More Information?

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☐ **To promote the consensus among clinicians, manufacturers, regulatory agencies, engineers, specialty organizations, and inventors regarding clinical, design, and development issues related to vascular access.**

"Probably the loftiest vision statement is the one about achieving consensus," Hadaway says. "We want to bring everybody together. One of the things that's different about NAVAN is that we encourage membership from multidisciplines. We have physicians, nurses, pharmacists, and manufacturers' representatives, engineers, sales, marketing, design people, researchers; everybody is invited to the table."

[Editor's note: Membership in NAVAN costs $75 per year and includes a subscription to JAVAD. *For further information, contact NAVAN, PMB 205, 11417 South 700 East, Draper, UT 84020. Telephone: (888) 57-NAVAN. Web site: www.navannet.org.]* ■

NEWS BRIEFS

Some infusion services deemed medically unnecessary

According to a Health and Human Services' Inspector General's Office audit, about 50% of infusion therapy services provided to nursing home patients from 1995 to 1998 were medically unnecessary. Among the findings were suppliers charged skilled-nursing facilities up to 10 times the going rate for infusion drugs — a cost that was then passed along to Medicare. Three companies accounted for about 20% of the infusion therapy costs reimbursed on a national basis by Medicare. ▼

First entirely new antibiotic awaiting FDA approval

A new synthetic compound, Zyvox, is being described as the first entirely new antibiotic developed in more than 35 years. Zyvox works against gram-positive bacteria such as strep, staph, and enterococci bacteria found in septicimia, pneumonia, and skin and urinary tract infections. Pharmacia & Upjohn, manufacturer of the new drug, hope to have approval from the Food and Drug Administration and other regulatory agencies by the end of this year. ▼

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Technologies enter vascular access device markets

Increasing demand for patient treatment in non-hospital settings appears to drive the growing sales of infusion pumps, especially those that are ambulatory-capable. The health care group at Mountainview, CA-based Frost & Sullivan estimates the total 1998 revenues for implantable infusion pumps (programmable and nonprogrammable), insulin infusion pumps, enteral feeding pumps, syringe infusion pumps, ambulatory infusion pumps, and large-volume infusion pumps at $674.9 million — a growth rate of approximately 22% over 1997. The 1998 market revenues for insulin infusion pumps were estimated at $59 million, reflecting a growth rate of 20% over the previous year's total.

Overcoming limited Medicare reimbursement coverage is the top challenge for infusion pump manufacturers, and continues to shift patient distribution to alternate care facilities. The major trend in the U.S. infusion pump markets is the increasing amount of programmable devices and telemedicine features that allow for more end-user flexibility. In 1998, the large-volume infusion pump segment dominated the overall U.S. infusion pump industry, accumulating 55% of the total revenues.

As for the future, Frost & Sullivan predicts that implantable infusion pumps and insulin infusion pumps will achieve the highest compound annual growth rates at 18.7% and 17% through 2005, respectively. Strategic alliances with drug companies should increase product penetration of implantable products, while insulin infusion pumps have the potential to capture a large, undiagnosed diabetes population in dire need of proper treatment.

"Among the U.S. diabetes population, 5.4 million are still undiagnosed," says Frost & Sullivan medical device analyst **Meltem Buyukonat**. "In order to increase public awareness, diabetes associations and insulin pump manufacturers have launched several campaigns about the disease."

Frost & Sullivan presents market engineering awards to recognize companies that have worked hard to make a positive contribution to the medical device industry and the U.S. infusion pump markets. For further information, contact the company at (650) 237-4382 or visit its Web site at www.frost.com. ■