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Slowly but surely, safety legislation is coming to reduce needlesticks

States follow CA in introducing safe-needle bills

It didn't take long for the states to play follow the leader. After California passed legislation requiring health care providers to use safety measures such as needleless devices and safety catheters, no fewer than 17 other states followed suit. According to **Steve Trossman**, manager of campaign communications with the Service Employees International Union (SEIU) in Washington, DC, the steady flow of state bills is no surprise.

"More than 250 such devices have been approved by the FDA," he says. "The CDC [Centers for Disease Control and Prevention] says that these devices reduce needlesticks by 75%."

The 18 states with safe-needle legislation were already introduced, and each bill's status, according to Trossman, is:

1. Arkansas — recently introduced.

2. California — passed **(for more on California's groundbreaking legislation, see May 1999 *Home Infusion Therapy Management*)**.

3. Connecticut — introduced.

4. District of Columbia — introduced.

5. Florida — introduced, but stalled.

6. Illinois — recently passed the House unanimously.

7. Iowa — introduced.

8. Massachusetts — introduced.

9. Maryland — a study bill passed requiring the state and outside groups to study the issue.

10. Michigan — introduced.

11. New Hampshire — According to Trossman, the SEIU is in the process of petitioning the state labor commission for an administrative rule change on OSHA that would require safe needles.

12. New Jersey — passed.

13. New York — a bill may be introduced shortly.

14. Ohio — at press time, a bill awaited introduction.

15. Oregon — introduced.

16. Pennsylvania — legislation is being drafted.

17. Tennessee — legislation passed, but does not include an implementation date.

18. Texas — introduced.

Trossman notes that most of the bills are similar to California's, but there is no telling how much they may change when and if they become law. Also, he says that the SEIU is currently working with members of Congress to introduce a federal bill.

"We are trying to line up sponsors for bipartisan support, so this is something that could be introduced any time."

Pros and cons?

The reason for such legislation is obvious: protecting health care workers from suffering a needlestick injury that could lead to HIV, hepatitis C or hepatitis B. But there are several reasons that legislation is the necessary step to require the use of such safety devices. First is the cost.

"The devices are very common, but they are more expensive," says Trossman.

Lynn Hadaway, MEd, RNC, CRNI, principal of Hadaway and Associates, an infusion therapy consulting firm in Milner, GA, says the expense argument holds water.

"I can understand the cost," she says. "When you look at the low-end cost of a conventional catheter, 70 to 75 cents is the lowest contract, high-volume price out there. When compared to the cost of the safety devices at $1.75, that's a significant increase in cost. But when you look at the risk your health care workers are taking, you have to put that cost into perspective."

Trossman adds that as safety devices become more widespread, price should become less of a factor.

"We believe that the price will come down as more people begin to use them," he predicts. Even if they don't, though, they will still save you money over the long haul.

"When you factor in the cost of testing everybody who gets stuck and must go through a rigorous testing regimen and go on the HIV cocktail for six months, the cost is not just between Needle A and Needle B," he adds.

According to Trossman, all the bills introduced or passed allow for the use of standard devices where the safe needle technology is not available or as effective. But Hadaway says that should not be a concern.

"We've got almost all the bases covered: IV catheters, subcutaneous injections, connections on the IV lines, blood drawing and blood sampling devices, protected butterflies with stainless steel wings, and syringes. We're beginning to see more introducers for PICC and midline catheters."

According to Hadaway, the only area in which a safety device is unavailable is for the Seldinger technique. For Hadaway, though, it's not the availability of the needles that is the problem,

"The biggest thing is for clinicians to start using the technology," she says.

But that is proving no small task. Because of the learning curve, many nurses are unwilling to switch to a safety device.

"I don't think they understand the risk they are taking and exactly what can happen to them," she says. "There is a learning curve that goes along with switching devices, regardless if it is a safety device. In this particular case, I think they resist because they just don't understand the risk of contracting a dangerous, potentially deadly bloodborne disease." ■

The father of catheter innovations speaks up

Ron Luther looks into his crystal ball

When **Ronald B. Luther** talks, the home infusion industry listens — and with good reason. The founder and former chairman of Luther Medical Products, recently purchased by Becton-Dickson in Sparks, MD, has been one of the leading forces in the development of the catheter industry for the past several decades.

Now, he's back after stepping down from Luther Medical Products in 1997. Luther recently formed Luther Research Partners and is looking to introduce his three latest inventions to the catheter market. In this exclusive interview with *Home Infusion Therapy Management*, Luther provides insight into his latest innovations for the catheter market.

"I left Luther Medical in November of 1997. Since then, I have three patents on file which represent the distillation of the 39 patents I left at Luther," says the inventor.

Each of his new inventions are aimed at a specific segment of the infusion market. The first of his inventions he hopes to get to the market is a PICC (peripherally inserted central catheter) inserter.

"I have invented an inserter for PICC lines that uses a peel-away needle (not the Luther peel-away needle). As you finish with the needle, the two needle halves are trapped in a container, so there is no danger of secondary needlesticks," he says.

The second invention is aimed at a much larger market. While the market for PICCs is only about $40 million in the United States, according to Luther, the market for short catheters is $700 million worldwide, and $350 million to $400 million in the United States. Luther's most famous invention, the ProtectIV, was aimed at this market.

"For this market, I have concentrated not only on needle protection, but to give the patient more benefits," he says. "I have invented an entirely new type of over-the-needle catheter that benefits the patient and the caregiver, that requires no additional training on the part of the nurses. A company can hand this to a nurse and [say], 'Insert this like you would insert any over-the-needle catheter.'"

Multiple uses

Other than the dual benefits, Luther says the catheter will have a huge advantage in Third World countries.

"This catheter can be sold in lesser-developed countries because it can be reused many times," notes Luther. "The patient will take the inserter part of the catheter and wear it around his neck like a thermometer container. When his therapy is finished, you pull the catheter, reassemble the inserter, clean it and reuse it. This can probably be used 100 times due to the uniqueness of its construction."

Luther notes that he is aiming at the U.S. market, though, for which he says the benefits over current short catheters are numerous.

"All over-the-needle catheters today, once you use them, you tear up the tip and it's deformed," he explains. "I am putting a hard tip and a new type of inserter, so there is no danger of a secondary needlestick. It's more comfortable for the patient."

The catheter will also be made of very soft material, a lesson he learned at Luther Medical.

"With this catheter, you're going to put in a softer catheter than any of the other catheters. A soft catheter stays in longer," Luther says. "The new urethanes coming out are softer, stronger. You can make them more 'radiopaque,' and they are biocompatible. I have not been a fan of silicone, because of the weakness of the material. You can get so much more flow out of urethane with thinner walls."

The third and final patent involves a catheter finder that should be far and away the most economical on the market, adding just pennies to the cost of the catheter.

"The benefit is that any time the patient is checked — this is mostly for PICC lines in the home — you don't have to X-ray them," says Luther. "You can take this catheter finder — it's like a pencil with a row of lights on it — and run it up the patient's arm to verify exactly where the catheter is and where the tip is. You don't have to take the patient in for an X-ray."

Luther says he will probably give away the detector with any of Luther Research's catheters, or put something in the catheters themselves that will add very little cost to the catheter.

Now what?

Luther notes that, at this point, he has little control over when the above products hit the market.

"From the date I get funding or a partner, you can expect to see these products on the market in a year, because most of the development is done."

However, when the funding becomes available is anyone's guess. "I've got to raise $3 million to start the company, and there are two avenues I am looking at," Luther says. "One is to hire a professional moneyraiser who will approach a group of individuals. Or the way I would prefer is to get a partner early, such as a medical company that would be interested in the types of products I have filed patents on. The focus of the new company will be to ally ourselves with one of the larger medical companies and not try to go it alone like Luther Medical did."

Although preliminary discussions have been held with few companies — already three have expressed an interest — Luther says he still must raise funds to build prototype catheters and conduct clinical tests to prove his claims.

Stay focused

Luther notes there are three industry trends that will guide the design of any catheter he introduces to the market.

"There's one giant bear looming over all of us, and that is the requirement for safety devices," he explains. With California legislation already passed and numerous other states ready to follow suit, it may be just a matter of time before all providers are

required to use safety devices such as needleless tubing and safety catheters. This presents a challenge to manufacturers as well, according to Luther.

"That is going to impose a big burden on the companies who have these safety products for inservice," he says. "We need to consider how we can get around inservices. What you have to do is provide the safety without the inservice."

The second area is the always-present concern of exposure to blood.

"You want to eliminate as much blood as possible on a catheter insertion," he says. "Right now on every over-the-needle catheter, any time you pull the needle out of the inside of that catheter, you have blood squirting out the back of it. That's another thing we've set out to eliminate."

Lastly, Luther wants to dramatically reduce the frequency of needlesticks. As already mentioned, one way to do this is to design catheters that can remain in place for the duration of a patient's therapy.

"If you keep the safety of the caregiver in mind, eliminate the blood, and get a more comfortable catheter that can last longer, then you have some very worthwhile objectives that will allow you to compete in that giant market," says Luther.

Gimmick can't sell itself

The wrong way to go about it is to introduce a novelty and think that a new modification itself will sell the catheter.

"Some people come out with one gimmick on a catheter, like a valve in the hub," says Luther. "But that is not enough to make people change. You have to have the whole catheter, starting with the tip. You have to have a tip that is at least comparable to those on the marketplace. If your catheter doesn't go in as easy as theirs, you're out of business right there because the nurses aren't going to accept it." ■

The ins and outs of staff safety

Agency's approach to staying safe

It is impossible to guarantee the safety of staff who make field visits. However, there are steps you can take to ensure that nurses don't knowingly put themselves in dangerous situations, often enough to provide piece of mind and security to nurses.

Most urban providers use escort services of some type to serve this purpose. But choosing when to use an escort isn't a cut-and-dry proposition. Ranging from the formal to informal, there are many ways to decide when your staff should use an escort.

The informal approach

One way is an informal approach, like that used by the South Shore Visiting Nurse Association (VNA) in Braintree, MA, which covers 37 communities surrounding Boston.

"We have nurse managers for each team that covers a different geographic location, so people get to know their area very well — right down to the streets, the apartments and the clientele," says **Mary Walsh**, RN, CRNI, and the home infusion nurse manager for South Shore VNA. "We can pretty much pinpoint where we think a problem could arise."

South Shore VNA has a distinct advantage. Because it is owned by South Shore Hospital, one of the benefits is that the VNA has access to the hospital's security department. When a nurse is slated to visit a high-risk area, Walsh simply requests the use of the services of one of their security personnel (public safety officers).

Walsh is quick to point out that there is no permanent listing of areas where an escort is required. Instead, the decision when to use an escort requires direct and indirect feedback from many areas. One reason for not permanently naming areas as high risk is because of the constant evolution of most communities.

"Clientele in an apartment building can change. While there may be suspicious persons or activity around an area in the summer, during the winter, no one is around because they are all inside," says Walsh. "Variables like that really change whether you need an escort service or the nurse follows personal safety measures." **(See South Shore VNA's Personal Safety Measures, pp. 78-79.)**

Such intangibles require the VNA to look at its list of high-risk and safe neighborhoods each

quarter to evaluate that areas are properly identified. Walsh notes that there may be a high-risk area in a safe community or vice versa.

"Although we review this once a quarter, what constantly happens is nurses go out and see something such as no lighting in the hallway of an apartment complex in a perfectly fine neighborhood," she explains. "The nurse will come back and identify the problem with the nurse manager on call and let us know it is a problem. The nurse manager then problem-solves to find a solution. We look at the whole picture on a quarterly basis, but every nurse is educated to constantly be aware of the safety issues surrounding the visits."

Do a drive-by

Walsh says that nurses are educated to do a general assessment of an area before each visit.

"We ask them to drive around and make an assessment," she says. "If they are not comfortable, then they should call the patient from their car phone and reschedule the visit."

When surveying a community, nurses are trained to look for the following criteria:

- **Is there parking close to where they are making the visit?**
- **Do they have to use elevators rather than stairwells?**
- **Is there outdoor lighting so they can easily identify the numbers on the buildings?** "We don't want them searching for an apartment number, especially on evening visits when it is dark," Walsh says.
- **Is there any suspicious activity?**

At times, though, a particular apartment complex or street may be totally unfamiliar, so the instruction would be to err on the side of caution and use one of your most effective resources for information: the local police.

"We will sometimes call the local police department and tell them, 'We have to make a visit at this address and we're sending a nurse. Would you recommend we use an escort?'" says Walsh. "We get their opinion, because they'll know if it is a high-risk area."

Your local police department is good for more than a phone call though. Walsh once had an officer provide an inservice to her staff.

"We had the Norwood Police Department safety office come out," says Walsh.

"The safety officer talked to us about issues such as when to use Mace and the requirements to carry it. He was an outstanding educator and very knowledgeable."

It is impossible to send an escort with every nurse on every visit, but that's not to say a lone nurse has to be an easy target. Walsh says there are a few simple steps nurses can take to dramatically reduce the chance of their becoming a victim of violence or abuse:

1. "We don't do any visits for a patient who has a gun in the home," says Walsh. "When we are in the home the first time, we ask about lethal weapons."

2. "I teach my nurses to call their phone a cell phone, not a car phone, because it is not just for the car," says Walsh. "The cell phone is your connection to the outside world. Take it with you in your bag so you can call if you have an emergency. You may have to go into the bathroom or close the door while you are in the room with the patient, and those situations have happened to some of our nurses."

This is important even when a nurse has an escort.

Nina Elledge, CRNI, president of Access Professionals, a nurse consulting agency in Castro Valley, CA, says that escorts should not go inside a patient's residence.

"They are not allowed to go into the home for confidentiality reasons. The security person will escort them to the door and then wait outside until the nurse is done with the visit. Or the nurse will call, and they will come back and come to the door and escort them out of the area," Elledge explains. "They communicate through cell phones and pagers so the nurse does not have to leave the confines of the living quarters without an escort if she does not want to."

3. "We suggest that nurses keep a small flashlight in their bag to do a physical examination of their car before getting in by checking the back seat," says Walsh.

4. "Take a look at the family dynamics, where especially in hospice situations there can be a lot of tension in a family," notes Walsh. "They should try and pick up on that and try not to get caught in any domestic violence situation."

The difficulty in remaining safe is that many nurses put their patient's welfare above their own. But in the long run, that doesn't help the nurse or the patient, according to Walsh.

"Nurses often find themselves caught in the middle because they want to help the patient. I find that nurses will generally put themselves in danger — either knowingly or unknowingly in the interest of the patient — but that's not right." ■

SOUTH SHORE HOSPITAL
HOME AND COMMUNITY SERVICE DIVISION
Guidelines for Personal Safety

YOUR PREPARATION

1. Be alert and observant; develop a sense of consciousness regarding your effect on your immediate environment.

2. Do not daydream or let your thoughts wander; keep your mind on getting safely to your destination.

3. Carry a minimal amount of money, your driver's license, and ID. Do not carry credit cards. Keep wallets out of sight and not in your nursing bag. Keep a record of all items (credit cards, etc.) at home and/or office in the event of loss or theft.

4. It is not advisable to carry a purse while in the field.

5. Appropriate grooming and a general appearance that maintains an image of professionalism are important at all times. Keep jewelry to a minimum. It is not advisable to wear engagement rings or other valuable jewelry while on duty.

6. Keep a duplicate set of house and car keys with a relative or neighbor in the event of loss or theft.

7. Discuss your fears or apprehensions with your manager, because these are commonly shared concerns.

8. If you have any doubts or fears about a certain call, do not make it until discussed with the manager.

IN THE COMMUNITY

1. Be cautious when entering the home unless an adult gives permission to enter.

2. Be cautious when entering a house with bars on the windows or with deadbolts.

3. Avoid walking in dark, deserted places. Do not take shortcuts through secluded alleys or vacant lots.

4. Walk in the center of sidewalks away from buildings, lines of parked cars, and tall hedges.

5. Observe windows and doorways for loiterers.

6. Identify and make yourself known to appropriate tradespeople in the community.

7. Do not accept rides from strangers.

8. When approached by strangers, be courteously alert, maintain vigilance, and convey the idea that you are expected somewhere.

9. Walk around, rather than through, groups of people.

10. Never give your name, home address, or telephone number to strangers.

11. Look for and observe working order of public telephones in the neighborhood.

12. When unrest occurs around schools, neighborhoods, apartment buildings, etc., do not enter areas and notify your manager immediately.

13. To avoid appearing lost, if an address or building is not visible, drive down the street until the building is identified, then return to the patient's building and park.

14. If you choose to have a whistle, wear it outside your clothing on a breakable chain; if you choose a shrill alarm, carry it in your hand.

15. If you suspect you are being followed while walking, enter a business.

16. If a car is following you, cross the street and walk in the opposite direction.

17. If you suspect you are being followed while driving, drive to the nearest police, fire, or gas station.

18. If you are lost, call the manager from a public phone, or ask a police officer, fire fighter, mail carrier, or business owner for directions. Do not follow strangers.

19. If a group of people are loitering in the street and you feel uncomfortable, cross to the other side of the street.

20. If you are threatened by a bag-snatcher, **do not** attempt to resist. Give up your nursing bag and notify the police and your manager immediately.

21. If accosted by someone with a weapon, do not resist.

TRANSPORTATION

Cars:

1. If driving a car, lock the doors and keep windows up at all times. Keep valuables out of sight. If necessary, keep windows only partially opened while driving.
2. Keep your car in good working order. Before you leave home, have enough gas to carry you through the day. A gas cap that locks can prevent siphoning of gas from the tank.
3. Carry car keys in your hand for accessibility as well as a means of protecting yourself.
4. Before entering your car, check the back seat. When approaching your car, be sure to look under the car.
5. If using the car trunk, place items in it when leaving the office, your home, or a patient's home — not before entering a building.

Winter Weather Tips:

1. Keep salt, sand, or cat litter in your car or use a car mat beneath the rear tires; also have a shovel available.
2. A heavyweight chain (bicycle chain) placed in front of rear tires will provide traction.
3. When pulling out of an icy parking space, go in reverse first.
4. Some have had success asking drivers or city trucks to pull them out.
5. Keep a survival kit in the car containing food, additional clothing, flares, and blanket.
6. In sub-zero temperature, in addition to using some form of heat in the gas line, check to make sure the gas cap is tightly in place.
7. Keep your gas tank more than half full.

MAKING THE CALL

1. When you encounter someone, look the person in the eye, nod, say "Hi," and keep on going.
2. When entering an elevator, look before you enter. If concerned, do not enter. When on the elevator, stay near the door and control panel. Be observant of other passengers who enter the elevator. If the trap door is open, do not enter the elevator until checking with building/maintenance. Press the appropriate floor number; do not ask anyone else in the elevator to do it.

Source: South Shore Visiting Nurse Association, Braintree, MA. Used with permission.

Security Committee leads the way to safety

Boston provider uses formal approach to safety

For many years, the Visiting Nurse Association (VNA) of Boston had a security program in place that resembled many other providers. However in 1992, it opted to take a more formal approach to staff safety through its Security Committee consisting of clinical and administrative representatives as well as an outside consultant.

"Safety is our biggest concern, but it is a big-ticket item; we want to maximize our efficiency and spend our money the best way possible," says **Michael Taylor**, RN, MS, director of patient services for the VNA of Boston, and the chairman of its security committee.

The committee consists of Taylor, the director of the facility and administrative services, about six members of the nursing staff, nurse managers, representatives from the home health aide department, an *ad hoc* human resource representative, and an outside security consultant formerly with a local police department.

Outside sources help keep clinicians safe

Through the work of the committee, along with help from outside sources, the VNA of Boston has a very regimented approach to keeping its clinicians as safe as possible. For starters, each clinician has a VNA of Boston Police Service Directory.

"It is important that everyone who works in the field feel that they are connected," says Taylor. "We contacted all the police departments in our coverage area and have all the numbers for each

Making a list, checking it often

Categorizing escort zones for clinicians

For many years, the Visiting Nurse Association of Boston relied on staff perceptions to dictate when escorts were needed for visits. But that changed in 1992.

"Before 1992, we didn't really have any objective criteria in terms of how we designated what street needed an escort for home health clinicians vs. what street didn't," says **Michael Taylor**, RN, MS, director of patient services for the VNA of Boston and the chairman of its security committee. "It was done more by perceptions, and that can be dangerous because then you label unfairly based on someone's judgment or experience."

To alleviate the problem, VNA of Boston hired a security consultant to compile a list of objective criteria to determine area safety:

1. Volume of foot traffic.
2. Number and types of open businesses.
3. Access to major roadways.
4. Access to public transportation.
5. Number of vacant, abandoned or boarded-up buildings.
6. Number of abandoned or vandalized motor vehicles.
7. Known presence or activity of gangs.
8. Large amounts of graffiti with specific messages.
9. Crime watch or neighborhood watch signs or stickers.
10. Access to telephones.
11. Amount and type of residential housing.
12. Known drug and/or prostitution activity.
13. Presence of homeless or transients.
14. High rates of property vandalism.
15. Isolated parking or poorly lit parking area.
16. Types of street activity; groups gathering for no apparent purpose, public consumption of alcohol, obvious drug use.

Taylor notes that once a community is placed in a category, it is reviewed quarterly, such as the South End in Boston that has gone from escort to non-escort.

"If a street is a non-escort area, and a clinician parks their car and notices an increase in any of the above areas, we bring that to the committee's attention. With input from local police departments, [we] consider whether we need to change the street to escort for the time being, because neighborhoods change," he says.

It's not up to the staff to evaluate the community. Instead, it is truly a providerwide effort as Taylor, the security consultant, or the Boston Police Department also play a vital role in assessing the above areas and designating a community as escort or non-escort. ■

department, from the community service officer number to youth services and most of the detectives."

When an area is deemed a high-risk neighborhood **(see related story, p. 80)**, VNA of Boston has contracted with two local cab companies to provide escort services at a city-regulated rate of $20-an-hour. The specifics of each escort will vary with the visit, ranging from a walk-up who waits for the clinician, if necessary, to pairing up clinicians with one escort. After one clinician is in the building, the escort takes the second clinician to her visit and makes arrangements when to pick each of them up.

Taylor is quick to note that an escort does not guarantee safety. "If there is a group of young people in front of a building, you probably wouldn't want a clinician walking through that group. We advise them, even if they have an escort, call the patient and say, 'I need to make arrangements for a later time in the day. Right now there are 10 to 12 young people in front of your building, and I can't take that risk.'"

Problems inside the home

Not all problems happen outside the patient's residence. In some cases, whether a patient makes suggestive remarks or other members of the family make the clinician feel unsafe, problems may not begin until the clinician is inside. The security committee has had to address such issues in the past.

"In some situations when an employee's safety has been in question in a patient's home, we have had to make other arrangements — be it to do a contract with a family or whatever — to ensure that our employee is safe, because that is our primary responsibility," Taylor says.

One tricky issue is the use of drugs in the home, but Taylor says that visits are not conducted during any drug activity. "I know people have rights within their own environment, but if there is any drug activity going on, you leave, no questions asked," says Taylor. "You tell the patient that you can't be present while this is going on and that you are going to have to leave."

The VNA of Boston takes a similarly tough stand on weapons. "If there is a firearm, it must be removed," says Taylor. "Not necessarily leave the apartment, but it shouldn't be present during the visit."

VNA of Boston recommends that clinicians leave if remarks are made that could be threatening. In any of the above cases, the clinician calls the nurse manager *after* leaving. The manager will then typically call the physician and point out that the clinician is being placed in an unsafe environment.

When such situations arise and a contract is required, the contract between VNA of Boston and a patient can consist of any number of stipulations, such as no one being present other than the patient during a visit, or that visits will be made during the early morning when others are not around.

"If we have to stop the visits, then we have to come up with another plan with the physician. We have stopped visits because there are too many risk factors for the staff," Taylor explains. ■

Now you can get it, now you can't

Abbokinase was back on the market, as mentioned in the May 1999 issue of *Home Infusion Therapy Management*. But after the release of one lot of the product in January — which ran out by March — there has been no further release of the product.

According to Abbot spokeswoman Melissa Brotz, there is no timetable for the further release of Abbokinase. She adds that the new label addressed in the May story was specifically for the January release of the individual lot of product. She anticipates some, if not all, of the label for the January lot will apply to future shipments of Abbokinase. ▼

HCFA delays OASIS collection

After weeks of speculation, the Health Care Financing Administration (HCFA) recently announced it was delaying the implementation of all collection and reporting requirements for its Outcome and Assessment Information Set (OASIS). Providers who had not yet met the previously established requirements to encode and transmit OASIS data will not be held out of compliance. ▼

Study shows benefit of extended anticoagulation

A recent study published in the *New England Journal of Medicine* (1999; 340:901-907) indicates that patients who have a first episode of venous thromboembolism in the absence of known risk factors for thrombosis may benefit from longer anticoagulant treatment than the standard three months.

According to the study, such patients appear to have an increased risk of recurrence after anticoagulant therapy is stopped.

The double-blind study randomly assigned patients who had completed three months of anticoagulant therapy for a first episode of idiopathic venous thromboembolism to continue receiving warfarin or a placebo for another 24 months.

Study terminated for further analysis

The study, terminated due to "a prespecified interim analysis of efficacy," consisted of 162 patients followed for an average of 10 months. Of 83 patients who received the placebo, 17 had a recurrent episode of venous thromboembolism (27.4% per patient-year).

However, only one of the 79 patients who received warfarin had a recurrent episode of venous thromboembolism (1.3% per patient-year.)

Three patients in the warfarin group had nonfatal major bleeding (two gastrointestinal bleeding and one genitourinary bleeding), while none of the patients in the placebo group had nonfatal major bleeding.

In the editorial in the same issue of *NEJM*, Dr. Andrew Schafer of the Baylor College of Medicine, notes that a past study found that "the incidence of recurrent thromboembolism was 17.5% after two years of follow up, 24.6% after five years, and 30.3% after eight years." ▼

Fragmin approved for prevention of deep vein thrombosis

Bridgewater, NJ-based Pharmacia & Upjohn recently announced that the Food and Drug Administration (FDA) has approved its low molecular weight heparin, Fragmin (dalteparin sodium injection), for the prevention of deep vein thrombosis following hip replacement surgery.

Administered once daily, Fragmin was shown to significantly lower the risk of deep vein thrombosis that can lead to pulmonary embolism following patients undergoing hip replacement surgery.

Results from the study

In one prospective, randomized multicenter Phase III study that compared Fragmin with warfarin (Coumadin) in 382 patients who had elective total hip replacements, Fragmin lowered the incidence of total deep vein thrombosis to 14.6%, vs. 25.8% for patients receiving warfarin.

In a second study, Fragmin was compared to unfractionated sodium heparin (standard heparin) in 123 patients who had elective total hip replacements. The incidence of total deep vein thrombosis was lower in patients receiving Fragmin (30%), compared with those receiving heparin (42%).

Although statistically insignificant, Framan did prove superior to standard heparin in lowering the incidence of proximal deep vein thrombosis (9.5% vs. 30%). Fragmin was administered once a day; standard heparin was given three times daily.

Fragmin can be given to patients as a subcutaneous once-daily dose; standard heparin is often administered up to three times daily. Fragmin injection is available in packs of 10 single-dose prefilled syringes in two strengths, 2,500 IU and 5,000 IU, as well as a 95,000 IU multidose vial. ▼

COMING IN FUTURE MONTHS

- Step one: A step-by-step look at phlebitis
- Cut back: 13 easy tips to reduce costs
- New study: CDC looks at infection and needleless devices
- National benchmarks: B. Braun and NHIA start national collection effort
- Phone home: Voice-over-data remote programming technology

New hope for melanoma patients

A new treatment with the gp100 peptide vaccine followed by IV doses of interleukin-2 is showing promise on treating patients with melanoma. Each year, 38,000 people are diagnosed with melanoma — 7,000 die.

The new treatment is being offered at 18 centers around the country participating in the study developed at the National Cancer Institute. The treatment works by generating more activity from the body's immune system, thus killing the cancer. A protein in the peptide vaccine tricks the body's immune system into becoming more active to fight the melanoma. The IV treatment with interleukin-2 further increases the body's immune cell activity. ▼

HHCA files for bankruptcy

Home Health Corporation of America (HHCA) in King of Prussia, PA, recently filed voluntary petitions for reorganization with the United States Bankruptcy Court for the District of Delaware under Chapter 11.

The petitions allow HHCA to conduct business while under protection of the Bankruptcy Court, enabling the company to develop a plan to reorganize debt.

The company notes that several problems contributed to the filing, namely: The implementation of the Medicare interim payment system; overpayments and retroactive adjustments for previous Medicare cost reports; and the delay or denial of payments to HHCA by certain managed care and other non-governmental payors.

HHCA owns and operates 44 locations in Delaware, Florida, Illinois, Maryland, Massachusetts, New Hampshire, New Jersey, Pennsylvania, and Texas. ▼

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Alaris announces new pump launch

San Diego-based Alaris Medical recently announced the launch of its Signature Edition GOLD infusion pump platform, a large-volume single- and dual-channel infusion system to help clinicians provide more efficient and safer patient care.

The system builds on the human factors design, referring to the creation of a medical device with controls and displays designed to reduce operating error and simplify programming procedures.

The pump's unique clinical safety features include precision flow to provide continuity of drug delivery over time, and AIM, a system for monitoring and managing IV infusions which provides the clinician with an on-screen display of the infusion status and history. ■

• **INS Advanced Concepts in the Management of Central Venous Access Devices in the Alternate Care Setting** — July 31, Hyatt Regency Hotel, Chicago. For more information, call the INS at (800) 694-0298.

• **JCAHO: Preparing Your Health Care Organization for the Year 2000** — Sept. 23, Northbrook, IL. For more information, call (312) 906-6164.

• **NAVAN 13th Annual Conference —** Sept. 26-29, Hyatt Orlando, Orlando, FL. For more information, call the National Association of Vascular Access Networks at (888) 57-NAVAN.

• **National Association for Home Care 18th Annual Meeting and Home Care Expo** — Oct. 9-13, San Diego Convention Center. For more information, contact NAHC at (202) 547-7424.

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

• **CINA 1999** — Oct. 20-22, Toronto. For more information, call (416) 292-0687 or go to http://web.idirect.com/~csotcina.

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

• **1999 Fall National Academy of Intravenous Therapy** — Nov. 5-7, Westin Hotel Copley Place, Boston. For more information, call (617) 441-3008.

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

CE objectives

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

1. List the three areas most likely to effect catheter innovations and technology in future products.

2. Identify the most likely reason safe needle legislation has been required to institute the use of safe needles.

3. Identify an often overlooked resource when addressing staff safety. ■