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Parver: Prescription drug coverage could eventually include infusion

At this point, anything could happen in Washington

It wasn't long ago that the likelihood of any health care legislation seemed slim, at best. But recent developments on Capitol Hill have opened the door a bit more for change in federal health care legislation.

Alan Parver, JD, president of the National Alliance for Infusion Therapy in Washington, DC, says there is the chance of a prescription drug coverage that includes infusion drugs.

"The president's proposal would cover prescription drugs on a pretty broad basis," Parver explains. "The proposals coming out of Congress by the Republicans would also cover prescription drugs, but it would be more limited. The Republicans and the administration are pretty far apart right now, and I'm not predicting they are going to reconcile those differences and come up with a drug bill that is going to be acceptable to everybody. But I think it's becoming more likely that there will be serious consideration this year."

Not all good news

Parver notes there are concerns regarding how any legislation would cover infusion.

"Would they define infusion as including the professional services?" he asks. "If it is just delivering the drug and they don't pay for the compounding and other cognitive services, that obviously is a very important issue to us."

A second area of concern lies in PBMs, or pharmacy benefit managers. According to a summary of the president's proposal, PBMs would "competitively bid to manage the benefit for a particular geographic area."

"This could make it tough on providers because the PBMs would have an awful lot of leverage, and there is a concern that unless there

are appropriate safeguards built in, the lower-bid PBMs would not look to pay for services and recognize these therapies as we do," notes Parver.

Also in the president's proposal is a provision that would allow the Health Care Financing Administration (HCFA) to use competitive bidding with little, if any, restraint.

"These bills have not been written; right now, we only have summaries of what they want to do, so the extent to which this authority could be used is not clear now," Parver explains.

The good news

The president's proposal would call for increases in parenteral and enteral nutrition reimbursement rates after the current five-year freeze expires. According to Parver, this would call for the rates to increase by consumer price index minus 1% each year from 2003 to 2007.

It looks as though inherent reasonableness may be given a closer look also.

"In light of the problems everyone seems to have had with inherent reasonableness, there is going to be an effort to try to obtain some changes in the current authority," says Parver. "The changes may relate to the procedural steps HCFA would have to go through to undertake an inherent reasonableness adjustment. A proposal that came out earlier in the year from the administration said they were going to look at something called 'enhanced inherent reasonableness authority,' and it is not in the summary of the president's reform proposal. There might be something there, but it's not in the summary."

Lastly, Parver says relief may be on the way for many providers hit hardest in the last year or two: "It looks like there is a growing consensus that they have to give some relief to the industries that were really hit in the Balanced Budget Act of 1997: skilled nursing facilities, rehabilitation, rural hospitals, and maybe home health agencies." ■

Stability, cost factors in declotting substitute

Providers search for Urokinase replacement

Last month, *Home Infusion Therapy Management* looked at the use of Alteplase (t-PA) as a possible substitute for Urokinase, which is still unavailable due to the FDA's stopping Abbot from shipping the product. In the last of a two-part series, the procedure for a second alternative — Streptokinase — is presented.

According to **Nadine Nakazawa-Carpol**, BS, RN, CRNI, PICC program coordinator and VAD committee chairwoman at the Stanford University (CA) Hospital, says Streptokinase was the right choice as a substitute for Urokinase.

"We knew that Streptokinase and t-PA were available, and from there we went strictly on cost and stability," she explains. "It appears that Streptokinase, once reconstituted, is stable for about 24 hours and is relatively cheap."

A 250,000-unit vial of Streptokinase runs about $83 for Stanford. At 10,000 units / 3 mls, Streptokinase proves very affordable. Comparing this to t-PA, which is only available in 50 mg vials, cost became a major issue when stability was factored in.

"You only need 1 to 2 mg of t-PA, but it is only stable for about eight hours once it is reconstituted," explains Nakazawa-Carpol. "When we called Genentech [the manufacturer of t-PA] in January when we first wrote this Streptokinase / t-PA procedure, they would not guarantee t-PA's potency if frozen. That is why we did not go with the freezing protocol. So unless a patient is allergic to Streptokinase, we do not use t-PA."

Avoiding reactions

Another main concern for many providers is the concern over allergic reactions to Streptokinase. At Stanford, the adverse reaction rate has been much lower than anticipated. In the literature consulted by Nakazawa-Carpol and her colleagues, the adverse reaction rate was listed at 10% (including anaphylactic reactions).

"Based on that preliminary information, we decided to premedicate everyone," she says. "The anaphylactic rate is now about .1%, which is not has high as we thought. It is mostly a pyrogenic reaction, so premedicating with Tylenol should prevent that."

The premed for all patients consists of hydrocortisone 50 mg IV, diphenhydramine 25 mg IV, and Tylenol 650 mg. But in addition to — and prior to — premedicating, the Stanford policy also requires an assessment be done at the outset to not only determine if the catheter is clotted catheter but also if the patient had a recent streptococcal

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Procedure for Declotting Central Venous Catheters

Nursing Action	Key Points
A. Rule out all other forms of possible catheter obstruction before attempting to declot.	Refer to "Ruling Out Other Causes of Catheter Obstruction" section
B. Ask the patient or review chart for: 1. allergy to Streptokinase 2. recent streptococcal infection	If allergic to Streptokinase or has had recent streptococcal infection, obtain order for t-PA.
3. history of multiple drug allergies 4. history of asthma 5. history of recent MI treated with Streptokinase	If history of multiple drug allergies, asthma or recent MI treated with Streptokinase, may need to perform skin test prior to administration.
C. Obtain MD order to declot CVC with Streptokinase 10,000 IU/ 3 ml (or if appropriate, t-PA 1 mg/ml) in the following volumes: 1. 1 ml for PICCs 2. 3 ml for ports 3. 2 ml for all other CVCs OR if fibrin sheath is suspected, obtain order to infuse Streptokinase 1,000 IU per hour for four hours.	See Step R. for infusion procedure
D. Obtain MD order for: 1. IV NS at TKO	When giving Streptokinase to declot a CVC, it is desirable to have IV access in case of adverse reactions. A patent lumen on a multilumen CVC may be used for IV access.
2. Premeds to be given 30 minutes prior to administering Streptokinase: a. acetaminophen 650 mg PO/PR b. diphenhydramine 25 mg IV c. hydrocortisone 50 mg IV	
E. If patient has a history of asthma or multiple drug allergies, perform skin test 30 minutes prior to instilling Streptokinase. **NOTE:** Contact Pharmacy to obtain dose for skin test. 1. Inject 0.1 ml (100 IU) Streptokinase intradermally into patient's forearm. 2. Wait 30 minutes and then inspect area for erythema and/or induration. If any positive signs develop, do not administer Streptokinase, and obtain physician order for t-PA. 3. If skin test is negative, proceed with Streptokinase administration.	It is not known which patients will react adversely to Streptokinase, but these patients may be more at risk. Skin tests may not be indicated for every patient who receives Streptokinase. This decision is per the discretion of the MD.
F. Establish venous access by either using a patent CVC lumen, or starting or using a peripheral IV with NS at TKO.	See I.60 "Peripheral Line: Insertion and Care"
G. Premedicate patient as ordered if Streptokinase.	

(Continued)

Nursing Action	Key Points
H. Wait 30 minutes before starting the Streptokinase administration.	Premeds not required for use with t-PA.
I. Record baseline vital signs.	
J. Reconstitute Streptokinase: **NOTE:** Because Streptokinase has no preservatives, it should be reconstituted immediately before use. 1. Add 5 ml of Sodium Chloride for injection to 250,000 IU vial of Streptokinase. Direct the dilutent toward the side of the vial rather than into the drug powder. 2. Roll and tilt the vial gently to reconstitute. 3. This vial now has a concentration of 50,000 IU/ml. Withdraw 0.2 ml, which is 10,000 IU. 4. Further dilute the 10,000 IU by withdrawing 2.8 ml Sodium Chloride for injection into the syringe, for a final concentration of 10,000 IU/ 3 ml.	Avoid shaking, which may cause foaming. See Step R. for infusion procedure
K. Cleanse the joint with an alcohol swab.	
L. Clamp catheter, then disconnect SafSite valve and/or tubing. Attach syringe to catheter hub and unclamp catheter.	
M. Slowly pull back on syringe plunger to the 8-9 ml mark. Slowly allow plunger to move back to neutral position.	A gently push-pull technique will distend the silicone enough to "mix" to the tip. Do not force dissolving agent as it could cause the catheter to rupture or dislodge a precipitate. Call the physician if unable instill dissolving agent.
N. Reclamp catheter, taping syringe in place. Wait 5 to 15 minutes.	**Do not** clamp Groshong catheters and PICC catheters.
O. Unclamp catheter and attempt to aspirate dissolving agent. If blood can be withdrawn, proceed to Step Q.	Use push-pull technique as described above, which will help the Streptokinase continue to "mix" to the tip, dissolving the clot along the way.
P. If no blood is aspirated, reclamp catheter and wait an additional 15 minutes. Continue to check every 5 to 15 minutes for up to one hour.	Observe patient closely for any signs or symptoms of adverse reaction.
Q. If blood can be aspirated, withdraw 5 to 6 ml and discard. Irrigate catheter with 20 ml NS in a push-stop-push fashion.	A push-stop-push technique causes turbulence in the catheter and flushes out blood and drug more effectively.
R. For infusion (if fibrin sheath is suspected): 1. Reconstitute Streptokinase as described in Steps J.1 through J.3 above. 2. Further dilute the 10,000 IU by adding to 100 mg bag of normal saline or D5W, for a concentration of 100 IU/ml. 3. Infuse at 1,000 IU/hour (10 ml/hour) for four hours. Total dose of 4,000 IU or 40 ml. 4. Discard remainder of infusion.	

(Continued)

Nursing Action	Key Points
S. Resume infusion or heplock catheter.	
T. Record post-instillation vital signs.	
U. If unable to reestablish catheter patency, repeat above procedure. Do not give additional premeds.	
V. If unable to reestablish catheter patency after a second attempt, notify physician. All other possible causes of catheter obstruction should be ruled out.	In addition to those described in the Patient Assessment section above, other possible causes of catheter obstruction include catheter separation from portal reservoir, catheter fracture, total venous thrombosis or catheter tip malposition.
W. Discard remainder of reconstituted Streptokinase.	

Documentation

A, Record dosage of premeds and Streptokinase or t-PA on the Medication Administration Record (MAR) or other appropriate documentation form.

B. Record assessment, whether catheter patency was restored, patient tolerance to procedure and any pertinent observations on appropriate flow sheet.

C. Report any adverse reactions to area pharmacist for tracking purposes.

Source: Stanford (CA) University Hospital.

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infection or a recent Streptokinase infusion for any other reason. **(See pp. 111-112 and above, for part of Stanford's Streptokinase/t-PA procedure.)**

The risk of an adverse reaction to Streptokinase increases with exposure to either the streptococcal bacterium or Streptokinase, or a history of multiple drug allergies. By following the precautionary procedure, Stanford appears to have addressed the issue.

"In those three situations, the nurse does a skin test and waits half an hour," says Nakazawa-Carpol. "If the skin test is negative, then they proceed with the premeds, then the Streptokinase attempt to declot. If the skin test is positive, then we recommend t-PA."

Another reason Nakazawa-Carpol surmises that the reaction rate is minimal is due to the amount being used to declot the catheters.

"You are using a small fraction compared to an infusion of Streptokinase for coronary thrombosis," she says, "so the exposure to Streptokinase is very, very small and may not manifest much of a reaction. But we are still preceding the infusion with heavy premeds."

She adds that she has used higher doses than listed on the policy with positive outcomes.

"We have infused 25,000 units / 4 ml — a total of 100,000 units — over an hour by infusing it slowly," she says. "The patient was premedicated, there was no adverse reaction, and we had great blood return afterwards. Anecdotally, this was done with good effect."

Only time will tell

Although there are proponents of both t-PA and Streptokinase, Nakazawa-Carpol notes that it will take some time before anything concrete can be stated about the potential of either drug to declot catheters.

"We don't have enough experience; it will probably take a year of patients being exposed to Streptokinase to see an actual rate of adverse reactions," she says. "[Urokinase being taken off the market] has forced us to look at other fibrynolitics that are out there. If Streptokinase turns out not to be as dangerous as we thought, it could prove to be a fraction of the cost of Urokinase. Or t-PA may be the answer, the problem is the 50 mg vial. I don't think we have the answer yet." ■

It's more than just a phase

FDA's three-phase process of drug approvals

When a company announces an infusion drug has completed Phase II trials for Food and Drug Administration (FDA) approval, or has completed a Phase I trial, what does that mean to you in terms of how far away the drug is from a release to market? The truth is that a drug just entering a Phase I trial could be available to providers before a drug that long ago began Phase III trials.

Thomas Hassall, an assistant director of regulatory affairs for one of the FDA's five Offices of Drug Evaluation, says that a drug's trip through the FDA pipeline is anything but a set formula, particularly once testing begins.

Preclinical research

Before a drug even makes its way to the FDA, the manufacturer must have conducted animal testing to identify various properties of the drug and its toxicity in animals. However, there is no set standard as to the acceptable toxicity of a drug that the FDA will allow to progress to human testing. The level of risk that is acceptable depends to a large degree on the disease for which the drug is targeted. In essence, progress throughout the drug development is a series of risk-vs.-benefit decisions.

"If a drug may be a carcinogen over a long period of time, that wouldn't necessarily block it from study as an oncology drug if it has the potential to provide a significant survival benefit, and the likelihood of suffering carcinogenic effects in a human taking the drug for chemotherapy would be fairly remote," notes Hassall.

During preclinical research, the FDA requires a drug's sponsor to, at the minimum:

1. Develop a pharmacological profile of the drug.

2. Determine the toxicity of the drug in at least two species of animals.

3. Conduct short-term toxicity studies ranging from two weeks to three months.

Once this information has been compiled, the sponsor completes an investigational new drug application (IND), which Hassall notes is required for reasons other than you might suspect.

"The Food, Drug, and Cosmetic Act really has to do with shipping drugs in interstate commerce," he says, "and the IND is really asking for an exemption from the act's prohibition against shipping an unapproved drug in interstate commerce to the investigators who are going to conduct the additional research required for drug approval."

However, the act is considered to cover all the components of a drug, including packaging materials. So while it is technically possible to do everything in-state and avoid the FDA, it would be almost impossible for everything involved with a drug to come from within any one state.

Hassall points out that sponsors conduct preclinical studies on a drug without an IND because the compound isn't technically a drug until a claim for a specific use is made. The IND is required for the first time you want to administer the drug to a person in Phase I trials.

When the initial application is filed, there is a 30-day period from the day the FDA receives the IND that the sponsor cannot begin its study. That allows the FDA to review the IND and evaluate the potential risk to human recipients. If after 30 days the sponsor has not heard from the FDA, testing may begin. However, if the FDA finds something it feels is an unacceptable risk to the study subjects, the sponsor is contacted by phone, and a letter is issued giving the reasons that testing cannot begin.

"We don't invoke that lightly because it puts a stop on things going forward, and that is a clinical hold," says Hassall. "Where there are no unacceptable safety concerns, we may simply make suggestions to provide additional safeguards that are short of a clinical hold or simply to improve the quality of the data to be obtained from the study."

A sponsor does not necessarily have to follow the suggestions. In some cases, the FDA may request additional information before allowing the drug to progress to another trial. This is referred to as a partial hold. Issues addressed in a clinical hold or partial hold must be resolved before the drug can move on. The inability to clear up such concerns is where many drugs simply die on the vine.

Once the IND is filed and the FDA allows the sponsor's plans to go forward, the approval process isn't a simple, three-step, Phase I-Phase II-Phase III endeavor.

"The rate at which they progress is in the hands of the applicant," says Hassall. "There's no proclamation that they have finished Phase I. Most times, they don't do one study and wait until that is done until they do another. As the first study is progressing, the sponsor may initiate additional trials that will run concurrent with the first trial."

For each future study, regardless of which phase it is, the applicant must submit a new protocol to the IND. However, unlike the initial IND submission, testing may begin right away although the FDA can put the study on hold if upon review there are safety issues.

Phase I

Phase I trials usually involve just a handful of humans, and for good reason.

"It is essentially the first time the drug has been given to humans after you have gotten some idea of the pharmacology of the drug, and organ systems that might be affected by the drug — both adversely and in a favorable way," notes Hassall. "But because of species differences, when you first go into humans you're not going to go into them in a large scale."

The main thrust of Phase I trials is to determine the safety of the drug in humans. For the most part, Phase I trials don't focus on investigating the drug's effect on the disease it is being targeted for. Many times, subjects who receive a Phase I drug are healthy volunteers, although this is not always the case.

"Would you give an oncology drug with potential for serious toxicity to a healthy volunteer? Probably not," notes Hassall. "But, depending on the potential benefit, administration to patients with the disease may be acceptable with appropriate safeguards."

Investigators usually look to establish the various pharmacokinetic properties of the drug in humans, such as the degree of absorption, the rate of absorption, how it is metabolized and how it is secreted. In essence, this allows investigators for the first time to see how the drug behaves in humans. Additional Phase I trials may involve different dosages of the drug to further establish an initial safety profile and serve as a basis for the doses chosen for Phase II studies.

According to New York City-based investment company Bear Stearns, the typical Phase I period lasts a year and costs $9 million. Yet, 38% of drugs that enter Phase I trials fail.

Phase II

"Many drugs fall by the wayside in Phase I and others are able to go forward," says Hassall . "But the phases are not really distinct, and there are gray areas as you go from one phase to another. A company might do limited hypothesis testing in Phase I to develop the appropriate testing in Phase II."

Once a drug begins a Phase II trial, researchers have established the initial safety profile and pharmacokinetic properties of the drug. Phase II then exposes a greater number of humans with the targeted disease to the drug, with a typical patient sampling in each Phase II study in the neighborhood of 50 or 60. Because of the gray area, Phase I trials may still be ongoing when a Phase II trial starts, but the intent is now much different than focusing on safety.

"Phase II is the first place you begin to assess the efficacy of the drug," says Hassall. "The trials involve a larger number of patients and involve comparators, such as a placebo or some known treatment."

According to Bear Stearns, the Phase II period lasts anywhere from one to three years, costs $22 million, and has a failure rate of 40%.

Phase III

If the drug shows promise and survives Phase II trials, a sponsor will move forward to Phase III.

"This is when a sponsor will initiate what we call pivotal clinical trials that will result in writing a label for the product that will include the dose or range, the interval, how long to treat the patient, adverse events that have been observed in a large enough population that a clear profile of adverse events develops, precautions to take while taking the drug, and known drug interactions that have been determined," says Hassall. "Phase III trials are big numbers of patients where you are going to definitively determine what the drug does, and this can get from the hundreds into the thousands of patients."

In some rare instances, a Phase III trial may be the first trial in the United States.

"There may be products that have use elsewhere in the world that may not have been submitted for approval in the U.S.," says Hassall. "A company with a drug like that with sufficient information about the safety of the product may initiate the IND with a Phase III study. They can supplant Phase I and Phase II with information."

Final approval

If all trials go well, the sponsor still must submit a new drug application (NDA), a daunting task in and of itself.

"Picture 300 to 500 volumes of the Washington, DC, phone book," says Hassall. "The NDA is

usually that big because it includes full reports and data from all their studies."

The FDA currently tries to review an NDA within 10 to 12 months of receiving it, although priority drugs have a goal of six months.

"We either approve the NDA or not, and if we approve it they can go to market," says Hassall.

For applications that are not approved, the applicant is sent a letter describing all the deficiencies that need to be addressed before the drug may be approved. An applicant may then amend its application with the needed information. The FDA's goal is to complete its review of such amendments within six months of receipt. ■

Starting may be hardest part of data collection

Beginning useful, painless outcomes collection

There is a world of difference between making a decision and making an informed decision. It seems that, even with data collection requirements such as ORYX already in full swing, some providers still have yet to fully grasp the process and benefits of outcomes. If you feel slightly embarrassed in knowing you fall a bit short in data collection and putting that information to use, you should know you're not alone.

"I had been called in to two very large institutions," says **Lynn Moeser-Manly**, RN, CRNI, and owner / director of IV Technologies, a consulting firm in Biloxi, MS. "One said, 'We're using this particular catheter and it's causing infections, and we want you to come in and help us know what's going wrong'. And the other call was that a certain catheter was occluding so much they wanted to get rid of it."

Moeser-Manly's first question to both institutions was, "How many catheters a year are you placing?"

"These very large, and I might add prestigious institutions, looked at me dumbfounded and said, 'We don't have any idea,'" she recalls. "The first hospital only tracked catheter infection rates within their ICU / CCU. The second hospital said they had record of four catheters in the past year occluding after discharge to home care. They also commented that they had 'a lot of problems with catheters occluding all the time on the various units.' They had no idea of the total number of catheters placed, in use, or total discharged to home care. It could have been 4,000, 400, or 40. Nobody knew. I can't understand why the importance of this information isn't recognized."

Getting started

If you need any motivation to collecting data or finally putting all those numbers sitting in a database somewhere to use, realize that it could provide answers to most of the questions you're currently asking yourself and your peers. If providers took the time to collect, compile, and evaluate outcomes data, they would more often than not have their answers.

"Sometimes people call me and say, 'We flush with 10 units of heparin per cc, but everybody else says that's wrong. What should we do?'" says Moeser-Manly. "If you had outcomes, you would know whether that procedure works for you."

But outcomes allow for more than quality patient care and patient satisfaction. They should also help bring in new business.

"The practice you are promoting, selling, or claiming is good practice has to be validated in some way," says Moeser-Manly. "There has to be something that shows you do good practice. Clinicians have no business promoting their practice if they don't have outcomes to show."

Lastly, Moeser-Manly notes that information collected can ultimately lead to improvement in infusion therapy practice. She believes that "IV therapy is a continuum of learning. IV clinicians could / would / should be involved in practice design, direction and change, and that practice design, direction and change could / would / should involve the IV clinician.

"They don't realize that they could actually help change practice by publishing information," she continues. "Just because you aren't a research institution doesn't mean you can't do something relative to research. You work in the real world. Collect data about what you are doing, write about it, and get it out there."

Even if you don't publish such information, Moeser-Manly says there is still a valid reason to collect data and use it: "Practice success and practice validation."

If you're just starting out, Moeser-Manly agrees that it's OK to begin with a very specific goal in mind rather than jumping in with both feet right away.

"Data collection is essential, but this can be as horrendous as someone chooses to make it," she

says. "You don't have to necessarily start by tracking every IV catheter that is in place. You can begin with just PICCs placed in radiology, for example. Or you can begin by evaluating 20 out of 100 peripheral IVs. Start small and build from there with an ultimate intention of capturing 100% of the information in the future."

Good places to start, according to Moeser-Manly, are:

1. Evaluating PICC or midline catheters that remain operational to the end of treatment.

"But that's a tough one, because how do you define end of treatment? In a hospital setting is end of therapy when the patient is discharged? Not really. You might consider creating your own definition as a starting point, and in a perfect world it is the first step toward everyone using the same definition. Ultimately, we must strive toward a universal definition."

2. Phlebitis rate.

Moeser-Manly suggests using the INS phlebitis scale.

3. Occlusion.

"Everybody wants to argue about whether saline locks or heparin locks are most effective in maintaining catheter patency. If outcomes are being collected, they can check their own outcomes and see what is working for them," she says.

4. Catheter breakage or catheter leakage.

"Infusion nurses can do themselves in by thinking that they have to track 52 different monitors," notes Moeser-Manly. "Start with four, or even one, and build from there. Take in validating information on what you hope to show or prove without going into too many other areas of information. Just make sure to capture enough information that your end result is valid."

Two keys to success

Moeser-Manly notes that there are two ways to ensure that your data collection / outcomes process is productive. First, keep it as simple as possible.

"Ease of use is imperative," she says. "Any tool must be short, clear and concise. I like to see check boxes and objective reporting."

To help ensure the latter, make sure that everyone is defining phlebitis, for example, the same way. Issue a directive on how something is defined, such as a phlebitis scale chart," says Moeser-Manly.

The second way to ensure success is to provide feedback to those who are collecting the data.

"Somebody has to give feedback to the clinician in the field about results," says Moeser-Manly. "It has to validate practice or change practice, and that is the point of outcomes." ■

GUEST COLUMN

The history of our move toward needle safety

But there's still reason for concern

By **Nina Moore Elledge**, RN, CRNI
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By now, many of us should be aware of the changing climate in health care facilities regarding protection of its employees against accidental injuries with contaminated needles. When we look at the history that led to this change and the resulting legislation, we can see why it is so important to fully accept these changes and adjust our practice now.

In the late 1980s, the first generation of safety devices was introduced to the market in response to the discovery of HIV. With HIV came the potential of transitioning the workplace into a possibly life-threatening environment. IV lines, lab draw devices, and injection needles were introduced that would be shielding or self-blunting to protect workers from this newly discovered virus, as well as the more than 20 other bloodborne pathogens (BBP). However, many health care facilities did not carry these new safety devices due to cost and / or politics.

In the mid 1990s, health care workers' public outcry for safer devices in the workplace began. For the first time, there were names and faces in the stories behind the devastation of a contaminated needlestick injury. Cost analysis began to become apparent: An average workers' compensation claim for a needlestick injury was $2,000 to $3,000,[1,2] depending on which statistics you read, and that is if there is no seroconversion.

Analysts began to understand the volume of the government expense if the claimant becomes positive for a BBP. If these figures are multiplied by the number of employees exposed to sharps on a daily

basis (doctors, nurses, respiratory therapists, lab technicians, patient care aides, housekeeping, and environmental services staff), it was obvious that something had to be done on a regulatory level. If not, workers' compensation insurance premiums would skyrocket, resulting in the government incurring significant expenses to cover these claims. Health care facilities would need to pass on these costs in the form of increased premiums, cuts in services, or decreases in employee benefits.

Safety devices were 50% to 100% more expensive than conventional non-safety devices. However, the total cost for each device was still typically less than $2 per item.[3] Needleless systems were generally in use on intravenous lines, but there were limited safety devices available on hollow-bore needles.

A step to safety

The impact on home infusion providers is clear. In general, the patient population in hospitals is sicker than ever before, yet stays in the hospital for less time and receives IV therapy more than 90% of the time.[4] Alternate sites are becoming popular for IV therapy. We have non-RN staff providing care for patients, and many do not have the IV experience or device knowledge as in years past when IV teams cared for all patients with a vascular access device. This further increases the risk of needlestick injury. Training on the use of these devices is at times incomplete due to a variety of factors most likely due to the staffing crisis.

In August 1998, California became the first state to pass a safety initiative to protect health care workers from accidental needlestick injury by contaminated needles used to start IVs, draw labs, and give injections. The CalOSHA bloodborne pathogens standard will be revised as a result.

In May of this year, Tennessee and Maryland passed BBP protection revisions to their state Occupational Safety and Health Administration (OSHA) regulations. Twenty more states have similar legislation pending. Health care facilities won't be covered for needlestick injuries if the facilities do not have safety devices in use, i.e., are compliant with the new OSHA regulations. The Stark/Roukema bill was introduced in Congress to revise the federal OSHA regulation to include protection for health care workers against accidental needlestick injuries, similar to the California bill already enacted.

Shortly thereafter in July, California health care facilities have either put the safety devices into use or have a plan of action to implement their use within the next several months. Congress reconvenes to vote on the Needlestick Prevention Act of 1999. Health care workers are beginning to use these devices, many with successful transitions.

But the transition is far from complete. There are still health care workers who do not like safety devices, some of whom stash conventional product to fall back on if they do not have successful outcomes with the new safety products. Change is hard, particularly when it involves a product we are used to and have had success with. This is especially true when it involves an invasive and oftentimes painful procedure to our patients. However, remember that many of these safety devices were developed using input by health care workers themselves and, as a result, are user-friendly.

Safety devices reduce needlestick injuries

This change in practice must happen not only because of the protection offered to health care workers, but also the protection from accidental needlesticks offered to patients. Studies have shown that needlestick injuries significantly decrease when safety devices are put into use.[5] Health care costs have skyrocketed, and this measure is an attempt to put an end to a portion of it.

The upfront cost of health care is not the only concern. In addition, we need to look at health care workers' malpractice insurance coverages. It is unlikely that coverage would extend to a worker whose facility has safety devices to use and the worker opts not to use them. This is because facilities will be revising policies, or have already done so, to mandate use of safety devices. This keeps the facilities in compliance

COMING IN FUTURE MONTHS

- Outcomes: INS presents its data on CRNIs
- Comparison: Safety devices vs. one-handed recapping
- Crystal ball: The future of Urokinase
- Sci-fi? Biotechnology and infusion
- Safety first: The latest safety technology

with OSHA regulations and protects them from legal liability as well.

We are seeing manufacturers stand behind their legal obligation to properly train health care workers who use their devices. This will also limit their legal liability in a needlestick injury case.

This change to a safer work environment is a long time coming, similar to construction workers who wear their hard-hats at work every day. But the process won't be complete until all workers take advantage of this simple precaution.

References

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4. Baranowski L, et al. *Intravenous Therapy, Clinical Principles and Practice.* New York: W.B Saunders & Co.; 1995.
5. International Health Care Worker Safety Center. *Prevention of Occupational Blood Exposures in Health Care Settings. Prevention, Management, and Chemoprophylaxis of Occupational Exposure to HIV*. Charlottesville, VA; 1997. ■

CALENDAR

- **NAVAN 13th Annual Conference** — Sept. 26-29, Orlando, FL. For more information, call (888) 57-NAVAN.

- **Safety of IV Drug Delivery** — Sept. 27-28, Phoenix. For more information, call (614) 292-1514.

- **Eighth Annual Nutrition Symposium** — Oct. 2, Doubletree Hotel, San Diego. For more

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• **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 October issue of *Home Infusion Therapy Management*, CE participants will be able to:

1. Identify the benefits of Streptokinase over t-PA as a declotting agent.
2. Explain how a drug moves from one phase to the next in the FDA drug approval process.
3. List three areas that are likely the best place for a home infusion provider to start collecting outcomes data.
4. Define the average workers' compensation claim for a needlestick injury, not including seroconversion. ■