AMERICAN HEALTH CONSULTANTS®

HOME INFUSION THERAPY MANAGEMENT™

INSIDE

FEBRUARY 2000

VOL. 8, NO. 2 (pages 13-24)

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Will you hold, please? DHHS action overdue

Infusion industry awaits coding decision

"In essence, what we are trying to do is achieve recognition and reimbursement for all professional services that are provided with infusion therapy," says **David M. Franklin**, director of reimbursement for Continuing Care Services at Bon Secours Health Services in Grosse Point, MI, and a member of the Home Infusion Electronic Data Interchange Coalition (HIEC). "We are going about this in a number of ways, perhaps most significantly through our efforts toward national standardization of coding procedures."

Franklin says HIEC was created by home infusion providers across the United States to address industry concerns related to the lack of standardized coding mechanisms for home infusion services and the need to increase electronic data interchange (EDI) and electronic claiming capabilities in the infusion industry. The HIEC Coordinating Committee says its objectives are intrinsically linked to the objectives of the National Home Infusion Association (NHIA), and that the industry at large would be best served by combining the activities of the two organizations. Franklin says HIEC's objectives include:

- **decreasing days of sales outstanding throughout the infusion industry nationwide;**
- **supporting and standardizing EDI transmission of infusion-related data on a national basis;**
- **standardizing infusion coding methodologies nationwide;**
- **decreasing the cost of processing and adjudicating home infusion claims;**
- **increasing the efficiencies in infusion billing and reimbursement processes;**
- **facilitating documentation of and the billing and reimbursement for professional and cognitive services provided by infusion industry professionals.**

HIEC's proposal made to and accepted by NHIA points out that "lack of standardized coding mechanisms and EDI capabilities have plagued the infusion industry since its inception. Administrative inefficiencies and bureaucratic-related expenses have caused infusion providers to direct inappropriate amounts of resources towards the funding of accounts receivable and excessive overhead costs."

Know your code

Franklin says the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires coding accepted on a federal level for all health care services. HIPAA presented a unique opportunity for the home infusion industry to obtain a devoted coding system. Language contained within this legislation states the intent to improve "the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information."

The Department of Health and Human Services (DHHS), responsible for implementing this section of the legislation, failed to publish the final choice of allowable codes in November 1999 as agreed. DHHS is required to select from existing standards unless they do not meet the needs of affected parties. Health care payers will be required to accept the standards adopted by DHHS. The opportunities for the infusion industry are clear. If the industry is able to convince the DHHS that none of the existing standards meet the needs of the industry, it is possible that the HIEC codes, which are solely devoted to the purpose of describing home infusion products and services, could be adopted as a national standard and infusion professionals could finally begin receiving reasonable reimbursement for their services.

Supervision required

According to Franklin, none of the existing codes appear adequate for infusion services. "There are other codes out there standardized on a national basis. They all have different functions, but none of them are for infusion." As Franklin points out, the American Medical Association's current procedural terminology codes require the direct supervision of a physician, something not generally found in home infusion services. Health Care Financing Administration's Common Procedure Coding Systems codes are strictly product-driven and don't describe infusion services. International Classification of Diseases Volume 9 codes describe disease and injury states and certain surgical procedures. No section of this system describes home infusion services. National Drug Codes describe medications only.

The per-diem structures that have become the standard reimbursement methodology in the infusion industry would not be allowed under the HIPAA legislation, and the administrative simplification that is the intent of the HIPAA legislation would not be possible for the home infusion field. Franklin says that the most troublesome and disturbing possibility is that the drug element of infusion therapy would be split out, treated as a retail drug transaction, and reimbursed at cost plus a nominal dispensing fee. This reimbursement methodology would fail to acknowledge and compensate professionals for reviewing lab work, recommending medication changes due to clinical findings, compounding medications, monitoring potential drug interactions, and coordinating therapy with other health care professionals.

No standard set

Franklin's HIEC group developed a coding system specific to infusion therapy and last spring asked the government to include it in its national standards. "We're not expecting them to do so," he says. "But they haven't published their final standards yet, so we can't say for sure they're not going to. Keep in mind that these codes we've designed are still under review. All infusion providers have not accepted them as a national standard. If they were, there are still some changes that would need to be made before we could start using them."

HIEC's proposal notes that "the current HIEC system has been designed for the private sector mirrors the per diem methodologies most common in private sector infusion reimbursement and is not designed or intended for use with the Medicare system, which has limited infusion benefits and its own coding structure." The HIEC (draft) for an

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infusion coding system, has been well-received by the infusion industry, with provider support growing rapidly within a short period of time. (**See HIEC coding system, inserted in this issue.)** "It is perhaps the single most widely recognized system that is specific to infusion products and services," says Franklin, "and is accepted by more than 80 payers across the country." ■

Reduce infections caused by poor habits

Agency spent years honing this process

No home care quality manager wants to hear that the agency has a problem with infection control, or even that the agency has one patient with an easily avoidable infection. But now that patients and their caregivers are taking over more responsibilities in handling intravenous care, infection control is a greater challenge than ever before. So it's a good idea to have an ongoing quality improvement process that measures infection rates and assesses the cause of all patient infections.

The Visiting Nurse Association of Southeast Missouri has had an extensive infection control program since 1996, lately focusing on patients with central venous catheters and bladder catheters. The program has worked. The agency's infection rate for central venous catheters has been 0.5 infections per 1,000 device days, which is practically nothing, says **Pat Huttegger**, RNC, BSN, quality improvement director in the Cape Girardeau, MO, office. The agency has five offices in southeast Missouri. The bladder catheter rate has ranged up to 4.4 infections per 1,000 device days. While this rate is higher than managers would like to be, it has improved since the agency implemented some quality improvement changes.

Path to improvement

Here's how the agency has improved its infection control program:

• **Track down the cause of each infection.** The Visiting Nurse Association of Southeast Missouri has a standing policy that requires a culture whenever a patient has a suspected infection related to a central line catheter, Huttegger says.

"Late in 1998, we had a patient who developed an infection and I suspected what the problem was before the culture was ordered," she says. "It was an organism caused by a failure to wash your hands; it's very common when hand washing isn't done."

In this case, the patient had been doing the infusions and apparently had not been using the good hand washing techniques the home care staff had taught. Coincidentally, another patient had a central line catheter infection within the same quarter, and again the cause was the patient's poor hand washing technique.

By methodically finding the cause of each of those infections, Huttegger could see the beginning of a trend that needed to be stopped. The agency began to use clinical teaching pathways that nurses use to document all of the different techniques they have taught patients. During each visit, nurses review the teaching material. The one-page pathways have columns for five visits in which nurses record the dates of the patient teaching. More pages can be used if the visits continue.

• **Assess safety of equipment.** Huttegger wasn't pleased with the agency's bladder catheter infection rate, which ranged from 2.2 infections per 1,000 device days to 4.4 infections per 1,000 device days.

"We studied these rates within the agency and found that the offices that were using silicone catheters were having fewer infections and less frequent infections than the offices using other types of catheters," she says.

Huttegger showed the manager of an office where the silicone devices were not being used the infection data, comparing that office to the ones where the silicone devices were used. "I said that I had another office that used to have a fairly high rate and they have switched over to the silicone catheters and their rate dropped."

The office manager decided to switch, and the following week Huttegger spoke with a field nurse who said she could already see a difference among the patients whose catheters were switched to silicone devices. Those patients, who had previously complained a great deal, were calling the office far less.

• **Monitor how caregivers/patients handle the catheters.** Some patients have a family member who takes care of the catheter care and cleaning. In those cases, the nurse will visit the patient only once a month to change the catheter and review

whether the caregiver is following the procedures correctly.

"We check to see if they're using a good technique to prevent infection," Huttegger says. "For example, if they empty the Foley bag and leave the drainage spot dangling while they're emptying the urine, then there's an avenue for potential infection, for bacteria to travel up through the bag and into the bladder."

Monitoring sterile techniques

To prevent those types of problems, nurses monitor the caregivers and patients as they perform the procedures, reinforcing hand washing and other sterile techniques. This patient education has increased in recent years as the agency has cut visits to handle Medicare and interim payment system pressures.

"There are fewer visits, so we teach families how to do IV therapy," Huttegger explains. "In 1996, we didn't teach them to do it to the extent that we do now."

In the beginning, nurses spend more time walking patients through the process of caring for their catheters. "It usually takes longer when it's someone with IV therapy and we have to teach them to do their own infusions and flush their lines," she explains.

For example, patients who do their own infusion care must flush out their catheter line with saline and give themselves the proper dose of medication. Then they have to clean the injection caps and be careful not to touch and contaminate anything where the tubing attaches to the needle. Nurses mostly continue to do the dressing changes, which is a very sterile procedure, although there are occasions when a patient's caregiver is comfortable enough with the procedure to be taught how to do it. ■

Budget bill brings some BBA relief

Home health consolidated billing repealed

Two provisions destined to have a significant negative effect on infusion therapy services under Medicare have been repealed or restricted, thanks to final federal budget negotiations. Those steps were taken in conjunction with a broad range of provisions for mitigating adverse effects of Medicare provisions caused by Balanced Budget Act of 1997.

The following major provisions affecting infusion therapy were included in the final legislation:

• **The Health Care Financing Administration's (HCFA) authority to use inherent reasonableness (IR) granted under the BBA of 1997 has been suspended until the publication of the General Accounting Office (GAO) study on HCFA's implementation of IR thus far.**

HCFA must also publish a new final rule in the *Federal Register,* respond to comments raised by the GAO study, re-evaluate the criteria used to apply its IR authority, and "take appropriate steps to ensure the use of valid and reliable data when exercising such authority."

The BBA gave HCFA broad authority to implement IR to adjust rates by as much as 15% per year for Medicare Part B-covered items (except physician services) — if current reimbursement was found to be "inherently excessive or deficient."

• **A detailed study published by the Lewin Group demonstrated numerous flaws in the data to recommend those cuts.**

Joint comments submitted by the National Alliance for Infusion Therapy and National Home Infusion Association raised these concerns, including the use of inappropriate data and the improper use of an interim final rule to implement its authority. For example, the proposed enteral cuts appeared to be primarily justified using retail-pricing data on enteral products that do not include clinical services and are not equivalent to those typically covered under Medicare.

Those significant issues, supported by the Lewin analysis, prompted key members of Congress to request a GAO study into HCFA's use of IR. The study is expected to be published in the coming months.

Medicare B . . . or not?

Home health consolidated billing — slated to be part of the implementation of home health prospective payment in October 2000 — has been eliminated for Medicare Part B durable medical equipment items (DME). Parenteral and enteral nutrients, which are not considered home health services, will similarly not be subject to consolidated billing. Consolidated billing was designed

as an integral component of Medicare's new prospective payment systems for both home health services and skilled nursing facility services. Under the home health consolidated billing provisions of the BBA, only home health agencies would be eligible to submit claims for Medicare Part B covered services for those patients who are under a home health plan of care.

Consolidated billing rules

Accordingly, the proposed rule for home health prospective payment system (PPS) published on Oct. 27, 1999 — just a few weeks prior to passage of the BBA Refinement Act — includes provisions on consolidated billing. Those would have required home health agencies to bill for all home health services, includes nursing and therapy services, routine and nonroutine medical supplies, and home health aide, medical social services, and DME.

"The law requires that all home health services paid on a cost basis be included in the PPS rate," HCFA explained. "Therefore, the PPS rate will include all nursing and therapy services, routine and nonroutine medical supplies, and home health aide and medical social services. However, durable medical equipment will not be included in the PPS rate because it is reimbursed according to the DME fee schedule, yet must be billed by the HHA."

Based on the BBA Refinement Act, this provision would *not* be included in the publication of the final rule for home health PPS.

Study has four elements

HCFA has been instructed to conduct a study of the extent to which intravenous immune globulin (IVIG) could be delivered and reimbursed under the Medicare program outside of a hospital or physician's office. In conducting this study, HCFA must:

- consider the sites of service that other payers, including Medicare+Choice plans, use for IVIG;
- determine whether there are health and/or safety issues associated with home administration of IVIG;
- determine whether home IVIG coverage can reduce overall Medicare spending;
- determine the effect on beneficiary access to care. ■

NHIA offers conference, workshops, new book

The National Home Infusion Association (NHIA) annual conference in Cincinnati, May 17-20, 2000, will feature educational programs on operational, clinical, reimbursement, marketing, and business topics.

The annual conference includes the high-level executive conference; two program workshop tracks on management and clinical operations; the NHIA trade exposition; industry-sponsored symposia, and networking events. The conference is the association's primary business and political meeting, offering opportunities to participate in committee and task force activity to address current issues in infusion therapy.

NHIA provides information, education, and legislative and regulatory representation to the nation's approximately 5,000 home infusion therapy companies nationwide.

Home infusion therapy involves the administration of intravenous medications in home and other outpatient settings, representing a cost-effective and patient-preferred alternative to inpatient care. Today, home infusion therapy represents approximately $4 billion in annual health care expenditures. ■

Two NHIA-sponsored workshops offered

Lisa Thomas-Payne, of Medical Reimbursement Systems, Albuquerque, NM, will present "Reimbursement and Billing for Home Infusion Services" on Feb. 17, 2000, in Las Vegas. This is a one-day, intermediate-to-advanced-level crash course for mastering home infusion therapy billing.

Topics covered will include the revenue cycle; Medicare and private insurance coverage and documentation requirements; per diem and unbundled billing methods and their impact on receivables; and detailed reimbursement review of the most difficult infusion cases.

Program objectives for participants are the ability to: describe the typical infusion revenue cycle and how it affects days sales and the company's ability to provide clinical services; identify the coverage requirements for Medicare and private payers for the most common infusion therapy services; and list the principal advantages and

disadvantages of per diem and unbundled billing and their impact on receivables. Cost for the workshop is $300 for National Home Infusion Association (NHIA) members and $350 for nonmembers.

Alison Cherney, MBA, of Cherney & Associates, of Brentwood, TN, will present "Strategic Positioning of Infusion Therapy in the Managed Care Market" on Feb. 18, 2000, in Las Vegas. Designed specifically for infusion therapy owners, managers, and executives, this all-day workshop will examine managed care trends and opportunities, targeting profitable managed care organizations, creating infusion value-added services for managed care, the ins and outs of risk-sharing, presentations to managed care organizations, and managed care contracting strategies. Program objectives for participants are the ability to: describe three strategies for successfully positioning infusion therapy services with managed care organizations; identify four key variables that influence the viability of managed care agreements for infusion therapy; and list four factors that may jeopardize the viability of managed care contracting for infusion therapy services. Workshop cost is $350 NHIA for members; $399 for nonmembers.

NHIA has also published a new business resource book by Cherney, *Creating a Marketing Plan: A Workbook for Infusion Therapy and Homecare*, that includes practical information and worksheets covering market assessment and planning. Topics include:

- how to calculate local market size;
- revenue analysis;
- market assessment for all primary referral source markets;
- competitive market analysis;
- analyzing revenue and market assessment data;
- writing home care marketing plans;
- a sample marketing plan.

The workbook's primary focus is infusion therapy; however, it also includes information on home medical equipment and intermittent and extended care nursing services. *Creating a Marketing Plan* is available from NHIA, 205 Daingerfield Road, Alexandria, VA 22314. Telephone: (703) 549-3740. Fax: (703) 683-1484. E-mail: nhia@vais.net. Cost is $149 for NHIA members and $199 for nonmembers, plus $12 shipping and handling.

NHIA educational programming is cosponsored by the National Community Pharmacists Association. Register by calling NHIA at (703) 549-3740. ■

Joint Commission changes its pain standards

There are five new or revised Joint Commission on Accreditation for Healthcare Organizations (JCAHO) standards related to pain assessment and management, says **Darryl Rich**, PharmD, MBA.

Rich, JCAHO's associate director of pharmacy services for Home Accreditation Services, says these changes are effective on all surveys conducted after Jan. 1, 2000. "In the year 2000, they will be scored but will not count toward the accreditation decision or grid score."

The "Rights and Ethics" chapter stresses that under RI.1.1.8, the patient has the right to appropriate assessment and management of pain: "Pain can be a common part of the patient's experience. Unrelieved pain has adverse physical and psychological effects. The patient's right to pain management is respected and supported. The organization plans, supports, and coordinates activities and resources to assure the pain of all patients is recognized and addressed appropriately. This includes:

- initial assessment and regular reassessment of pain;
- education of relevant providers in pain assessment and management;
- education of patients regarding their roles in managing pain, as well as the potential limitations and side effects of pain treatments;
- after considering personal, cultural, spiritual, and / or ethnic beliefs, communicating to patients and families that pain management is an important part of care."

Make the commitment

Suggestions to home care organizations for implementing this include putting a commitment to pain management in its mission statement, patient and family bills of rights, or service standards. (For example: "Patients have the right to expect a quick response to reports of pain.")

The following statement on pain management is given to all patients receiving home health services in their admission information packets:

Patient Rights

As a patient of this home care agency, you can expect:
- your reports of pain will be believed;
- information about pain and pain relief measures;
- a concerned staff committed to pain prevention

and management;
• health professionals who respond quickly to reports of pain;
• effective pain management.

Patient responsibilities

As a patient at this clinic, we expect that you will:
• ask your nurse what to expect regarding to pain and pain management;
• discuss pain relief options with your nurse;
• work with your nurse to develop a pain management plan;
• ask for pain relief when pain first begins;
• help your nurse assess your pain;
• tell your nurse if your pain is not relieved;
• tell your nurse about any worries you have about taking pain medication.

JCAHO pain assessment defined

Pain is considered the fifth vital sign. Pain intensity ratings are recorded along with temperature, pulse, respiration, and blood pressure on the home care agency's flow sheet.

In its initial patient assessment, the home care agency identifies persons with pain or at risk for pain according to criteria developed by the patient care team overseeing pain assessment and treatment. Further assessment is then completed for patients identifying pain or at risk for pain.

All new patients and their families receive information verbally and in an electronic or printed format that effective pain relief is an important part of their treatment. Pain is assessed as a part of every patient contact if the patient reports pain or is at risk for pain.

The organization educates its entire staff, including nursing, pharmacy, home medical equipment, and respiratory care staff about pain, the untoward effects of uncontrolled pain, pain assessment, myths and barriers to reporting pain and using analgesics, and pain management. The organization also formulates a policy and procedure for those patients who report pain receive further assessment and appropriate management.

In the pain assessment chapter, new/revised regulations state that: "In the initial assessment, the organization identifies patients with pain. When pain is identified, the patient can be treated within the organization or referred for treatment. The scope of treatment is based on the care setting and services provided. A more comprehensive assessment is performed when warranted by the patient's condition. This assessment and a measure of pain intensity and quality (for example, pain character, frequency, location, and duration), appropriate to the patient's age, are recorded in a way that facilitates regular reassessment and follow-up according to criteria developed by the organization."

To implement this:

All patients are asked on admission the following screening or general questions about the presence of pain: Do you have pain now? Have you had pain in the last several weeks or months? If the patient says "yes" to either question, the organization, based on its scope of practice, either conducts an in-depth assessment or refers the patient for further care.

When clinicians consistently observe discordance between verbal self-report of pain and associated behaviors and ability to function, further assessment is done to ascertain the reason for the discordance. The discordance may be due to a variety of causes, such as stoicism, learned coping skills, expectations about the conditions necessary for adequate analgesia, previous experience that the medication will be immediately discontinued if pain is rated as improved, family dysfunction, or adversarial relationships among the individual, family, and health care team. A home care organization may want to seek out the expertise of an interdisciplinary team to consult on such patients, including representatives from social work, psychology, and chronic disease specialists.

All patients receiving home health services in the initial evaluation are asked the following screening or general questions about the presence of pain: Do you have pain now? Have you had pain in the last several weeks or months? If the patient responds "yes" to either questions, additional assessment data are obtained about the following elements:

• Pain intensity (use a pain intensity rating scale appropriate for the patient population; pain intensity is obtained for pain now, at worst, and at best or least; if at all possible make every attempt to use the same rating scale each time pain is assessed);

• Ask the patient to mark on a diagram or point to the site of pain; and about quality, patterns of radiation, if any, character, using the patient's own words whenever possible; onset, duration, variation, and patterns of pain; alleviating and aggravating factors; present pain management regimen and effectiveness; pain management history (including a medication history, presence of common barriers to reporting pain and using analgesics, past interventions and response, manner of expressing pain); effects of pain (impact on daily life, function, sleep, appetite, relationships with others, emotions, concentration, and so forth); the patient's pain goal (including pain intensity and goals related to function, activities, quality of life); and physical exam/observation of the pain site.

• A home care organization decides to use the 0-10 pain scale (0 representing no pain, 10 representing the worst pain imaginable) as its standard measure of pain intensity. However, certain populations may not be able to use this numeric scale, so the organization may need to use other pain scales for special patient populations such as infants and children, older adults, and the cognitively impaired. Developmental stage, chronological age, functional status, cognitive abilities, and emotional status should be considered in the choice of assessment methods and tools. To ensure continuity, the home care organization encourages its affiliated

hospitals, clinics, hospice program, and nursing home also to adopt the same pain intensity measures.

• Patients often have more than one site of pain. An assessment system or tools with space to record data on each site is provided on the assessment sheet.

• A home care organization may need to use more than one pain intensity measure. For example, an agency serving both children and adults selects a scale to be used with each of those patient populations. Assessment of cognitively impaired patients may also require assessment of behavioral factors signaling pain or discomfort.

• Staff are educated about pain assessment and treatment including the barriers to reporting pain and using analgesics. Staff encourage the reporting of pain when a patient and/or family member demonstrates reluctance to discuss pain, denies pain when pain is likely to be present (for example, postoperative, trauma, burns), or does not follow through with recommended treatments.

• For organizations using critical pathways or computerized documentation, pain assessment and management is incorporated.

• A home care organization serving children includes in its orientation materials for parents information about pain and pain assessment, including the parent's role in interpreting behavioral changes of the child that may indicate pain or discomfort.

Patients are educated on the pain assessment process and methods for pain management, as identified in the plan of care.

The goal of patient and family education is to involve patients and families in the management of the patient's pain. As part of its pain management improvement initiative, a home care agency provides information to all patients and families on admission about the common reasons why patients hesitate to report pain and use analgesics. Based on the reason for admission and the scope of services provided, additional information is given which addresses specific management options and the organization's policy and process to handle uncontrolled pain or pain management options.

Once is not enough

The literature indicates that, to have the desired effect, patient and family information should be presented more than once, and because patients and families seek information from multiple sources, in more than one way. For patients receiving home health services, specific information included in a comprehensive individual and family education program is as follows:

A. A general overview includes:

— pain can be relieved;

— the causes of pain;

— pain assessment and using a pain rating scale to communicate pain;

— using diaries to record pain occurrences, intensity, times of medication, and relief;

— talking to doctors and nurses about pain and pain management;

— using a preventive approach to pain control.

B. Pharmacological management information includes:

— use of drugs, with specific suggestions to optimize efficacy and safety;

— overcoming fears of addiction (psychological dependence) and drug tolerance;

— controlling common side effects of drugs.

C. Nonpharmacological management information includes deep breathing, relaxation, imagery, distraction, calming self-statements, heat, massage, and exercise.

D. Information about health care system issues includes using effective self-advocacy skills and behaviors in obtaining pain relief.

Scoring and additional information on JCAHO standards changes can be found on the group's Web site at www.jcaho.org. ■

Update on Prolastin

According to **Lorrie Kline Kaplan**, director of the National Home Infusion Association (NHIA), Bayer Corporation has not responded to NHIA's questions and concerns about the company's new marketing arm Bayer Direct, as raised in letter NHIA sent to Bayer last November.

"We have been receiving calls from patients who called to register for their Prolastin with Bayer Direct in early November — as soon as they heard about the new program — and they still have not received a single shipment of Prolastin. They have been calling daily and cannot even get a return call from Bayer. Bayer can take a step in the right direction right now by establishing a task force of patients, providers, and physicians to set up a truly fair and equitable ongoing health care system for Prolastin patients."

Bayer representatives were unavailable for comment. ■

Blood-clotting breakthrough

Researchers have found more details for how a key blood-clotting protein works. The new information could lead to new treatments for hemophilia, strokes, and heart attacks. The protein, known as human factor VIII, is partly responsible for stopping bleeding after injuries. Hemophiliacs are often treated with infusions of that protein, but sometimes develop an immune reaction that causes factor VIII to cease working. One in 10,000 American men have hemophilia, which is carried by women but does not affect them.

Mapping the protein at the atomic level showed scientists how it interacts with other molecules to form blood clots, or, as in the case of hemophiliacs, why bleeding does not stop. It appears that a specific region of the protein is responsible for finding injury to the circulatory system and triggering the clotting response. A detailed "map" of the region may be used to help design drugs to target those areas, possibly enabling drug developers to create new variations of the protein that can outfox the patients' immune systems.

Developing drugs that have the opposite effect for patients at risk of stroke or heart attack may also be expedited by factor VIII. Unlike current blood thinners, drugs that only target the factor VIII protein would likely have few side effects. ▼

ZYVOX seems safe through Phase III trials

"There is currently a very real clinical need for a well-tolerated antimicrobial available in both IV and oral formulations that is effective against gram-positive bacteria that are resistant to currently licensed drugs. Such a medication in both IV and oral formulations would help ensure that patients could complete their course of therapy in the most convenient way possible," says **Robert Moellering**, MD, physician-in-chief and chairman, the Department of Medicine, Beth Israel Deaconess Medical Center in Boston.

Moellering, speaking at the 37th annual meeting of the Infectious Disease Society of America, also commented that "the safety profile for ZYVOX is promising."

ZYVOX has been developed in both IV and oral formulations. The oral formulation is 100% bioavailable, meaning no dose adjustment was necessary when switching from IV to oral dosing in clinical trials. Phase III clinical trial data released last September suggest that ZYVOX is effective in treating infections caused by gram-positive bacteria. The availability of an IV, tablet, and oral suspension formulation of ZYVOX would allow physicians to select the appropriate administration route for their patients.

Data collected during several large Phase III clinical trials for ZYVOX (linezolid), an investigational new antibiotic under development by Pharmacia & Upjohn, evaluated the safety of ZYVOX in the treatment of infections caused by gram- positive bacteria. The incidence of all individual drug-related adverse events in patients treated with ZYVOX and patients treated with active comparators was less than 5%.

Information presented included summaries of adverse events for 2,046 patients treated with ZYVOX and pooled results for 2,001 patients treated with active comparators. The most common side effects reported for patients treated with ZYVOX were similar in incidence and severity to the most common side effects reported for patients treated with commonly used antibiotics selected as the active comparators in the trials. The most frequent drug-related adverse events in both the group treated with ZYVOX and the group treated with comparators included mild to moderate diarrhea, nausea and headache, which each occurred in 5% or fewer patients in both groups. The comparators included ceftriaxone and cefpodoxime proxetil (cephalosporins), dicloxacillin and oxacillin (beta-lactams), clarithromycin (a macrolide), and vancomycin (a glycopeptide). ▼

I-Flow incision pain product gets FDA approval

I-Flow Corp., manufacturer of drug infusion systems, recently announced that the Food and Drug Administration has approved marketing of the company's Soaker Catheter, used for pain management of large surgical incisions. The

catheter distributes fluid in the same manner that a soaker hose saturates a lawn, allowing the delivery of local anesthetic without the undesirable side effects of narcotic pain relievers. "I-Flow's Soaker Catheter provides a continuous, even infusion of a non-narcotic, local anesthetic directly across long incisions for post operative pain management for such surgeries as hysterectomies, C-sections and open-heart procedures," says **Donald Earhart**, I-Flow's CEO. ▼

Liver cell infusions look promising

Two studies presented at the Radiological Society of North America annual meeting in November indicate that infusions of liver cells can keep patients alive while they are waiting for hard-to-find liver transplants. Compatible liver cells from donated livers or parts of livers that were left over after a transplant were injected into either the liver or spleen of 12 patients in Virginia. Four patients died while waiting for a transplant, but the others lived and received transplants.

The second study done at the University of Nebraska Medical Center in Omaha, NE, involved five patients. One, an infant born with a liver defect, was kept alive with an infusion for five months before receiving a successful transplant. Another, an 11-year-old girl with a genetic liver defect, is still alive two years after receiving a cell infusion and does not need a transplant. Three others in that study died. ▼

Shortage of one type of penicillin

The shortage of one type of intravenous penicillin, which began last spring, has grown — causing the government to urge doctors to use remaining supplies carefully. However, officials of the Food and Drug Administration (FDA) say there is no cause for alarm as intravenous penicillin G is the preferred therapy for only a handful of rare infections, for which other types of penicillin or newer antibiotics can also treat successfully. Those conditions include babies born with syphilis and people whose syphilis has spread to the nervous system, and prevention of group B streptococcus from spreading in pregnant women to the fetuses they carry.

The shortage began in June, when Marsam Pharmaceuticals ceased to manufacture the drug and called its supplies due to an inspection that cited serious manufacturing deficiencies the FDA said raised questions about the drug's safety. Pfizer Inc., the other major manufacturer of IV penicillin G, has back orders with pharmacies awaiting new supplies as soon as it can make them. The FDA is working to increase IV penicillin G supplies by helping Pfizer and other suppliers increase their production. It is also considering imported supplies. ▼

Medicare should pay for diet advice

The Institute of Medicine, the medical arm of the National Academy of Sciences, says Medicare should pay for coverage of patients sent home with feeding tubes for intravenous feeding. Currently, Medicare treats the feeding as a device, not a service.

Three separate panels reported on whether Medicare should pay for immune-suppressing drugs for transplant patients, nutritional services, skin cancer screening, and patients taking part in clinical trials.

Congress recently extended coverage of the immune-suppressing drugs that must be taken by patients for life after an organ transplant from three years to 44 months, or just over three and a half years. The Institute's report calls for eliminating this time limit, and says that Medicare benefits should include nutritional counseling for some patients and should pay for pricey but vital transplant drugs for a patient's life.

COMING IN FUTURE MONTHS

- PPA effect: Elimination of venipuncture benefit fallout
- Sound off: The use of ultrasound in infusion therapy
- Outcomes: Designing a work model that works
- Unapproved drugs: A lawyer looks at de-clotting lines

"The committee recommends that nutrition therapy, upon referral by a physician, be a reimbursable benefit for Medicare beneficiaries," the report said, noting that it is very hard to change to a healthy and many elderly patients cannot make the changes without help. ▼

Clinical point-of-care documentation system improved

Simione Central Holdings Inc. has released version 2.5 of The Smart ClipBoard clinical information system.

The Smart ClipBoard is the home health care industry's leading Windows 95, pen-compatible, clinical information system. It provides a clinical solution designed to assist home health care providers in co-managing the cost and quality of the care they deliver through an understanding of their clinical and administrative processes. Version 2.5 offers improvements to the existing Smart ClipBoard functionality including improved replication, plan-of-care merge function, user-defined ICD-9 subsetting, revised order screens, and several new report options.

For further information, contact **R. Bruce Dewey**, president and CEO, at (770) 644-6700. Web site: www. simcen.com. ▼

CINA relocates

The Canadian Intravenous Nurses Association (CINA) has relocated its office to 18 Wynford Drive, Suite 516, North York, Ontario, M3C 3S2, Canada. Telephone: (416) 445-4516. Fax: (416) 445-4513. E-mail: cinacsot@idirect.com. Web site: www.web.idirect.com/~csotcina. ▼

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

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

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Editorial Questions

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Latex gloves used in handling food an allergen contaminant

The latest research in latex allergy points to food handlers who wear latex gloves as a potential danger.

According to a study presented by D.H. Beezhold at the 1999 annual meeting of the American College of Allergy, Asthma, and Immunology, latex glove use by food handlers can be the source of latex allergen contamination. Immunodetection showed that fingerprints of latex protein could be lifted on cheese touched with powdered latex gloves, but not with vinyl gloves.[1,2] Transfer of latex protein to lettuce was also tested using an inhibition ELISA for latex protein. Again, traces were detected on lettuce handled with powdered gloves.

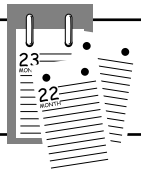
Since patient avoidance is currently the only method of preventing adverse reactions to latex, the results of those tests are especially significant. To avoid such unsuspected exposure, food handlers should either follow appropriate hygienic procedures or use nonlatex gloves.

References

1. Beezhold DH, Reschke J, Allen J, et al. Latex protein: A hidden food allergen. Abstract 50. Program and abstracts of the 1999 annual meeting of the American College of Allergy, Asthma, and Immunology. Chicago; November 1999.

2. Bahna S. *New Findings in Food Allergy Research.* Program and abstracts of the 1999 Annual Meeting of the American College of Allergy, Asthma, and Immunology. Chicago; 1999. ■

CALENDAR



• **Intravenous Nurses Society Annual Meeting** — May 8-11, Minneapolis. For more information, call (617) 441-3008.

• **Ninth Annual National Home Infusion Association (NHIA) Conference** — May 17-20, Fort Lauderdale, FL. For more information call (703) 549-3740. Fax: (703) 683-1484. E-mail: nhia@vais.net.

• **NAVAN** Annual Conference, Sept. 6-9, San Diego. For more information, call (888) 57-NAVAN.

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

CE objectives

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

1. Describe effective infection control procedures.
2. Discuss four kinds of reimbursement codes.
3. Define changes in the Health Care Financing Administration's ability to use "inherent reasonableness."
4. Cite changes in the Joint Commission on Accreditation for Healthcare Organizations' standards for pain assessment and management. ■