AMERICAN HEALTH CONSULTANTS®

CHF DISEASE MANAGEMENT™

The Complete Congestive Heart Failure Resource

INSIDE

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Experts say success with CHF is now tied to information age

Research, daily care depend on getting and using the right data

What do caregivers need to improve the services CHF patients receive today? Regardless of their particular station along the checkpoints of CHF treatment, many say it comes down to getting the right information and being able to use it well.

Pharmaceutical investigators, for example, had anticipated a spring approval of the new natriuretic peptide, Natrecor (nesiritide), to treat acute episodes of heart failure during hospitalization. The researchers produced plenty of information to show the preparation is effective. But regulators from the Food and Drug Administration (FDA) still need to know more about the risks associated with its use, especially with symptoms of hypotension.

Expecting to sail through the approval process, the investigators learned they needed to be more specific about how data were collected on patient side effects. They are now determining how to provide the information the FDA still needs for the drug's approval.

Observers can call for a change in focus in the CHF data being collected.

Researchers have known for a long time that men and women develop and experience heart disease in distinct ways. New studies are showing some sex differences carry over into CHF care. But researchers say women have been severely underrepresented in heart failure studies and such information is just becoming available now. It

KEY POINTS

- CHF caregivers say generating and using the right information is key to improving the way CHF patients are treated.
- Observers can call for a change in focus on where data are being collected, such as concentrating on CHF issues particular to women.
- New technology that organizes and presents information can mean better access for patients and an easier method of handling patient volume.

will take much more investigation to provide caregivers with the missing data they need to get a better handle on women's heart failure and how it relates to their male counterparts.

Collecting and acting on information has long been part of taking care of CHF patients. Today caregivers often take to the telephones to track patient status between formal office visits. But newer tools like e-mail, electronic patient files, and computer software can literally keep more lines of communication open between clinician and patient, so problems can be identified and patients realize people care about them.

CHF Disease Management presents the following articles with hopes that information will be useful to you. ■

FDA: More information needed on nesiritide

Rejection sends investigators back to more trials

A bid to put a new acute care drug for hospitalized CHF patients into use by this summer hit a snag April 27, when the Food and Drug Administration (FDA) rejected a new drug application for nesiritide.

Investigators had been rallying on the drug's earlier successes. In January, the FDA's Cardiovascular and Renal Drugs Advisory Committee recommended the formal panel approve the biologically engineered natriuretic peptide.

In March, researchers presented their results at the scientific meeting of the American Heart Association, demonstrating how the drug can reduce CHF symptoms as well as improve hemodynamic values such as capillary wedge pressure and cardiac index. **(See *CHF Disease Management*, May 1999, p. 56, for more on the optimism for nesiritide.)**

KEY POINTS

- The Food and Drug Administration rejected a new drug application for the genetically engineered drug nesiritide.
- Researchers say they still need to define when associated hypotension is clinically significant.
- New clinical trials are needed to collect the data, which should take another year.

But in making the recent decision, the FDA noted there were important data still unknown such as the specifics relating to the risk of hypotension.

"My impression is that this is an approvable drug," says **William T. Abraham**, MD, researcher and director of the heart failure and cardiac transplantation section at the University of Cincinnati College of Medicine. He notes, however, the FDA wants more data on the ratio between benefit and risk.

Right up to the application, regulators had plenty of proof about the benefits. "They said unequivocally the drug is effective," Abraham says, adding that now it's time to widen the database on how blood pressure can drop in some patients.

Defining the parameters

He notes the researchers now have to be more specific on defining the parameters of hypotension. At the time of the FDA decision, the researchers had learned that generally:

• At a dose of 0.015 mcg/kg/min, 8% of the subjects suffered hypotension.

• At a dose of .03 mcg/kg/min, 14% of the patients became hypotensive.

Abraham says these trials did not standardize when hypotension was clinically significant. If

COMING IN FUTURE MONTHS

- ■ Highlights from a CHF hospital round table
- ■ The biochemistry of CHF
- ■ Tips to help patients limit fluid intake
- ■ Five effective strategies for reducing readmissions
- ■ Prioritizing and managing comorbidities

More About Nesiritide

- ❤ Pending Food and Drug Administration (FDA) approval, it will be sold under the brand name Natrecor.
- ❤ It was developed by Scios, Inc. — a biotechnology firm in Sunnyvale, CA.
- ❤ Scios entered an agreement with Bayer AG to market the drug.
- ❤ In a company press release, Richard B. Brewer, president and chief executive officer, noted his disappointment the drug did not gain FDA approval but said he will work toward securing that approval. Company representatives say they had no further comment until clinical trials get under way.

one patient, for example, reported feeling dizzy or lightheaded, it would probably prompt the doctor to check the blood pressure to note if it was low.

But it's possible to have another patient not feel dizzy at the same blood pressure reading. In this instance, there would not be the complaint present to signal a blood pressure check in the second patient. So not every instance of hypotension was recorded.

At press time for this issue of *CHF Disease Management*, Abraham says he has been talking with other investigators by phone, designing new clinical trials that would record the blood pressure symptoms and readings in the new subjects treated with the drug.

"My expectation is it probably will take one or two additional moderately sized multicenter studies." The new project should take about a year, he says, which should provide the FDA with the information needed to approve the drug and make it available to U.S. hospitals.

A need for a nesiritide

Abraham says he still is optimistic about the drug. Although the FDA rejected the first attempt at getting it approved, it should not be difficult to provide what is still needed.

"They could have set the pole very high if they did not want it approved," he says.

Today, when CHF patients can't keep the disease under control and need to go to the hospital, they often need drugs, which carry their own risks, says **David S. Roffman**, PharmD, BCPS. Roffman is associate professor at University of Maryland's School of Pharmacy in Baltimore and a therapeutic consultant for the cardiac care unit in the University of Maryland's Medical System.

He says patients in this situation often need to be given dobutamine or milrinone. These inotropic agents have a potential to create tachycardia. (Rhythm disorders also can result, but they are less common.)

"The newer agents, which are not inotropics, may give us a safer way to manage patients," he says.

An added benefit to the drug is that although it is a vasodilator, it has properties of a diuretic. That can be helpful, Roffman says, as CHF patients often have become resistant to traditional loop diuretics. Because the natriuretic peptides work on a different level of diuresis, it gives new opportunity to help hospitalized patients shed some fluid.

Seeing the hypotension associated with nesiritide use is no surprise, he says, since nesiritide is a vasodilator. But doctors need to know the specifics about how a drug may drop the blood pressure in CHF patients. Many times, he says, a CHF patient already has low blood pressure, but it is fairly stable and usually doesn't go down significantly on its own.

Another drug to titrate

"The issue of titration is a practical one," Roffman continues. Doctors have to know how to gradually work patients up to effective levels of medications without bringing on too many symptoms that outweigh the benefit they are trying to get with the drug.

Research also had to work out the specifics of titrating established CHF drugs like beta-blockers. "Don't forget that beta-blocker research has been going on for 15 years," he says. And once doctors knew how to titrate it, they could then change their goal to demonstrating how it could improve the survival of these patients.

Roffman says he suspects the learning curve will be easier than the one doctors experienced with beta-blockers. He notes the natriuretic peptides are being developed specifically for treating heart failure. Other types of drugs — like the beta-blockers — were developed for treating different types of disease such as hypertension, and doctors had to learn how to make the transition to using them to treat CHF patients. ■

Women have advantage with some types of CHF

Observers intrigued, but more research needed

A study from the University of North Carolina in Chapel Hill reports that under some specific conditions, women with severe heart failure had better survival than men with similar disease.

Kirkwood F. Adams Jr., MD, and his team re-examined FIRST data (Flolan International Randomized Survival Trial) to compare the outcomes of men and women who had either NYHA Class III B or IV heart failure.

Difference in non-ischemic disease

In the study group, men were more likely to be white and have developed their CHF after suffering ischemic heart disease. But when comparing only the patients who developed CHF from non-ischemic causes, men had three times the relative risk of death than women. The researchers did not find statistically significant difference in risk between the sexes in ischemic-based CHF.

The original study, FIRST, assembled 471 patients to test the drug. (The FIRST trial was stopped early because of higher mortality among subjects taking the drug.)

The patients had these characteristics of end-stage heart failure:

❒ severe left-ventricular ejection fraction of 18 +/- 4.9%;

❒ standard drug therapy regimen including a loop diuretic, digitalis, and ACE inhibitor for at least a month;

❒ cardiac index of less than 2.2 L • min^{-1} • m^2;

❒ pulmonary wedge pressure greater than 15 mmHg (unless on intravenous vasoactive drugs).

Patients also received non-invasive tests, which included a six-minute walk test. Participants were then assigned to one of four primary CHF causes: ischemic, hypertensive, idiopathic, or other.

The patients were randomized to the drug or standard CHF care and followed up with clinical visits after two weeks and one month, then returned monthly. Home health visits were also used to make sure patients were seen at least twice a month.

In addition to gender of the patient, the original study was designed with these CHF characteristics as patient variables:

❒ age;
❒ race;
❒ height, weight, body surface area, and body mass;
❒ geographic location by continent;
❒ primary cause of CHF;
❒ NYHA functional class;
❒ use of dobutamine at baseline;
❒ diabetes history;
❒ CHF duration;
❒ atrial fibrillation;
❒ serum sodium;
❒ serum creatinine;
❒ cardiac index;
❒ pulmonary artery wedge pressure;
❒ right atrial pressure;
❒ systolic blood pressure;
❒ mean pulmonary artery pressure;
❒ heart rate;
❒ left-ventricular ejection fraction;
❒ six-minute walk test results;
❒ group randomization.

Women won in the survival comparisons after many statistical adjustments.

Adams' team corrected for CHF variables in many different ways, but women still had increased survival in cases of non-ischemic heart disease. The trend of men having about twice the risk of death held whether the team adjusted for the long list of baseline characteristics, those that were found to be independent predictors of survival, or omitted results on the walk test.

Some observers say they find the study and results interesting.

"It's a confirmatory finding," says **Amparo C. Villablanca**, MD, director of the Women's Cardiovascular Health Program and clinic at the University of California, Davis, School of Medicine. The Framingham Heart Study has

KEY POINTS

- A study from the University of North Carolina found women have a survival advantage compared to men in cases of CHF of non-ischemic origin.
- The survival advantage is seen only in a small subset of overall CHF patients.
- Observers say the study is needed to fill in the gaps of what is known about the disease in women.

made similar findings, she says, so the concept that women may have a survival advantage in some types of heart failure is not new.

The study is helpful, she says, because it hints at how the cause of the heart failure can make a difference in patient survival.

Villablanca says a caveat of the study was the results of the formal interaction testing. When the researchers tested the relationship between the cause of heart failure and the association of gender with outcome, the result was not statistically significant. But when they performed a stratified analysis based on whether ischemic or non-ischemic disease caused the heart failure, the result was statistically significant. "It really depended on how they looked at it."

Villablanca adds the study is interesting because it showed fewer patients died overall who had ischemic-based CHF, compared to patients who had non-ischemic disease.

It's important to remember the study was only reporting on a subset of all the people with heart failure, Villablanca says, considering the majority of heart failure cases occur as a result of ischemic heart disease.

And another consideration is that women who infarct usually go on to do worse than men who have a myocardial infarction, says **Marjorie Stanek**, MD, director of the Women's Heart program at Albert Einstein Medical Center in Philadelphia.

Both Villablanca and Stanek say it also would have been interesting to know if any of the female subjects were on hormone replacement therapy. But both say it's a good continuation of looking at how heart disease affects women.

Interesting details of the study

The FIRST trial used a six-minute walk test to help assess the extent of the subject's heart failure. Overall, women could not walk as far during that time as men could, although women had a better chance for survival. The difference in performance can be attributed to several different facets of the patients, say Stanek and Villablanca.

First, overall, women in the study were older than the men. With age could have come comorbidities or just age-related symptoms that could have kept women from walking as far as men.

Also, men may tend to push a little harder during exercise, says Stanek, who is also the director at Einstein's cardiac stress lab.

The walk test was not the sole determinant of severity of disease, adds Villablanca, noting the original study looked at factors such as use of Dobutamine at the onset of the research. ■

Missing: Adequate data on CHF in women

After searching through the literature, comparing the CHF findings between men and women, a Scottish team not only mapped out differences between the sexes, but notes there are dramatic unknowns that need to be studied — if researchers are interested enough to pursue them.

"I'm sure women have been neglected, but we do not know why," says **John J.V. McMurray**, MD, FRCP, FESC, from the Medical Research Council Clinical Research Initiative in Heart Failure in Glasgow. McMurray responded to questions from *CHF Disease Management* through e-mail.

"Do they not get referred to a hospital? Are they not asked to participate in trials? Do they refuse to participate in trials? Do upper-age limits or exclusion comorbidities disproportionately exclude women from trials?" McMurray speculates. "We simply don't know but should!"

McMurray and the rest of the team found numerous differences in CHF in women. Here are just a few highlights:

1. Among patients suspected of CHF, left-ventricular systolic dysfunction is not as common in women.

2. The numbers of CHF patients are about equal between the sexes, but women are older.

KEY POINTS

- After reviewing the literature on CHF, a research team from Scotland reports CHF has distinct characteristics in women that go largely unstudied.
- It's not known why women are so understudied in CHF trials.
- Women frequently exhibit CHF symptoms without showing left-ventricular systolic dysfunction, which may in part be attributed to obesity. There also may be types of CHF unique to women.

3. Women have distinct differences in CHF risk; more go on to develop it once they have hypertension.

4. While women are not as likely to get coronary artery disease compared to men, when they do develop it, more go on to CHF than men. In black CHF patients, more females have coronary artery disease than men.

5. Women are more likely than men to develop CHF after coronary bypass graft.

6. Of CHF patients, women are more likely to be diabetic and exhibit their own type of cardiomyopathy and left-ventricular wall mass.

7. For treatment, women are more likely to be treated by generalists. They are less likely to be referred to a hospital. When they are hospitalized, women are less likely to go to a teaching hospital and are less likely to be managed by a cardiologist.

8. Women with CHF appear to have lower quality of life and exercise performance.

"We basically compared men and women in all published reports concerning (1) heart failure — with no determination of left-ventricular systolic function and (2) heart failure, where, by definition, all patients had a low LVEF," says McMurray.

Also, the team asked what could be wrong with women who don't seem to have left-ventricular systolic dysfunction, yet lead their doctors to believe they have heart failure.

McMurray says he suspects obesity is "almost certainly an issue," and that "there may well be a different 'female heart failure' syndrome where 'diastolic function' or something else we haven't thought of is important."

Suggested reading

1. Adams KF, et al. Gender differences in survival in advanced heart failure. *Circulation* 1999; 14:1,816.

2. Petrie, et al. Failure of women's hearts. *Circulation* 1999; (17):2,334. ■

Three approaches to telemanagement

It's a simple concept: Use trained caregivers to stay connected with CHF patients over the phone. Here's how three different facilities make it work for their program.

Case 1: The heart failure and transplantation unit at MCP Hahnemann University Hospital, Philadelphia.

It takes four full-time nurses to keep up with the needs of 800 CHF outpatients. One additional nurse works with in-patients, teaching and interacting with house staff.

If it's a clinic day, as many as three out of the four nurses will be on the phone. "More often than not, they're on the phone all day," says unit director, **Jane Fitzpatrick**, MD.

The nurses all have bachelor's degrees in nursing. Some are advanced practice nurses. Fitzpatrick says it's preferred if the nurses have a master's degree, such as in education or practical nursing because it is helpful in their roles as patient counselors and teachers. There have been "diploma nurses" on the phones as well.

"It's probably not necessary all are advanced practice," Fitzpatrick says, adding what counts is to have had the training and experience that gives some autonomy to the job, which is very different from the traditional office nurse. Overall, there is a "nice mix" of experience and training among the telephone staff.

They need it, she says, because they are handling so many different tasks over the phone. For example, patients may need direction with their diuretics because they have gained two pounds. Some may be renal patients, with delayed response to diuresis, so it may take longer to see the desired effects of the therapy. Others may be upset about their symptoms or need explanation about how to

KEY POINTS

- Telemanagement of CHF patients is becoming an integral part of controlling the disease.
- Facilities find providing the service is a full-time commitment to staffing, research, and new technologies.
- Getting everyone on board means issuing standard forms to fill out, education materials, and references.

take their medicine or need to hear again why they are taking it. Nurses keep up with how other doctors are treating the patients — making sure the patients haven't been taken off standard CHF therapies. Those cases, in particular, call for some diplomacy with consulting physicians who may not realize an ACE inhibitor cannot just be stopped.

Standard issue: Nurses

Each nurse gets an independent outside phone line and personal voice mail.

They are armed with photo charts of all medications patients usually receive and give a copy of the grid to each patient. All is standardized so the nurse can instruct the patient to trace a finger down a particular column and over two others to find the right one to take. But with generics coming out with different versions of the same drug all the time, the task still is difficult. Patients learn they need to come to the phone with their drug grid and their medication containers so they will know what to do.

Nurses also use a sliding scale for diuretics. If patients begin to gain weight, there is a corresponding response that is appropriate for them. Fitzpatrick says few patients are able to regulate their own diuretics at home and usually call in with their changes in weight to be advised on how to adjust diuretic dosing. "The majority of patients are not facile with that," she says.

Standard issue: Patients

Beside the medication charts, patients can get automated prescription refills. Pharmacists know containers have to have the medication name on them as well as instructions. Prescriptions are verified with the unit to make sure dosing and instructions stay current.

Patients can reach the nurses during regular business hours. All other times, their calls go to on-call staff. At the end of each shift, the nurses sign out to on-call staff and the next shift that will be coming in the next day.

At the beginning of a shift, staff can listen to the sign-out report and know what happened the night or day before and what may be expected to happen during the day. Often, a patient who may have called in the night before needs a follow-up call to make sure everything is under control and that he or she isn't stressed, since it can be frightening to have to call at night, Fitzpatrick says.

"It's upsetting to have to call in at night. But nurses can reassure patients, saying 'It's OK that you have these symptoms. We should be expecting this, and we have ways to help.'"

An exception is pre-transplant candidates, who work through their assigned case coordinator.

Days are divided into three parts for nurses who handle the phones: receiving calls, consulting doctors about them, and getting back to the patients with instructions.

Fitzpatrick says nurses are encouraged to learn how to anticipate the doctor's response, so they will say to the doctor, "I know when this usually happens, you tell the patient to do this — is that right in this case?" Not only does anticipation help with the interaction with the physician, but the patient can be prepared, too. Before ending a call, the nurse can prepare patients by telling them how the doctor probably will instruct them.

Patient charts are updated as changes happen. Staff also try to determine any trends they are experiencing, such as patients who are calling a lot. That could indicate there are deeper problems or issues that need to be addressed, she says, such as if patients are anxious or do not have a good support system at home.

"What we are trying to get across is a concept that this is a partnership. It does no good to give patients a treatment routine they are not able to follow," Fitzpatrick explains.

Tips

Fitzpatrick says these are some common situations that phone staff not only have to know about, but attempt to search out and diffuse:

- ❤ Be wary of confused patients. Patients often do not understand what they need to do and which medication is which.
- ❤ Be careful when giving medical or drug information over the phone. Use a standard chart, get patients to read the directions and other drug information on the bottle over the phone to you so you know you are talking about the same prescription. Make sure the drug name and directions are printed on the bottle, even refills.
- ❤ Tell patients to avoid finishing a prescription before getting a refill. Not only do patients run low, but if they use the last pill, they have nothing to use as an example when they get on the phone for help.

❤ Verify with the pharmacy what medications patients are taking so dosages stay current and everyone stays on the same page.

Look out for pitfalls

Other physicians treating your patients may change a prescription or instruction that is vital to controlling CHF. Fitzpatrick says her team really urges all physicians to keep in touch with them about any new drugs or instructions patients may be getting after an appointment — which could be something completely separate from CHF, since comorbidity can be common. "We like to be on top of that," she says. "A lot can happen between patient visits on clinic days."

"We've seen some disasters that can befall patients," she continues, noting it can often be traced back to an outside physician changing the regular routine. He or she may stop the ACE inhibitor because the blood pressure is low. "That's really unacceptable," Fitzpatrick says. Other doctors may take patients off of diuretics when the team has been trying to titrate them on beta-blockers. "Not being on the same page could lead to needing to admit the patient; it can lead to an admission that can be avoided."

The patient's diet should also be considered. Be aware of how consistently patients eat particular foods. Green, leafy vegetables, for example, contain a lot of vitamin K, which can affect the absorption of drugs like Coumadin. So a patient who eats a lot of these foods may need to be put on higher doses to get the right amount of drug in the body. But if the diet changes, more drug may be absorbed, sometimes becoming harmful. Grapefruit juice is another potential confounder. It can add to the absorption of antihypertensives. *(Editor's note: For more information on the effects of grapefruit juice on drug absorption, see the April 1999 issue of* Pharmaceutical Research*, produced by the American Association of Pharmaceutical Scientists.)*

Patients suffering from pulmonary pressure caused by excess fluid build up may get relief from a nitroglycerin tablet or spritz with the spray. "We have had a very good success rate," Fitzpatrick says, noting it may be needed especially at night, when patients lie in bed and fluids can settle. Many calls are prompted when this happens and patients wake up short of breath and can become excited.

Fitzpatrick says the key to a successful telemanagement service is to offer patients as much easy access to help as possible. She says her unit is just starting to make e-mail available to patients, which will help them communicate with staff without having to call. Staff also can leave written e-mails to the next shift as part of their sign-off routine. And ultimately, having patient files available in an electronic format would make them more accessible as well as make them easier to update.

Case 2: Vivra, a telemanagement contractor for patients in south Florida, Massachusetts, Rhode Island, Connecticut, Virginia, Maryland, and Delaware.

A staff of 25 registered nurses manages 2,800 patients with CHF for this telemanagement contractor, says Vivra vice president **Frank Basile**, MD. Nurses have either formal training in CHF management or a "tremendous amount" of experience working with cardiovascular patients. Nurses work an eight-hour shift each day.

Insurance companies usually contract with Vivra to cover their customers in a particular region, then the firm gets involved with the area's doctors. Vivra operates in south Florida, the Northeast (MA, RI, CT), and the Mid-Atlantic (VA, MD, DE). Calls may come from any of the regions, but they go to the telemanagement center in Maryland.

Basile says there are three primary goals Vivra tries to accomplish when interacting with patients by phone:

1. Understand and assess patient symptoms (such as breathlessness or changes in weight).

2. Monitor the level of compliance (with items such as diet and medication).

(Continued on page 71)

Alert from the American Medical Association

The American Medical Association recently released a Quality Care Alert on offering the pneumococcal polysaccharide vaccine to many different groups of patients who could benefit from the protection. **(See copy of alert, pp. 69-70.)**

The elderly, CHF patients and those suffering comorbidities such as diabetes are all included. ■

Quality Care

ALERT

Important New Developments in Patient Care

Prevention of Pneumococcal Disease: Use of the Pneumococcal Polysaccharide Vaccine

The Issue: Pneumococcal disease, caused by the *Streptococcus pneumoniae* bacterium, kills 10,000 to 20,000 people a year in the United States—typically resulting in more deaths per year than any other vaccine-preventable bacterial disease—and annually accounts for approximately 225,000 cases of hospitalized pneumonia, 52,000 cases of bacteremia, and 3,000 cases of meningitis.[1] Moreover, resistance of *S. pneumoniae* to antibiotics, especially penicillin, has increased dramatically,[2,3,4,5] and strains resistant to oral antibiotics have been identified. While a safe and effective vaccine is available,[2,4] pneumococcal immunization rates remain as low as 45% in the vulnerable over-age 65 population.[2,6]

This ***Quality Care Alert***, developed collaboratively by physician members of relevant medical specialty societies and the American Medical Association, provides a synthesis of the most recent evidence/recommendations for use of the pneumococcal polysaccharide vaccine. In this era of antimicrobial resistance,[3] the importance of pneumococcal immunization cannot be overstated.

Recommendations: All persons at ***increased risk of invasive pneumococcal disease should be immunized,*** including:

- Immunocompetent persons aged ≥65 years.[2,7]
- Immunocompetent persons aged 2-64 years with chronic illnesses, including persons with: cardiovascular or pulmonary disease, including congestive heart failure, cardiomyopathies, chronic obstructive pulmonary disease, recurrent bronchitis, and emphysema, diabetes mellitus, alcoholism, chronic liver disease, including cirrhosis, cerebrospinal fluid leaks, and functional or anatomic asplenia, including sickle cell disease and splenectomy.[2,4,5,7]
- Immunocompetent persons aged 2-64 years in special environments, including: persons in nursing homes or other long-term care facilities, and certain Native American populations and the Alaskan-American population.[2,4,5,7]
- Immunocompromised persons aged ≥2 years, including persons with: functional or anatomic asplenia, including sickle cell disease and splenectomy, Hodgkin's disease, lymphoma, leukemia, multiple myeloma, chronic renal failure, other conditions, such as organ transplantation, or drug regimens causing immunosuppression, and HIV infection.[2,4,5,7]
- Persons in identified risk groups whose vaccination status is unknown or uncertain.[2]

Revaccination: Because the benefits and safety of the vaccine appear to outweigh its risks, in the absence of firm evidence/consensus to support or refute revaccination, ***<u>revaccination</u>*** is recommended ***<u>once</u>*** for the following high risk individuals:

- Immunocompetent persons ≥65 years of age, if the person received his/her first vaccination before age 65 and if more than 5 years have elapsed since that first dose.[2,4]
- Immunocompromised persons and persons with asplenia, if the person is >10 years of age and more than 5 years have elapsed since the first vaccination; if the patient is ≤10 years of age, consider revaccinating once after 3 years have elapsed since the first vaccination.[2]

continued

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Other Considerations:

- In order to minimize ***missed opportunities***,[8,9,10] pneumococcal immunization status should be assessed—whenever feasible—during any health care encounter. **NOTE:** If appropriate, health care personnel should avail themselves of the same opportunities to inquire about other immunizations, especially influenza.
- ***Pregnant women*** at increased risk of invasive pneumococcal disease (risk categories noted above) may be vaccinated, preferably during the second and third trimesters of pregnancy.[6,11]
- The effectiveness of the current polysaccharide vaccine has not been demonstrated against non-invasive (non-bacteremic) pneumococcal disease—upper respiratory tract infections, otitis media, sinus infections—in the elderly and other adults at increased risk (risk categories noted above).[2,4]
- The currently available vaccine is **not** recommended for children less than two years of age because it has not been demonstrated to be immunogenic in this population.[2,3]
- The vaccine is covered by ***Medicare.***[12]

For additional information, call your specialty or local medical society, the National Immunization Program (404 639-8254), or the National Center for Infectious Diseases (404 639-2215).

In addition, the following references may be useful:

1. Personal Communication: Benjamin Schwartz, MD, Assistant Chief, Epidemiology Section, National Center for Infectious Disease. Centers for Disease Control and Prevention. August 20, 1998.
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This *Quality Care Alert* is an educational mailing that recommends the use of pneumococcal vaccine for select patients. It is not a fixed medical regimen; it identifies a course of vaccination as recommended by experts in the field and researchers in the medical literature. Individual patients may require different treatment. Treatment must be based on individual patient needs and professional judgment. No information contained herein should be construed as medical advice constituting the practice of medicine. This *Quality Care Alert* should be viewed as an important communication from the medical community, which may prompt the physician to investigate the appropriateness of pneumococcal vaccination for his/her patients. Publication herein does not suggest an endorsement of content or a validation of conclusions by the AMA or any of the referenced organizations or individuals.

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3. Emphasize and repeat key educational messages (to make sure messages are understood).

"That's really it in a nutshell," Basile says. "If you can achieve these things over the phone, you are going to do very well."

Standard Issue: Vivra and physicians

Nurses are guided through the course of each call with a computer software package. Basile says Vivra's company protocol for handling each call is embedded in the software. Depending on the particular needs of the caller, questions and alerts pop up on a screen to guide the nurse handling the call, making sure Vivra's three main goals are achieved.

Vivra also sends a form to the patient's doctor to fill out according to the patient's treatment. Copies of the form go to the doctor, Vivra, and the patient.

"We're all on the same page," Basile says. He notes that the form represents what the doctor wants to see happen with the patient's treatment. Any changes in care prompts an update on the sheet and distribution of the new copy.

Basile says patients receive an entire CHF curriculum. They learn how to create a picture of themselves, the status of their disease, and the routine they need to do to stay in control. "We work very hard to make sure they follow it," he says.

Patients learn how to assess symptoms such as edema. They learn what pitting edema is, the importance of regular weigh-ins, and what to do if their status changes. In many cases, Vivra can call the patient's physician or dispatch someone to the home to help.

Basile says Vivra's primary clients are insurers, but with the changes in managed care, he expects to be doing more business with independent practice associations.

Case 3: Sharp Healthcare, San Diego.

Sharp Healthcare is using its five hospitals in San Diego to test the best treatment strategies for CHF patients, says **Beverly Carlson**, RN, MS, CCRN, the system's project director for cardiac research.

Patients tend to be older than those who go to transplantation centers such as UCLA, with average ages of 73 to 74. And because San Diego is such a large area, telemanagement helps keep track of patients who may not be able to visit facilities in person, especially if they are immobile due to their age.

Testing of a multidisciplinary approach to disease management began in January 1996. Three hospitals tested the procedures on 240 patients, and the remaining two hospitals acted as controls.

Patient care brought together social services, pharmacists, and nutritionists to help with patient teaching while patients were still in the hospital.

A three-ring binder of easy-to-read standardized educational materials about the disease, medications, and care is issued to each patient.

Cardiac nurse home visits are conducted for six months after discharge to monitor progress and teach self-care, then the nurses "pass the stick

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back to the case manager" for telemanagement, after patients have been shown how to manage the disease day to day.

Monthly support meetings are held, featuring different topics, such as diet. Meetings include plenty of time for questions and answers and are attended by the clinicians from many disciplines as well as case managers.

Kickertips, a publication named by the patients, is distributed quarterly. It repeats a lot of the topics covered in the monthly meetings for the patients who could not attend and reinforces the themes for the patients who did.

During the study, telemanagement nurses were concurrently testing contracted software developed by Pfizer Inc., assessing how helpful it could be in monitoring these patients as a beta-site for the drug company.

Tips

Tailor your patients' protocols according to their particular needs. "To think one thing will work for everybody is naive," Carlson says, noting the procedures set up to work with the patient from hospitalization to home should be an entire program that includes telemanagement. She says her health system's whole concept is to train patients to be able to take care of themselves the way diabetics handle their condition.

"You really need to look at patient stratification," she says. Assessing each patient according to functional status, age, and comorbidity ("In that order!" she insists) is essential to making the plan fit the patient. It's important to note that in assessing functional status, Sharp doesn't use the traditional New York Heart Association classes, because Carlson notes their validity hasn't been proven like the Specific Activity Scale, which she says was developed by Goldman and fellow researchers from Brigham and Women's Hospital and Harvard University in Boston. This scale is similar, she says, ranging from no symptoms in stage one to symptoms at rest in stage four.

Another tip is to standardize all patient educational material. Take a look at what a lot of patients are getting, Carlson says, and not only will you find they get it from many different sources, but often the information varies. An example is knowing when to call for a weight gain. One pamphlet may say to call when a patient is two pounds heavier. But another brochure says do it at three pounds, and a fact sheet may give the instruction for a five-pound gain. That gets confusing, and the patient often does nothing but throw it all in the trash. No prepared materials suited Sharp's needs, Carlson says, so the staff created their own, keeping in mind reading levels and large-size print for readability.

The study is finished at one site and winding up in the other two. The staff then wants to publish a report in a peer-reviewed journal. Carlson says Sharp plans to study how to help patients with impaired cognitive skills — something many other studies exclude from their scope. ■

CE objectives

After reading *CHF Disease Management*, health care professionals will be able to:

1. Identify management, clinical, educational, and financial issues relevant to the care of CHF patients.
2. Explain how those issues affect CHF patients and the providers who care for them.
3. Describe practical ways to solve problems commonly encountered by care providers in their daily activities. ■