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Case Management

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The New Technology: Tools for Case Management

From telemedicine to e-health, case management opportunities abound

Here's advice from professionals leading the charge

It's an old, familiar problem. Case managers are trying to provide adequate and appropriate services with fewer resources. The good news is that thanks to the Internet and other communication channels, there are some new solutions to that ever-present challenge.

Michael L. Jones, PhD, founding director of the Virginia C. Crawford Research Institute at Shepherd Center in Atlanta, knows firsthand. "We found that we were having to discharge patients earlier and earlier, and we weren't able to send our staff out for home assessments as we did in the past or provide as much follow-up support as we'd like," he says. Shepherd Center is a 100-bed hospital specializing in spinal cord- and brain-injured patients. "In 1996, we started exploring the use of telemedicine to help us fill the gaps in service caused by early discharge and to help prevent secondary complications such as pressure ulcers

CM caseloads: How much is too much?

American Health Consultants, publisher of *Case Management Advisor*, and the Case Management Society of America (CMSA) in Little Rock, AR, are collaborating on a unique caseload survey. Case managers in both the payer and provider settings will be surveyed as we investigate the secrets of setting and managing appropriate caseloads across the care continuum. Look for more information in future issues of *CMA* and its sister publications, including *Hospital Case Management*, on the American Health Consultants Web site at www.ahcpub.com and on CMSA's Web site at www.cmsa.org. ■

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Hot news: HIPAA's final rules released

The Department of Health and Human Services in Washington, DC, has issued its final rules for the Health Insurance Portability and Accountability Act (HIPAA). The rules list case managers under covered "atypical services." That means case managers will be held strictly accountable for protecting the privacy of their patients as they share information with providers and others. The rule has significant consequences for e-health, legality and liability, and the practice of case management in the 21st century. *Case Management Advisor* will take a closer look at the impact on case managers in their daily practice in an upcoming issue. ■

and urinary tract infections." (See stories, pp. 164 and 166, for further discussion of the Shepherd Center's telemedicine experience.)

In addition to telemedicine, which typically links patients and providers through a system of telephone lines, video cameras, and monitors, many health care organizations are looking at Internet solutions to provide low-cost yet effective services such as helping patients with chronic diseases better manage their health.

Stan Bernard, MD, MBA, president of Bernard Associates, a health care Internet consulting firm in Neshanic Station, NJ, has coined the term "care space" to describe this growing Internet segment. He divides the "care space" into the following two segments:

1. Care management. "These are Internet-based approaches to comprehensive care services to patients. This is not the same as 'content space' or health care sites whose primary purpose is to provide information in generic form that may or may not be provider-validated," Bernard notes. "Care management sites involve on-line interactions between a patient and their own health care professionals with the primary objective of better health outcomes."

2. Care tools. "These applications monitor, measure, or record health status," he explains. "Some of these sites offer home testing options which allow patients to . . . upload tests such as pinprick glucose or cholesterol tests directly to the Web. The site's health care professionals then tell you the meaning of your results and may make suggestions for lifestyle changes."

Whether organizations are using Internet applications or other telemedicine technology to provide patient education and monitoring services, professionals familiar with those applications agree on the potential benefits for patients and providers. They include:

- **Better access for patients.** "Patients are tired of sitting in waiting rooms reading old magazines," says **Joan Bristow, RN, MA**, vice president of risk management for The Doctors' Company, a health care professional liability insurer in Napa, CA. "Telemedicine options give patients greater access to their providers."

- **Convenience.** "Most of our patients are discharged from Shepherd Center in a wheelchair," Jones says. "They are going to have transportation and access hassles every time they try to get back to the clinic for a visit. With the use of telerehabilitation technology, we have been able to save patients a clinic visit and still monitor their progress and provide necessary education and support."

- **Cost reductions.** "Shepherd serves patients in several states. To move some of our patients across the state for a follow-up clinic visit involves a \$3,000 to \$4,000 ambulance trip," Jones says. "The telerehabilitation program eliminates the need for that ambulance trip, and we can still make sure the patient receives necessary follow-up visits."

- **Delivery of the appropriate intervention at the appropriate time.** "The care space [Internet] creates the ability to provide the most appropriate care — the right provider at the right time at the appropriate site," says Bernard. "The patient doesn't always need to come into the hospital. Many times the patient can be treated in the home or the physician's office. Monitoring and

COMING IN FUTURE MONTHS

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communicating with the patient via the Internet allows the health care professional at the care management site to help direct the patient to the most appropriate care.”

Perhaps the largest remaining barrier to the continued growth of the “care space” and other remote patient intervention efforts is physicians, say Bernard and Jones. “Patients want to interact with their physicians on-line, but their physicians aren’t compliant,” notes Bernard. “One recent survey found that 77% of patients prefer to get on-line health information from their own physicians, but only 10% of physicians have a Web page or give their e-mail addresses to patients.”

Liability concerns

Physicians continue to shy away from the Internet for legitimate reasons, Bernard adds, such as patient confidentiality concerns, fear of additional uncompensated work time, and professional liability concerns.

Bristow points out that physicians are right to remain cautious about communicating with patients via the Internet and other remote communications systems. “In moving from physical, face-to-face house calls to telephone calls to e-mail replacing telephone calls, we are dealing with the potential for new medical malpractice issues,” she notes. **(See story, p. 167, for information on liability risks associated with e-health and telemedicine programs.)**

Although providers and case managers may remain reluctant, Bernard predicts that consumer demand will force them to communicate with patients on-line. “In addition to [their] other potential, Internet applications are much less expensive than telemedicine models,” he says. Health care organizations should consider preparing now, if they haven’t already, to create their own “care space” or risk being frozen out of the rapidly proliferating e-health market, he adds.

Bernard says case managers and their organizations should consider using these strategies for expanding their current products and services via the Internet:

- Design Internet clinical delivery models and processes.
- Promote member/patient recruitment and retention using highly personalized communications and information.
- Counter physician resistance to Internet use by engaging physicians to help develop Web-based clinical applications.

Just what are we talking about, anyway?

The new era of using technology to link patients and providers has created its own vocabulary. **Joan Bristow, RN, MA**, vice president of risk management at The Doctors’ Company, a health care professional liability insurer in Napa, CA, says that whether you choose to call your method telemedicine or e-health, most of the products and services fit into one of these descriptions:

- use of technology to link providers and patients in geographically dispersed areas;
- real-time transfer of medical information from facilities of lesser medical capabilities to facilities with greater capabilities;
- use of two-way video to connect a provider in one location with a patient in another location;
- transfer of health information over a telecommunication network;
- audiovisual recording of health care interventions, either by the health care provider or by the patient/family. ■

- Use physician “e-reminders” to modify physician behavior in areas such as improved Health Plan Employer Data and Information Set performance measures.

- Use patient e-reminders to improve treatment compliance.

“People inside and outside of health care tend to hold one of three views about whether or not the Internet can deliver patient care,” notes Bernard. “One view is that the entire discussion on health care and the Internet is way overblown, and the Internet will never be able to deliver on all of its promises.”

By contrast, a second view holds that the Internet will dramatically change health care delivery in the United States, he says. “Finally, there is a third view that falls somewhere in between the first two. This view basically is that the Internet will change the way health care is delivered, but as a complement to existing health care delivery services.”

Bernard holds the third view. “Consumers are driving the growth of the e-health space in their

search for better health care. I think the Internet can enhance care management capabilities as a complementary tool that helps empower patient/provider relationships.”

While many health care professionals argue that the Internet and other telemedicine applications are “dehumanizing,” Bernard argues the opposite. “Patients now get about seven minutes with their physician. They are frustrated with the current system. The Web can offer patients that additional information and care they’re searching for from their providers. Providers that offer Web services are telling patients, ‘I’m caring for you 24/7. I wasn’t able to do that before the Internet.’ In that way, the Web can actually increase interactions and improve patient satisfaction within the patient/provider relationship.”

In addition, Bernard says that when health care organizations develop their own Web sites, they control the information their patients receive via the Internet. Other sites on the Internet can dissociate the patient from the provider. “The patient goes on-line and gathers information without telling the physician and then acts on that information, which may not be medically appropriate. This is a real source of potential conflict and is happening every day,” he notes.

(For more on the use of the Internet in health care, see *Case Management Advisor*, May 2000, pp. 73-81, and June 2000, pp. 93-98.) ■

Telerehab supports community reentry

Technology eases gaps caused by shorter stays

Shepherd Center in Atlanta saw its average length of stay dwindle from about 90 days to 30 days over the past decade and a half, primarily due to pressure from managed care organizations. The 100-bed specialty hospital, which works with the most complex spinal cord- and brain-injured patients, found that 30 days was not adequate time to prepare patients for reentry into the community.

“Some of our initial reductions in length of stay were due to improved efficiencies, but by far the biggest impact on our length of stay has been managed care,” notes **Michael L. Jones**, PhD, founding director of the Virginia C. Crawford Research Institute at Shepherd Center. “We began

looking at telerehabilitation models around the country in 1996 as a means to fill the service gaps left by early discharge.”

Jones says “telerehabilitation” is simply the use of telecommunication and electronic technologies to provide rehabilitation and long-term support to people with disabilities in remote settings. He explains that this new capability has

some definite benefits for patients reentering their communities:

- **Extended follow-up after discharge.** “As our lengths of stay got

shorter, we tried to cram everything we used to do in 100 days into the 30 days we had,” notes Jones. “Our patients and their families were leaving overwhelmed with the intensive training we put them through in such a short time. We sent them home with mountains of manuals and hoped that they would figure it all out when they got home.”

Now, Shepherd Center sends some patients home with telerehabilitation systems that allow Shepherd’s professional staff to provide ongoing monitoring, education, and support for patients who are either too disabled or too remote to travel easily back to the center for follow-up.

- **View into the home environment.** “Video cameras allow the Shepherd staff to ‘tour’ the patient’s home even when there is no coverage for a home assessment,” says Jones.

- **Remote monitoring of functional status.** “It’s very helpful for the therapists to see how patients function in their own homes, not just in the physical therapy clinic,” he says.

- **Elimination of transportation hassles.**

- **Expert consultation.** “Patients who live in rural areas may have difficulty finding local providers with adequate training in the care of spinal cord injury,” Jones says.

Many patients in remote areas also may have difficulty finding the help they need to set up their equipment, he says. Shorter lengths of stay mean that most Shepherd patients are discharged in loaner chairs. If a patient lives in Atlanta, it’s not difficult to get them into the seating clinic when their own wheelchair is ready for a final seating. However, if the patient lives in rural Georgia, it may be impossible for the patient to return to Atlanta for seating follow-up, he notes.

“A DME [durable medical equipment] vendor may deliver the patient’s new seating system by UPS. It’s going to be left on the patient’s doorstep

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in a box. A patient may be able to find a bicycle mechanic who can figure out how to assemble the system, [or] he may not," Jones explains. "The telerehabilitation systems allow us to have our seating clinic specialist guide someone through the types of fine adjustments necessary for proper positioning to prevent complications such as pressure ulcers."

Jones urges health care organizations considering telemedicine programs to let patients' needs rather than technology drive their programs. "We spent more than a year visiting other health care facilities who were doing telemedicine. We talked to them and learned from their experiences, and then we developed some guiding principles that we used as we began to implement our telerehabilitation program," he says.

Practicality, simplicity are key

Here are those principles:

- **Put people first.** "We talked to some folks who had purchased systems without first determining any practical use for them. We didn't just want to buy a system because it was there," he notes. "We first asked how we were going to use an available system. We asked ourselves, 'What is the patient problem we can solve with this technology?' And we let the answer to that question drive what systems we bought."

He also recommends that health care organizations start small and keep things simple. "You can easily get set up with as little as \$15,000 of equipment. Don't be glitzed by available technology. Decide on the application first and then go out and research the available technology."

- **Gear efforts to home- and community-based services and support.** Everything Shepherd Center has done to date is designed for use over POTS (plain old telephone systems) to maintain support in the home, he says. There are other telecommunication channels available, including cable modem systems that offer faster transmission and clearer images. However, Jones cautions that even the best technology breaks down, and not every area offers the more advanced options.

"Telephone lines work fine for almost any application you might consider and are available everywhere," he notes.

- **Use technology to support, not replace, hands-on interaction.** "When we first tried to roll out this program, our therapists didn't want anything to do with it," says Jones. "They were afraid we would take them away from their patients.

We made it a firm rule that remote intervention never, except in very extreme circumstances, replaces hands-on interventions. In addition, all the initial rehabilitation and assessments are done hands-on."

- **Use technology to support, not replace, local providers.** Shepherd also recognized that local providers might be concerned that telerehabilitation systems would ease them out of business, says Jones. "We've made it a major tenet of our work that we don't practice medicine over the telephone lines," he notes. "Local providers were concerned that we would come in as a major specialty hospital with our new technology and replace them, but in fact, we support them in their work with our patients and in some cases may actually have created more work for them."

If Shepherd observes a problem during a remote visit, the center encourages the patient to go to the local provider for treatment or further evaluation, he says. "Our specialists also serve as consultants to local providers. It's not unusual to find physical therapists in remote locations who have not worked with spinal cord-injured patients since their clinical training," he says.

- **Appoint a staff member to spearhead the telemedicine program.** "You have to have a staff member dedicated to the program to help clinical staff with training," says Jones. "Don't start something like this without identifying a point person."

Shepherd faced three main challenges to implementing its telerehabilitation program: technical, legal, and financial, he says.

"The best way to minimize technical issues is to visit other organizations currently using telemedicine applications and learn from their mistakes," he says. "We visited one hospital whose IS [information systems] department had purchased a cutting-edge system that still wasn't in use because the clinical staff couldn't find an application for it."

As for legal issues, the entire area of telemedicine and e-health is still so new there is very little case law to turn to for guidance, Jones notes. "We are following federal guidelines [HIPAA, the Health Insurance Portability and Accountability Act] for protecting patient privacy and confidentiality. And we require staff members who work with out-of-state patients in the telerehabilitation program to be licensed in every state in which they interact with patients," he says. "It's a conservative approach, but we feel it's worth the investment. And when we're

in doubt about a patient, we send the patient to a local provider rather than risk trying to practice medicine or nursing or therapy over the telephone lines.” (See story, p. 167, for more on liability issues.)

Finally, Jones says Shepherd hopes to develop a global pricing strategy and assume some risk for secondary complications in order to get more payers to buy into the telerehabilitation program. “We’ve had some limited luck approaching workers’ comp payers to purchase an additional add-on telerehabilitation follow-up protocol for patients at risk for certain complications,” he says.

In addition, some rural states have funded telerehabilitation for Shepherd patients through their Medicaid and Medicare programs, he says. ■

Say ‘cheese!’ The rehab camera is rolling

Here’s sensible advice for ‘tele-visits’

New technology creates not only its own language, but also its own rules of etiquette — a whole new spin to the phrase “bedside manner.” After four years and more than 1,500 “tele-visits,” Shepherd Center, a 100-bed specialty center in Atlanta, offers the following advice

for successful remote patient/provider interactions:

- **Obtain informed consent.** “We obtain a separate informed consent

form for telerehab. We treat telerehab like alternative medicine and use a special consent form for those services,” says **Michael L. Jones, PhD**, founding director of the Virginia C. Crawford Research Institute at Shepherd Center in Atlanta.

- **Set mutually agreed-upon goals with the patient.** “Before you begin remote communication with a patient, set clear goals for how the technology will be used and what the goals of remote communication are,” Jones suggests. “Make sure you explain the limitations of the technology as well as the limitations of telerehabilitation.”

Jones adds that it helps to explain the limitations of the technology to providers, too. “A physician may come in for a remote consultation,

see a bad image, and storm out in the middle of a tele-visit,” he says. “Paint the worse-case scenario. Then, if the image is decent, the physician will be pleasantly surprised and more supportive of the program.”

- **Set rules for beginning and ending transmissions.** “If you’re using a speaker phone, it’s very easy for one party to cut the other off,” he explains. “Set some rules for the communication. For example, tell the patient that you’re going to say ‘Roger out’ when you are finished speaking and that they should do the same. Tell the patient that when the session is over, you will say, ‘We’re finished. You may turn the machine off.’”

- **Establish adequate lighting.** Through a process of trial and error, Shepherd has found that halogen lights create the best light source for tele-visits. “Tall standing lamps are the best. You want to create a bright, overall light that’s nonglaring for the best possible image,” says Jones. “Natural daylight works for some situations. If you do use daylight, make sure that the source of daylight is behind the camera. You want diffuse lighting rather than spotlighting directly on the individual.”

- **Remove distractions from the room.** “Excess movement in the camera is a real challenge. It causes the image to break up, and then the patient and provider have to wait for the image to clear before continuing the tele-visit,” he says.

He suggests that children and pets be removed from the room. In addition, ceiling fans should be turned off, as well as radios and televisions. “The wonderful thing about tele-visits is that we can get a snapshot of how the patient is functioning in the home. The problem is the average home has many distractions that interfere with the technology.”

Providers also must make an effort to remove distractions, he says. “You have to avoid nervous habits like tapping a pencil for the same reasons. That simple movement can slow down the image and cause it to distort or break up.”

- **Maintain a comfortable personal space.** “Some patients love seeing themselves on camera, and some don’t,” Jones says. “Keep your image and the patient’s image life-size. Try to frame the speaker in the screen.”

- **Maintain eye contact.** “Just as you would during a face-to-face interview, keep eye contact during remote visits,” he suggests. “Keep a true camera angle so that the provider and the patient are looking directly into the camera while it’s taking the picture.”

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• **Speak clearly and concisely.** “Providers can’t run on and on,” he notes. “They have to plan the visit in advance and be succinct.”

As for the best audio quality, Jones says Shepherd Center has found that headsets create the best sound quality. “Speaker phones are fine, too, but headsets are best.” ■

Take care: Technology raises liability questions

Plan carefully to reduce risks

Health care professionals nationwide have turned to Internet and telemedicine applications to fill service gaps in the health care delivery system. There is little doubt that these types of remote patient/provider interaction lead to

timely interventions, as well as patient convenience and satisfaction. Whether case managers and providers contact patients via e-mail for a

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simple appointment or medication reminder or conduct home visits using telemedicine systems, however, these new methods of health care communication carry as much risk as promise, says **Joan Bristow**, RN, MA, vice president of risk management for The Doctors’ Company, a health care professional liability insurer in Napa, CA.

There are many questions health organizations should explore before adopting any new methods for interacting with patients, whether by telephone, video monitor, or the Internet, says Bristow. For example:

• **Who has responsibility for the image and the equipment?** “If equipment fails during a telemedicine visit, who is responsible for that failure? Is it the provider? Is it the payer who has covered the service? Is it the equipment manufacturer? These are issues that should be established,” she says.

• **What safeguards are available in the case of transmission failure?** Are there alternatives? Have participants taken steps to retry or reschedule transmission?

• **Who owns the medical record created?** “Fathers have been videotaping births in the delivery room for years, but if there is an incident in the delivery room, who owns the videotape?”

Internet patient disclaimer

The Doctors’ Company, a health care professional liability insurer in Napa, CA, urges health care professionals who communicate with patients over the Internet to use a disclaimer such as the ones below for entry into their Web sites. **(For more advice on appropriate Internet use, see story at left and *Case Management Advisor*, June 2000, pp. 93-98.)**

I am aware that I am not entering into a patient/provider relationship.

I am aware that I will be receiving medical education only.

I am aware that no one will diagnose, advise, or treat me or my condition. ■

It’s quite clear the tape goes home with the family, and that can be an issue. The tape can be altered, and quite simply, if a lawsuit results, the plaintiff has access to evidence that the defense doesn’t. How do you prepare a defense in that case?”

Before you begin a telemedicine program or Internet application, determine who owns the medical record that will be created and how it will be stored, she urges.

• **Can the medical record created be stored and reproduced, if necessary?** Before you replace outdated technology, think about the medical records you have made with the old system. Can they be reproduced on the new system, if necessary?

• **Can the transmission be guaranteed to be confidential and private?** “I think it’s fair to say, ‘No.’ However, you can take steps to provide as much privacy as possible,” says Bristow.

• **Where does the responsibility for follow-up belong?** “The majority of lawsuits we see are due to a lack of follow-up. Patients fall through a hole, due to system failure. Make sure the patient and the provider are clear about how, when, and who will follow up with the patient.”

• **Is there a defined geographical area?** “All 50 states have a different set of licensing guidelines,” she says. “You must be licensed where you are practicing, and you should not practice where you are not licensed.”

In addition, some states require providers to contribute to patient compensation funds, she notes. “Pennsylvania has a patient compensation

fund. If a doctor in California is practicing medicine over the Internet and the patient lives in Pennsylvania, we're in trouble if the patient sues in Pennsylvania courts and that doctor has not contributed to the patient compensation fund. It means we probably have no defense, and we urge the doctor to settle."

Internet and telemedicine applications also raise issues concerning community standards, explains Bristow. "If you go to a doctor in a small town in Texas who offers you a telemedicine referral to a major teaching hospital, and another patient goes to a doctor across the street who can't offer that telemedicine referral, has the standard of care in the community changed?"

- **What constitutes patient abandonment?**

"It's not always clear in telemedicine when the patient relationship begins and ends," she notes. Patient abandonment rules vary by state, just like licensing requirements.

- **Will use of the new technology increase patient volume?** "When you look into telemedicine and Internet applications, you have to consider whether or not increased patient volume will increase the potential for medical errors," she says.

- **How will informed consent be obtained?**

"Health care providers have a responsibility not only to go through the process of informed consent, but also to assess the patient's understanding of that consent. Many patients will be unfamiliar with telemedicine. Make sure they know what to expect; the limitations also must be clear," she says.

"The trick to telemedicine is communication," Bristow concludes. "We are dealing with a very well-informed public. The average consumer knows a great deal and has access to more information than ever before. Providers must be more careful than ever how they interact with their patients using new communication methods."

In general, Bristow says, The Doctors' Company recommends that providers use communication methods such as e-mail with discretion. "For example, we recommend that physicians only use e-mail to communicate with patients they've known for many years and know everything that is likely to affect that patient. We suggest that they not communicate with new patients via e-mail. If it's a new patient, how can the physician know whether the patient will answer questions truthfully or accurately?" (See box, p. 167, for a sample health care Web site disclaimer.)

In addition, she suggests that providers set a specific time for responding to patient e-mail.

"We also suggest that providers tell patients that e-mail will be answered between certain hours of each day so that patients don't send an e-mail message early in the morning and expect it to be answered immediately. And, of course, document every provider/patient communication that is sent out via the Internet. E-mail communications should become part of the medical record." ■

Professional development

Expect pediatric clinical trials to surge

How to help parents decide whether to participate

A new law goes into effect in December requiring that all new drugs and new formulations of existing drugs be tested for use in children. On a national level, roughly 80 pediatric drug trials run each year, according to the Food and Drug Administration (FDA). However, based on the number of drugs approved in the last five years with potential benefit for children, the FDA estimates that, under the new law, an additional 375 pediatric drug trials will run each year.

"Anytime a patient gets a drug, it's an experiment to see if it works for that particular patient. But with children, we're even more in the dark because we don't have the same quality information as we do for adults. Currently, only about 20% of the drugs on the market are well-studied in children," says **Mark S. Schreiner**, MD, medical director of The Children's Clinical Research Institute at The Children's Hospital of Philadelphia.

That predicted dramatic increase in the number of pediatric clinical trials raises a number of issues for pediatric case managers and the parents of the children whose care they coordinate. "From my perspective, there is never a justification for any individual patient to take on undue risk to benefit the rest of society. On the other hand, if children do not participate in trials, then children as a group will not benefit," he says.

"One of the principles behind all research is the idea of distributive justice. That is, there must be a balance between the burdens of research and

(Continued on page 173)



Reports From the Field™

HIV/AIDS

Skin conditions may indicate HIV infection in women

Women are the fastest-growing population at risk for HIV in the United States, and many skin conditions commonly associated with HIV or AIDS that affect women are treated as a single problem rather than an indication for further testing, according to a presentation at the American Academy of Dermatology's annual meeting in San Francisco.

Dermatologists have observed that common skin conditions such as recurring vaginal yeast infections can be early markers for HIV infection, says **M. Joyce Rico**, MD, deputy chief of staff at the Veteran's Affairs New York Harbor Health System and associate professor of dermatology at New York University in New York City. Women who are immune-suppressed often develop severe treatment-resistant vaginal yeast infections with milky white discharge and white patches on the skin, she says, adding that a recent study found that 37% of women with recurrent yeast infections eventually sought care for HIV.

"Too often, patients and their physicians treat a specific incidence of a sexually transmitted disease or yeast infection without looking at the overall pattern of these conditions," notes Rico. "We need to focus on the increasing number of cases of HIV in women and be aware that if a woman has specific recurring problems with certain dermatologic conditions, she may be at risk for HIV."

Some skin conditions occur so frequently in HIV-infected women that they are now considered signs of the disease, she adds. Skin conditions that should lead dermatologists to suggest an HIV test include herpes zoster, or shingles; oral candidiasis, or thrush; oral hairy leukoplakia; and molluscum contagiosum.

"Until recently, there has not been much attention to the relationship between skin conditions and HIV infection in women," explains Rico. "Women and their physicians need to be aware that complacency is part of the tragedy of this epidemic." ▼

Stress speeds AIDS progression

A recent study suggests that stress, poor coping mechanisms, low levels of social support, and depression may speed progression to AIDS in HIV-infected individuals.

Researchers studied 82 homosexual men with HIV type-I infection every six months for 7.5 years. Men were recruited from rural and urban areas in North Carolina, and none was using antiretroviral medication at entry. Disease progression was defined as CD4 count < 200/ μ l or the presence of an AIDS indicator condition.

Researchers found that faster progression to AIDS was associated with higher cumulative average stressful life events, coping by means of denial, lower cumulative average satisfaction with social support, and higher serum cortisol levels. Other variables, including tobacco use, age, education, and risky sexual behavior, did not significantly predict disease progression. Researchers

found that the risk of AIDS roughly doubled for each of the following:

- every 1.5-unit decrease in cumulative average support satisfaction;
- every cumulative average increase in severe life stressors;
- every unit of denial;
- every 5 mg/dL of cortisol.

[See: Leserman J, Petitto JM, Golden RN, et al. Impact of stressful life events, depression, social support, coping, and cortisol on progression to AIDS. *Am J Psychiatry* 2000; 157:1,221-1,228.] ■

Behavioral health

Depression and its treatment costs employers big bucks

Employers are paying more for treatment of depression than for hypertension or several other common conditions, according to a recent study. Researchers examined data from the files of 15,153 employees of a major U.S. corporation who filed health claims in 1995. They compared the mental health costs, medical costs, sick days, and total health and disability costs associated with depression and four other conditions: heart disease, diabetes, hypertension, and back problems. Regression models were used to control for demographic differences and job characteristics.

Findings include:

- Employees treated for depression incurred annual per capita health and disability costs of \$5,415, significantly more than the cost for hypertension and comparable to the cost for the three other medical conditions studied.
- Employees with depressive illness plus any one of the other studied conditions cost 1.7 times more than those with one of the studied medical conditions alone.
- Depressive illness was associated with a mean of 9.86 annual sick days, significantly more than any of the other conditions.
- Depressed employees under age 40 took 3.5 more annual sick days than those 40 or older.

Researchers conclude that the cost of depression to employers, particularly in lost workdays, is equal to or greater than the cost of many other common medical illnesses. In addition, the strong

association between depressive illness and sick days in younger employees suggests that the impact of depression may increase as these workers age, they add.

[See: Druss BG, Rosenheck RA, Sledge WH. Health and disability costs of depressive illness in a major U.S. corporation. *Am J Psychiatry* 2000; 157:1,274-1,278.] ■

Diabetes

Patients fail to control diabetes

A potentially disastrous failure of many diabetics to take their medication properly and to achieve recommended cholesterol and blood pressure levels was reported at the recent American Diabetes Association's 60th Annual Scientific Sessions in San Antonio.

"Only one-third of the people with type 2 diabetes have their prescriptions filled often enough to take at least 90% of their pills," says **Andrew D. Morris**, MD, senior lecturer in medicine and diabetes at the University of Dundee, Scotland, noting that this finding is even more surprising coming from Scotland, where prescribed medications are paid for by the National Health Service.

The Scottish researchers accessed prescription records for 400,000 residents of Tayside, Scotland. They examined records for all patients taking oral medication for type 2 diabetes over a three-year period. Researchers defined adequate adherence as having prescriptions filled often enough to enable the patient to take at least 90% of the recommended dosage of each medication.

"Of nearly 3,000 people with diabetes, only 31% of those taking sulfonylureas and 34% of those taking metformin filled their prescriptions often enough to maintain adequate adherence," Morris says. "Adherence for those who were supposed to take both medications was even lower at 13%."

Researchers found that patients who were expected to take only one pill per day did the best, with a 22% decrease in adherence for each increase in the frequency of the daily dose. Beyond frequency of diabetes pills, overall adherence was best in patients who took fewer co-medications and who had had diabetes for the least amount of time.

Reports from the Centers for Disease Control and Prevention (CDC) in Atlanta found similar dismal results in U.S. diabetics. In fact, based on a review of tests of blood pressure, cholesterol, and other lipids in more than 1,000 U.S. adults with diabetes who participated in the Third National Health and Nutrition Examination Survey, the CDC found that U.S. diabetics also run a high risk of cardiovascular disease.

Recent CDC studies have found that among 97% of adult diabetics with one or more cholesterol abnormalities, only 1% had reached recommended treatment goals. Among 71% of diabetics with hypertension, only 12% had reached recommended treatment goals. "Based on their lipid profiles, risk of cardiovascular disease was considered high for 76% and borderline for 21% of patients," says **Anne Fagot-Campagna**, MD, medical epidemiologist in the CDC division of diabetes translation. "However, only 32% reported being treated by diet, exercise, or prescribed medicine, and in nearly every case, lipid levels did not reach today's standards even among those being treated."

Bruce Zimmerman, MD, president of the American Diabetes Association in Alexandria, VA, adds, "When patients don't take proper care of themselves and don't achieve desired goals, we must look to the health care system to ask why not. All too often, doctors and other health care professionals don't take diabetes seriously, and people don't receive adequate patient education. This must change." ■

New drug updates

New fast-acting insulin offers flexibility

Novo Nordisk A/S in Princeton, NJ, has received Food and Drug Administration approval for NovoLog, an insulin analog for treating diabetes. It has faster absorption, faster onset of action, and shorter duration of action than regular human insulin. The quick onset of blood sugar lowering after injection of NovoLog allows people with diabetes to inject themselves immediately before eating, offering greater flexibility to patients than regular human insulin, which must be injected 30 minutes before meals. Visit www.novo-nordisk.com for more details. ▼

Eye drops lower intraocular pressure

The Food and Drug Administration recently approved Rescula, a new synthetic docosanoid compound for the treatment of open-angle glaucoma or ocular hypertension.

Rescula, manufactured by CIBA Vision, the Atlanta-based eye care unit of Novartis, lowers intraocular pressure when used as either a monotherapy or in combination with other drugs. In clinical studies, Rescula maintained a constant level of intraocular pressure throughout the day and showed no loss of efficacy over 12 months.

Patients use Rescula, in the form of eye drops, twice a day. It penetrates the cornea and achieves maximum effect in as soon as 24 hours. It is indicated for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension who are intolerant of other intraocular pressure-lowering medications or who fail to achieve target intraocular pressure after multiple measurements over time while taking another intraocular pressure-lowering medication.

More information is available on-line at www.cibavision.com. ▼

Asthma medication approved for young children

AstraZeneca in Wayne, PA, recently announced that its new asthma medication for young children and infants has received approval from the Food and Drug Administration. Pulmicort Respules is the first asthma treatment approved for children and infants as young as 12 months. It is also the first corticosteroid available as a nebulized formulation.

Previously, inhaled corticosteroid therapy was only approved for children 4 years of age and older and typically was administered with an asthma inhaler, which few children are able to use properly, says **Frank Casty**, MD, executive director of respiratory and inflammation at AstraZeneca.

"Now with the approval of Pulmicort Respules, physicians will have a way to administer inhaled corticosteroid therapy in infants and young children," he says, adding that Pulmicort Respules is a preventive medication that helps

control asthma, not a quick-relief medication for use during an asthma attack.

In three 12-week double-blind clinical trials involving 946 children ages 12 months to 8 years, Pulmicort Respules reduced the need for bronchodilators and improved nighttime and daytime asthma symptoms.

Prescribing information is available by calling (800) 942-0424, ext. 1974. ▼

Drug pump improves treatment response

The Food and Drug Administration recently approved two new uses for an implantable drug pump manufactured by Minneapolis-based Medtronic. The IsoMed Constant-Flow Infusion System received regulatory approval for use in a promising colorectal liver cancer treatment that delivers cancer-fighting medication directly to the liver, the most common place for colon cancer to spread, and for use in delivering morphine sulfate directly into the spinal fluid as a treatment for chronic pain.

“There are two reasons why patients respond better to treatment with the pump than to traditional treatment,” says **Elin Sigurdson, MD**, director of surgical research at Fox Chase Cancer Center in Philadelphia.

“First, the pump delivers the drug directly into the liver. It’s not diluted in the blood. The second reason is that we can actually give much larger doses of the same type of drug than we can give systemically because the drug is cleared by the liver. As a result, response rates tend to be much higher,” Sigurdson says.

Medicine flows constantly

For patients with colorectal cancer that has spread to the liver, the IsoMed Constant Flow Infusion System accurately delivers high concentrations of floxuridine on a continuous basis directly to the liver through the hepatic artery. The pump is surgically placed under the skin of the abdomen and filled with the appropriate medication. A catheter that runs from the pump to the hepatic artery delivers medication at a constant rate from the pump into the liver.

The IsoMed system also was approved for

delivering morphine directly into the spinal fluid as a treatment for chronic pain in patients who have not found relief or who suffer intolerable side effects from oral or intravenous medications.

The implantable pump delivers small doses of analgesics directly into the fluid surrounding the spinal cord, which contains the receptors that transmit pain signals to the brain. Compared with oral or intravenous administration, direct infusion often provides effective pain relief in small doses with fewer side effects.

Information on the implantable pump’s use for treatment of colorectal cancer is available on-line at www.medtronic.com/neuro/hai. Information on the pump’s use for treatment of chronic pain is available at www.medtronic.com/neuro/apt. ▼

FDA approves outpatient ovarian cancer therapy

Bristol-Meyers Squibb in Princeton, NJ, recently announced that the Food and Drug Administration has approved a new, shorter administration regimen for Taxol injection for the treatment of advanced ovarian cancer.

The new three-hour regimen can be administered in the outpatient setting, avoiding the hospitalization required for standard therapy.

In a clinical trial of 680 women with stage IIb through stage IV ovarian cancer, women were randomized to receive either Taxol at 175 mg/m² followed by cisplatin at 75 mg/m² in a three-hour infusion every three weeks or cyclophosphamide 750 mg/m² followed by cisplatin 75 mg/m² over three hours, every three weeks for a median of six courses.

Women in the Taxol group experienced significantly improved overall survival compared with women in the cyclophosphamide group, 35.6 months vs. 25.9 months. Further, progression-free survival in the Taxol group remained significantly higher for the women who received Taxol at 15.3 months, compared with 11.5 months for the cyclophosphamide group.

Full prescribing information for Taxol is available by calling (800) 426-7644 or visiting Bristol-Meyers Squibb’s Web site at www.bms.com. ■

(Continued from page 168)

the benefits of research,” he adds. “We have inadequate information regarding the safety and effectiveness of drugs for children. As a result, children have not been equal recipients of the great advances in medicine and drug research. If we want to see children partake of the benefits, then we, as parents and society, must accept a communal obligation to bear part of the burden.”

Case managers can play an important role in helping parents decide whether to enroll their children in a clinical trial. Schreiner suggests you prepare for the questions parents are most likely to ask about the safety, potential benefits, and risks of participating in a pediatric clinical trial.

Parents must make decisions as trustees for their children because children are not legally or developmentally able to make those decisions on their own, he notes.

Questions and answers

The following are Schreiner’s answers to what are, in his experience, the most common questions parents raise about enrolling their children in clinical trials. His advice, based on his own pediatric clinical trials, should help case managers counsel families through what may be a difficult decision-making process.

1. Why have we been approached to have our child participate in a clinical trial? A child’s pediatrician may ask parents to participate in a clinical trial based on personal knowledge of their child’s medical history, Schreiner says. “If your child is hospitalized or is being seen in a clinic, you may be approached directly by an investigator or a clinical coordinator. Some hospitals maintain a database of patients and diagnoses.

The database may be searched if researchers are looking for a particular disease or condition. In a hospital setting, physicians meet at least once a week to review challenging cases, and your child’s case may be one of them. It’s very important that you do not feel pressured into making a decision, even if it is your child’s pediatrician asking you to participate.”

2. Does my child have the disease or problem that the study targets? A drug study should always be a match for the child. “Obviously, a child should not participate in the study of an epilepsy drug unless the child has epilepsy,” notes Schreiner. “However, some conditions are so common that all children will benefit from

having your child participate. For example, researchers may be investigating a new drug to treat fever or ear infections in children.”

3. Will my child be able to cope with a trial? No one understands a child’s temperament better than the child’s parents, he notes. “You know your own child better than anyone else. Does your child have the temperament and personality to cope with the disciplined regimen required by a clinical trial? Children have a great sense of altruism, and they will benefit by understanding that they’re helping others.”

4. What is a protocol? Case managers may need to explain to parents in clear, layman’s terms about clinical protocols, says Schreiner. “A clinical protocol is the document by which all research studies flow. It’s essentially the research ‘bible’ that outlines the exact procedures for the investigator to follow. There must be no deviation. A protocol begins by explaining what is being studied and why. It also includes the name of the sponsor and names of the principal investigators. The protocol will explain the study design, how many people will be in the study, how many times each patient will be seen, what laboratory tests will be done, and how often. It will also explain the risks and potential benefits of the study.”

5. What is involved in the study? Parents should receive a verbal explanation of the study, and the details of the protocol should be included in a written consent form, Schreiner says. “Although the consent form should give you most of the details, there are a few extra items [parents should] ask about,” he explains. “For example, will you be actively involved with collecting and reporting data? If your child is older, will your child be required to keep a diary or to phone in results? How many visits will there be? Will blood be drawn? What are the risks? What are the expected benefits?”

6. What are the doctor’s hours? Parents should find out whether the investigator keeps evening and weekend hours, he suggests. “You’ll want to minimize disruptions to your work schedule and to your child’s school day. When you arrive at the doctor’s office, will you be seen promptly? When you are participating in a trial, you should be seen right away without waiting as you might for a routine office visit.”

7. Is it safe? “When we conduct clinical trials, the safety of the child is our utmost concern. All aspects of a clinical trial are preapproved by the FDA and by an institutional review board [IRB],” he says. “This means all of the investigators are

performing the same procedures in the same way. And from an educational point of view, everyone involved in conducting the trial shares information and experiences and contributes to problem solving. The level of surveillance in terms of number of provider visits and attention to the individual child is usually much higher than during routine medical care. The result? A well-written clinical trial reflects the best care.”

FDA helps ensure safety

In addition, drugs are usually tested in adults first, notes Schreiner. “So we do know more about the drug and its likely benefits before we start a pediatric clinical trial. An exception would be when the drug affects only children. For example, a clinical trial for a new vaccine may be tested only in babies.”

Finally, the FDA has established strict guidelines for how clinical trials are to be conducted. It requires the sponsor of the trial to scrutinize the credentials of the clinical investigators who conduct the trial.”

8. Will we be compensated for participating?

If there are no extra visits or procedures, parents should not expect to receive any compensation. However, if there are, parents should be compensated for the trouble they take to participate in a study, Schreiner notes. “This includes reimbursement for transportation, meals, and overnight accommodations. Your child may also be offered a small gift, such as a savings bond or a gift certificate for toys or books. However, be wary of expensive gifts as a lure to participate in a study.”

9. What if my child is a girl of childbearing age? “[Because] there is so little information about the effects of drugs on pregnant women and developing fetuses, drug companies and clinical investigators will want to be sure that your daughter is not pregnant and will not become pregnant during the course of the trial,” says Schreiner. “This may be a difficult issue for parents of young girls who are capable of childbearing but are not yet sexually active. A pharmaceutical company may require your daughter to take a pregnancy test and may also require her to use some form of birth control. Some companies may accept abstinence as a means of birth control.”

10. Is the investigator experienced? Has the investigator conducted previous studies? You have a right to ask for the credentials of the principal investigator and of anyone else involved in the trial, he notes.

11. Is there an experienced study coordinator, nurse, or other resource person who is going to be available to me? Schreiner recommends that parents ask to meet the principal investigator, the study coordinator, and anyone else who will work with them and their child during the trial. “It’s important for parents to be at ease with all of them and to be confident they will be available whenever you have questions or a problem.”

12. Has the protocol been reviewed by an IRB? The IRB is a committee within the organization or hospital that ensures the protection and ethical treatment of all participants in a clinical study, explains Schreiner. “The IRB is an impartial, independent group that has no relationship with the individual clinical trial.”

13. If my child is injured during the trial, who is responsible for paying for the cost of treatment? “This issue is usually addressed in the consent form,” notes Schreiner. Parents should discuss this issue with the investigator before signing the consent form, he recommends.

14. Can we drop out at any time? Parents should understand that they can drop out of a trial at any time, for any reason, without a penalty, says Schreiner.

15. Do I understand the consent form? Parents will get a detailed consent form to sign, written in the language the parents speak with words they understand. “Informed consent is not a single event. It is an ongoing process during which parents must have time to understand, to make an informed decision, and to continually re-evaluate their willingness to participate. Parents should be given a copy of the consent form so they can reread it to refresh their memory about the study details.”

16. What if I have trouble making a decision? Sometimes parents are overwhelmed, especially if they have just learned that their child has a serious illness, notes Schreiner. “Parents should listen to what their child’s physician and the principal investigator have to say. They should also read through all of the materials presented to them,” he says, adding parents should be reassured that it’s OK to say no if they feel the study is not right for their child.

Many more parents will be approached by physicians asking for permission to enroll their children in drug trials, cautions Schreiner. “We were all children, many of us will have children, and our children will have children. So we all have a stake in this. It’s ironic that, to date, by protecting children from risks, we have also denied them the benefits.” ■

Lawmakers, consumers disagree on health needs

Consumers plan to take frustration to the polls

When Americans head to the voting booths in November to elect the next president of the United States, health care policy will play an important role in their decision, according to a recent poll by Bethesda, MD-based Discovery Health Channel.

In fact, 54% of Americans polled said health care issues would play an “extremely important” role in their vote in the November election.

Unfortunately, the same survey found that less than 25% of Washington policy-makers believe

Less than 25% of policy-makers believe health care will play an important role in the upcoming election.

health care will play an important role in the coming election. The Discovery Health Channel poll, titled “Americans and Washington Insiders on Health Issues: Does Health Information and Policy Require First Aid?” surveyed the general public and Washington policy-makers to

better understand the growing importance of health information to consumers.

The Discovery Channel commissioned the bipartisan research firm SWR Worldwide in Washington, DC, to conduct a telephone poll of 1,000 Americans ages 18 or older. SWR also conducted an on-line survey of 179 Washington insiders, including current and former congressional staff, former federal agency staff, lawyers, lobbyists, association executives, and members of the media.

By the numbers

Findings include the following:

- More than 65% of Democrats, 41% of Republicans, and 53% of independents surveyed said health care will be “extremely important” in determining their presidential vote.

- Fifty percent of consumers surveyed — compared with only 23% of political insiders — reported that government should be “very involved” in rating physicians and other medical professionals.

- Less than 25% of Washington insiders

reported that the government should be involved in providing information on alternative health care, compared with 48% of consumers surveyed.

- More than 66% of consumers surveyed reported that the government should be “very involved” in releasing to the public information on new medicines, compared with 51% of Washington insiders.

- Of women surveyed, 61% rated health care as “extremely important” to determining their vote, compared with 47% of men.

- Nearly 90% of consumers surveyed reported being skeptical about health information from private companies, and 84% reported being skeptical about information from the media.

- Nearly 80% of consumers surveyed said they had difficulty sorting through what they believe to be conflicting health information.

- Nearly 60% of the consumers surveyed reported difficulty understanding health information they consider too technical.

Out of sync

In every area surveyed, Washington insiders underestimated the importance to consumers of access to health information. For example, 71% of consumers surveyed reported that prescription drug information was “very important” to them, while only 59% of Washington insiders reported that drug information was “very important” to consumers.

Other findings include these:

- Nearly 60% of consumers surveyed reported that mental health information was important to them, compared with roughly 30% of Washington insiders.

- More than 65% of consumers surveyed reported that women’s health issues were important to them, compared with 40% of Washington insiders.

“From traditional surgical procedures and illnesses to mental health and alternative medicine, we found that . . . the political insiders underestimated the amount of information the public wants and the public’s desire for the government or some trusted third party to provide this information in a timely manner,” says **Greg Schneider**, chairman and chief executive officer of SWR.

(Editor’s note: Highlights from the poll and an on-line poll with select survey questions are available on the Web at www.discoveryhealth.com.) ■

Payer adds depression screen to prenatal program

9% of participants screened scored positive

One payer found that adding a postpartum depression screen to its prenatal program struck a chord with new mothers. In fact, 99% of new mothers who received the postpartum depression screening packet reported thinking the program was a great idea, and roughly 10% reported that before receiving their packets, they were unfamiliar with the condition.

Since adding a postpartum depression screening and treatment program to its Humana-Beginnings prenatal program, Louisville, KY-

“If we could reach even one woman and prevent tragic consequences, we will count the program a success.”

based Humana has seen 40% of women members who received the tool participate in the program. Humana contracted with Magellan Behavioral Health in Columbia, MD, to provide the postpartum depression screening to its members. Magellan

has mailed more than 1,800 personal letters, educational brochures, and Edinburgh depression scales to Humana members in the immediate postpartum period.

“This impressive return rate is a great indication that women are looking for information and answers about this serious yet often unrecognized illness,” says **Arthur Lazarus**, MD, vice president and corporate medical director for behavioral health for Humana. “We’re very pleased that Humana is successfully reaching out to more women who have little or no knowledge of postpartum depression and providing them with important resources that they can use to improve their health.”

Lazarus says Humana recognizes that a disproportionate number of covered health care services were going to women members. “Although pregnancy is not a disease, it’s the number one most frequent condition in any health plan. We know we have a high volume of births, and with a 10%

to 15% incidence of postpartum depression nationally, we felt this program would reach a significant number of members,” he says. “If we can reach even one woman and prevent tragic consequences, we will count the program a success. And we have significant evidence through member testimonies that the program is working as we hoped.”

In a letter to Magellan, one Humana member wrote: “I suffered in silence with the birth of my first child from postpartum depression. This survey could reach out to those who don’t understand what’s happening to them or how to make it better. I applaud Magellan and Humana’s participation in this program.”

“We receive a list of new mothers from Humana every two weeks. That list has the mothers’ names, addresses, and telephone numbers,” notes **Kary L. VanArsdale**, EdD, regional prevention coordinator for Magellan.

Those mothers are sent a packet that includes the following:

- an introductory letter;
- the depression scale;
- a brief demographic survey that includes questions about past history of depression, marital status, number of children, employment, and age;
- an educational flip-sheet on postpartum depression which includes self-help information and numbers to call for further help;
- a return envelope addressed to Magellan.

Treatment is encouraged, not forced

Women who screen positive for depression are contacted by telephone by a Magellan care manager who encourages them to receive further evaluation and to schedule an appointment with a network provider, notes VanArsdale.

“We try to make an appointment within the next couple of days. Although our intervention ends once the appointment is made, we do follow-up with providers to see whether members keep their scheduled appointments and to see how many members followed through with treatment,” she says.

Humana receives a monthly report from Magellan that lists how many members were sent packets, how many returned packets, and how many screened positive. “This program ends with referral to treatment. We’re not collecting outcomes,” explains Lazarus. “This is a screening and intervention model consistent with

prevention. It's similar to an immunization program. You identify members at risk for disease who need immunizations. You immunize the person. You expect the medicine to be efficacious."

Magellan and Humana both have taken steps to encourage women to participate in the screening program. "We've been using touches like handwritten thank you notes to help personalize the process and encourage responses," says VanArsdale. "In addition, Humana has printed articles about the program in its member newsletter. We've been delighted to see that in recent months, the survey response rate has increased to more than 50% in some markets."

Of Humana members screened to date, 9% screened positive for postpartum depression, says VanArsdale. In addition, 14% reported a past history of depression.

"We know that past depression is a risk factor for depression before, during, and after pregnancy and that underrecognition and undertreatment are serious problems that affect maternal and infant outcomes, as well as the mother's significant other," adds Lazarus.

Humana recently launched a pilot effort in Florida to offer the postpartum depression screen through a telephonic interactive voice response (IVR) method. "We're anxious to compare the response rate to the IVR system to that of the paper and pencil screen," says Lazarus. "Basically, we've taken the depression scale and automated it so that members can use their telephone keypad to answer the questions. Members who test positive are immediately transferred to a Magellan care manager." ■

Telephone improves depression outcomes

Symptoms decrease 50% when nurses call

It doesn't always take the newest technology to make a big impact on patient outcomes. Kaiser Permanente in Oakland, CA, found that when primary care nurses maintain regular telephone contact with patients suffering from depression, patients improve. In fact, 18% more of those patients contacted by phone showed a 50% reduction in their depressive symptoms than did depressed patients who did not receive telephone calls.

"That 18% difference is almost as large as the difference seen in previous studies between placebo and prescribed antidepressants," says **Enid Hunkeler**, MA, a Kaiser Permanente researcher and lead author of the study published recently in the *Archives of Family Medicine*.¹

A total of 302 patients starting antidepressant drug therapy seen at two managed care adult primary clinics were randomized into one of three groups. One group received usual care. One group received telehealth care, or telephone contact with a trained primary care nurse. The third group received telehealth care plus peer support.

Personalizing care

Patients in the telehealth group received emotional support and focused behavioral health interventions in 10 six-minute telephone calls from primary care nurses during a four-month period. Nurses also monitored medication compliance and offered suggestions about dealing with side effects. Patients in the telehealth and peer support group received the same scheduled telephone calls from a primary care nurse, plus in-person supportive contacts by trained health plan members who had successfully recovered from depression.

"This model uses the nurses already in primary care offices, and it builds on the bond patients already have with their doctors," says Hunkeler.

"Since the nurses work within the primary care setting, they can help a patient with depression improve and monitor their own overall health, not just their depression," adds study co-author **Joel F. Meresman**, PhD. "And the information the nurses can then relay to the patient's physician helps complete the circle to their total health care."

Researchers found that 58% of the patients in the telehealth group showed a 50% reduction in their symptoms six months after baseline, compared with 37% of patients in the control group. Adding peer support to the nursing intervention did not improve primary outcomes.

Reference

1. Hunkeler EM, Meresman JF, Hargreaves WA, et al. Efficacy of nurse telehealth care and peer support in augmenting treatment of depression in primary care. *Arch Fam Med* 2000; 9:700-708. ■

Advocacy group battles MCOs for patients

76% of toughest cases resolved by case managers

Consumers nationwide are battling their health plans over denial-of-care issues for what they believe to be appropriate and necessary medical services. Managed care case managers often are torn between their patient advocacy role and the realization that a patient's plan simply doesn't provide coverage for the proposed treatment plan.

Now, when managed care case managers run into barriers to coverage, their patient advocacy role doesn't have to end. They can refer their patients to the Patient Advocate Foundation (PAF) in Newport News, VA, a nonprofit group with an amazing track record for resolving conflicts between patients and health plans.

"We do whatever it takes to help the patient. However, our approach has always been to start our communication with the payer by saying that the denial of care or denial of payment after care has been delivered is probably a simple misunderstanding," says **Nancy Davenport-Ennis**, founder and executive director of PAF.

Denial of care and refusal to pay for care rendered comprise roughly 80% of the more than 29,000 calls PAF received in 1999; other cases have involved job discrimination issues related to a patient's illness or disability. Of the more than 29,000 cases, 76% were resolved by PAF's case managers, and the rest were referred to one of the 154 attorneys in the organization's network.

"We started this organization in 1996. In the four years and several months that we've been helping patients, only one case went to court, and that was simply to get an injunction from a judge for a patient to be admitted to the hospital immediately," she says. "I think that payers know that when we contact them on behalf of a patient, we're not going to go away. We don't scream, and we're always fair. However, if we don't get resolution from the payer, we're going to go over the payer's head to the next person to get the patient help."

The first contact patients have when they call the toll-free PAF number is with an intake counselor. The counselor enters the patient's initial data

into the system and then refers the patient to the appropriate staff member. "The intake counselors know from the coding system which staff member is best suited to help the patient resolve their problem," notes Davenport-Ennis.

PAF employs nurse case managers, social workers, psychologists, and attorneys. Staff receive extensive training — including homework each night — during their first two weeks of employment, she says. "We want staff members to be prepared to handle any service area a patient might be confronted with including prescription needs, transportation, food, and clothing."

She attributes PAF's success to the following three factors:

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1. Personal dedication. “Everyone in this organization is here to make sure that Americans have access to the medical care they need,” she says. “We’ve hired several case managers who came to us from managed care organizations in the past few months. They became tired of telling patients they couldn’t get the care they were requesting and wanted to be part of the solution.”

2. Consensus and negotiation. She says PAF staff are masters at this. “We’re not here to be offensive to health plans. We work hard to resolve cases on a case-by-case basis.”

3. Thorough preparation. Before PAF staff contact a patient’s health plan, they go to great pains to make sure “all our ducks are in a row,” she says. “We review the health plan document, We ask physicians on our medical board to gather medical efficacy documents about the proposed treatment. We ask our attorneys for every judicial precedent available that this particular treatment is no longer considered experimental. Then we call the plan and offer to send them the documents. Most of the large plans we’ve dealt with in the past know we’ll bury them in paper, if they ask.”

Patients who call PAF are never charged for services. “The last thing you need when you’re ill and have huge medical bills piling up is another expense,” she says. In addition, PAF has published several patient advocacy publications that also are available to patients at no charge, including a managed care answer guide to help patients solve their insurance problems and a new job discrimination guide to help consumers file their own job discrimination claims.

Case managers can refer patients to PAF’s toll-free number at (800) 532-5274 or the organization’s Web site (www.patientadvocate.org). All of PAF’s publications are available through the site. ■

Patients think payers influence medical care

Yet trust in physicians remains high

More than 40% of Americans think payers’ rules influence physicians’ decisions about their medical care. At the same time, a study released by the Center for Studying Health System Change (HSC) in Washington, DC, found that only 7% of Americans surveyed felt physicians fail to put patients’ needs first.

“Society is faced with having to balance the cost savings of influencing doctors’ decisions about referrals, tests, and treatment against concerns that insurer interventions may threaten the quality of care,” says **Lee Hargraves, PhD**, study author and HSC researcher. “Even though the public is split on whether insurers have gone too far, patients express overwhelming confidence in their doctors.”

The HCS study, “Patients Concerned about Insurer Influences,” examined results from the 1998-1999 Community Tracking Study household survey, a nationally representative telephone survey of roughly 32,000 households and 59,000 individuals.

Findings include the following:

- 56% of African-Americans and 54% of

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Editorial Questions

Questions or comments? Call **Lee Reinauer** at (404) 262-5460.

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Editor: **Lauren Hoffmann**, (770) 955-9252, Fax: (770) 956-1781.

Vice President/Group Publisher: **Donald R. Johnston**, (404) 262-5439, (don.johnston@ahcpub.com).

Associate Managing Editor: **Lee Reinauer**, (404) 262-5460, (lee.reinauer@ahcpub.com).

Senior Production Editor: **Terri McIntosh**.

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THOMSON HEALTHCARE

Sticker shock: Employers see steep rise in premiums

Employers face an 11% to 12% average premium increase for health care insurance in 2001, according to an analysis of rate projections in 22 states by Corporate Research Group (CRG) in New Rochelle, NY. That increase may come as a shock to employers, who saw average premium increases of 8% to 10% in 2000 and 7% to 9% in 1999.

Texas, Ohio, and Michigan are the hardest hit states with the Houston Business Group on Health, which represents 40 employers, facing a reported premium hike of 20% in 2001.

CRG predicts these premium increases will push employers and employees out of HMOs and into self-insured plans. ■

Hispanics agreed that their physicians were influenced by insurance rules, compared with 40% of whites.

- 10% of Hispanics agreed that physicians would not put their medical needs first, compared with 7% of African-Americans and 6% of whites.

- 53% of Americans below the poverty level agreed that physicians are influenced by insurance company rules, compared with 40% of those with incomes at least four times the poverty level.

- 46% of Americans in fair or poor health agreed that physicians are influenced by insurance company rules, compared with 43% of those in good to excellent health.

- 9% of Americans in fair or poor health agreed that physicians would not put their medical needs first, compared with 7% of those in good to excellent health.

- 70% of Americans surveyed “strongly agreed” that their physicians would put medical needs first.

Those figures have remained stable since HCS' first study in 1997 despite the growing managed care backlash among consumers.

“The challenge to policy-makers on the Hill and in the White House is to reconcile consumer unease about insurer influence, on the one hand, with their overwhelming confidence in their doctors, on another, and decide whether or not to intervene legislatively,” says **Paul B. Ginsburg**, PhD, president of HSC. ■

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CE objectives

After reading this issue, continuing education participants will be able to:

1. Identify clinical, legal, legislative, regulatory, financial, and social issues relevant to case management.

2. Explain how those issues affect case managers and clients.

3. Describe practical ways to solve problems that case managers encounter in their daily case management activities. ■

Resource Bank™

A monthly compilation of news you can use from *Case Management Advisor*

Video provides support for men with prostate cancer

A new video, "Not By Myself," provides a basic overview of prostate cancer, as well as intimate interviews with African-American prostate cancer patients and their families. The video, which was introduced at the recent National Medical Association annual meeting in Washington, DC, is designed to reassure African-American men experiencing the trauma of diagnosis and treatment for prostate cancer that they are not alone.

The free video covers the following issues:

- common reactions to cancer diagnosis;
- tips for coping with the emotional and physical side effects of treatment;
- discussing treatment with your physician.

The video is made possible through grants from Amgen, a global biotechnology company based in Thousand Oaks, CA, and PRAECIS PHARMACEUTICALS in Cambridge, MA. To obtain a free copy of the video, call (877) 550-9624. ▼

Books help your patients get fit and age gracefully

Case managers who work with seniors know that safe exercise prevents many complications of chronic illness, as well as lessening the risk of falls and other complications of aging. The Center for the Study of Aging in Albany, NY, has several resources designed to keep seniors active throughout life.

To order any of the resources described in this article, contact the Center for the Study of Aging, 706 Madison Ave., Albany, NY 12208-3604. Telephone: (518) 465-6927. Fax: (518) 462-1339. E-mail: IAPAAS@aol.com.

• **Who? Me?! Exercise? Safe Exercise for People over 50.** This 42-page booklet contains sensible advice and reasonable guidelines to

help mature adults who are not exercising start to change their lifestyles and improve their health. It also includes suggestions for alternative activities for adults with physical problems. The humorous book includes illustrations and exercises.

The cost is \$3.95 plus postage (\$1.75 for the first booklet and \$.75 for each additional booklet). Quantity discounts are available.

• **Safe Therapeutic Exercise for the Frail Elderly: An Introduction (2nd Edition).** This 162-page book is used as textbook in physical therapy schools, nursing homes, assisted-living centers, and home care agencies. The easy-to-read, illustrated manual highlights safe therapeutic exercises and introduces a variety of creative activities and programs to motivate and improve mobility and muscle strength in older adults. It includes programs for the bedridden and persons with Alzheimer's disease. The exercises have been tested for more than 30 years.

The cost is \$14.95 plus postage (\$3.95 for the first book and \$1.50 for each additional book).

• **Volume I: Prevention and Human Aging.** This 285-page book is the first in a series titled *Lifelong Health and Fitness*. The multidisciplinary volume brings new meaning to prevention and health by covering prevention of disease and looking at holistic health. Readers are challenged to encourage older adults to take responsibility for their physical and mental health and quality of life.

Volume I includes the latest research on managing and improving the health of older adults. It presents moral and ethical questions arising from living longer and suggests new ways to enlist older adults in the effort to enhance their own wellness and prevent disease. In addition, the book describes practical medical, rehabilitative, and environmental techniques that help individuals take responsibility for improving their health and adding meaning to their lives.

Issues covered include:

— prevention of repetitive hospital admissions in elderly patients with congestive heart failure;

- prescribed postoperative exercise;
- functional health status as a predictor of healthy aging and health care utilization;
- application of the revised physical activity readiness questionnaire to a community sample of low-income, minority, older adults;
- memory improvement through a dietary supplement;
- the spiritual, religious, and existential aspects of prevention;
- individual responsibility in allocating scarce resources;
- preventing falls among the elderly in communities;
- minimizing complications while maximizing quality of life in the hospitalized elderly.

The cost is \$19.95 for the paperback edition or \$39.95 for the cloth edition, plus postage (\$3.95 for the first book and \$1.50 for each additional book). ▼

Check out these easy patient resources

Pritchett & Hull Associates in Atlanta recently released several new patient education materials. To order the materials described below, contact Pritchett & Hull, 3440 Oakcliff Road N.E., Suite 100, Atlanta, GA 30340-3079. Telephone: (800) 241-4925. Web site: www.p-h.com.

• ***A Stronger Pump: A Guide for People with Heart Failure.*** This 40-page booklet is based on the latest disease management guidelines. The book uses a low reading level and colorful illustrations to cover the following issues:

- recognizing and controlling heart failure symptoms;
- medications;
- rest, exercise, and stress management;
- limiting fluids;
- other ways to improve heart function and other heart failure treatments;
- cardiac tests, heart transplants, and left-ventricular assistive devices;
- causes of heart failure.

In addition, the booklet includes an easy-to-use information sheet and medicine chart to personalize for each patient. The wholesale cost to health care professionals is \$3.75 plus shipping and handling. All orders have a \$30 minimum with quantity discounts available.

• ***Pulmonary tear pads.*** These 8½- x 11-inch double-sided tear sheets come 50 sheets to a pad. The sheets are colorful and include easy-to-use instructions to help patients with chronic lung disease breathe easier and feel better. Topics covered include:

- pulmonary rehabilitation;
- pursed-lips breathing;
- postural drainage;
- controlled coughing;
- incentive spirometer use.

The cost is \$10 for a tear pad of 50 sheets plus shipping. All orders have a \$30 minimum with quantity discounts available. Samples of the tear sheets can be viewed on-line at www.p-h.com. ▼

Surf for newest ADA issues

CanDo.com, an on-line resource based in Mountain View, CA, for people with disabilities, recently entered a partnership with the World Institute on Disability, an international public policy center that carries out research on disability issues, in Oakland, CA. They will develop a dedicated resource channel on the CanDo.com site that features developments on employment, health benefits, and disability policy.

The channel will provide strategies to help people with disabilities seek and maintain long-term employment and leverage new laws. The first of such legislation, the Americans with Disabilities Act (ADA), celebrates its 10th anniversary this year. ■

Send us *Resource Bank* items

If you have a new resource, conference, or seminar of interest to other case managers, send items for publication to: Lauren Hoffmann, Editor, *Case Management Advisor*, P.O. Box 740056, Atlanta, GA 30374. Telephone: (770) 955-9252. Information on conferences and seminars must be received at least 12 weeks before the event to meet publication deadlines. ■