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Covering Case Management Across The Entire Care Continuum

INSIDE

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Professional development

Experts predict 21st century will usher in continued consumerism

Here's what that may mean for case managers

The new millennium has dawned and with it a new consumer-driven health care industry has arrived, according to a new PricewaterhouseCoopers report, *Healthcast 2010: Smaller World, Bigger Expectations.* The report was released at the corporation's recent Thought Leadership Forum in Cambridge, MA. Case management industry leaders agree with that assessment, among other *Healthcast 2010* report predictions, and say understanding the impact of this Internet-armed, better informed, more demanding consumer will provide both challenges and opportunities for tomorrow's case managers.

"The need to become outstanding educators and partners of our patients will require case managers to take advantage of more opportunities than ever to keep current with rapidly evolving health care advances," says **Kathleen Moreo**, RN, BSN, BPSHA, CDMS, ABDA, CM, owner and president of Professional Resources in Management Education (PRIME), a case management consulting and education firm in Miramar, FL, and president of the Case Management Society of America (CMSA) in Little Rock, AR.

"In the near future, successful case management will mean good riddance to our too-often paternalistic care coordination, and hello to true, patient-centered, patient-driven approaches," predicts Moreo.

"We will assist the patient/family in accessing appropriate medical information and support the family/patient in mapping out individualized health care plans — much like financial planners assist clients with portfolio selections. We will assist families, employees, and seniors in determining health care choices, help them ask their physicians the right questions and ensure that information is documented

in their care coordination records. We will provide assistance in selections of care maps for wellness coverage so that their health care is well-planned in advance — when they are healthy and able to make sound choices regarding their own at-risk disease processes," she says.

Just a little guidance, please

Others agree. "Consumers will take a more active role in their health care and will seek advisors to assist them in navigating that system," says **Nancy E. Skinner**, CCM, RN, principal consultant for Riverside Health Care Consulting and immediate past president of CMSA. "Case managers will be those advisors, and hospitals and physician groups will offer case management to consumers as a value-added service. Empowered consumers will privately hire case managers to maximize health care dollars, obtain information regarding alternative health care options, identify methods for receiving continuing care services in the home, and advocate for the delivery of quality health care services."

The days when consumers viewed providers as authority figures whose word was law is past, adds Skinner. "Baby boomers have established a pattern of challenging authority — asking questions and obtaining validation of those answers from multiple sources. Baby boomers are computer literate and will seek information via the Internet — not only from traditional sources such as professional organizations, but also from sources dedicated to complementary and alternative medicine [CAM]."

Skinner predicts that baby boomers will expect Medicare to provide expanded coverage for CAM. Additional impacts Skinner expects aging baby boomers to have on the health care marketplace include:

• **More pressure on government officials to improve benefits.** "More pressure will be placed at all levels of government to provide quality health care services, including pharmaceuticals and coverage of traditional therapies," says Skinner.

• **More retiree programs.** "We will also see an expansion of employer programs for their retirees that is secondary rather than supplemental to Medicare, she says.

• **More direct-to-consumer advertising by providers.** "Physician groups, hospitals, pharmaceutical companies, home health agencies, rehabilitation facilities, and other continuing care providers will all increase direct advertising to the consumer. This advertising will be in both print and electronic media," says Skinner.

Yet, while many point to the new, educated, well-informed health care consumer, others caution that not all consumers have jumped into the information age with both feet.

"The problem is that there is still a large group of people who are not catching onto this excitement and they are the ones case managers often work with," says **Anne M. Llewellyn**, RN, CCM, CRRN, owner of PRIME. "Those are the poor and uneducated, who often make poor choices. This is the 20% of the population that utilizes 80% of our health care resources. The case manager's goal will be to identify this population and work with them to educate them about their health issues and cut through the red tape that seems to trip these people up in life."

True continuity

Llewellyn points to another prediction of the PricewaterhouseCoopers report as a possible solution to some of the problems common to this 20% of the population that consumes so many health care resources — e-commerce.

She offers the following scenario to illustrate how e-commerce will improve health care services in the very near future:

An HIV-positive patient who is noncompliant with his medication regimen and also an IV drug abuser comes into an emergency room on a Saturday night. His personal physician is in another state. The patient has been visiting his mother for the past two months. He states he is on a "ton of meds," but did not bring them with him.

Today, the attending emergency room physician must start from scratch with this patient. In the future, that same physician could access the patient's records through the computer. The treating physician could access the current treatment plan and also read the patient's primary physician's notes regarding the education the patient has received about his IV drug abuse and noncompliance. This gives the new physician a place to start instead of reinventing the wheel. It also gives the case manager a clear idea of this patient's needs and the tools to begin an aggressive education effort. This patient will get better and more appropriate care because of technology. Instead of starting over, there can be true continuity of care.

PricewaterhouseCoopers interviewed and surveyed 400 thought leaders and health care executives in the United States, Europe, Canada, and the Pacific Rim about their predictions on the factors shaping the future of health care. The report also predicts a rise in genomics and a health care paradigm shift to a prevention model. In fact, 38% of the survey respondents in the United States predict that third-party genetic mapping businesses will spring up and become the primary source for an individual's genetic map.

"Genetic mapping may become more available and with it will be a need to answer ethical questions that are tied to these services. Will a genetic tendency to develop catastrophic disease interfere with a consumer's ability to receive appropriate health care coverage? Will case managers work with consumers who have these genetic tendencies to develop appropriate strategies to address anticipated health care needs?" Skinner wonders.

Too close for comfort

Perhaps no area of the report hits closer to home for case managers than *Healthcast 2010*'s predictions for how the industrialized world will pay for tomorrow's health care. PricewaterhouseCoopers' thought leaders predict that health care financing trends will converge, with the United States moving toward a more governmental model and Europe and Canada moving away from a government model toward more privatization.

Specifically, the survey found:

• 60% of respondents believe that most American employers will offer employees the option of medical savings accounts by 2010.

• 64% of respondents think employers will move to defined contribution programs for health benefits.

• 56% of respondents predict that Medicare also will move to a defined contribution program for health benefits.

Moreo also expects employers to offer medical savings accounts and sees that as an opportunity for case managers to educate consumers. "In South Africa, for example, medical savings accounts are already offered to employees in private industry and are fraught with problems," she notes. "All medical savings accounts are capped per annum, and can roll into major medical depending on the intensity of service. Due to caps, parents often disregard their own health needs in order to protect the savings for their children. This is a nationwide problem in South Africa. Further, physicians are falsifying the intensity of service necessary for patients in order to help their patients save their medical savings, accessing major medical funds, instead. As these medical savings accounts become available to consumers, case mangers must take a role in educating employees about their best use."

Paying for tomorrow's health care is a problem that every country is facing, says Llewellyn. "With the aging of our world and the slow population growth, we will not have the support that has been previously in place," she predicts. "Employers will pull out of the insurance business and this will become the responsibility of the individual and for those who cannot afford the cost of health insurance, the government will step in.

"Due to these pressures, consumers, case managers and others in the health care system will need to deal with issues regarding end-of-life that up until now we have not always been willing to tackle," adds Llewellyn. "The 99-year-old woman living in a skilled care facility in a fetal position who develops a fever will not be as aggressively treated as she would be today. Quality of life will have to be looked at and hard decisions will need to be made. This is slowly coming into play, but will really become a reality when the family of that 99-year-old woman has to pay the bill themselves. This will take education and support."

In addition, Llewellyn sees the chronically ill needing to take increasing responsibility for their own health care.

"The pressure will be on all health care

workers to deal with this, but I see the role of the traditional case manager becoming more prominent if we are willing to take the challenge," she says. "The role of the traditional case manager will change to deal with that 20% who spend the 80% of our health care resources in an aggressive manner that recognizes that we do not have an endless supply of money and choices have to be made. Case management has tremendous potential if we are willing to change, learn, and take the lead in shaping health care policy. The case manager is the one professional who has the foresight to understand the holistic needs of the customers who use the health care system."

"We can all take a look at trends and guess what the future may hold," Skinner concludes, "but I firmly believe that the role of the case manager will be significant in tomorrow's health care delivery system. I believe that case management will come out of the closet to become a powerful consumer tool for establishing the delivery of quality, appropriate, and cost-effective care both in this country and internationally."

The PricewaterhouseCoopers' *Healthcast 2010* report is available on the company's Web site at www.pwcglobal.com/healthcare. ■

Prepaid legal services protect your license

You don't have to face your licensing board alone

It's not liability insurance. It's not insurance at all, but it may mean the difference between losing your livelihood and a long and successful career as a case manager.

Licensing Protective Services (LPS) in Severna Park, MD, launched a prepaid legal service late last year for the sole purpose of helping professionals defend complaints against their licenses. "Many professionals assume that their liability insurance or their employer will provide coverage to defend their professional licenses, but that's not the case. Your insurance company will address issues of malpractice, but not help you defend license," says **Roy L. Mason**, JD, CEO of LPS, a lawyer with more than 20 years of experience helping physicians and other professionals defend their licenses against state board action. "The first mistake people make is to try and deal with complaints against their licenses on their own. Maybe they don't want to tell their employer. But that license is their livelihood — and how they respond to an investigator or to a complaint is critical."

Mason and his partners believe that they have found a way to make legal protection an affordable, sensible business expense for professionals operating in an increasingly litigious society. LPS provides up to $25,000 in reimbursed legal costs and expenses each year, with no deductible, for an annual fee that ranges from $99 to $299 depending on the profession. In addition, the fees are a tax-deductible business expense for most professionals.

"The whole society has become more litigious. Add to that a consumer who is so much more aware — a quick tour of the Internet can tell your client whether you have a valid license to practice in most states," notes **Barry Fontaine**, president of LPS. "Under the guise of consumer protection, state licensing boards have awesome power to investigate and discipline professionals without the normal due process a citizen is entitled to in a court of law. If someone files a complaint against you to your state board, they don't complain for settlement — the only thing at stake is your license."

It's quantity, not quality

State boards have become lightning rods for consumer complaints, notes Mason. "We have found the enemy and it is us. The turf battles being fought in many health care professions are reflected on the boards themselves. The makeup of the board and the decisions the boards make are always two or three years behind current professional practice — that's just the way government works.

"I tell all potential clients that a complaint to the board has nothing to do with the quality of your work and everything to do with the volume of your work. The more clients you serve, the more likely it is that one of those clients is going to write a complaint to your state board. And the newer or more controversial your position, the less likely you are to find a friend on the board," he says.

(Editor's note: Nurse case managers in New Hampshire had to defend their role to their state licensing board last year. See Case Management Advisor, *October 1999, pp. 149-154, 159.)*

State boards are under increasing scrutiny themselves, Mason adds. "States set up professional boards to govern the professional practice of each individual in the profession. State licensing board members are generally appointed by the state governor to multiyear terms to develop the rules and regulations that govern that profession. Boards need to provide proof that they are disciplining their members appropriately in order to grow," he explains.

"Boards are given authority to investigate those individuals practicing the profession. Whenever a state licensing board receives a complaint about a professional, it is charged with the responsibility to investigate the complaint. These state licensing board investigations have no time limitations, nor do they have to be limited to the scope of the original complaint," says Mason.

Professionals often greet state board investigators as peers. "They are coming from your state board. Later, you find out that the investigation has widened from the issue of the original complaint and become a review of your records, and suddenly the situation doesn't seem so simple anymore," says Mason.

LPS doesn't hire lawyers or brokers, so most states don't consider the prepaid legal services the fledgling company provides to be insurance. "That means we can keep this simple and easy for our members. We use no brokers and require no lengthy contracts. We simply sign up members and connect them with a qualified local legal professional when there's a problem," says Mason, adding that the lawyers were selected through referral sources who recommended them as lawyers experienced in state license defense work.

The important thing to remember about a consumer complaint or other action against your professional license is that unless there is a personal injury involved, there won't be a lawyer representing the other side, says Mason. "An experienced counsel knows what the state board is looking for and can often resolve these issues with a telephone call or a letter. The experienced lawyer will also work quickly to contain the investigation and force a resolution of the issue, which is helpful to the professional who has this cloud hanging over his or her head."

LPS is using the Internet as a sales and service medium, notes Fontaine. To learn more about LPS, visit the company's Web site at www.licproserv.com. ■

Workers' comp/disability management

Nonsurgical treatment helps correct clubfoot

50 years of success have not brought acceptance

The work of a lifetime has become a crusade to change the way orthopedic surgeons correct congenital clubfoot. Armed with 50 years of successful outcomes and the support of a few colleagues and scores of thankful parents, **Ignacio V. Ponseti**, MD, an 85-year-old orthopedic surgeon at the University of Iowa Health Care in Iowa City, has set off on the lecture circuit, hitting medical conferences and major teaching hospitals worldwide to promote a nonsurgical, low-cost treatment for correcting clubfoot deformity.

"It's my hope that vehicles such as these classes and the new Web site launched by the University of Iowa Health Care will inspire other physicians and parents to more actively and vocally promote nonsurgical treatment for clubfoot," says Ponseti. "Ultimately, each child with clubfoot should have the least traumatic and most effective treatment possible." **(See box on p. 6 for Web address and other resources on treatment of congenital clubfoot.)**

The Ponseti Method for clubfoot treatment is a nonsurgical procedure that begins with the orthopedist's understanding of foot anatomy mechanics, says Ponseti. The technique involves manual manipulation and straightening of the foot and the application of toe-to-groin plaster casts. The casts are changed weekly in the outpatient setting after the clinician manipulates the softened foot ligaments to gradually achieve near normal muscle and bone alignment. Five or six cast changes spaced one week apart are sufficient to correct most clubfeet.

The bones of an infant's feet are mostly cartilage, making the foot easy to manipulate without any pain to the infant. Roughly 80% of the children must have their Achilles tendon severed with a thin, cataract knife using local anesthetic after the third or fourth cast is removed. "It is very difficult to release the heel chord by stretching alone. In infants this young, the tendon regenerates to the proper length in a few weeks with no lesions. After the tendon is severed, a last

cast is applied that remains in place about three weeks," says Ponseti.

After the last cast is removed, the infant must wear shoes attached to a metal splint full-time for about two months followed by nighttime-only wear for anywhere from two to four years to prevent the correction from reversing itself. "You have some families who will not comply with the brace. Not everyone is going to faithfully continue to put the brace on every night. You have to make families aware that the brace is an important part of the entire treatment. The alternative is reversal of the correction and surgery," says **John E. Herzenberg**, MD, associate professor of orthopedic surgery at the University of Maryland Medical School in Baltimore.

Herzenberg began using the Ponseti Method three years ago after 10 years of performing the traditional invasive procedure used by 98% of orthopedic surgeons for clubfoot correction. "I had dinner one night with a friend who works with Ponseti at the University of Iowa. Every orthopedic surgeon has heard about the method, but no one really believes it works. My friend told me it really did work and I trusted him. Then, Ponseti wrote a book that describes the procedure in detail and I read it three times before deciding to try the method on my own patients."

Looking back on correction

In a recent review of the first patients he treated with the Ponseti Method, Herzenberg compared 12 patients treated with Ponseti's Method to 12 patients treated with traditional invasive surgery. "Only one patient in the Ponseti group required a follow-up surgery to provide further correction, compared to 11 out of 12 of the patients treated with traditional surgery," he says. However, the reason he's decided to make Ponseti's Method his standard treatment for congenital clubfoot is the appearance and function of his patient's feet. "Children treated with Ponseti's Method have marvelous-looking feet that are strong and supple compared to the feet of children treated with traditional surgery. Those children tend to have feet that are stiff and not as strong."

Ponseti agrees. "The feet of children treated with surgery appear good in the beginning. The feet appear aligned," he notes. "But later, the feet become painful and stiff. The reason is that the ligaments of the foot are severed and replaced by scar tissue. Orthopedic surgeons are now seeing patients who are 30 or 40 years old who had surgical clubfoot corrections as children. Now these adults have painful feet and the surgeons are at a loss to help them."

Ponseti, Herzenberg, and the handful of other orthopedic surgeons worldwide who now regularly use the Ponseti Method to correct clubfeet have documented thousands of successful outcomes. In addition, because it is done on an outpatient basis, the Ponseti Method is much less costly than surgical correction. At the University of Iowa Health Care, the Ponseti Method costs $2,000 from start to finish compared to average surgical charges of $11,000 for the traditional procedure.

In addition, as many as 25% of children treated surgically require a second surgery later, which can cost as much as $25,000, note Ponseti and Herzenberg. "A number of children treated with the Ponseti Method, roughly 30%, require surgery to move a tendon from the inside of their foot to the center to straighten out the foot alignment. That is usually an inpatient surgery often done at about 2½ years, and parents should be aware of that possibility," adds Herzenberg.

Why have surgeons been so reluctant to adopt a method that is both cost-effective and produces

Resources on Congenital Clubfoot

- Ponseti IV. *Congenital Clubfoot: Fundamentals of Treatment*. New York: Oxford University Press; 1996.
- Laaveg SJ, Ponseti IV. Long-term results of treatment of congenital clubfoot. *J Bone Joint Surg* 1980; 62A:23-31.
- Cooper DM , Dietz FR. Treatment of idiopathic clubfoot: A 30-year follow-up note. *J Bone Joint Surg* 1995; 77A:1477-1489.
- Ponseti IV. Common errors in the treatment of congenital clubfoot. *International Orthopaedics* 1997; 21:137-141.

In addition, information on the Ponseti Method is available on the University of Iowa Health Care's Web site at www.uihealthcare.com/DeptsClinicalServices/Clubfoot/. The site answers commonly asked questions about the method. A 20-minute digitized video for Web use is also available through the site.

such positive outcomes? One reason may be economics, notes Herzenberg. "I have a friend who works as an orthopedic surgeon in Israel. He introduced the Ponseti Method to his colleagues there at a medical meeting and one stood up and said, 'Why are you doing this? You're taking away one of the last good operations we have!' That may be part of the answer. I can't say for sure. Personally, I'm willing to take a drop in my income if it means doing something good for kids." ■

Behavioral health

Bill provides services for the mentally ill homeless

Here's how agencies plan to succeed

Your mission, should you chose to accept it, is to use $10 million in state taxes to provide integrated services to the homeless and mentally ill in your community in an effort to keep them off the streets and out of the criminal justice system. Here's the catch: To retain your state funding, you must prove that you've made a significant improvement in the health and function of this population in roughly six months.

Would you accept this assignment? Two mental health service providers in California say they are up to the challenge. The Turning Point Community Programs in Sacramento and The Village Integrated Services Agency of the Mental Health Association of Los Angeles County in Long Beach have accepted the challenge presented them by California state legislators and are actively working to develop a service model that keeps the homeless, mentally ill off the streets and on the road to rehabilitation.

AB 34 was signed in mid-October 1999 and the two agencies primarily responsible for developing the pilot programs have hit the ground running. Turning Point Community Programs, which is running AB 34-sponsored programs in Sacramento and Stanislaus counties, received its AB 34 funding the first of November and already had enrolled and housed 17 clients by the third week of that month — just a small start on the projected 100 clients it will eventually serve.

"We've been working at a fast and furious rate," says **John A. Buck**, MBA, executive director of the Turning Point Community Programs in Sacramento. "This legislation is beyond anything previously attempted in mental health. The legislation was just passed and we have to show objective and measurable results by May 2000. We didn't have time to sit and talk about how this should be done. We had to bolt ahead," he notes. **(For information on how AB 34 providers plan to measure outcomes, see story on p. 8. For more on the bill and how it was passed, see p. 10.)**

"AB 34 is the most exciting development in mental health care in this country in recent years. It means more agencies are going to involved in an integrated service model that is really designed to rehabilitate the mentally ill, not warehouse them," says **Richard Van Horn**, president of the Mental Health Association in Los Angeles County, which operates The Village Integrated Services Agency. "We're ready for the challenge."

Seeking an edge

The need to show results before the next state budget cycle in May of this year led the State Department of Mental Health to turn to experienced providers with a proven track record to run the three pilot programs authorized by AB 34, notes **Vince Mandella**, BS, chief of adult systems of care for the California State Department of Mental Health in Sacramento.

"Given the short time span, we had to look for an edge. Both Turning Point and The Village have a long history of providing community-based mental health services. We knew by turning to them, it would take very little for these agencies to piece together services they already had delivered to other populations and move down the road to success. Under the circumstances, we couldn't select providers we had to spend time explaining how to do this. We needed folks who could begin the minute the funding arrangement was completed."

The Village has a 10-year history of providing capitated, community-based, mental health services to the seriously mentally ill. "When we first started, Los Angeles County was spending an average of $23,000 and change annually [per patient] on services to the seriously mentally ill

How to prove your worth in six months or less

Stop and answer this question: If your boss allocated money for you to set up a new case management program with the condition that you be able to show positive outcomes in no more than six months, could you?

That's exactly what the state of California has challenged pilot mental health programs for the homeless to do. That task is daunting, but proponents of these integrative service programs are determined to give it a try. **(See related stories on California's newly passed mental health bill AB 34 and the pilot programs it sets up on pp. 7 and 10.)**

One of the groups participating in the pilot program established by California's AB 34, Turning Point Community Programs in Sacramento, has identified seven indicators of success that it is fairly confident it can influence even in the short time span given. "We are actually measuring a total of 25 elements, but within that group we have singled out about seven that we think we can impact and measure even in just a few months," says **John A. Buck**, MBA, executive director of Turning Point Community Programs.

Those measures are:

- number of outreach contacts, including the number of homeless mentally ill who refuse enrollment after outreach measures;
- number of days incarcerated;
- number of days spent homeless;
- number of clients accepting enrollment into addiction recovery programs;
- number of clients graduated from addiction recovery programs;
- number of clients on probation or parole.

"The most important issues we have to prove to the state Legislature before the next budget cycle are whether we can eliminate homelessness and eliminate the impact on ancillary services like law enforcement in this population," says Buck. "We want to show improvements in quality of life, but it's not realistic to think that in five or six months we can bring a homeless, mentally ill individual into a fully benefited, half-time job. We are keeping our goals realistic and focusing on some very basic outcomes for this initial time period."

Initially, any change impressive

Those involved must remain pragmatic about outcomes, agrees **Vince Mandella**, BS, chief of adult systems of care at the California State Department of Mental Health in Sacramento.

"If we can show that the programs work and have a positive impact, there is a greater likelihood that the governor and the state legislators will continue the program — it's that simple," he says.

"There is pressure to have something to say before the next budget cycle in May of this year. We just have to show a slight edge in improving basic domains of life. Are there fewer hospitalizations in this population than before AB 34? Are there fewer contacts with law enforcement? Are more homeless mentally ill people housed than before AB 34?

"If we can show even slight indications that the programs are working, it will probably serve as strong evidence that they should be continued," he adds. ■

with 71% of the population in 24-hour care. We changed that to an average of $17,000 a year with only 17% in 24-hour care."

Turning Point provides a similar program for the seriously mentally ill in Sacramento and Stanislaus counties. Both Buck and Van Horn attribute the success of their programs to an integrative approach to mental health services that addresses the issues that often prevent the mentally ill from remaining stable and becoming productive.

The plan Turning Point presented to the state calls for an "active, assertive, ongoing partnership model with community resources, such as mobile assessment teams, medical teams, case management, and other service providers."

Specific targeted services identified in the plans written by Turning Point and The Village include:

- **Housing.** Clients will be assisted in choosing, getting, and keeping housing of their choice which is the most independent and least restrictive feasible in the community.

"Housing is a major focus of ours," says Buck.

"It's the first thing we address. It's not to tell the client, 'You need a psychiatrist.' It's to say, "Where can you be comfortable and safe?' Other needs are secondary to getting these folks temporary housing."

Finding that temporary housing for clients, has been a real challenge, he adds. "All of our folks are becoming housing experts. We have found places for clients in hotels, in apartments. We have to be very aggressive about finding housing, and it has to be appropriate housing. When it comes to finding temporary shelter, we could get a room at the Hyatt for $200 a day, but would our clients be comfortable there? Would the Hyatt be comfortable with our clients? We could also go to the other end of the spectrum and probably find space in some flea-bag motel, but is that where we want to put someone we are hoping to rehabilitate? No, we're looking for mid-range options — Spartan, but clean and nice."

• **Comprehensive wrap-around services.** "This just means coordinating care with existing community service agencies, such as veterans' services, consumer advocacy groups, and developing a homeless peer advocacy group — people have worked their way successfully out of homelessness to give hope to our clients," says Buck.

Clients are referred into the pilot programs through a variety of sources. In Sacramento and Stanislaus counties, most referrals come from outreach workers who actually walk the streets and levies along the Sacramento River talking to the homeless and offering them service options. "The outreach workers are part of a homeless project that marries law enforcement officers with outreach workers from community agencies such as the Vietnam Veterans and Volunteers of America," says Buck. "We are staffed 24 hours a day. If an outreach worker convinces someone to come in, we want someone there for them to talk to and a place ready for them to stay."

• **Case management/brokerage services.** "We must have case management to assure continuity of care and to help clients access mental health, medical, educational, vocational, social, legal, and housing services," notes Buck. "Case management services start with plan development and that means listening to the client's needs."

The Village has been careful to avoid the term "case management," notes Van Horn. "The consumer movement, and particularly the mentally ill, hate the term 'case management.' Consumers respond, 'I am not a case and I don't want to be managed.' Instead, we call care coordinators 'personal service coordinators.' Most of our personal service coordinators are bachelor's level people. We also have an RN, a LCSW, and a half-time psychiatrist on a team, with each team being devoted to 40 clients."

Van Horn notes that the psychiatrist never acts as team leader. "The team leader is appointed from within the team, but is never the psychiatrist. We don't want our psychiatrists burdened with administrative work — they're too expensive," he says, adding that teams meet weekly to discuss clients on their caseloads.

At The Village, team members share a work area that is completely without private offices. "We wanted all members of the team, even the psychiatrist, working as peers to provide care to the clients. It takes special people. Especially our doctors. They have to be fairly devoid of ego," says Van Horn.

"When you focus that kind of attention on clients, you really reduce your hospitalization usage. You know when trouble is starting and you can address it before a client completely decompensates. If you listen, this system works well. Most people given a free choice will chose health and well-being. If you are willing to listen to clients and take them seriously, they are probably going to make choices that move them towards health."

• **Treatment of psychiatric conditions in appropriate settings.** Settings identified by Turning Point include emergency care, crisis residential facilities, acute hospital care, skilled nursing facilities, day treatment facilities and transitional and long-term residential treatment facilities, notes Buck.

• **Medication support services.** "We have set up a system to prescribe, administer, dispense, and monitor psychiatric medications necessary to alleviate symptoms of mental illness," says Buck. "Most of our clients are convinced they need medications. We use education to improve compliance, especially those who are resistant because they were on heavy-duty medications with unpleasant side effects in the past. We can't and don't force our clients to take anything, even when we think it might help them. If we do, they will run."

Instead, Turning Point encourages its psychiatrists to spend extra time with each client convincing them that a particular medication may be worth trying. "We never tell a client that we will refuse service if they resist treatment. We also try to link them up with other clients who

have successfully used a medication. Often, having another client say, 'I tried this medication, and it really helped. I have a house. I have a job,' is more effective than the psychiatrist saying, 'I really think this medication will help you.' We just get a better response from the client to peer counseling in many cases."

The Village takes a similar approach to the use of psychiatric medications. "Our goal is not complete symptom relief, but maximum functionality. We ask the client, what dose, what medication works to help you do what you want to do? We look at medication as series of choices that help the client reach established goals. If you take that approach, then compliance becomes a non-issue because the client is helping to make medication decisions."

• **Specialized group and individual programming.** "This is meant for dually diagnosed patients who are mentally ill and also have a substance abuse problem," notes Buck. "We really push the recovery model. Rehabilitation is what we do for the client. We teach. We train. We link them up with people who have been successfully recovered from substance abuse."

• **Individual service plans.** "We try to establish plans that include the client's stated goals and strengthen the client's competence over his or her own life. We look at cultural issues, independent living arrangements, education, and employment, and we always put the client's needs first," notes Buck.

"Our philosophy from the initial contact on is to put the client first. Our approach is to ask what is it you need or want that will help you to get out of this situation. And, more times than not, their first answer is to ask for a pair of underwear and a pair of socks. When you're homeless, underwear and socks take on great importance. We could provide psychiatric services first, but we would probably have people running right back to the streets because all they wanted was clean clothes and something to eat."

The Village has a similar philosophy. "Our bias is to put the consumer first. Our approach has been that whatever somebody needed or desired we should find a way to make it available," says Van Horn. "When we first started asking clients what they wanted, they usually answered that they wanted easier access to a psychiatrist and 50-minute therapy hours and not much else. They simply didn't know what to ask for because they had never been offered anything else. We had to suggest to them that there were more things. We had to make them aware of the possibility of rehabilitation. How would you like a house? How would you like a job? How would you like a girlfriend? Those questions were not within their realm."

• **Round-the-clock crisis intervention.** Turning Point has set up a crisis line for crisis interventions to help cope with an emergency that might lead to a hospitalization, or other threat to a client's maintaining status as a community member.

The Village even addresses crises by providing psychiatric house calls. "We have found that one well-timed house call can avoid a hospital stay. It could be to address an emergency or it could be a client who has simply developed a fear of leaving the house and is running out of medication. If the client says, 'I really can't go anywhere,' the doctor or the nurse, depending on the needs, brings the medication to the client and evaluates the situation."

"I've read the plans written by both The Village and Turning Point and what they plan to do is very exciting. Everything has been engineered to get these programs off to the best possible start. If we can show some improvement, with a relatively small, new program, it's going to be fascinating," says Mandella. ■

Advocates of mental health bill present a united front

How a bill becomes law

California recently passed into law a historic measure to expand proactive mental health treatment programs as a test effort for the homeless mentally ill in three communities. Mental health advocates hope that these programs can reverse the damage caused when the state deinstitutionalized its mental health care system.

"It was a grass-roots effort. We collected more than 3,000 signatures and delivered them to the governor, lobbied state legislators, urged newspaper editors to write editorials in support of the bill, and held a press conference to get this bill passed. It was an organized campaign we hope delivers on its promise," says **Rusty Selix**, JD, executive director of the Mental Health Association in California and the Council of

Community Mental Health Agencies, both in Sacramento.

"When we held our press conference, we were careful to keep mental health advocates in the background," notes Selix. "Instead, we asked law enforcement officers to carry the message about why we needed this bill. We believe that was a key step in getting this bill passed. The arguments of the law enforcement officers had more authority for legislators than the arguments they had heard many times from mental health advocates.

"Officers explained how many mentally ill people ended up in trouble with the law because they didn't have the medications and support services they needed," notes Selix. "They argued that these untreated mentally ill people were placing a huge burden on the state's law enforcement system."

To support that argument, Selix says the Mental Health Association used grant money from pharmaceutical companies to sponsor a study that showed the amount of money spent in the criminal justice system on the mentally ill. "We found that the amount spent was more than the entire state budget for mental health care," he notes.

California bill AB 34 specifies how $10 million will be spent on community-based mental health programs. "These pilot programs will help get people back on their feet early, rather than waiting until they have a run-in with the law and end up serving time in jail in order to get proper treatment," says Selix.

"The need to address this population has been under discussion for a long time in California," notes **Vince Mandella**, BS, chief of adult systems of care in the California State Department of Mental Health in Sacramento. "It wasn't hard to gain support from law enforcement agencies," he adds. "Law enforcement at the local level sees the impact of this group and is called upon to intervene with the mentally ill, homeless population regularly. They have been disappointed to find that there is this hole in the human service agency structure that these folks don't fit. AB 34 is designed to try to plug that hole.

"Another key element in getting this landmark legislation passed was an early recognition of the constituency groups that would have to come together and present a unified front of support. Those included law enforcement, mayors from California's major cities, mental health advocacy groups, and the professional associations, such as the state chapters of the American Psychiatric Association."

The pilot programs set up under the new bill take an intense, integrative service approach, he adds. "The miracle of new modern medicines has made it possible for many people who previously needed intensive treatment to become virtually self-sufficient and lead productive lives. However, we believe that medications alone are not enough. These people need a variety of support services, including housing assistance, life skills training, and treatment for substance abuse. If you don't treat and train, you won't succeed. You have to take an integrated approach. **(See related story on how these integrated mental health pilot programs have hit the ground running on p. 7.)**

"This bill is a major step towards ending the criminalization of the mentally ill," says Selix. "It's our first real step in the direction of helping someone get treatment before they break the law, not after. Not only is that good public policy, but it is the right thing to do."

A bill passed by the California state Legislature about 10 years ago established state-funded pilot programs to treat the severely mentally ill.

"What we need to prove now is that the integrated approach used by those programs can work for the homeless on the street who may be resistant to help, and that by doing so we can make a dent in the incarceration rate for the mentally ill. And, of course, that it translates into cost savings for the criminal justice system," says Selix. ■

Study: Antidepressants safe during pregnancy

Researchers hope more women will get help

It's not just the blues. Roughly 9% of all pregnant women suffer from clinical depression that prevents them from eating and sleeping properly to the point of losing weight and endangering their babies.

A new study finds that there is clear evidence in the literature that many antidepressants are safe during pregnancy.

Researchers compiled and analyzed data from four drug-specific studies published in the literature from 1993 to the present. They organized

study findings into five categories and found some encouraging news for pregnant women with depression and their physicians — there is strong evidence that antidepressants are safe throughout pregnancy for both women and their children.

Researchers evaluated studies for the following categories:

- intrauterine fetal death;
- physical malformations;
- growth impairment;
- behavioral abnormalities;
- neonatal toxicity.

"We found no evidence that tricylcic antidepressants, specifically fluoxetine, and newer SSRIs (selective serotonin reuptake inhibitors) increase risk for intrauterine death or major birth defects," says **Katherine L. Wisner**, MD, psychiatrist and associate professor with University Hospitals of Cleveland and Case Western Reserve University, both of Cleveland.

Weighing the risks

Researchers also found that exposure to tricyclic antidepressants and SSRIs did not increase risk for growth impairment. "There were some reports of lower birth weights. However, we know that major depression commonly causes women to lose weight anyway. It is possible that an undertreated mood disorder, and not the drug itself, could affect the weight of both mom and baby. We recommend that doctors monitor the weight gain carefully in pregnant women being treated with antidepressants."

The study also found that there was no evidence that children prenatally exposed to tricyclic antidepressants had any problems with cognitive function, temperament, or general behavior compared to children who were not exposed to those drugs. No data were available for prenatal exposure to SSRIs, Wisner notes.

The one area of concern researchers found was the incidence of withdrawal symptoms in some newborns whose mothers were treated with antidepressants near the end of their pregnancies. Those symptoms included jerky movements and seizures, rapid heartbeat, irritability, feeding difficulties, and profuse sweating. Researchers suggest that those symptoms could be avoided by tapering to a lower dosage or even discontinuing antidepressants 10 to 14 days prior to a woman's due date, Wisner says.

"When women and their physicians are weighing the benefits vs. the risks of drug therapy during pregnancy, they must look at just how severe the depressive symptoms are," says Wisner. "Being suicidal, not eating properly or enough, can do more harm to a pregnancy or fetus than an antidepressant. We share the hope that our paper will be a catalyst for improvements in the care of pregnant women with depression."

[See: Wisner KL, Gelenberg AJ, Leonard H, et al. "Pharmacologic treatment of depression during pregnancy." JAMA 1999; 282(13):1,264-1,269.] ■

Disease management/Research briefs

Guidelines for bladder cancer are issued

Guidelines urge use of follow-up therapies

Physicians should consider using IV chemotherapy or immunotherapy as adjuvant therapy following surgery for nonmuscle invasive bladder cancer, according to recently released treatment guidelines from the American Urological Association (AUA) in Baltimore.

Currently, there is wide variation in the use of adjuvant therapy after transurethral resection of the bladder for the more than 50,000 new bladder cancer cases diagnosed each year, note members of the expert panel that developed the guidelines.

"For patients who have not had prior IV therapy, adjuvant IV chemotherapy or immunotherapy is an option for treatment after endoscopic removal of low-grade bladder cancers," the AUA guidelines state. "All the intravesical agents studied, when used after transurethral resection, result in lower probability of recurrence than surgery alone."

However, the data evaluated by the AUA panel indicate that although the IV agents decrease bladder cancer recurrence rates, there is no evidence that they affect long-term progression of the disease and they may not be appropriate in all cases, notes the panel. "Careful follow-up is required because bladder cancer patients are at risk for progression to muscle-invasive cancer,

which may require bladder removal," says panel chair **Joseph A. Smith Jr.**, MD, of Vanderbilt University Medical Center in Nashville, TN.

The guidelines include recommendations for three types of patients. They are:

- a patient who presents with an abnormal growth on the urothelium but has not yet been diagnosed with bladder cancer;
- a patient with established bladder cancer of any grade, stages Ta or T1, with or without carcinoma in situ, who has not had prior IV therapy;
- a patient with carcinoma in situ or an aggressive cancer that has begun to penetrate the bladder wall, who has had at least one course of IV therapy.

The panel further categorized its policy recommendations into three grades of flexibility as determined by the strength of the available evidence and the expected amount of variation in patient preferences. The three levels are:

- standards, which are the least flexible;
- guidelines, which are more flexible;
- options, which are most flexible.

Recommendations by the panel include the following:

1. As a standard of practice, physicians should discuss with all three types of index patients treatment alternatives and the benefits and risks of each alternative, including side effects.
2. For the patient who presents to a physician with an abnormal growth on the urothelium but has not yet been diagnosed with bladder cancer, the panel recommends as a standard that a biopsy should be obtained for pathological analysis. If a diagnosis of bladder cancer has been established, the panel recommends as a standard that complete removal of all tumors should be performed if surgically feasible and if the patient's medical condition permits.
3. As an option that adjuvant IV chemotherapy or immunotherapy be used after surgical removal of tumors because the outcomes data "show a decreased recurrence probability for all the IV therapies studied, compared to transurethral resection alone." However, the panel notes that many patients with low-grade tumors do not require adjuvant IV therapy due to the low risk of disease progression in this group.
4. Panel members recommend as a guideline IV use of either BCG or mitomycin C for treatment of carcinoma in situ and for treatment after removal of tumors that have begun to penetrate the bladder wall and high grade Ta tumors. The guidelines state this recommendation is "based on evidence from the literature and panel opinion that both BCG and mitomycin C are superior to doxorubicin or thiotepa for reducing recurrence of these tumors."
5. The panel states that as an option bladder removal may be considered as an initial treatment option in certain patients based on several factors including large tumor size, high grade of tumor, and tumor location.

[For a complete copy of the Bladder Cancer Clinical Guidelines Report, *write the Guideline Division, American Urological Association, 1120 N. Charles St., Baltimore, MD, 21201, or fax a request to (410) 223-4375, or phone (410) 223-4367.]* ■

Studies reveal the latest findings in heart disease

Researchers share findings at national meeting

Heart disease researchers nationwide gathered recently in Atlanta to share the latest findings in heart disease management with their peers at the 72nd Annual American Heart Association (AHA) Scientific Session. Heart disease remains one of this aging nation's most costly killers. The studies summarized below offer case managers valuable information on how to achieve better outcomes for their patients.

A glimmer of HOPE

Researchers released data from the HOPE (Heart Outcomes Prevention Evaluation) Study, which clearly show that the antihypertensive drug ramipril could prevent cardiovascular deaths, heart attacks, and stroke in 22% of patients at risk for cardiovascular disease.

"We consider these results amazing," says **Salim Yusuf**, MD, HOPE Study chairman and professor of medicine at McMaster University in Hamilton, Ontario, Canada. "Based on the findings of HOPE, we believe that if ramipril is used in the appropriate patients we could prevent more than 1 million premature deaths, heart attacks, and strokes each year. This news gives

great hope to everyone with heart disease or those at risk for heart disease, particularly those with diabetes."

The study was conducted in 267 centers in 19 countries over four-and-half years and included more than 9,500 patients with a history of coronary artery disease, peripheral vascular disease, or individuals with diabetes who are at high risk for cardiovascular problems. The study examined ramipril, an angiotensin-converting-enzyme inhibitor vs. placebo in reducing cardiovascular events. It also examined the use of vitamin E versus placebo on heart disease and cancer. The vitamin E arm of the study will continue for several more years.

The numbers speak

Study findings include:

• The combined rate of heart attack, stroke, and cardiovascular death was 13.9% in the ramipril treatment group and 17.5% for the placebo group, with a 22% relative risk reduction. The individual relative risk reductions in this composite endpoint were: 25% reduction in cardiovascular death, 20% reduction in nonfatal heart attacks, and 32% reduction in nonfatal strokes.

• The rate of revascularization procedures, such as coronary angioplasty, coronary artery bypass graft, and peripheral angioplasty, was 15% lower in patients receiving ramipril.

• Significantly fewer people in the ramipril group developed diabetes compared to those in the placebo group.

• The rate of new and worsening congestive heart failure was 7.4% in the ramipril group and 9.4% in the placebo group, with a 22% risk reduction.

Ramipril is marketed in the United States under the brand name Altace, manufactured by Monarch Pharmaceuticals in Bristol, TN.

Researchers released findings from the second heart failure study comparing the high blood pressure medicine losartan potassium to captopril, an ACE inhibitor. ACE inhibitors are currently considered the standard in heart failure treatment.

The 3,152-patient study was designed to evaluate whether losartan potassium, the first and most widely prescribed angiotensin-II antagonists (AIIAs) for hypertension was superior to captopril at reducing deaths in patients with heart failure. The study also assessed whether losartan potassium was better tolerated than captopril.

The study, called ELITE II, was conducted after results of a smaller trial known as ELITE showed superior survival benefits and tolerability for patients taking losartan potassium compared to patients taking captopril. Neither losartan potassium nor any other AIIA is currently approved for the treatment of heart failure in the United States.

"ELITE II did not confirm the survival advantage seen for Cozaar [losartan potassium] over captopril in the earlier ELITE study," said **Bertram Pitt**, MD, professor of medicine in the department of internal medicine at the University of Michigan in Ann Arbor, who presented the study findings in Atlanta. "In both studies, however, Cozaar was better tolerated than the ACE inhibitor, with significantly fewer patients stopping therapy due to adverse experiences such as persistent cough."

Cozaar is manufactured in the United States for Merck & Co. in West Point, PA, by DuPont Pharma in Wilmington, DE. Based on the results of ELITE II, Merck will not seek regulatory approval for Cozaar in heart failure in the United States. Merck will request removal of first-line indication in any country where Cozaar is approved for first-line use in heart failure.

Study findings showed no statistically significant difference between Cozaar and captopril in reducing overall deaths or in reducing sudden cardiac deaths or resuscitated cardiac arrest. Findings include:

• 250 patients, or 15.9% of the 1,574 patient captopril group died during the two-year trial, vs. 280 patients or 17.7% of the Cozaar group.

• 228 patients, or 14.5% of the captopril group discontinued therapy due to an adverse experience during the trial, compared to 149 patients, or 9.4% of the Cozaar group.

Survey shows need for education

A national antihypertensive medication survey released by the Association of Black Cardiologists reveals that nearly four out of every 10 patients being treated for high blood pressure may stop taking their medication due to drug tolerability problems. Researchers also told attendees at the recent Atlanta meeting that 95% of patients believe that their blood pressure is under control, yet 35% of patients report elevated or uncontrolled systolic blood pressure, suggesting that this leading cause

of cardiovascular morbidity and mortality is poorly understood by many patients.

Researchers surveyed both patients and physicians. Both qualitative and quantitative research methods were used with each audience. The patient research consisted of a small-scale, telephone-based, qualitative study of 20 clinically diagnosed, hypertensive patients. Findings from that research were used to design a more in-depth telephone questionnaire. The survey gathered information from 314 patients for the quantitative questionnaire.

The physician audience included primary care physicians and cardiologists. The qualitative phase included telephone interviews with 12 physicians. The resulting structured questionnaire was completed by 101 physicians.

Findings include:

• 36% of patients treated for hypertension reported changing their medications at least once because of the severity of side effects.

• 13% of patients reported their current medication dosage had to be adjusted at least once due to adverse events.

• Younger patients, defined as those under age 54, are more likely than their older counterparts to report that side effects have a significant impact on their life.

• 44% of African-American patients, compared to 31% of Caucasian patients, reported systolic reading greater than 140 mm Hg.

• More than 50% of physicians surveyed reported believing that controlling systolic pressure is the most important goal in treating elderly hypertensives compared to roughly 20% who reported that controlling diastolic pressure is the most important goal of therapy.

Researchers noted that systolic pressure is a major predictor of cardiovascular disease and concluded that there is a great need to do a better job controlling systolic pressure in key patient groups. They also noted that the survey indicates a need to better educate both patients and physicians about what constitutes elevated hypertension.

When questioned about treatment regimen, physicians reported the following:

• Thirty-nine percent of patients receive combination therapy.

• The most commonly prescribed class of medication is the ACE inhibitor, prescribed to 31% of patients.

• Of patients treated with beta-blockers, the average percentage of patients experiencing fatigue as a side effect is 34%.

• Of patients treated with diuretics, the average percentage of patients having electrolyte imbalance as a side effect is 30%.

• Of patients treated with calcium channel blockers, the average percentage of patients having edema as a side effect is 26%.

• Of patients treated with ACE inhibitors, the average percentage of patients having cough as a side effect is 21%.

Toprol-XL increases survival

Adding the beta-blocker Toprol-XL manufactured by AstraZeneca in Wayne, PA, to standard treatment in patient with congestive heart failure who participated in the Metropolol CR/XL Randomized Intervention Trial in Heart Failure (MERIT-HF) reduced all-cause mortality and hospitalizations for heart failure by 31%, researchers told their colleagues at the AHA meeting.

Toprol-XL also reduced the combined endpoint of death and the number of patients requiring heart transplantation by 32%.

Nearly 4,000 patients with moderate-to-severe heart failure from 14 countries participating in the MERIT-HF study were randomized to once-daily doses of placebo or Toprol-XL.

Findings include:

• 34% reduction in overall death rate;

• 41% reduction in sudden deaths;

• 49% reduction in heart failure deaths.

The study found that the addition of Toprol-XL benefited patients regardless of the severity of the disease, with similar response patterns for patients in New York Heart Association (NYHA) classes II, II, and IV. In addition, patients in the Toprol group improved significantly in both NYHA class and self-reported quality of life.

Studies find enoxaparin sodium saves lives

Results of two multicenter studies reported found that patients hospitalized in the United States with medical illnesses including acute heart failure benefit from treatment with the blood thinner Enoxaparin sodium (enoxaparin sodium) injection to prevent life-threatening blood clots.

The MEDENOX (MEDical patients with ENOXaparin) trial included 1,102 patients and compared two regimens of the low-molecular-weight heparin enoxaparin sodium (20 mg and 40 mg given subcutaneously once daily) with placebo for

prevention of venous thromboembolism (VTE) in acutely ill patients. The study demonstrated that 40 mg of enoxaparin sodium given subcutaneously once daily for six to 14 days significantly reduced the risk of VTE in patients with congestive heart failure as well as patients with other medical illnesses, including respiratory failure and infectious disease. Efficacy results indicate that at day 14, the overall incidence of VTE was 4% in the enoxaparin sodium group compared to 14.6% in the placebo group. The MEDENOX study found no reduction in the rate of VTE in the patients treated with 20 mg of enoxaparin sodium compared with placebo.

The PRINCE (Prevention IN Cardiopulmonary Disease with enoxaparin) trial 665 patients in two sub-studies (PRINCE I and PRINCE II) compared enoxaparin sodium 40 mg once daily with unfractionated, or standard, heparin for the prevention of VTE. The PRINCE I study included 332 patients hospitalized for respiratory disease. The PRINCE II study included 333 patients hospitalized for heart failure.

The PRINCE II investigators found that the incidence of VTE was 9.7% in enoxaparin sodium patients, compared to 16.1% in the standard heparin group. In addition only five patients in the enoxaparin sodium group experienced minor hemorrhage compared to 12 patients in the standard heparin group. The PRINCE I and II studies found that the incidence of VTE was 12.6% in heart failure patients compared to 6.5% in respiratory patients.

Add acetaminophen to your arsenal

Research from Baylor College of Medicine in Houston suggests that acetaminophen may help protect against atherosclerosis, or hardening of the arteries, adding an inexpensive new weapon to the war against heart disease in the United States. In a 12-week study of rabbits, the Baylor team found that acetaminophen exerts an antiatherosclerotic effect when administered in doses therapeutically relevant to man.

"Last year, we reported findings in healthy human volunteers indicating that acetaminophen may have a potential antioxidant effect," **Addison A. Taylor**, PhD, professor of medicine and pharmacology and chief of the division of hypertension and clinical pharmacology at Baylor, told colleagues at the AHA conference. "We documented an association between the use of acetaminophen at recommended doses and a significant inhibition of the oxidation of certain low-density lipoprotein (LDL) components, which carry the form of cholesterol commonly described as bad cholesterol."

Taylor and his team induced above-normal levels of cholesterol in rabbits, half of which received doses of acetaminophen comparable to the recommended doses for humans. "At the end of the 12-week study, we examined the rabbits for evidence of fatty streaking in the aorta, an early manifestation of atherosclerosis. The rabbits that received acetaminophen had 50% less fatty streaking compared with controls," says Taylor.

Compliance causes costs to nosedive

Patients with untreated severe high blood pressure can run up an average of $14,582 annually in medical bills due to complications and illness. On the other hand, researchers who met in Atlanta report that it costs an average of $895 annually to effectively treat those patients.

The study examined an extensive pool of data from 2,500 patients at seven managed care and preferred provider organizations, as well as the Framingham Heart Study and other resource databases to calculate the average cost of treating hypertension. Researchers believe that the costs suggest the most successful practice for the treatment of hypertension will be to educate physicians, pharmacists, and patients on the importance of aggressive diagnosis, treatment, and therapy compliance.

The AHA has identified noncompliance as a national hidden health threat. The organization recently launched an aggressive compliance awareness and education program called the Compliance Action Program. The program targets physicians, allied health professionals, and patients. Two key elements of the program are a "Physician's Compliance Tool Kit" and a new patient brochure, *Knock Out America's Hidden Health Threat*.

The tool kit includes educational materials to help providers teach their patients how to follow a health regimen. The companion patient booklet contains consumer-friendly information on the benefits of compliance, compliance tips, an inventory of compliance tools, questions to ask their physician, and a wallet card to track prescription medications, cholesterol level, blood pressure and weight.

The materials are free. To order call (800) 242-8721. The compliance information is also available on the Internet at www.americanheart.org/CAP. ■

Arthritis meeting highlights progress

New vaccines look promising

At the recent 63rd Annual Meeting of the American College of Rheumatology in Boston, researchers shared the latest findings on how to reduce the pain and disability associated with rheumatoid arthritis and osteoarthritis. These studies may help you offer your patients new treatment options for these crippling diseases.

A pooled analysis of clinical studies of celecoxib capsules, a drug designed to target only the COX-2 (cyclooxygenase-2) enzyme, indicates that the drug helps elderly osteoarthritis patients more easily perform a variety of activities of daily living, including getting out of bed, putting on socks, and rising from a chair.

Researchers studied 956 patients with osteoarthritis of the hip or knee who were at least 70 years old. The study used a subset analysis of three pooled 12-week studies involving 3,255 patients. Researchers assessed pain, stiffness and physical functioning using the Western Ontario and McMaster Universities Osteoarthritis Index and the Short-Form 36 Health Survey.

The 956 patients were randomized to receive celecoxib capsules (50 mg, 100 mg, or 200 mg), naproxen, or placebo. Overall, celecoxib was as effective as naproxen and better than placebo at improving patients' functioning.

Roll up your sleeve

Researchers from Johns Hopkins University in Baltimore told colleagues at the meeting that data from a Phase IIb clinical trial of a therapeutic vaccine indicate that it appears safe and effective for the treatment of rheumatoid arthritis.

The Immune Response Corp. in Carlsbad, CA, manufactures the vaccine IR501 which in an earlier Phase II trial of 99 rheumatoid arthritis patients appeared safe and well-tolerated with apparent clinically meaningful improvement, or marked reduction of tenderness and swelling of joints, after 24 weeks of treatment.

In the current double-blind trial, 340 patients received either 30 mcg or 90 mcg of IR501 therapeutic vaccine; 30 mcg or 90 mcg of IR 703 therapeutic vaccine; or placebo. Treatments were administered as a single intramuscular injection at weeks zero, four, eight, and 20. Patients were followed for 24 weeks.

Findings include:

- Patients receiving either doses of IR501 (30 mcg or 90 mcg) and the higher dose (90 mcg) of IR703 appeared to have clinically meaningful improvement in their disease condition after three injections.
- An increased positive clinical response was observed after each of the three primary monthly injections. After week 16, this clinical response appeared to decrease until a fourth injection was administered at week 20. Following the last injection, the clinical response increased back to the levels observed at week 16 for both the 30 mcg IR501 group and the 90 mcg IR703 group.

For best results . . .

Researchers noted that those results suggest that continued monthly injections appear to maintain a clinical response and should be evaluated in any future trials to confirm or extend the therapeutic benefit. In addition, they reported that the therapeutic vaccine may be most effective in patients in early-stage disease. In a subset of patients who had the disease for less than three years, a statistically significant treatment effect was observed in both the 30 mcg IR501 and the 90 mcg IR703 groups at the end of the trial. After the final injection, 50% of patients from both of those treatment groups appeared to improve, compared to less than 10% of the control group.

Researchers told their colleagues that the oral disease-modifying rheumatoid arthritis medication, Arava (leflunomide), which is manufactured by Kansas City, MO-based Hoeschst Marion Roussel, is still safe and effective after two years. In fact, patients on leflunomide therapy showed statistically significant improvement at two years in tenderness and swelling of the joints compared to patients on the active control drug, methotrexate.

In a one-year, Phase III placebo-controlled trial presented at last year's meeting, 482 patients were given one of three treatments:

- leflunomide 20 mg/day after a loading dose of 100 mg/day for three days;
- placebo;
- methotrexate 7.5 mg/week with an increase to 15 mg/week for continued active disease.

Researchers followed 235 patients in the second-year continuation of the trial. "The data

showed that clinical and radiographic improvement observed with leflunomide and methotrexate at one year was maintained at two years, providing evidence of the durability and consistency of leflunomide's efficacy and safety," said **Vibeke Strand**, MD, clinical associate professor at Stanford University in Palo Alto, CA. "Additionally, at two years, leflunomide demonstrated significantly significant improvements in clinical response rates compared to the active control, methotrexate."

In the same study, improvement in physical function with leflunomide remained consistent over two years and was statistically significant compared to methotrexate. A separate scientific analysis of leflunomide presented at the meeting compared and analyzed results of three large, multinational, controlled trials. Leflunomide consistently retarded the structural damage associated with rheumatoid arthritis across all three clinical trials regardless of patient disease duration.

Child's play

More than 70% of children with severe, long-standing juvenile rheumatoid arthritis respond — often dramatically — to etanercept therapy, according to an ongoing three-year study at the Children's Hospital Medical Center of Cincinnati.

In this clinical trial, 74% (51 of 69) of children age 4 to 17 demonstrated clinically significant improvement when treated with etanercept for three months. In the second segment of the study, the 51 children who showed improvement were randomized to receive either etanercept or placebo. In this segment, 72% of patients treated with etanercept continued to improve on treatment without any arthritis flares, compared to only 28% of patients treated with placebo.

"These findings show a significant, often profound, improvement for most children with juvenile rheumatoid arthritis when treated with etanercept over placebo," said **Daniel J. Lovell**, MD, MPH, a pediatric rheumatologist at Children's Hospital and Medical Center, principal investigator of the study. "Before etanercept treatment, many children with severe juvenile rheumatoid arthritis had poor response to existing treatment options. Often they had to stop attending school. They'd be stiff for hours in the morning and experience pain every time they walked. Now there's hope for these children."

The third segment of the study is an open-label extension study of etanercept to treat juvenile rheumatoid arthritis. Results to date show that with continued treatment with etanercept, 80% of children who demonstrated initial clinical response to the drug continued to respond for more than one year.

Patients in the study had an average of 29 active inflamed joints when starting this trial. Of those patients, 31% no longer have joints with active arthritis after one year of treatment with etanercept. In addition, 32% of patients have been relieved of all joint pain, and 76% no longer experience morning stiffness.

Hip-hip-hooray

Fosamax (alendronate sodium), manufactured by Philadelphia-based Merck & Co., prevents the early loss of bone mass that often occurs in patients following hip replacement surgery.

The two-year study brings good news to the nearly 300,000 patients who undergo hip replacements each year in the United States. The surgery causes a redistribution of load to the bone around the implant, which can lead to rapid bone loss following surgery and ultimately to loosening of the hip implant.

Researchers presented data from a two-year, double-blind, single-center, placebo-controlled, randomized trial. In the first year of the study, 49 patients between 46 and 81 years of age who underwent hip replacement were divided into the following three patient groups:

- 16 "acute" patients with a recent hip replacement within 30 days of entering the study;
- 17 "chronic" patients with hip replacement more than five years prior to the study with no evidence of loosening of the implant due to bone loss;
- 16 "revision" patients with hip replacement surgery performed more than five years ago and loosening of their implant due to bone loss. Those patients were enrolled in the study while waiting revision surgery to replace the loose implant.

Patients were randomized to receive either Fosamax (10 mg once daily) or placebo. All patients were supplemented with 500 mg elemental calcium daily. Bone mineral density was measured by dual-energy X-ray absorptiometry (DXA).

Findings include:

- Acute patients treated with Fosamax had a $0.8 \pm 1.06\%$ gain in bone mineral density from baseline compared to a loss of $4.78 \pm 0.47\%$ from

baseline in patients treated with placebo.

• Chronic patients treated with Fosamax showed no significant difference compared to those treated with placebo.

"These results show that it may be more beneficial to begin treatment with Fosamax soon after hip replacement surgery in order to prevent loss of bone mass," said **Albert Leung**, MD, PhD, associate director of endocrine and metabolism clinical research for Merck Research Laboratories. ■

Long-term care/geriatrics

Test brings fast, accurate help for pneumonia

Patients leave with correct antibiotics

Roughly a half-million Americans contract streptococcal pneumonia each year, but now a 15-minute test recently approved by the Food and Drug Administration allows physicians to accurately diagnose the disease and prescribe the right medication before the patient leaves the office, potentially reducing the need for hospitalization.

The NOW(R) *S. pneumonia* Urinary Antigen Test developed by Binax in Portland, ME, is the first self-contained urine test for streptococcal pneumonia, a serious disease that often results in hospitalization in the elderly and the very young. Streptococcal pneumonia requires immediate and proper treatment with targeted antibiotics. However, until now, physicians often prescribed antibiotics without testing for the disease, or had to wait more than a week for test results that were sometimes inaccurate.

"Without having a definite diagnosis, doctors often hedged their bets by prescribing broad spectrum antibiotics to cover all conceivable pathogens, despite the fact that *S. Pneumoniae* is the more common cause of bacterial pneumonia," says **Victor Yu**, MD, professor of medicine at the University of Pittsburgh. "Ironically, broad spectrum antibiotics often cover the other causes of pneumonia, but are not as potent against *S. pneumoniae*."

The rapid test allows physicians to prescribe the best antibiotic for the specific infection immediately, adds Yu. "The availability of this rapid test allows doctors to know immediately and with confidence that the cause of the pneumonia is *S. pneumoniae*. Then, doctors can select the best antibiotics and prescribe them right away. Immediate treatment with targeted antibiotics means that patients get relief faster and they are less likely to develop complications," says Yu. "Targeted antibiotics are also cheaper than broad spectrum antibiotics."

The use of targeted antibiotics also helps prevent the rise of antibiotic resistance, says Yu. "This can help curb the emergence of 'super bugs' — or bacteria that are resistant to a number of antibiotics. These 'super bugs' are now multiplying at an alarming rate worldwide, and this is becoming a major health problem as antibiotics are rapidly losing their effectiveness."

For more information, visit the Binax Web site at www.binax.com. ■

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Drug promotes weight loss in elderly

Lowers blood pressure and cholesterol, too

A pooled analysis in a subpopulation of elderly obese patients indicates that the drug Xenical, manufactured by Hoffmann-LaRoche in Nutley, NJ, is effective for weight loss in this population. Use of Xenical also results in improvements in many of the health risks associated with obesity, according to data presented at the annual meeting of the North American Association for the Study of Obesity held recently in Charleston, SC.

Patients in this analysis were aged 65 years or older and had a body mass index (BMI) of 30 or more. Patients were treated with a reduced-calorie diet plus 120 mg of Xenical or placebo in two separate double-blind, placebo-controlled trials. The results indicate that patients treated with Xenical experienced significantly greater weight loss than patients receiving placebo. In addition, cardiovascular disease risk factors also improved more significantly among patients treated with Xenical.

The Xenical clinical trial program is the longest and largest of any anti-obesity medication. In seven separate, one- and two-year, double-blind, placebo-controlled, and randomized clinical trials involving more than 7,000 patients worldwide, those who took Xenical with reduced calorie meals containing 30% fat achieved significant weight loss, with improvements in other health risk, such as high blood pressure and diabetes.

Data from the analysis of the elderly obese presented at the NAASO meeting as well as pooled data from other clinical trials show:

• Almost three times as many patients taking Xenical in addition to a reduced calorie diet vs. reduced calorie diet alone achieved weight loss of more than 10% body weight.

• Nearly twice as many patients taking Xenical lost at least 5% body weight as those not taking Xenical.

• Patients losing weight with Xenical had statistically significant reductions in total and low-density lipoprotein (LDL) cholesterol and systolic and diastolic blood pressure, as well as improved concentrations of fasting glucose and insulin.

For more information, call toll-free (800) 746-5456 or visit the drug Web site at www.xenical.com. ■

CE objectives

After reading this issue of *Case Management Advisor*, CE participants will be able to:

1. List future trends that may shape their practice.
2. Describe a noninvasive method for correcting clubfoot in infants.
3. Implement a strategy for influencing legislators to pass health care reforms.
4. List new guidelines for treatment of bladder cancer. ■

Resource Bank™

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

Video helps children cope with pain

A new video from Fanlight Productions in Boston helps clarify questions about how children perceive and cope with pain.

"No Fears, No Tears — 13 Years Later" features a clinical psychologist and seven young adults who survived painful medical treatments in childhood. These seven young adults were featured in the award-winning film, *No Tears, No Fears,* which 13 years ago documented how eight children, ages 3 to 12 years, with cancer managed painful medical treatments.

The new film explores the long-term impact of having learned as a child how to deal with fear and pain. The seven young adults still vividly recollect their painful childhood experiences. However, they also describe how learning to master the pain has affected their attitudes toward it, as well as their relationships and lives today. Their stories challenge myths about childhood pain and demonstrate the power of hypnosis, imagery, breathing, and distraction. Their stories also prove that children can actively help themselves through taxing medical treatment.

The video runs 46 minutes and costs $195 plus shipping and handling. It can be rented for $50 a day. To order, contact Fanlight Productions, 4196 Washington St., Suite 2, Boston, MA 02131. Telephone: (800) 937-4113. Web site: www.fanlight.com. ▼

Free video helps people live with HIV infection

MEE (Motivational Educational Entertainment) Productions in Philadelphia recently released its latest video, "Life Is What You Make It," to raise awareness of HIV / AIDS treatment options within America's inner cities.

The video was produced for African-Americans and Latinos living with HIV / AIDS.

The free, 23-minute video features people living with HIV / AIDS, an example of a support group, and comments from a physician who specializes in HIV / AIDS treatment. The video helps adults diagnosed with HIV better understand the range of treatment options and services and encourages them to become actively involved in choosing a treatment regimen that fits their lifestyles.

Subjects covered

Issues included in the video are:

- the importance of treatment;
- access to treatment resources;
- barriers to an effective treatment regimen;
- hidden concerns and anxieties about living with HIV and its long-term treatment;
- control and empowerment.

Community action teams will distribute the video at appropriate events and activities in urban settings nationwide.

The video also can be ordered by calling toll-free (877) 633-7763 or visiting the company's Web site at www. meeproductions.com. ▼

Workers' comp conference features legal, medical issues

SEAK Legal and Medical Information Systems in Falmouth, MA, brings its Ninth Annual Workers' Compensation and Occupational Medicine Seminar to the Wyndham Emerald Plaza in San Diego March 29-31. Sessions include:

- preventing a workers' compensation case from becoming a discrimination case;
- evaluation and proof of low back injury;
- integrated disability management;
- getting the dysfunctional injured worker back to work;
- psychiatric fitness for duty exams;
- evaluating symptom magnification, deception, and malingering;

• effective use of investigation in workers' comp cases;

• diagnosis, prognosis, compensability, treatment, and impairment in fibromyalgia.

In addition, two one-day preconference seminars will be offered on March 28. They are:

• "Delayed Recovery: What Works";

• "Return-to-work Programs that Work: How to Develop and Implement a Comprehensive Cost-Effective Program."

The preconference seminars cost $295 each. The main conference costs $565. To register or to receive a conference program, contact SEAK, P.O. Box 729, Falmouth, MA 02541. Telephone: (508) 457-1111. Fax: (508) 540-8304. Web site: www.seak.com. ▼

Managed care conference looks to the future

Annual meeting to be in Atlanta

The National Managed Health Care Congress returns to the Georgia World Congress center in Atlanta April 16-19 for its 12th Annual Conference, "NMHCC/2000: Delivering the Future of Health Care."

As usual, NMHCC organizes its conference into professional tracks to help attendees select the sessions best suited to meet their needs. This year's tracks are:

• behavioral health care;

• managed care organization executives;

• hospital and integrated delivery system executives;

• information systems for health care;

• pharmacy;

• disease management;

• alternative medicine;

• physicians;

• employers investing in health;

• Web-enabled technology;

• case management;

• hot topics.

The conference costs $1,595 for a four-day pass and $1,395 for a three-day pass. Discounts are available for government employees and academicians. To register or to receive more information, contact NMHCC, P.O. Box 102713, Atlanta, GA 30368-2713. Telephone: (888) 882-2500. Web site: www.nmhcc.org. ▼

Info sheets get patients back on their feet

Customize a plan

Pritchett & Hull in Atlanta recently released double-sided tear sheets on a variety of orthopedic issues.

The double-sided 8½ x 11 sheets come in 50-sheet tear pads for $10 per pad plus shipping. Each of tear pads presents stretching and strengthening exercises suitable for both prevention and rehabilitation. The sheets include easy-to-read instructions with an interactive format that allows you to customize each patient's exercise plan.

Available titles include:

• "Strengthening Your Back";

• "Strengthening Your Hips";

• Strengthening Your Knees";

• "Strengthening Your Shoulders";

• "Learning to Use Crutches";

• "Learning to Use a Cane";

• Learning to Use a Walker."

To order any of the information sheets above, call toll-free (800) 241-4925 or order on-line at www.p-h.com. ■

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. ■